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Are Financial Incentives Effective and Cost-Effective in a 'Real Life' Smoking Cessation Program for Pregnant Women? A Phase IV 'Before and After'Study to Provide Evidence to Secure Long-Term Funding.

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Abstract

Objectives: The aim was to secure, long term, financial voucher incentives for pregnancy Stop Smoking Services. Objectives were integration without disruption, improved outcomes and cost-effectiveness assessment.

Design: Prospective phase IV non-randomised time-matched 'before and after' study.

Setting: Maternity Public Health Programme in the most deprived United Kingdom city.

Participants: Women who self-reported current smoking at first antenatal visit (a least 1 cigarette in last 7 days) and lived in National Health Service Greater Glasgow and Clyde Health Board area. 672 mostly white Caucasian women age ≥ 16 years were approached from Jan-Jun'18 pre-incentives and 739 from Jan-Jun'19 with incentives.

Interventions: Specialist advisers telephoned inviting an 'engagement' face-to-face appointment when a quit date was set. Dispensed through local pharmacies, free Nicotine Replacement Therapy was offered with weekly telephone counselling-Withdrawal-orientated Therapy-for 12 weeks. At 4, 12 (plus 24 weeks incentives period only), follow-up included self-report and Carbon Monoxide (CO) breath test. Incentive cards were topped-up with £ 20 for 'engaging', £ 40 at 4 and 12 weeks, and £ 60 at 24 weeks for CO-verified (<4 ppm) abstinence, total £ 160.

Primary outcomes: Engagement, cessation at 4 and 12 weeks, and Incremental Cost-Effectiveness Ratio (ICER) per 4 and 12-week quitter. Secondary outcomes included SSS signposting and 24-week cessation with incentives.

Results: Before incentives, 277/672 (41.2%) accepted support compared with 375/739 (50.7%) with incentives p<0.001, [difference 9.5% (95%CI 4.3%-14.7%)]. CO verified cessation increased from 52/672 (7.7%) to 83/739 (11.2%) p=0.032, [difference 3.5% (95%CI 0.4%-6.5%)] at 4 weeks and 35/672 (5.2%) to 59/739 (8.0%) p=0.047, [difference 2.8% (95%CI 0.2%-5.4%)] at 12 weeks. Offering incentives to 24 and 31 women produced one extra 4 and 12-week quitter. After 24 weeks, 34/739 (4.6%) remained abstinent with incentives. ICER was £ 517 and £ 546 per 4 and 12-week quitter.

Conclusions: Financial voucher incentives were integrated successfully; significantly increasing CO verified cessation at 4 and 12 weeks and was cost-effective.

Keywords: Public health; Reproductive medicine; Maternal medicine; Obstetrics; Health economics; Health services administration and management; Epidemiology; Health economics

Abbreviations: NHSGGC: National Health Services area of Greater Glasgow and Clyde, SSS: Stop Smoking Services, QALY: Quality Adjusted Life Year, ICER: Incremental Cost-Effectiveness Ratio

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Introduction

Glasgow Scotland UK and Craiova Romania, have the lowest female life expectancy documented in 24 European cities. Smoking during pregnancy is a global health concern and a key priority for national tobacco control including policies of the Scottish government [1]. It is only after the childbearing years, age 40, that continued smoking significantly reduces lifespan [2,3]. Eighty percent of women have at least one baby, so pregnancy is an opportunity to help nearly all women to stop before irreversible damage has occurred [4,5]. For babies, detrimental health effects of maternal smoking during and after pregnancy include an increase in still birth and pre-term delivery and over a quarter of infants with poor foetal growth (Small for Gestational Age) [6]. Hospital admissions are increased for bronchiolitis (Population Attributable Risk 10.1%), respiratory infections (6.7%) and asthma (7.1%). Children between three and 24 months of age also exhibit neurodevelopmental difficulties that impair motor, language and social adaptation life skills [7]. Children are likely to follow parental smoking behaviours through adolescence and adulthood causing more harm [8]. Economic implications include significantly increased cost to the UK National Health Service (NHS) of up to £ 64 million and £ 23.5 million for treating mothers and infants between 0-12 months, respectively [9].

In the UK and the US, the proportion of pregnant women who smoke has declined [10-12]. In Scotland 30.7% of women self-reported as current smokers at first maternity visit in 1998 compared with 13.8% in 2020. This reduction has been confirmed by widespread use of carbon monoxide breath testing advocated by NICE [13,14]. Less smoking has been accompanied by a 35% reduction in early miscarriage from 6.9 in 1998 to 4.5 miscarriages/1000 women age 15 to 44 years in 2016 and a 40% reduction in babies born small for Gestational Age, from 4.2% in 2001 to 2.5% in 2016, recorded in Scotland [15-17].

In 2010, the UK National Institute for Health and Care Excellence (NICE) published comprehensive guidelines on cessation support that should be offered to pregnant women by the NHS. Stop Smoking Services (SSS) should offer standard care comprising behavioural support and pharmacotherapy for up to 12 weeks to all pregnant smokers identified at their initial antenatal visit [15]. “Opt-in” where smokers are asked, and “opt-out” automatic referral; groups and individual counselling; telephone, clinic, pharmacy and home-based care are themain UK SSS configurations offered to pregnant smokers. In the National Health Services area of Greater Glasgow and Clyde (NHS GG&C) Scotland, “opt-out” services are run by specialist advisors. Midwives pass details of smokers either directly to specialist advisors at antenatal clinic or via an antenatal computer system and the specialist advisors contact pregnant smokers to discuss cessation support and invite them for an initial appointment [18,19].

Women who now continue to smoke during pregnancy may be unwilling to engage with cessation services with fewer women setting a quit date. In Scotland, engagement in NHS SSS continues to decline year on year 20. In 2019/2020, a total of 1154 quit attempts were made by a total of 643813 self-reported pregnant smokers through the Stop Smoking Services (SSS) with 44.9% (518) and 32.8% (379) reported as non-smokers at 4 and 12 weeks, respectively [19]. Despite the encouraging outcomes, initial and continued engagement of pregnant smokers with NHS SSS remains a challenge and strengthened efforts are required to improve engagement and subsequent cessation [20].

Incentives hold the promise to improve engagement and follow-up in smoking cessation programs especially in high-income countries. Providing financial incentives attracts criticism, and so public acceptability and proven effectiveness are vital for successful implementation [21-23].In 2010 NICE highlighted the lack of evidence in a UK context and developed a research question: ‘Within a UK context, are incentives an acceptable, effective and cost-effective way to help women who smoke to quit the habit when they are pregnant or after they have recently given birth? [24]. Compared with current services, do they attract more women who smoke, do they lead to more of them completing the stop-smoking programme and do more of them quit for good? What level and type of incentive works best and are there any unintended consequences?’ To address this research question, Tappin [15]. conducted the Cessation in Pregnancy Trial II (CPIT) in the National Health Service Greater Glasgow and Clyde (NHS GG&C) Health Board area from 2011-2013 [25]. This exploratory trial reported the efficacy of the offer of financial incentives (up to £ 400) compared with usual care-behavioural support and NRT (Nicotine Replacement Therapy). At 34-38 weeks gestation, incentivised participants were 2.58-fold more likely to quit than usual care participants (95% CI: 1.63-4.07). [25] In addition, the first-ever cost-effectiveness analysis reported a short-term incremental cost per quitter of £ 1,127 and long-term cost per Quality Adjusted Life Year (QALY) of £ 482, far below the NICE threshold of £ 20,000 [26]. The findings suggested that financial incentives are feasible and efficacious as part of NHS SSS for pregnant women. Although other trials support these findings there remains a paucity of data in ‘real-life’ conditions [22-23].

‘Historically, assessment of how interventions work in ‘real-world’ public health programmes has been relatively neglected. A common goal of Phase IV studies is to provide evidence that the health intervention can be successfully and safely integrated into public health or clinical practice where ‘successful’ means that it is not only feasible to do so, but also that the intervention remains effective and its implementation is not associated with any serious adverse effects. There are multiple observational designs and evaluation schemes that can be used in Phase IV studies to assess the effectiveness, cost-effectiveness, and safety of an intervention in real-world settings’. Building on the successes of the CPIT II trial, the pregnancy SSS secured £ 93,000 from NHS Greater Glasgow and Clyde Endowments Committee for a program to assess if financial incentives introduced as part of routine care would attract more pregnant smokers to accept cessation support, initiate quit attempts and sustain abstinence [27]. Assessment of costs and benefits was also undertaken [25].

Aim and objectives

This phase IV study hypothesised that: financial voucher

incentives could be introduced to an established NHS pregnancy SSS without significant disruption, incentives are effective at encouraging pregnant smokers to make and maintain cessation attempts and are cost-effective in the short-term.

Primary outcomes: Proportion signposted who engage with Stop Smoking Services (SSS) arrive at their face-to-face appointment and set a quit date, cessation at 4 and 12 weeks post quit date, and Incremental Cost-Effectiveness Ratio (ICER) per 4 and 12-week quitter.

Methods

Design

A phase IV non-randomised time matched before and after evaluation of a public health smoking cessation program for pregnant women in NHS GG&C Health Board area.

Two methods were undertaken: A secondary analysis of routinely collected data over 6-months periods before (January to June 2018) and during the incentive period (January to June 2019). A comparative within study economic evaluation utilising quantitative outcomes and service costs to estimate incremental costs per 4- and 12-week quitter.

Study populations

Inclusion criteria: The study population were pregnant women 16 years and above signposted to SSS who self-reported as current smokers at first maternity visit and lived in the NHS GG and C Health Board area during time matched periods Jan-June 2018 as the before incentives usual care control group and Jan-June 2019 with the additional offer of incentives as the after group.

NHS GG&C is the largest UK health board providing health and social care services for 1.2 million people. In the year ending March 2019, 1277/11472 (11.7%) women self-reported as current smokers at first maternity visit. SSSs provide free support with tailored services for pregnant women [28].

The pre-incentive "before" population were offered usual care-behavioural telephone support and pharmacotherapy for up to 12 weeks.

The incentive "after" population were offered usual care plus financial vouchers for engaging with SSS (£ 20) and for CO-verified abstinence at 4 (£ 40), 12 (£ 40) and 24 (£ 60) weeks post quit date.

Sample size

A formal sample size calculation was not undertaken. The Endowments Committee grant for the SSS service evaluation allowed for 6 months before and 6 months with incentives once the necessary service changes had become embedded. The before population size was 600-700 women treated by the pregnancy Stop Smoking Services (SSS) over 6 months. A 5% quit rate at 12 weeks post quit date before incentives provided 80% chance of detecting a doubling of quit rate to 10% with incentives with a two-sided confidence level of 95% with 437 women before and 437 with the offer of incentives for engagement and smoking cessation.

Intervention design

Consultation with key stakeholders on how to integrate financial voucher incentives into the established pregnancy SSS was undertaken from July to September 2018 when the incentives programme began.

Initial incentive development sessions included: Reviewing criteria for eligibility onto the incentives programme and subsequent eligibility at each time point, including

- How this would be ascertained (eg. Postcode, CO Validated) and recorded.
- Process for card distribution, activation (pre-loaded and password activated), and subsequent top up.
- Service paperwork and database requirements.
- Incentives specific paperwork required (eg. Incentives agreement for the women to sign, information leaflet)
- Service incentive SOP produced and updated to ensure that all staff were aware of responsibilities at each time point.

A 'Financial Incentives for Smoking Cessation in Pregnancy' working group was also established. This included stakeholders from midwifery, e-health, pharmacy, Health and Social Care Partnerships, university researchers and the pregnancy Stop Smoking Services (SSS). This group was to oversee and agree final processes for the implementation, including the development of a stakeholder engagement and communication strategy. The group met on a regular basis until the programme was established reporting actions and outcomes to NHS GGC's strategic tobacco control group.

Final intervention and activities

Figure 1 describes the final intervention activities and stages. At their initial antenatal visit, pregnant women self-report their current smoking habit and all undertake a carbon monoxide (CO) breath test. All self-reported smokers – at least one cigarette in the last 7 days and pregnant women with CO readings of 7 Parts Per Million (ppm) and above are referred. Those with CO reading of 4 ppm-6 ppm but not identified as self-reported smokers are signposted and SSS sends a letter informing them of the service. Women who have stopped within the past two weeks-"former smokers"are also referred. Service users are eligible for incentives if they have a valid NHS GG&C postcode, receive antenatal care from NHS GG&C Health Board and have a validated CO ≥ 4 ppm either taken at the first maternity visit or at the 'engagement' individual face-to-face interview with an SSS adviser. Specialist advisers telephone pregnant women inviting them for an initial face to face appointment. At that appointment, a quit date is set indicating a day the service user commits to begin their attempt to stop smoking. The service generates follow-up dates for monitoring cessation outcomes required for the health board and Scottish Government performance monitoring and which meets Scottish Minimum Dataset requirements [29]. Nicotine Replacement Therapy (NRT) is discussed and dispensed through local pharmacies for up to 12 weeks usually in the form of skin patches, chewing gum or lozenges. Weekly telephone counselling using

Withdrawal-orientated Therapy is offered after the initial face to face appointment for up to 12 weeks [30]. Follow-up points are set at 4, 12 and 24 weeks post-quit date to assess self-report smoking and take CO breath tests. The "before" population were followed for 12 weeks and the "after" population for 24 weeks-the time of the final financial incentives voucher payment. A CO breath test of less than 4 Part per Million validates cessation allowing the voucher card to be recharged.

Data sources

Effectiveness: Four routinely collected datasets were provided for quantitative analysis. These were merged using Community Health Index a unique identifiers used for health care purposes in Scotland.

Pregnancy SSS data: Contained information on pregnant women referred either electronically from antenatal clinics or directly. Completed by specialist advisers, the dataset contained baseline

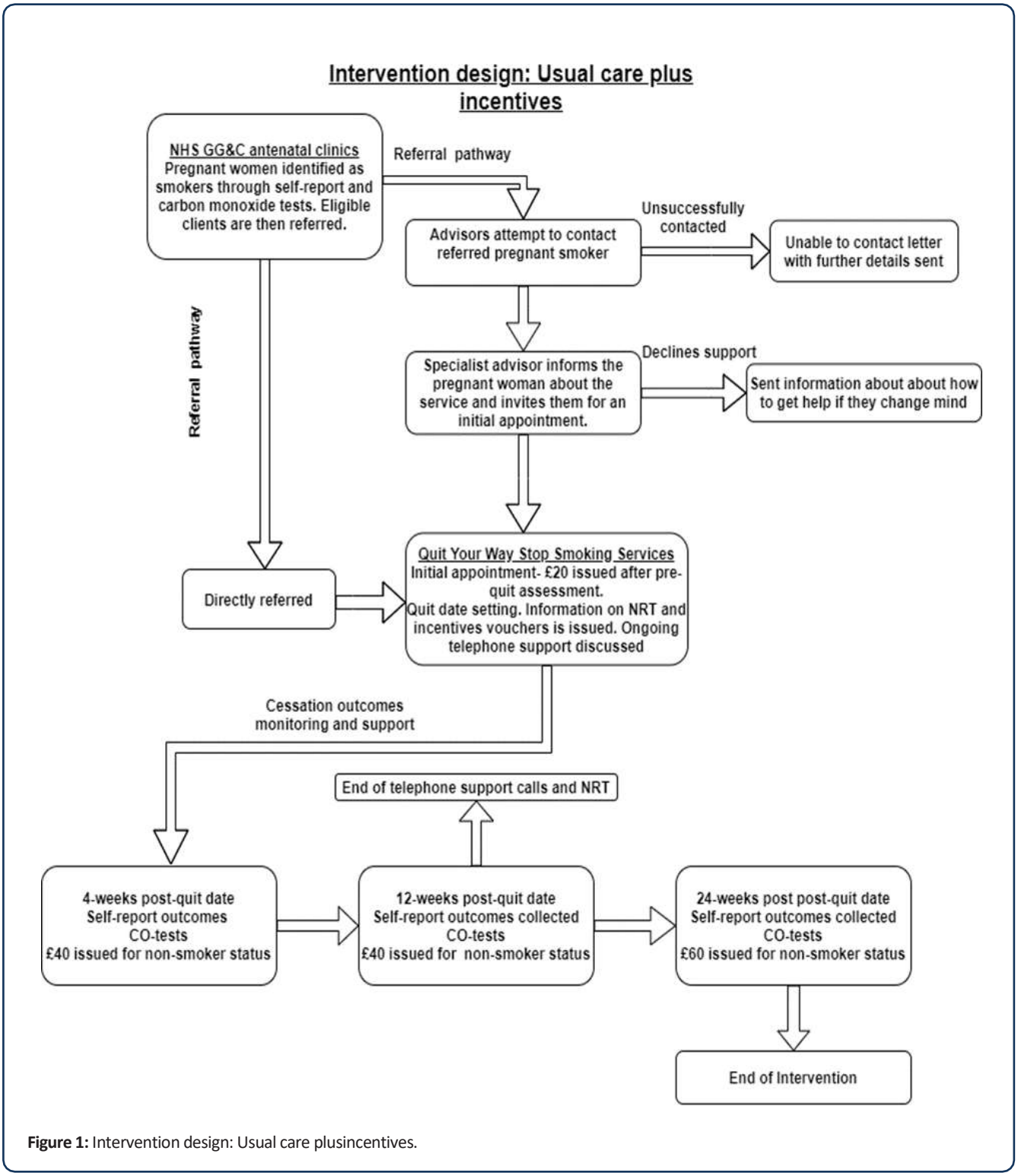

Figure 1: Intervention design: Usual care plusincentives.

and socio-demographic characteristics, and self-reported smoking cessation outcomes.

Scottish Minimum Dataset for smoking cessation services: Socio-demographic characteristics and smoking cessation outcomes both self-reported and CO validated recorded by specialist advisors and pharmacists [29].

Coppish SMR02-maternity Inpatient and day cases: Contained information on first maternity visit CO readings and self-reported smoking status. Completed by midwives, the dataset provided the denominator to assess smokers identified and referred, and the proportion who engaged and were followed up at intervention stages.

Incentive management database: Contained information on card activation, total payment, smoking cessation outcomes both self-reported and CO validated recorded by specialist advisors and pharmacists. The process involved specialist advisors and service administrator input and included up to the end of the incentive outcome at 24 weeks post quit date.

Cost-effectiveness: Health Board expert opinion provided information on duration for initial appointment and telephone follow-up to estimate advisors' costs. Unit costs were obtained from published sources, whereas NRT costs were from NHS price list [31]. Patient level data was obtained from the quantitative analysis. This included service users supported at each assessment stage and information on NRT weekly use. NRT is dispensed from the pharmacy on a fortnightly basis for up to 12 weeks but data on weeks used was underreported and therefore estimates based on cessation outcomes were used to obtain total NRT costs for each of the study periods.

Data analysis

Effectiveness analysis: Analysis was undertaken comparing groups-before incentives and with the offer of incentives. No blinding was employed. Analysis was by intention to treat with those lost to follow-up treated as smokers.

Wilcoxon rank sum tests were used to compare differences in socio-demographic and baseline characteristics. Chi-square tests were used to compare engagement variables and study periods. 2-sample tests of equality of proportions without continuity correction checked for significant differences between the study periods. Furthermore, risk difference with corresponding 95% Confidence Intervals (CI) were calculated for the likelihood of accepting the offer of cessation support, attending an initial meeting, setting a quit date, and being smoke free at 4 and 12 weeks.

Data cleaning and preliminary analysis were conducted using Excel while the main analysis was conducted on R version 4.0.0 (Foundation for statistical computing, Vienna, Austria).

Cost-effectiveness analysis: The cost-effectiveness analysis was performed from an NHS perspective. An Incremental Cost-Effectiveness Ratio (ICER) was obtained by comparing the costs and effects of the "after" period to the "before" period at the 4 and 12-week follow-up point. Mean costs per 4 and 12-week quitter was derived from applying the number of service users who set a quit date and those verified as non-smokers at the 4-week assessment stage. The mean quit rates for 4 and 12 weeks calculated in the statistical analysis were applied for the effects. To compute the ICER at 4 and 12 weeks follow-up point, the differences in mean costs between periods were divided by the difference in mean quit rate. In addition to the base-case analysis, a scenario analysis for each of the analyses were evaluated. For 12 weeks cost-per quitter, an average of eight support calls and the most expensive NRT among the options provided-Niquitin, a patch normally dispensed to service users with higher nicotine dependence was applied. For 4-week cost per quitter, Niquitin price was also applied. Cost-effectiveness analyses were computed on Microsoft Excel for office 365.

Patient and public involvement

Patients and other stakeholders were interviewed for a sister qualitative Masters in Public Health thesis at Glasgow University entitled: To investigate service users and health professional's views of the smoking cessation with financial incentives service for pregnant women within NHS Greater Glasgow and Clyde. August 2019. The executive summary of this thesis is available on request.

Results

Difficulties and challenges with implementation

Initially, capturing the CO for women at both the 4 and 12-week time points was through pharmacy services with support from the Public Health-Health Improvement Pharmacy team. This brought some data capture challenges and increased administration. By the time of the study period (January-June 2019), clients attended the pregnancy SSS to establish CO validated abstinence status. Overall, the main challenge has been administration of incentives, which can be time consuming and can impact on service capacity. Other staff have been trained to provide support during busy periods. In addition, dedicated named contacts with the procurement team has helped to minimise payment issues.

Quantitative before and after analysis

The analyses were performed on a combined dataset (n=1411) of pre-incentive (January-June 2018) 672 (47.6%) and incentive period (January-June 2019) 739 (52.4%) pregnant smokers. All in each group were offered usual care and during the second period incentives were offered to all for engagement with Stop Smoking Services (SSS) and CO verified cessation. All were included in the analysis.

Socio-demographic and baseline characteristics: Table 1 shows

that characteristic of women during the two periods are similar, before incentives and with incentive payments.

Engagement and smoking cessation outcome variables: Table 2

Shows the engagement and smoking cessation outcomes in both periods. More smokers offered incentives engaged with SSS, remained engaged and quit smoking.

Resource use information

Characteristics	Before: Jan-June 2018	After: Jan-June 2019	P-values
Women signposted	672 (100%)	739 (100%)	0.211#
Contact successful	424 (63.1)	490 (66.3)	
Contact unsuccessful	206 (30.7)	196 (26.5)	
Directly referred (in clinic)	42 (6.3)	53 (7.2)	
CO reading at booking	Median (IQR)	Median (IQR)	0.387*
	25 (6-35)	25 (7-35)	
Missing	128	133	
Age-groups (years)	N (%)	N (%)	0.841*
<20	55 (8.2)	67 (9.1)	
20 to 24	164 (24.4)	174 (23.5)	
25 to 29	206 (30.7)	231 (31.3)	
30 to 34	163 (24.3)	168 (22.7)	
35 to 39	66 (9.8)	84 (11.4)	
40 plus	18 (2.7)	15 (2.0)	
SIMD (quintile)	N (%)	N (%)	0.135*
1 (Most deprived)	473 (70.4)	541 (73.2)	
2	107 (15.9)	122 (16.5)	
3	55 (8.2)	41 (5.5)	
4	22 (3.3)	20 (2.7)	
5 (Least deprived)	15 (2.2)	15 (2.0)	
Note: #=Pearson chi-square, *=Wilcoxon rank sum test, ♦=Chi-square test for trend.			

Table 1: Baseline and socio-demographic characteristics.

Characteristics	Before: Jan-June 2018 (Before-incentives) N (%)	After: Jan-June 2019 (With incentives) N (%)	Difference (95%CI)	P-values
Women included	672 (100%)	739 (100%)		
Accepted invitation for initial meeting	277 (41.2%)	375 (50.7%)	9.5% (4.3%, 14.7%)	<0.001
Attended meeting	150 (22.3%)	209 (28.3%)	6.0% (1.4%, 10.5%)	0.012
Set a quit date	131 (19.5%)	172 (23.3%)	3.8% (-0.5%, 8.1%)	0.096
4-weeks quit	52 (7.7%)	83 (11.2%)	3.5% (0.4%, 6.5%)	0.032
12-weeks quit	35 (5.2%)	59 (8.0%)	2.8% (0.2%, 5.4%)	0.047
24-weeks quit	NA	34 (4.6%)	NA	NA

Table 2: Engagement and cessation outcomes of pregnant smokers referred to SSS.

Table 3 shows the resource use information with respective sources, including vouchers and duration with the Stop Smoking Services (SSS) adviser. 113 and 132 women accepted the offer of NRT during pre-incentive and incentive periods respectively. The cost of SSS advisor time at top NHS band 5 was £ 20.14-Scottish Government Directorate for Health Workforce, Leadership and Service Reforms for the financial year 2019/20. The cost of NRT 14 mg/24 hours was £ 9.40 for Nicotinell and £ 11.48 for Niquitin from NHS National Services Scotland [31].

Incremental Cost-Effectiveness Ratio (ICER) estimates

Overall, estimated costs **(Table 4)** and effects (quit rates) **(Table 2)** were higher during the incentive period. ICERs for all analyses were between £ 500 and £ 600 per quitter.

Resource	Value/Amount/Number		Source
	Pre-incentive	Incentive	
Vouchers issued up to 12 weeks (£)	0	6000 a, 7920 b	Study dataset
Time taken during the initial appointment (minutes)	45	60	Expert opinion
Time taken for telephone support calls (minutes)	15	20	Expert opinion
Nicotine Replacement Therapy	Offered for up to 12 weeks		Study dataset
Note: a=Total voucher value issued at 4 weeks, b=Total voucher value at 12 weeks			

Table 3: Resource use information.

Within study analysis	Study period	Mean cost (£)	Mean effect	Incremental cost (£)	Incremental effect	ICER (£)
Base-case analysis	Before	66	0.397	41	0.076	517
(4-week quitter)	After	110	0.482			
Scenario analysis	Before	73	0.397	42	0.076	508
(4-week quitter)	After	117	0.482			
Base-case analysis	Before	108	0.267	44	0.085	546
(12-week quitter)	After	150	0.343			
Scenario analysis	Before	130	0.267	43	0.085	547
(12-week quitter)	After	172	0.343			
Note: £= British pounds rounded off to whole numbers						

Table 4: Incremental Cost-Effectiveness Ratio (ICER) estimates.

DISCUSSION

This phase IV study of a service development showed that adding modest financial voucher incentive payments to a specialist pregnancy SSS that adheres to current NICE guideline recommendations could be achieved, without significant detriment to service delivery [15]. A before and after analysis indicated that adding financial incentives significantly increased engagement of pregnant smokers referred, leading to 25% more setting a quit date and 50% higher quit rates at 4 and 12 weeks post quit date. Cost-effectiveness analysis provided an estimated ICER of about £ 500 per extra quitter. This level of extra cost per quitter indicates good value for money [26-32].

The strengths of this phase IV study are

Integration of an efficacious intervention into a 'real life' situation to assess effectiveness and understand the practical difficulties of providing financial incentives outside a clinical trial; as a service evaluation, the study allowed the overall effect of incentive payments on the pregnant smoking community to be assessed rather than participants in a trial who would have been enrolled at some point along the clinical path from becoming pregnant as a smoker to after engagement with Stop Smoking Services (SSS); cessation outcomes in this study 'before' incentives were not always CO verified as it was SSS policy but not compulsory to document smoking outcomes, whereas cessation outcomes with incentives were CO verified as a 'CO negative' test was required to top-up financial incentive voucher cards, making the reported increase in cessation a likely underestimate.

Weaknesses of the study were

Random allocation was not used so that presumptions about even distribution of unmeasured confounding variables between groups cannot be made. For cost-effectiveness analysis, using expert opinion to provide estimates on resource use could have provided a potential source of information bias. However, this was the only feasible approach considering the real-life conditions; it was also impossible to quantify the additional costs used in terms of extra follow-up calls, text reminders and sending out letters to pregnant women after incentives had been introduced. Even though patient level data was used in both study periods, it is expected that increased workload during the incentive period meant additional costs which we could not estimate; there was significant under reporting of weeks used for NRT as it was impossible to estimate the exact number of weeks and types used by pregnant women. To calculate the NRT costs for both periods, smoking cessation outcomes were extrapolated to estimate the weeks used. Just as the proportion of women who stop smoking reduced as the weeks increased, the same was assumed with NRT use. This was seen in CPIT II NRT use [26]. Despite the fact that incremental cost per quitter provides important insights into cost implications, it does not incorporate longer term cessation outcomes. Generic health outcomes such as Quality Adjusted Life Years (QALYs) are of more use to decision makers as benefits of smoking cessation are seen over the long-term [26-32].

Aligning with existing literature, a 10% increase of pregnant smokers who accepted the offer of cessation support indicates that financial incentives can help start the process of engagement with SSS **(Table 2)**. Incentivised women in a qualitative study in England considered financial incentives an additional motivation. Smoking cessation outcomes compare favourably with Give It Up For Baby (GIUFB) in NHS Tayside [33]. At twelve weeks, the incentive period in the present study reported a similar quit rate of 34.3% (59/172) to that in Tayside, 31.8% (125/393) [34]. If a pregnant woman in GIUFB recorded negative tests and received weekly vouchers of £ 12.50 at twelve weeks the total would be £ 150. In this phase IV study, total voucher value at twelve weeks is £ 100. The fact that 57.6% (34/59) of 12 week quits were sustained to at least 24 weeks post-quit date (end of pregnancy) in this service evaluation can be explained by the offer of the highest voucher value of £ 60 at 24 weeks. Successful quits to 24 weeks were achieved without behavioural and NRT support which finishes after 12 weeks. For the Glasgow CPIT II trial, a £ 200 voucher was issued towards the end of pregnancy which resulted in a quit rate of 28% (69/248), 25 higher than the present study of 19.8% (34/172). It would be worth exploring whether increased voucher value would yield greater quit rates. Cost-effectiveness analysis was limited to an in-study assessment (ICER). However the costs per 4 and 12 week quitter of £ 517 and £ 546 respectively were in keeping the ICER found in the CPIT II trial at the same site of £ 1127 per quitter towards the end of pregnancy (about 24 weeks post quit date). The CPIT trial within study ICER translated to a lifetime ICER of £ 482/QALY which is well below the £ 20,000 threshold set by NICE. As just over half of the 12-week quitters in the intervention period in this phase IV study, remained quit at

24 weeks post quit date without additional support and inherent costs, the ICER is in keeping with the CPIT trial and translates to a very cost-effective lifetime ICER.

This phase IV study points to an overall positive impact of financial incentives when added to existing routine NHS GG&C pregnancy SSS. NRT is in widespread use throughout the UK to help pregnant smokers quit [35]. Estimates of cost-effectiveness in terms of ICER per quitter are 5 to 10 times higher for NRT compared with financial incentive payments calculated in this study and in CPIT [26].

Generalisability of incentives to other pregnancy SSSs with varied service delivery needs to be examined. This format of service evaluation using a time-matched pre-incentives control group and a limited cost-effectiveness analysis provides a workable model. If these local service evaluations were co-ordinated, an important question, posed by NICE, about effectiveness and cost-effectiveness regarding different levels of incentive payments, could be addressed [15].

Conclusion

This study has shown that adding financial incentives to usual care is an effective and cost-effective intervention to help pregnant smokers to quit and stay smoke free. As a feasible intervention that has been widely tested in trials, incorporating financial incentives in a real-world setting improves usual care. Financial incentives strengthen support for women to stop smoking during pregnancy protecting them from life shortening conditions and improving the health of their offspring in the short and longer term.

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Authors' Contribution

ET conceived the study, was involved in design, data analyses and drafting the paper. CH was involved in reviewing and editing the paper. NM was involved in reviewing and editing the paper. GL was involved in data acquisition, project design and reviewing the paper. DT was involved in project design, data analyses and editing the paper. All authors revised the manuscript and approved the final paper.

Ethical Consideration

The study was designated as a service evaluation by the West of Scotland Ethics Service. The dataset contained no identifiable fields as names were anonymised and addresses converted to SIMD categories.

Data Sharing

Raw data and files from this study belongs to NHS GG&C and may be made available on request by Geraldine Lucas. The analysis was not pre-registered, and the results should be considered exploratory.

Authors' Information

Elsie Too: Public Health practitioner with experience in Water, Sanitation and Hygiene activities in rural communities in Western Kenya. Undertook this work as a Master of Public Health project at the University of Glasgow and was involved in project design, data analyses, and writing the paper.

Claire E Hastie: Lecturer in Public Health and data scientist with experience in analysing large administrative datasets and UK Biobank data. Claire fully supervised the master's project and was involved in writing the paper.

Nicola McMeekin: Research assistant in health economics and has experience in designing and undertaking economic evaluations alongside clinical trials. Nicola fully supervised the master's project and was involved in writing the paper.

Geraldine Lucas: Health Improvement Lead (Tobacco), Quit Your Way Stop Smoking Services at NHS Greater Glasgow & Clyde. Geraldine provided the dataset, expert opinion and was involved in project design and writing the paper.

David Tappin: Senior Research Fellow at University of Glasgow and Co-principal investigator of Cessation. In Pregnancy Trial II and III. David has extensive experience in clinical trials related to smoking cessation in pregnancy. He was involved in project design, data analyses, and writing the paper.

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