**Effect of 3 months and 12 months of financial incentives on 12-month postpartum smoking cessation maintenance: a randomised controlled trial**

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**Abstract**

**Background and aims** Offering financial incentives is effective for smoking cessation during pregnancy. We tested effectiveness of financial incentives for maintaining postpartum cessation, comparing 12-months and three-months incentives with each other and with usual care (UC).

**Design** Pragmatic, multicentre, three-arm randomised controlled trial.

**Setting** Four English, National Health Service, stop smoking services.

**Participants** 462 postpartum women (≥16 years old), who stopped smoking during pregnancy with financial incentives, validated as abstinent from smoking at end of pregnancy or early postpartum.

**Interventions** (i) UC; (ii) UC plus up to £60 of financial voucher incentives offered to participants and £60 offered to an optional significant-other-supporter, over three months postpartum, contingent on validated abstinence (‘three-months incentives’); or (iii) UC plus ‘three-months incentives’ plus £180 of vouchers offered to participants over nine months postpartum, contingent on abstinence (’12-months incentives’).

**Measurements** Primary outcome: biochemically validated abstinence at one year postpartum. To adjust for testing all comparisons between groups with equal precision, P<0.017 was necessary for significance. Secondary outcomes: self-reported and validated abstinence at three months postpartum; self-reported abstinence at one year postpartum.

**Findings** Primary outcome ascertainment: abstinence was 39.6% (63/159) 12-months incentives, 21.4% (33/154) three-months incentives, and 28.2% (42/149) UC. Adjusted odds ratios (95% confidence interval): 12-months versus three-months incentives 2.41 (1.46 to 3.96), P=0.001; 12-months versus UC 1.67 (1.04 to 2.70), P=0.035; three-months versus UC 0.69 (0.41 to 1.17), P=0.174. Bayes Factors indicated that for 12-months versus three-months incentives and 12-months versus UC, there was good evidence for the alternative hypothesis, and for three-months versus UC there was good evidence for the null hypothesis.

**Conclusions** This randomised controlled trial provides weak evidence that up to £300 of voucher incentives over 12 months is effective for maintaining smoking abstinence postpartum compared with usual care. There was good evidence that 12-months incentives are superior to those over only three months, for which there was no evidence of effectiveness relative to usual care.

314 words

**Key words:** Pregnancy, postpartum, smoking, abstinence, relapse, intervention, financial incentives, vouchers, randomised controlled trial

**INTRODUCTION**

More women stop smoking during pregnancy than at any other time; around half are likely to cease smoking ‘spontaneously’ [1]. This is an opportunity to help women stop smoking permanently.Most women who cease smoking in pregnancy say they wish to remain abstinent [2]. However, up to three-quarters are likely to return to smoking within six months of giving birth [3], increasing their risks of smoking-related illness and mortality [4,5] as well as their children’s risks of passive smoking [6] and of becoming smokers [7]. Also, there are marked health inequalities, as women with lower socio-economic status and education are more likely to relapse [8]. Reducing postpartum return to smoking may be one of the few interventions that can reduce health inequalities in early life.A review of 15 trials assessing interventions for reducing postpartum return to smoking, focussing on education and counselling, found no significant benefit of the interventions [9]. New approaches need to be developed and evaluated.

In 2023, a review of 12 trials showed that offering financial incentives is highly effective for smoking cessation during pregnancy, with those offered incentives twice as likely to remaining abstinent from smoking compared with those not offered incentives [10]. In the UK, since 2021 the National Institute of Health and Care Excellence has recommended financial incentives for pregnant women who smoke, based on their economic modelling demonstrating cost-effectiveness [11]. Such interventions are now being implemented in routine prenatal care[12]. Prompted by recent demonstrations of cost-effectiveness in UK and US trials [13,14] and further evidence of effectiveness in a UK trial [15], the UK government announced that all pregnant women in England who smoke will be offered incentives to stop smoking by the end of 2024 [16].

It is plausible that extending the offer of incentives into the postpartum period will assist maintenance of smoking cessation. The above review [10] identified five US studies that offered incentives during postpartum [17, 18, 19, 20, 21), with incentives ranging from $100 for postpartum women and $50 for a significant-other-supporter (SOS) over two months [17], to $520 for postpartum women over three months [21]. These incentives appeared to be acceptable to participants. However, women who smoked were randomised in early pregnancy, to examine the impact of incentives on smoking cessation during pregnancy; therefore, it was not possible to examine the separate effect of postpartum incentives on maintenance of postpartum smoking cessation among those achieving abstinence at end-of-pregnancy. Moreover, the number of women abstinent at end-of-pregnancy was too small (range 19 to 41 women) to examine trends among those offered incentives versus those not offered. This paper reports a large randomised controlled trial, which is the first, to test whether postpartum financial incentives can aid maintenance of postpartum smoking cessation. Specific hypotheses were that: (i) 12-months and three-months incentives will be more effective than usual care (UC); (ii) 12-months incentives will be more effective than three-months incentives; and (iii) there will be a significant linear trend in abstinence across the three study groups, with rates increasing from UC through to 12-month incentives.

**METHODS**

**Design**

The FIPPS study (Financial Incentives for Preventing of Postpartum return to Smoking)was a pragmatic, multicentre, phase III, parallel-group, three-arm, individually randomised, controlled trial. It compared smoking abstinence rates at three-months and one-year postpartum for three groups: (i) UC, (ii) UC plus financial incentives offered for up to three-months postpartum, and (iii) UC plus incentives offered for 12-months post-partum, among women who were abstinent from smoking at end-of-pregnancy.

**Participants**

Eligible women were participating in a programme offering financial incentives for smoking cessation during pregnancy (see published protocol/Supplement A. [22]), between 34 weeks gestation and two weeks postpartum, self-reported not smoking a single puff of a cigarette for at least four weeks, exhaled carbon monoxide (CO) reading was <4 parts per million (ppm), 16 years or older, intended remaining abstinent from smoking after the birth, English speakers and willing and able to give written informed consent for participation. In order to take their own CO measurements, they required a mobile phone compatible with the iCOTM (single-person use) CO monitor (Bedfont Scientific Ltd. [23]) app.Recruitment was from National Health Service stop smoking services (mid-wife led and non-midwife led) serving four maternity hospitals in Greater Manchester, UK, covering large areas of deprivation and including a city, several provincial towns, suburban and rural areas. Births at the sites ranged from 2,230 to 12,150 per year.

**Interventions**

During postpartum, control participants received care as usual, with no support for avoiding return to smoking. During pregnancy, all participants, as part of routine care, received brief, face-to-face, individual advice about maintaining smoking abstinence during postpartum and the long-term. All participants were offered a £20 voucher for completing research assessments at three months and one-year postpartum.

All participants in the two, individually delivered, intervention groups received UC and were also offered financial incentives for up to either three or 12 months postpartum, by experienced, trained stop smoking advisors. They could also identify a SOS, to help them to remain abstinent, who was also offered incentives. Incentives were Love2shop shopping vouchers, given or posted. For participants, payments were conditional on self-report of not smoking a single puff of a cigarette since their last quit date during pregnancy and an exhaled CO reading of <8 ppm. During pregnancy, due to metabolic and respiratory changes, a CO cut-off of <4 ppm is recommended [24,25]; out of pregnancy a cut-off of <8 ppm is more standard [26]. For the SOS, the payment was conditional on an exhaled CO reading of <8 ppm, irrespective of whether they had been a smoker. Initially, interventions were delivered face-to-face at a hospital facility. During covid-19 restrictions, most participants opted for telephone contact (using iCO monitor) or a home visit, and the SOS was confirmed as abstinent based on self-report alone (see protocol for covid-19 adaptations [22]). Interventions sessions lasted around seven minutes.

In the three-months incentive group, participants were offered up to £60 of incentives, with £20 offered at one, two and three-months postpartum. At three-months postpartum, SOSs were offered a £60 voucher if both participant and SOS were validated as abstinent.

In the 12-months incentive group, in addition to the incentives offered to participants and SOSs in the three months group, participants were offered £60 at six, nine and 12 months postpartum. In total, this group was offered £300. All the interventions were delivered uniformly across the sites.

**Procedures**

On joining the pregnancy stop smoking programme, women were informed that, if they were abstinent at the end of their pregnancy, they may be invited to join a study examining the effects of offering shopping vouchers on abstinence during the first year after their baby’s birth. Those reporting not currently smoking and confirmed as abstinent (CO <4 part per million) by the stop smoking service at around 32 weeks gestation were given a ‘generic’ participant information sheet. Stop smoking advisors enrolled participants at between 34 weeks gestation and four weeks postpartum. Baseline and consent questions were completed before the advisor requested automated randomised group allocation online, ensuring concealment, with the participant present. Participants were randomised to one of three conditions within site. During Covid-19 restrictions, when written consent for trial participation could not be obtained face-to-face, written or verbal consent was obtained by ‘distanced’ methods (see protocol [22]).

Randomisation (1:1:1 allocation) was stratified by site, using randomly permuted blocks of varying size. The randomisation sequence was computer generated and stored in a secure online programme. Due to the nature of the intervention, in this pragmatic trial, it was not possible to blind participants to treatment allocation. Nor were the advisors conducting the assessments blind to allocation, as the advisors both delivered the intervention and conducted assessments, with the assessments being part of the intervention. The statisticians were blinded to allocation.

The trial protocol was approved by the North-West-Liverpool Central Research Ethics Committee (ref: 18/NW/0838). Trained researchers at the University of Stirling added data to a secure trial database and conducted data monitoring (see Supplement B). Trial planning, including preparation of participant materials, included two patient and public involvement and engagement (PPIE) representatives who had smoked during pregnancy. We carefully assessed the burden of the trial interventions on participants. There was additional PPIE representation on the Trial Steering Committee that included input on plans for dissemination of the findings.

**Measures**

At three-months and one-year postpartum follow-ups, stop smoking service advisors conducted assessments and were trained to do so. Initially, advisors assessed participants’ smoking status over the telephone (up to five contact attempts). Those reporting not smoking a single puff (since at least four weeks prior to randomisation) were asked to biochemically verify their smoking status with their advisor at either a face-to-face appointment or remotely during Covid-19 restrictions, as outlined in the protocol [22].

The primary outcome was self-report of sustained, lapse-free, smoking abstinence at one-year postpartum, biochemically validated by an exhaled CO reading of <8 ppm, and/or saliva cotinine or anabasine estimation. Women were verified as not smoking if their saliva cotinine concentration was <10ng/ml [27], or where current nicotine replacement therapy or e-cigarette use was reported, saliva anabasine was ≤0.2ng/ml [28]. Where possible, both a CO reading and saliva sample confirmed abstinence; where only one of these measures was collected that was used to confirm abstinence. At three-months postpartum, if a participant could not be contacted or if they self-reported abstinence but this was not validated by a CO reading (mostly due to Covid restrictions), they could still satisfy the primary outcome if they were validated as abstinent at one-year postpartum. If at three-months they reported smoking or had a CO reading >8ppm they were counted as having relapsed for the primary outcome.

Secondary assessments, at three-months and one-year postpartum, were the proportion of women self-reporting: abstinence from smoking; use of nicotine replacement therapy, electronic-cigarettes and heat-not-burn products; a partner who smokes; smokers living in their home; use of additional smoking cessation support beyond that in the trial; use of the iCO monitor beyond that required for assessments. We also assessed biochemically validated (CO <8ppm) self-reported abstinence from smoking up to three-months postpartum. Assessments for cost-effectiveness and process evaluation are reported in the protocol [22] and the findings will be reported elsewhere.

**Data analysis**

Analyses followed a pre-specified statistical analysis plan (<https://osf.io/nckj9/>, registered 7th June, 2022) using Stata (StataCorp, release 17; College Station, TX) and SPSS (version 29). Hypothesis tests were two sided. The intention-to-treat population was defined as ‘all participants who were randomly assigned to the study and eligible to participate’.The planned sample size was 900 participants (300 per trial group), giving 90% power at 1.7% significance, to detect a difference in abstinence rates across any two groups of 13.6%. The estimate of 13.6% difference was based on the difference found in a UK study of pregnancy incentives [29]. With the sample size achieved (N=462), and the above estimate of effect sizes, we had 0.6 power for 3-month versus 12-month incentives and 0.82 and near 1.0 power for no incentives versus 3-month and 12-month incentives, respectively. For examining a linear contrast across the three groups we had near 1.0 power.

Baseline data were summarised descriptively by study group for all participants, and for participants who provided smoking status for the primary outcome [30]. We used chi-squared tests to compare follow-up rates between study groups. For analysis of biochemically validated smoking outcomes, where outcomes were missing participants were assumed to be smokers [26].

Analysis for the primary outcome used a mixed-effects logistic regression model with randomised treatment group as a fixed effect, and recruiting site adjusted for as a random effect (random intercept only - to control for non-independence of observations within sites) [31], with pairwise comparisons between treatment groups, using a significance level of P<0.017 (Bonferroni correction for multiple comparisons [32]). Bayes Factors (BFs) were produced using an online calculator (<http://www.lifesci.sussex.ac.uk/home/Zoltan_Dienes/inference/Bayes.htm>) to examine whether there was evidence for the alternative (H1) or null (H0) hypothesis. Usual conventions were applied (i.e., good evidence for H1 over H0 if BF>3; good evidence for H0 over H1 if BF<1/3; otherwise, inconclusive evidence). We set the hypothesised OR to 1.5, but also examined the effect of varying the lower bound from 1.2 to 2, using a one-tailed test. We also looked for a linear trend in abstinence across the three groups, control to 12-month incentives (significance P<0.05).

We conducted secondary analyses for the primary outcome, adjusting for key baseline variables predicted to be related to postpartum smoking status [8,33] (i.e., education (A-Level or equivalent or higher versus lower qualifications), cigarette consumption before pregnancy, depression (Edinburgh Depression Scale score [34], and age. We also conducted sensitivity analysis to examine effects on the primary outcome for other baseline variables that had a marked difference between groups and were associated with smoking status. We compared rates of validation of smoking abstinence, and sizes of effect of interventions between the pre- and post-Covid-19 periods (cut-off 16th March 2020) in sensitivity analysis, to assess the impact of Covid on the primary analysis. For the primary outcome, sensitivity to missing data was assessed using three methods: complete case analysis, multiple imputation by chained equations, and a pattern-mixture model to assess sensitivity to deviations from the missing data assumptions of the primary analysis.

Further secondary analysis, with the same adjustments as for the primary outcome, included group comparisons for self-reported smoking cessation at three-months and one-year postpartum, and validated smoking cessation at three-months postpartum. Descriptive statistics were generated for three-months and one-year postpartum assessments of use of nicotine products, smoking in the home, partner smoking status, use of additional smoking cessation support, and use of the iCO monitor beyond that required for research assessments. The number/percentage of SOSs who received a £60 incentive was reported by study group. We added some outcomes that were not pre-specified: we presented the proportion in the 12-month incentives group verified as abstinent at six-months and nine-months postpartum, to show the progression of relapse across time; we reported the proportion counted as having returned to smoking by the first month postpartum, as this was notably high. No outcome data were excluded.

**FINDINGS**

From 22 March 2019 to 31 August 2021, 661 women were screened, of whom 180 (27.2%) were ineligible. 481 (72.8%) participants were randomised (Figure 1). Subsequently, 18 participants were identified as being ineligible (mostly due to baseline CO reading >3ppm, n=9). The independent trial steering committee reviewed each case (blind to study group) and recommended withdrawing all 18 participants [35]. A further participant was withdrawn due to the infant dying. Data for the remaining 462 individuals were analysed (12-month incentives n=159, three-month incentives n=154, UC n=149). Due to the interruptions of covid-19, including lack of face-to-face screening of women’s smoking status during pregnancy [36] and reduced staffing due to illness or ‘shielding’, trial recruitment did not meet the target of 900 participants randomised, despite an extended period of recruitment. We did not have the resources to further extend recruitment.

**Baseline data**

The mean age of the 462 participants was 28.3 years, 87.2% were recruited in late pregnancy (mean gestation 36.4 weeks) and 12.8% joined in early postpartum (Table 1). In 95.5% of cases, the intervention was delivered by a midwife-led stop smoking service; therefore, we did not adjust the analysis for type of service. At baseline, use of nicotine replacement therapy was reported by 13.2% of participants and e-cigarette use by 28.6%. On average, participants reported being abstinent from smoking for 22.7 weeks. The groups had similar baseline characteristics, except the 12-month incentives group tended to report higher levels of education and was more likely to have a SOS than the other groups, the 12-month and UC groups reported more confidence for maintaining smoking abstinence than the three-month group, and the three- and 12-month groups reported more use of nicotine replacement therapy and e-cigarettes than UC.

**Primary outcome**

Table 2 presents the primary outcome analysis. Follow-ups were completed 18th October 2022. Overall, 76.4% (353/462) of participants completed self-report of smoking status at one-year postpartum, with rates of completion around 11% higher for 12-month incentives than the other two groups (P=0.029). Baseline characteristics of those who did and did not self-report smoking status were similar (Table 1). There were some differences in characteristics of those who did and did not undergo biochemical verification of abstinence (see Supplement C). Overall, among those reporting smoking abstinence, 75.3% underwent verification and rates of providing this verification were around 16% lower in the three-month incentive group compared with the other groups (P=0.063).

For the primary analysis, adjusting only for site, validated abstinence was higher for 12-month incentives (39.6%) compared with three-month incentives (21.4%); adjusted odds ratio (aOR) 2.41 (95% CI 1.46 to 3.96); percentage difference 18% (95% CI 8% to 28%), P=0.001. The difference in validated abstinence between 12-month incentives and UC (28.2%) was not significant with the Bonferroni correction; aOR 1.67 (95% CI 1.04 to 2.70); percentage difference 11% (95% CI 1% to 22%), P=0.035). Nor was the difference significant between three-month incentives and UC (aOR 0.69 (95% CI 0.41 to 1.17); percentage difference 7% (95% CI 16% lower to 3% higher), P=0.174). We made the a-priori decision to fit a model with centre as a random effect [31]. Despite the degree of clustering being negligible, we retained this model as it was pre-specified. In an alternative model specification including centre as a fixed effect there was no impact on study findings nor was there a site by treatment interaction.

BFs indicated that for 12-months versus three-months incentives, and for 12-months versus UC, there was good evidence for H1 (BF>3). At a hypothesised effect size of 1.5, the BF for three-months versus UC was 0.27, implying good evidence for H0, though inconclusive for expected effect size of 1.37 or less. There was a significant linear trend in the proportion abstinent between UC, three-months and 12-months incentives (P=0.025), although ORs suggested a non-linear association. When examining the effects of pre- versus post-Covid periods on the primary outcome, and on rates of validation of self-reports, there were no apparent differences. Strenuous efforts were made to maintain study rigour, despite the disruption of Covid.

In a fully adjusted model, when further adjusting for pre-defined baseline maternal variables that were predicted to be related to smoking status, and for baseline variables that had a marked difference between groups and were associated with smoking status (i.e., whether support was provided by a SOS, intention to breastfeed, living with smokers, partner smokes), primary outcome findings were similar: validated smoking abstinence was higher for 12-month incentives compared with three-month incentives (aOR 2.25 (95% CI 1.35 to 3.77), P=0.002). The difference in validated abstinence between 12-month incentives and UC was not significant (aOR 1.56 (95% CI 0.95 to 2.57); P=0.082)). Nor was there a significant difference between three-month incentives and UC (aOR 0.69 (95% CI 0.40 to 1.19; P=0.183).

The findings did not change in the complete case analysis (12-month versus three-month incentives: aOR 2.15 (95% CI 1.27 to 3.66), P=0.005; 12-month incentives versus UC: aOR 1.41 (95% CI 0.84 to 2.37), P=0.187; three-month incentives versus UC: aOR 0.66 (95% CI 0.37 to 1.15), P=0.141) or by multiple imputation of chained equations (12-month versus three-month incentives: aOR 1.95 (95% CI 1.16 to 3.29), P=0.012; 12-month incentives versus UC: aOR 1.32 (95% CI 0.79 to 2.20), P=0.274; three-month incentives versus UC: aOR 0.68 (95% CI 0.39 to 1.20), P=0.179). Pattern mixture modelling showed that for the comparison of 12-month and three-month incentives interpretation was robust to large deviations from the missing data assumptions of the primary analysis. For comparison of UC with the two incentive groups the interpretation was less robust (see Supplement D).

**Secondary outcomes**

At one-year postpartum, a significant difference was observed in self-reported abstinence for 12-month incentives compared with both three-month incentives and UC but not between three-month incentives and UC (see Table 2). Other secondary and exploratory outcomes are summarised in Table 3. At three-months postpartum, overall, 87.2% (403/462) of participants provided a self-report of smoking status, with rates higher in the incentive groups than UC (P=0.044). Among those reporting smoking abstinence, 75.2% underwent biochemical verification, with similar rates across study groups (P=0.714). At three-months postpartum, there were no significant group differences for either self-reported or validated abstinence. The percentage of SOSs who received a £60 incentive (at three-months postpartum) was similar in the two incentive groups. Two participants reported returning to smoking before the birth (three-month incentive group=1, 12-month incentive group=1). Initial relapse rates were high, with 41% (188/462) counted as returning to smoking in the first month postpartum (UC 51% (76/149), three-month incentives 35% (54/154), 12-month incentives 37% (58/159)). In the 12-month incentives group, participants progressively returned to smoking between the three-month and one-year assessments; at six- and nine-months postpartum 53% (85/159) and 46% (73/159), respectively, were validated as abstinent. At both three-month and one-year follow-ups, less than 8% of participants reported using nicotine replacement therapy, and over a quarter reported using electronic-cigarettes, having a partner who smokes, and living with smokers.

**DISCUSSION**

To our knowledge, this is the first study to examine the effectiveness of postpartum financial incentives, to aid postpartum smoking cessation, among women who smoked during pregnancy but had quit by the time their baby was born. It shows substantial interest in the intervention and that adding a 12-month programme of postpartum incentives to current cessation support for pregnant women in England, can help maintain smoking cessation compared with a three-month programme. Offering up to £300 of incentives over 12 months postpartum achieved validated abstinence rates of 40%. This compared with rates of 21% when offering £120 over three months and rates of 28% for UC.

**Strengths and limitations**

The high recruitment rate of 70%, along with no reports of study withdrawals, supports generalisability. Around three quarters of participants were followed up at one-year postpartum, similar to the six-months postpartum follow-up rate in a recent UK trial of incentives for smoking cessation during pregnancy [15]. Only around half of the target sample size was achieved; however, abstinence rates were higher than anticipated which increased the power of the study and our Bayesian approach suggested evidence for an effect. It may, however, still be underpowered and this could explain the lack of significance for the comparison of 12-month incentives and UC. Our conservative approach of using a Bonferroni correction also contributed to the lack of significance for 12-month incentives versus UC. On reflection, considering the challenges of Covid and consequent reduced sample size, prior to commencing the analysis, we would have been justified in adopting a revised analysis plan. This could have included two primary analyses, comparing each incentive intervention with UC using P<0.05, and a secondary analysis comparing the incentive interventions using a Bonferroni correction, in which case the results would have been definitive. Follow-up rates were highest in the 12-month incentives group, as consistent with evidence that incentives improve retention [37]. This may have increased abstinence rates in this group, since missing data were analysed as smokers. However, this does not seem to explain the findings as results were similar with alternative approaches to dealing with missing data.

For the primary outcome, rates of providing biochemical verification were lower in the three-month incentive group compared with the other groups, which may have led to underestimation of the effect of this intervention. However, this is unlikely to have affected the findings for the primary outcome, as self-reports of abstinence mirror findings for the primary outcome, and the verification test changed the outcome from abstinent to not abstinent in only a few cases (see Table 2). Some baseline characteristics of those providing versus not providing verification were different; however, there was little evidence to suggest the missingness mechanism differed by randomised group (Supplement C). The primary outcome was assessed unblinded, but as the assessment involved biochemical verification, we consider there to be low risk of bias. We neglected to register the trial protocol until five participants had been recruited. However, as there was only a slight delay in registration, only a few participants had been randomised, and no substantive changes were made to the methods after the trial started, we consider that this does not affect the transparency, validity or reliability of the data. The findings are specific to England and to those having received incentives for smoking cessation during pregnancy; in England, from 2024, all pregnant persons who smoke will be offered financial incentives to stop smoking. This limits generalisability to other smokers who have not taken part in incentive schemes to help them stop smoking during pregnancy. A final limitation is that almost all participants were of white ethnicity, although this is consistent with previous UK trials of incentives for smoking cessation during pregnancy [15,29].

**Comparisons with other studies**

This was the first randomised controlled trial to examine whether offering postpartum financial incentives reduces postpartum smoking. It was also the first study to offer incentives up to 12 months after birth. Consistent with five trials of financial incentives for smoking cessation in pregnancy [17,18,19,20,21], postpartum incentives were considered acceptable by both participants and those offering the incentives (reported elsewhere, in the process evaluation). Consistent with one previous study providing postpartum incentives [17], the offer of incentives for a SOS was well received. Around half of participants recruited a SOS, with around half of these achieving an incentive payment.

**Implications for policy and research**

The findings suggest that providing postpartum incentives to women who have quit smoking during pregnancy can help maintain long-term abstinence. However, our results suggest that incentives need to be over a long period. We found no benefit for abstinence for three-months postpartum incentives. There is promising but not definite evidence for 12-months incentives. There was over a two-fold increase in abstinence compared with the three-month intervention; yet the comparison with UC was not significant, using a Bonferroni correction. However, at the upper confidence interval, this comparison suggested a possible two- to three-fold benefit for the 12-month intervention, and a point estimate suggesting an effect (OR=1.67) that is likely to be clinically meaningful.

A definitive trial is needed to confirm whether an incentives intervention for 12-months postpartum is effective compared with UC. The evidence from the present study could provide an informative prior for a Bayesian trial design [38]. It is important to assess abstinence in the long-term, after incentives are withdrawn and we are assessing abstinence in this trial beyond two-years postpartum. Research should examine what format and incentive level, at what frequency and duration achieves the most effective and cost-effective outcome [39] and whether the intervention is generalisable to women not receiving pregnancy incentives. Relapse rates were high in the first month and a more intensive initial intervention may be needed; a recent trial offered 16 incentives over three-months postpartum with promising results [21]. We were unable to examine how the effect of social support from a SOS plus incentives compares with incentives alone, and this merits investigation. Research needs to explore the potential benefits of combining postpartum incentives with other behavioural interventions (e.g., [40]) and with pharmacological interventions. Around a third of participants had a partner who smoked and/or lived with smokers. Interventions need evaluating which target these individuals, as having a partner or household member who smokes increases risk of postpartum relapse [8], and household smoke is harmful to children [6]. Little is known about triggers to smoking relapse during postpartum (e.g., stress of childcare, mood disturbance [41,42); these triggers need to be clearly identified, so that interventions can target them and support behaviour change.

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**FIGURE LEGEND**

**Figure1**.: αThis eligibility criteria was subsequently replaced with ‘self-reported not smoking a single puff of a cigarette for at least four weeks’, to include those who had had some earlier lapses but were abstinent >4 weeks. Those recruited before this amendment were all abstinent for >4 weeks and following this amendment no one was excluded for having smoked in the last four weeks.

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| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Table 1. Baseline characteristics of all participants in analysis, and participants providing smoking status for primary outcome, by study group**  Data are number (%) of participants unless otherwise stated | | | | | |  |  |  |
|  | **All participants in analysis** | | | |  | **Participants who provided smoking status for primary outcome** | | |
|  | Usual care (n=149) | Three-month incentives (n=154) | 12-month incentives (n=159) | | Total  (n=462) | Usual care (n=108) | Three-month incentives (n=112) | 12-month incentives (n=133) |
| **Demographic characteristics** |  |  |  | |  |  |  |  |
| Maternal age in years Mean (SD) | 27.7 (5.6) | 28.6 (5.4) | 28.6 (5.9) | | 28.3 (5.7) | 27.6 (5.5) | 28.8 (5.4) | 28.7 (6.0) |
| A-level, degree or equivalent | 72 (48.3)m[2] | 77 (50.0) | 93 (58.5) | 242 (52.4)m[2] | | 72 (50.9)m[2] | 56 (50.0) | 81 (60.9) |
| White ethnicity | 140 (94.0) | 142 (92.2) | 145 (91.2) | | 427 (92.4) | 103 (95.4) | 105 (93.8) | 121 (91.0) |
| **Type of stop smoking service**  Midwife led | 144 (96.6) | 145 (94.2) | 152 (95.6) | | 441 (95.5) | 106 (98.1) | 107 (95.5) | 127 (95.5) |
| **Smoking history** |  |  |  | |  |  |  |  |
| Pre-pregnancy cigarettes smoked a day Mean (SD) | 12.9 (7.2)m[1] | 13.5 (6.7) | 12.4 (6.8)m[2] | | 12.9(6.9)m[3] | 13.2 (7.0)m[1] | 14.0 (6.9) | 12.5 (6.9)m[2] |
| Weeks of continuous smoking abstinence Mean (SD) | 22.8 (6.4) | 22.1 (6.6) m[1] | 23.3 (6.3) m[1] | | 22.7 (6.5)m[2] | 22.8 (6.3) | 21.8 (6.8) m[1] | 23.4 (6.4) m[1] |
| Expired CO level ppm Mean (SD) | 1.1 (0.8) | 1.2 (0.7)m[1]a | 1.2 (0.8)m[1]b | | 1.2 (0.8)m[2] | 1.1 (0.8) | 1.2 (0.7)m[1]a | 1.3 (0.8)m[1]b |
| Very or extremely confident in maintaining smoking abstinence | 107 (71.8)m[1] | 99 (64.3) | 110 (69.2) | | 316 (68.4)m[1] | 72 (66.7)m[1] | 72 (64.3) | 89 (66.9) |
| Uses nicotine replacement therapy | 15 (10.1) | 22 (14.3) | 24 (15.1) | | 61 (13.2) | 13 (12.0) | 15 (13.4) | 21 (15.8) |
| Uses electronic-cigarettes | 36 (24.2) | 51 (33.1) | 45 (28.3) | | 132 (28.6) | 25 (23.1) | 34 (30.4) | 42 (31.6) |
| Uses heat-not-burn | 4 (2.7) | 2 (1.3) | 4 (2.5) | | 10 (2.2) | 4 (3.7) | 1 (0.9) | 4 (3.0) |
| Use of smoking cessation support beyond that in trial | 0 | 0 | 0 | | 0 | 0 | 0 | 0 |
| Partner smokes | 47 (31.5) | 49 (31.8) | 49 (30.8) | | 145 (31.4) | 34 (31.5) | 36 (32.1) | 40 (30.1) |
| Living with smokers | 49 (32.9) | 56 (36.4) | 57 (35.8) | | 162 (35.1) | 34 (31.5) | 42 (37.5) | 48 (36.1) |
| Has significant-other-supporter | 66 (44.3) | 72 (46.8) | 86 (54.1) | | 224 (48.5) | 49 (45.4) | 53 (47.3) | 72 (54.1) |
| **Pregnancy** |  |  |  | |  |  |  |  |
| Weeks pregnant Mean (SD)c | 36.4 (1.0) | 36.3 (1.0) | 36.5 (1.2) | | 36.4 (1.1) | 36.4 (1.1) | 36.3 (1.0) | 36.5 (1.1) |
| Days postpartum Mean (SD)d | 8.1 (5.2) | 8.4 (4.1) | 7.6 (4.1) | | 8.0 (4.4) | 7.7 (5.8) | 8.8 (4.7) | 7.3 (4.4) |
| Parity Mean (SD) | 1 (1.1)m[2] | 1.2 (1.5) | 1.0 (1.1) | | 1.1(1.2)m[2] | 0.9 (1.1)m[1] | 1.2 (1.6) | 1.0 (1.1) |
| Intend to bottle and breastfeed | 25 (16.8) | 23 (14.9) | 30 (18.9) | | 78 (16.9) | 16 (14.8) | 17 (15.2) | 25 (18.8) |
| Intend to breastfeed only | 77 (51.7) | 75 (48.7) | 78 (49.1) | | 230 (49.8) | 58 (53.7) | 51 (45.5) | 69 (51.9) |
| Intend to breastfeed for >4 months | 54 (36.2) | 48 (31.2) | 48 (30.2) | | 150 (32.5) | 40 (37.0) | 35 (31.3) | 43 (32.3) |
| **Alcohol Use Disorders Identification-Consumption** |  |  |  | |  |  |  |  |
| Risk drinking (score >5) | 2 (1.3) | 4 (2.6) | 3 (1.9) | | 9 (1.9) | 1 (0.9) | 1 (20.9) | 3 (2.3) |
| **Edinburgh Depression Scale** (EDS) |  |  |  | |  |  |  |  |
| Overall EDS scores Mean (SD) | 6.0 (5.0)m[4] | 5.4 (5.1)m[5] | 5.3 (4.7)m[2] | | 5.6 (4.9)m[11] | 6.0 (5.0)m[4] | 5.4 (5.1)m[5] | 5.3 (4.7)m[2] |
| Major Depressive Disorder  (EDS >11) | 29 (19.5)m[4] | 29 (18.8)m[5] | 27 (17.0)m[2] | | 85 (18.4)m[11] | 22 (20.4)m[4] | 20 (17.9)m[5] | 23 (17.3)m[2] |

m[ ] Missing data [number missing], SD=standard deviation, CO=carbon monoxide, ppm=parts per million

aMissing due to medical condition, b Missing due to Covid-19 distancing, c relates to those recruited in pregnancy, drelates to those recruited postpartum

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Table 2. Primary outcome derivation and primary analysis, by study group**  **Data are number (%) of participants** | | | | |
| **At one-year postpartum** | Usual care (n=149) | Three-month incentives (n=154) | 12-month incentives (n=159) | Total  (n=462) |
| **Self-reported smoking status**† |  |  |  |  |
| Abstinent | 53/149 (35.6) | 53/154 (34.4) | 81/159 (50.9) | 187/462 (40.5) |
| Smoking  Missing self-report  due to no contact | 55/149 (36.9)    41/149 (27.5) | 59/154 (38.3)  42/154 (27.3) | 52/159 (32.7)  26/159 (16.4) | 166/462 (35.9)  109/462 (23.6) |
| **Self-reported as abstinent**  **and underwent biochemical verification test** |  |  |  |  |
| Yes | 45/56 (80.4) | 35/55 (63.6) | 69/87 (79.3) | 149/198 (75.3) |
| Noa | 11/56 (19.6) | 20/55 (36.4) | 18/87 (20.7) | 49/198 (24.7) |
| **Verification test changed outcome from abstinent**  **to smoking** (i.e., failed test) |  |  |  |  |
| Yes | 3/45 (6.7) | 2/35 (5.7) | 6/69 (8.7) | 11/149 (7.4) |
| No | 42/45 (93.3) | 33/35 (94.3) | 63/69 (91.3) | 138/149 (92.6) |
| **Biochemically verified smoking status (primary analysis)** |  |  |  |  |
| Abstinent  Smoking | 42b/149 (28.2)  107/149 (71.8) | 33c/154 (21.4)  121/154 (78.6) | 63d/159 (39.6)  96/159 (60.4) | 138/462 (29.9)  324/462 (70.1) |

†Group comparisons for self-reported abstinence, fully adjusted ORs (95% CIs): 12-month vs three-month incentives 1.90 (1.19 to 3.03), P=0.008; 12-month incentives vs UC 1.88 (1.17 to 3.03), P=0.009; three-month incentives vs UC 0.99 (0.61 to 1.62), P=0.982. Excludes 11 individuals who self-reported abstinence but failed verification test.

aIn five cases lack of a verification test was due to insufficient saliva to conduct the analysis (control=1, 3-month incentives=2, 12-month incentives=3), b5 participants had self-report only at 3-month follow-up and 3 could not be followed up at 3 months, c4 participants had self-report only at 3-month follow-up, d10 participants had self-report only at 3-month follow-up.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Table 3. Secondary outcomes by study group. Data are number (%) of participants** | | | | |
|  | Usual care (n=149) | Three-month incentives (n=154) | 12-month incentives (n=159) | Total  (n=462) |
| **Self-reported smoking status**  **at 3-months postpartum**† |  |  |  |  |
| Abstinent | 100/149 (67.1) | 104/154 (67.5) | 123/159 (77.4) | 327/462 (70.8) |
| Smoking  Missing self-report due  to no contact | 22/149 (14.8)    27/149 (18.1) | 32/154 (20.8)  18/154 (11.7) | 22/159 (13.8)  14/159 (8.8) | 76/462 (16.5)  59/462 (12.8) |
| **Self-reported as abstinent at 3 months postpartum and underwent verification testa** |  |  |  |  |
| Yes | 73/100 (73.0) | 81/104 (77.9) | 92/123 (74.8) | 246/327 (75.2) |
| No | 27/100 (27.0) | 23/104 (12.1) | 31/123 (25.2) | 81/327 (24.8) |
| **Biochemical verification at**  **3-months postpartum**†† |  |  |  |  |
| Abstinent  Smoking | 73/149 (49.0)  76/149 (51.0) | 81/154 (52.6)  73/154 (57.4) | 92/159(57.9)  67/159 (42.1) | 246/462 (53.3)  216/462 (46.8) |
| **Uses NRT**  At 3-months postpartum  At one-year postpartum | 10/118 (8.5)  2/78 (2.6) | 8/128 (6.3)  4/74 (5.4) | 12/135 (8.9)  3/102 (2.9) | 30/381 (7.9)  9/254 (3.5) |
| **Uses electronic-cigarettes**  At 3-months postpartum  At one-year postpartum | 25/118 (21.2) 20/78 (25.6) | 36/128 (28.1)  30/74 (40.5) | 39/135 (28.9)  31/102 (30.4) | 100/381 (26.2)  81/254 (31.9) |
| **Uses heat-not-burn**  At 3-months postpartum  At one-year postpartum | 0/118  0/78 | 1/128 (0.8)  0/74 | 1/135 (0.7)  0/102 | 2/381 (0.5)  0/254 |
| **Additional use of iCO**  **monitor for >6 days**  At 3-months postpartum  At one-year postpartum | 1/73 (1.4)  0/54 | 7/83 (8.4)  2/52 (3.8) | 2/8 (0.7)  3/60 (5.0) | 10/236 (4.2)  5/166 (3.0) |
| **Use of extra cessation support**  At 3-months postpartum  At one-year postpartum | 1/118 (0.8)  0/78 | 0/128  0/74 | 0/135  0/102 | 1/381 (0.3)  0/254 |
| **Partner smokes**  At 3-months postpartum  At one-year postpartum | 26/118 (22.0)  28/78 (35.9) | 36/128 (28.1)  23/74 (31.1) | 39/135 (24.4)  21/101 (20.8) | 97/379 (25.6)  72/254 (28.4) |
| **Living with smokers**  At 3-months postpartum  At one-year postpartum | 31/118 (26.3)  30/78 (38.5) | 38/127 (29.9)  23/74 (31.1) | 36/135 (26.7)  19/102 (18.6) | 105/380 (27.6)  72/254 (28.4) |
| **SOS received incentive** | NA | 33/72 (45.8) | 38/86 (44.2) | 71/158 (44.9) |

Group comparisons for self-reported a and validated abstinencec, respectively: fully adjusted ORs (95% Cis): 12-month vs three-month incentives (1.45 (0.86 to 2.43), P=0.162; 1.15 (0.72 to 1.83), P=0.561); 12-month incentives vs UC (1.60 (0.95 to 2.69), P=0.075; 1.39 (0.87 to 2.23), P=0.164); three-month incentives vs UC (1.11 (0.95 to 2.69), P=0.690; 1.21 (0.76 to 1.95), P=0.420).

aIn no cases did verification test change outcome from abstinent to smoking. SOS=significant other supporter, NRT=nicotine replacement therapy, iCO=single-person use carbon monoxide monitor

**Figure 1. Trial profile of potential participants, participants who were enrolled and randomly assigned to a group, and participants whose data was analysed**

661 Screened for eligibility

Enrollment

180 Excluded

140 Not interested 7 >two weeks postpartum

4 Intending to return to smoking 1 <16 years of age

15α Smoked since last quit attempt in pregnancy 2 Did not speak English

4 Expired carbon monoxide >3 parts per million 7 Other reason

481 Randomised

Allocation

164 allocated to 12-month incentives & 159 received

159 allocated to 3-month incentives & 154 received

158 allocated to usual care 149 received usual care

8 Withdrawn from

study as ineligible

1 withdrawn as baby

died

5 Withdrawn from

study as ineligible

5 Withdrawn from

study as ineligible

**159 Included in primary analysis at 12 months** **postpartum**

133 Provided information

26 Assumed to be

smoking

**149 Included in primary analysis at 12 months** **postpartum**

108 Provided information

41 Assumed to be

smoking

Follow-up/Analysis

159 Included in secondary analysis at 3 months postpartum

145 Provided information

14 Assumed to be

smoking

**154 Included in primary analysis at 12 months** **postpartum**

112 Provided information

42 Assumed to be

smoking

154 Included in secondary analysis at 3 months postpartum

136 Provided information

18 Assumed to be

smoking

149 Included in secondary analysis at 3 months postpartum

122 Provided information

27 Assumed to be

smoking