National Institute for Health and Care Excellence

Final

Tobacco: preventing uptake, promoting quitting and treating dependence

[I] Evidence reviews for incentives during pregnancy

NICE guideline NG209

Evidence reviews underpinning recommendation 1.20.12 to 1.20.14 in the NICE guideline

November 2021

Final

These evidence reviews were developed by PH-IGD

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Incentives during pregnancy

Review questions

Are incentives effective and cost effective for increasing smoking[a] cessation among women who are pregnant?

Are incentives to increase smoking cessation acceptable to pregnant women who smoke and to healthcare providers who would deliver them? What are the barriers and facilitators to uptake of incentives?

Introduction

Smoking during pregnancy is associated with a variety of health risks for mother and baby. New evidence is emerging about the use of incentives, financial and otherwise, to help pregnant women to quit. This review aims to establish which types of incentives are effective and cost effective, and whether they are acceptable.

PICO table

The following table summarises the protocol for this review.

Table 1: PICO inclusion criteria

Population	Women who are pregnant and who smoke.
Interventions	Incentives offered to pregnant women with the aim of helping them to quit and to stay quit. Interventions which also offer incentives to a 'significant other supporter' (SOS) will be included. Types of incentives include: • Risk-based reward (e.g. lottery or raffle tickets) • Rewards contingent on a quit • Rewards not contingent on a quit • Participant's deposit returned
Comparator	• No intervention • Usual care, for example usual smoking cessation information and advice • Other appropriate comparators, including active interventions.
Outcomes	**Quantitative outcomes (I.i.)** <u>Critical outcomes</u> Smoking status at longest available follow-up prior to birth, and longest total follow-up. Measured as: • Abstinence from smoking (relative risk) *Where continued abstinence is presented, this is preferred over point-prevalence abstinence. Point prevalence measures will only be used where no continuous measure is reported.*

[a] Throughout, smoking refers to the use of all smoked tobacco products.

	Where biochemically validated measures are available, these will be preferred to self-reported measures. Important outcomes • Adverse or unintended (positive or negative) effects (for example people who don't smoke enrolling; modified smoking to meet inclusion criteria; negative psychological effects of intervention). • Health-related quality of life (using validated patient-report measures, for example EQ-5D). **Qualitative outcomes (I.ii.)** Qualitative evidence on incentives for pregnant women who smoke will be examined where available. Evidence should relate to views of pregnant women who smoke and healthcare providers who would deliver eligible interventions on: • The acceptability of the incentive for smoking cessation, including the source of the incentive and the type of incentive. • Barriers or facilitators to taking up or to delivering incentives for smoking cessation. **Cost/resource use associated with the intervention** The following outcomes will be extracted in reviews of the health economic evidence, where available: • cost per quality-adjusted life year • cost per unit of effect • net benefit • net present value • cost/resource impact or use associated with the intervention or its components

Methods and process

This evidence review was developed using the methods and process described in Developing NICE guidelines: the manual (2018). Methods specific to this review question are described in the review protocol in Appendix A.

Declarations of interest were recorded according to NICE's 2018 conflicts of interest policy.

See the methods chapter for additional information on methods for the Tobacco guideline.

Identification of public health evidence

Included studies

A systematic search was undertaken in April 2019 for relevant studies published since 1998 and in the English language. It was decided to search for studies in the past 20 years (from when protocols were written). This limit is applied because before this point it is likely that the context of stop smoking support would be too different to be relevant and applicable to the guideline. Website searches were conducted in line with the protocol. Further details on the search strategy are available in Appendix B.

A recently updated Cochrane systematic review (Notley 2019[b]) on incentives for smoking cessation was identified during the evidence sift.

After removal of duplicates 1,399 unique database results were identified and 26 papers from this search with potential to answer the review questions were ordered for full-text review. Of these, 12 papers (12 studies) met the inclusion criteria for this review, and 2 additional studies were identified from Notley 2019[b] (sourced from a separate systematic review). In total, 11 studies (10 studies also identified in Notley 2019[b]) are randomised controlled trials (RCTs), 2 studies are qualitative and 1 includes a mixed methods approach (qualitative component of relevance to this review question).

NICE guideline PH26 previously considered some evidence (3 randomised controlled trials) on financial incentives paid to pregnant women for smoking cessation, however this was not evaluated as part of a complete formal evidence review. As such, the review presented here is a new review for this guideline. All 3 studies identified in NICE guideline PH26 were reassessed in relation to this review question, 2 studies were included and 1 was subsequently excluded based on the study design (see Appendix K).

A joint website search was completed for review questions on opt-out stop smoking support and incentives during pregnancy. Website searches identified a further 7 results that were screened separately. No includes from website searches were identified.

Excluded studies

Of the 26 papers retrieved at full-text review, 14 were excluded. See Appendix K for a full list of excluded studies and the reasons for exclusion.

Table 2: Summary of quantitative public health studies included in the evidence review

Study	Setting	Population	Intervention	Comparator	Outcome(s)
Baker 2018 RCT	Antenatal clinics, Wisconsin, USA	Pregnant women who smoke 1,014 participants	Usual care + cash incentive. Contingent reward.	Usual care (counselling), no incentive.	Abstinence from smoking (biochemically validated) at 6 months post-birth
Donatelle 2000a RCT	Antenatal clinics [Women, Infants and Children (WIC)	Pregnant women who smoke	Usual care + voucher incentive for participant and social supporter.	Usual care (baseline advice and quit kit), no incentive.	Abstinence from smoking (biochemically validated) at 8 months gestation

[b] Notley C, Gentry S, Livingstone-Banks J, Bauld L, Perera R, Hartmann-Boyce J. Incentives for smoking cessation. Cochrane Database of Systematic Reviews 2019, Issue 7. Art. No.: CD004307. DOI: 10.1002/14651858.CD004307.pub6

Study	Setting	Population	Intervention	Comparator	Outcome(s)
	programme sites], Oregon, USA	220 enrolled, 207 participants in primary analysis	Contingent reward.		and 2 months post-partum.
Donatelle 2000b RCT	Antenatal clinics (WIC programme sites), Oregon, USA	Pregnant women who smoke 186 participants	Usual care + voucher incentive for both intervention groups, feedback on biotesting for one group. Contingent reward.	Usual care (5 A's intervention), no incentive	Abstinence from smoking (biochemically validated) at end of pregnancy.
Donatelle 2002 RCT	Antenatal clinics, Oregon USA	Pregnant women who smoke 298 participants enrolled, 293 participants in primary analysis	Usual care + voucher incentive of two different values for both intervention groups. Contingent reward.	Usual care (5 A's intervention + smoking cessation guide), no incentive	Abstinence from smoking (biochemically validated) at 8-months gestation.
Harris 2015 RCT (pilot study)	Antenatal clinics, rural Appalachia Ohio and Kentucky, USA	Pregnant women who smoke 17 participants	Voucher and cash incentive. Contingent reward.	Phone-delivered cessation counselling, no incentive	Abstinence from smoking (biochemically validated) at end of pregnancy.
Heil 2008 RCT	Obstetric practices + WIC programme, Burlington, USA	Pregnant women who smoke 82 participants enrolled, 77 participants in primary analysis	Usual care + voucher incentive. Contingent reward.	Usual care + non-contingent voucher	Abstinence from smoking (biochemically validated) at end of pregnancy, 12 and 24-weeks post-partum.
Higgins 2014 RCT	Obstetric practices + WIC programme, Burlington, USA	Pregnant women who smoke 130 participants, enrolled, 118 participants in primary analysis	Usual care + voucher incentive for both incentive groups, differing on value initially available. Contingent reward.	Usual care (counselling) + non-contingent voucher	Abstinence from smoking (biochemically validated) at end of pregnancy and various time points up to 24-weeks post-partum.
Glover 2015	Auckland, New Zealand	Pregnant women who smoke	Usual care + voucher or product	Usual care, no incentives	Abstinence from smoking (biochemically

Study	Setting	Population	Intervention	Comparator	Outcome(s)
RCT (feasibility study)		24 participants	incentive. Contingent reward.		validated) at end of intervention (8-weeks).
Ondersma 2012 RCT (pilot study)	Antenatal clinics, Detroit, USA	Pregnant women who smoke 110 participants randomised, 94 included in primary analysis.	Voucher incentive available in 2 intervention groups. Contingent reward.	Treatment as usual, no incentives	Abstinence from smoking (biochemically validated) at end of intervention (10-weeks- end of pregnancy).
Tappin 2015 RCT	Antenatal clinics, Greater Glasgow and Clyde, UK	Pregnant women who smoke 612 participants randomised, 609 participants in primary analysis.	Usual care + voucher incentive. Contingent on engagement and/or quitting.	Usual care, no incentive	Abstinence from smoking (biochemically validated) at various time points, up to 6-months post-birth
Tuten 2012 RCT (feasibility study)	Center for addiction and pregnancy, Baltimore, USA	Pregnant, women who smoke 102 participants	Usual care + vouchers incentive, (1 contingent and 1 non-contingent group).	Usual care, no incentives	Abstinence from smoking (biochemically validated) at end of 12-week intervention (end of pregnancy) and 6-weeks post-partum.

Table 3: Summary of qualitative public health studies included in the evidence review

Study	Setting	Population	Intervention	Outcome(s)
Butterworth 2014 Qualitative study	Solihull, UK NHS hospital	Pregnant or post-partum women who smoke(d) 19 participants	Incentives for smoking cessation in pregnancy. Not all participants had experience of incentives.	Themes around initiatives to increase referrals and engagement with smoking cessation services.
Mantzari 2012 Qualitative study	Birmingham, UK, NHS primary care trust	Pregnant or post-partum women who smoke(d) 36 participants	Incentives (vouchers) offered for smoking cessation in pregnancy and usual care. Not all participants had experience of incentives.	Themes around reasons for wanting to quit smoking, factors perceived as facilitating and inhibiting the quit attempt.
Morgan 2015 Mixed methods study (qualitative element of relevance to this review question)	UK (Aberdeen, Lancashire, Greater Glasgow and Clyde). Primary and secondary health services, local authority	Pregnant or post-partum women who smoke(d) and providers of care 136 participants	Incentives for smoking cessation in pregnancy. Not all participants had experience of incentives.	Themes around acceptability of incentives for quitting, preparatory behaviours and contingent on verified outcomes. Other themes included the meaning and value of incentive components and the

Study	Setting	Population	Intervention	Outcome(s)
	and voluntary sector services.			acceptability of different types of incentives.

See Notley 2019[b] for characteristics of included studies and Appendix D for full evidence tables.

Synthesis and appraisal of public health studies included in the evidence review

Evidence appraisal

- This review addresses an intervention question. Randomised controlled trial (RCT) evidence was therefore assessed using Cochrane's *Risk of Bias* tool and the systematic review by Notley 2019[b] was assessed using the Risk of Bias in Systematic Reviews *ROBIS* tool, in accordance with the NICE Manual.
- All GRADE ratings start at 'high' and are downgraded as appropriate.
- All qualitative studies were assessed using the CASP checklist and confidence was assessed using GRADE CERQual.

See Appendix F for full GRADE and GRADE CERQual tables.

See Methods document for details of rationale for GRADE judgements.

Table 4: Minimal important differences (MIDs) agreed

Outcome	Importance	MID
Abstinence from smoking during pregnancy	Critical	Statistical significance

Data synthesis

11 quantitative studies were identified for inclusion in this review. A recently updated Cochrane review (Notley 2019[b]) was identified and deemed to be of both high quality and relevance to this review. Sections of text, data and analyses from Notley 2019[b] were either reproduced or utilised for additional analyses. The Cochrane review included 10 out of the 11 quantitative papers identified from the evidence sift. An additional paper (Glover 2015) was identified which had been excluded in Notley 2019[b] due to the length of follow-up, length of follow-up was not restricted in this review.

All 11 studies measured change in abstinence from smoking in those receiving incentives compared with those not incentivised to quit. All studies biochemically validated abstinence, with 2 studies biochemically confirming smoking status at baseline.

Notley 2019[b] conducted meta-analysis on the following outcomes using the Mantel-Haenszel method:

- Abstinence from smoking at longest follow-up: 10 studies (with the addition of 1 study, Glover 2015, identified from the evidence sift) measured change in abstinence from smoking in women who were randomised to receive an incentive for quitting compared to those who were not (see Figure 1 and GRADE profile 1). 1 study was not included in the meta-analysis due to reporting interim results only.

- Abstinence from smoking at the end of pregnancy: 7 studies measured change in abstinence from smoking in women who received incentives for quitting compared to those who did not at the end of pregnancy. (see Figure 2 and GRADE profile 1).

- Effectiveness of contingent rewards versus guaranteed payments on abstinence from smoking at longest follow-up: 3 studies assessed the effectiveness of contingent rewards versus guaranteed payments in relation to abstinence from smoking (see Figure 3 and GRADE profile 2).

For all meta-analyses reported by Notley 2019[b], a random-effects model was used. The level of heterogeneity for all meta-analysed data, as measured by the I^2 statistic was <50%. As such, analyses are presented using a fixed-effects model as outlined in the methods chapter for the Tobacco guideline.

Sensitivity analysis

Additional sensitivity analyses were performed:

- Sensitivity analysis was conducted to determine whether there were significant differences according to risk of bias in the study for the main meta-analysis (abstinence from smoking at longest follow-up).

There were no significant differences in abstinence from smoking in the studies with risk of bias judged to be either low or be at some concerns (2.21 95% CI 1.68, 2.91) compared with those at high risk of bias (2.23 95% CI 1.27, 3.94) (P = 0.97) (see Figure 4).

Funnel plot

As there were there ten studies contributing to the outcome at longest follow-up, publication bias was assessed using a funnel plot as described in the methods chapter (see Figure 5). The studies are generally scattered in a symmetrical manner around the effect line, with the standard errors being relatively similar for the included studies. There is little suggestion of publication bias, and therefore the outcome was not downgraded for this domain.

Economic evidence

Included studies

A joint search was used to identify evidence for the cost effectiveness elements of review questions H, I and J. This search incorporated elements from the original effectiveness searches and an agreed cost effectiveness filter. The joint systematic search was undertaken in July 2019 for studies published in the English language. No date limits were applied. Website searches were conducted in line with the protocol. The evidence reviews for PH26 were rechecked for cost effectiveness studies. 3368 results were downloaded and after removing 837 duplicates there were 2531 unique results for screening. A further 2 records were identified by the York Health Economics Consortium. Full details of all the search strategies are available in a separate document from the NICE Information Services team

2,533 records were assessed against the eligibility criteria for RQs H, I and J.

2,473 records were excluded based on information in the title and abstract for RQs H, I and J. One reviewer assessed all of the records and a second reviewer blind-screened 10% of the records. The level of agreement between the two reviewers was 100%.

The full-text papers of 60 documents were retrieved and assessed and 1 study was assessed as meeting the eligibility criteria for RQ I. One reviewer assessed all of the full texts and a second reviewer blind-screened 10% of the records. The level of agreement between the two reviewers was 100%. For RQ I, 1 study was included.

Excluded studies

59 full text documents were excluded for RQ I. The documents and the reasons for their exclusion are listed in Appendix K – Excluded studies. Documents were excluded for the following reasons: ineligible study design (n=27), ineligible intervention (n=22), ineligible patient population (n=6) and ineligible outcomes (n=4). The selection process is shown in Appendix G.

Summary of studies included in the economic evidence review

Table 5: Summary of the study included in the economic evidence review for incentives during pregnancy

Study	Limitations	Applicability	Other comments	Costs	Effects	Incremental cost	Incremental effects	Economic analyses outcomes	Uncertainty
Boyd 2016 (UK) Population: Pregnant smokers Sample size: 609 Intervention: Routine care (see comparator) plus financial incentives. Shopping vouchers up to the value of £400 were offered: • £50 for attending the first class • £50 for a 4-week carbon monoxide	No limitations [b]	Directly applicable [c]	None	Costs per participant Within trial period Routine care plus financial incentives: £243 Routine care: £85 Lifetime horizon Routine care plus financial incentives: £1,282 Routine care: £1,265	Late quit rate: Routine care plus financial incentives: 0.23 Routine care: 0.09 Lifetime QALYs: Routine care plus financial incentives: 19.137 Routine care: 19.101	Routine care plus financial incentives vs routine care Within trial period: £157 Lifetime horizon: £17	Late pregnancy quit rate: 0.14 Lifetime QALYs: 0.036	Cost per late pregnancy quitter: £1,127 Cost per QALY: £482	Full probabilistic sensitivity analysis (PSA) and scenario analysis explored uncertainty in all key parameters. PSA suggested that there was a 72% likelihood that the routine care plus financial incentives intervention would be cost-effective at a willingness to pay threshold of £20,000 to £30,000 per QALY. Scenario analysis suggested that higher incentives than those offered may also be cost-effective. It also showed that if the costs of smoking on future

Study	Limitations	Applicability	Other comments	Costs	Effects	Incremental cost	Incremental effects	Economic analyses outcomes	Uncertainty
(CO) validated quit • £100 for a 12-week CO validated quit • £200 for a 34 to 38 week CO validated quit Comparator: Routine care - routine referral to NHS Stop Smoking Services [a]									smoking-related healthcare costs to the mother were included then incentives would be a dominant strategy (the base case only included increased mortality to the mother from smoking and an increased likelihood and costs of low birth weight babies with smoking mothers)

CO: carbon monoxide; NR: not reported; PSA: probabilistic sensitivity analysis; QALY: quality-adjusted life-year; NRT: Nicotine Replacement Therapy; UK: United Kingdom

a) *Specialist pregnancy cessation advice via a 1 hour face-to-face appointment, followed by four weekly telephone support calls and 'free to the user' Nicotine Replacement Therapy (NRT) via local pharmacies for 10 weeks.*
b) *The analysis drew data from appropriate sources and were analysed in an appropriate manner.*
c) *The study was a high-quality analysis of a UK population and intervention directly relevant to the review question.*

Economic model

The evidence review identified one UK based cost-effectiveness study for financial incentives. However the PHAC raised some concerns with the quality of the study, including potentially overestimating the impact of incentives due to additional treatment (i.e. telephone contact) being provided in the intervention arm, that was not available in the comparator. To address their concerns economic modelling was considered to be informative for this research question.

The effectiveness of financial incentives was obtained by pooling across the seven RCTS identified in NICE evidence review I (13). The comparator in each of these studies was usual care without financial incentives. As there was potential for heterogeneity, NICE evidence review I conducted a quality appraisal where each of the seven 'no incentives' comparators were considered suitable for pooling (13). The absolute probability of smoking abstinence for the financial incentives comparator was obtained from NICE evidence review I (13) as the pooled rate of cessation across the seven RCT "no incentives" usual care control arms, equal to 9.0%.

Financial incentives were contingent on confirmed abstinence from tobacco smoking through biochemically validated measures (e.g. carbon monoxide readings). The base case analysis calculated the cost-effectiveness of staged financial incentives, where the intervention included incentives of increasing value provided according to duration of abstinence. The financial incentives intervention was delivered alongside usual care which included behavioural support and "free to the user" NRT. The comparator for the analysis was usual care without incentives. From herein we refer to this analysis as financial incentives versus no incentives. As all RR and probabilities of abstinence were obtained at childbirth for the financial incentives' intervention, no further adjustment for smoking relapse was required.

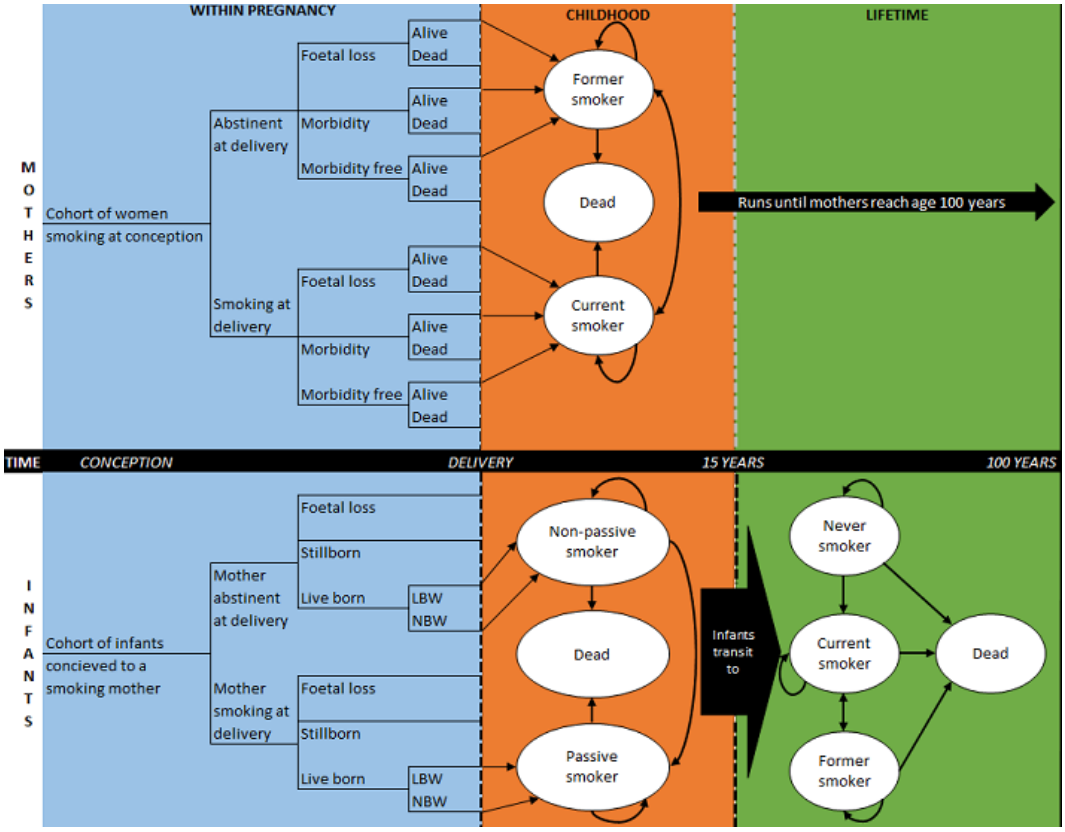
The analyses used a published economic model called the "economics of smoking in pregnancy" or ESIP model developed by the Division of Primary Care at the University of Nottingham (ref). The ESIP model estimates the lifetime costs and benefits of maternal smoking cessation during pregnancy for both mother and child. Parameter values, including unit costs and effectiveness rates were updated for each intervention and comparator.

The model adopts an NHS and personal social services (PSS) perspective for costs and incorporates health outcomes as QALYs. It calculates the cost-effectiveness of smoking cessation interventions separately for maternal outcomes only, infant outcomes only, and maternal & infant outcomes combined, each over several time horizons including pregnancy, childhood (<15 years), and lifetime (<100 years). Discount rates of 3.5% for both costs and benefits are applied (Developing NICE guidelines: The manual, 2018). A full description of the ESIP model, including model structure, input parameters, and methods to apply user defined inputs is provided in Jones et al. (2019).

A summary of the model structure and key results is provided below. A detailed report with full results and sensitivity analyses is provided in a separate economic modelling report (evidence review P)

In brief, the ESIP model progresses a cohort of 1000 pregnant women who smoke through an initial decision tree which maps maternal pregnancy outcomes. The cohort then enters a Markov model for the remaining time horizon. For mothers, the Markov component of the ESIP model contains health states related to smoking status, these being "current smoker", "former smoker", "dead". Between birth and 15 years infants enter an initial 'childhood' Markov model which estimates their burden of asthma, factoring in the impact of second-hand exposure to maternal smoking, according to their mothers smoking status. At age 16 years children transition to an 'adulthood' Markov model which estimates their life-time burden of smoking related morbidities and mortality. Different transition probabilities are applied according to the effectiveness of each intervention.

Figure 1 ESIP model structure



Model results

The stepped financial incentives intervention was cost-effective for the mother plus child analysis (dominant) and for the mother only analysis (ICER equal to £2,005), **Table**6. Financial incentives were associated with lifetime healthcare savings of £64 per mother and child. However, the intervention had slightly increased costs when compared with no incentives, equal to £82 for the mother only analysis. The increase in costs was due to the cost of administering and providing financial incentives. The slight increase in healthcare costs was more than offset by the substantial health benefits, where mean incremental QALYs were equal to 0.04 per mother, and 0.21 per mother and child vs. no incentives. Results for the base case mother and child analysis were driven by a substantial increase in the number of quitters (177 per 1000) causing: a decrease in the number of smoking related comorbidities per mother (20.87 per 1000), a reduction in fetal mortalities (6.28 per 1000) and a reduction in the number of children who become smokers during adulthood (1.3 per 1000).

Table 6: Cost-effectiveness results: Financial incentives

	Absolute Costs		Absolute QALYs		Incremental		
	Incentives	N.I. [a]	Incentives	N.I. [a]	Costs	QALYs	ICER
Mother + child [b]	£20,996	£21,030	47.05	46.85	-£64	0.205	Dominant
Mother [c]	£10,229	£10,147	23.24	23.19	£82	0.041	£2,005

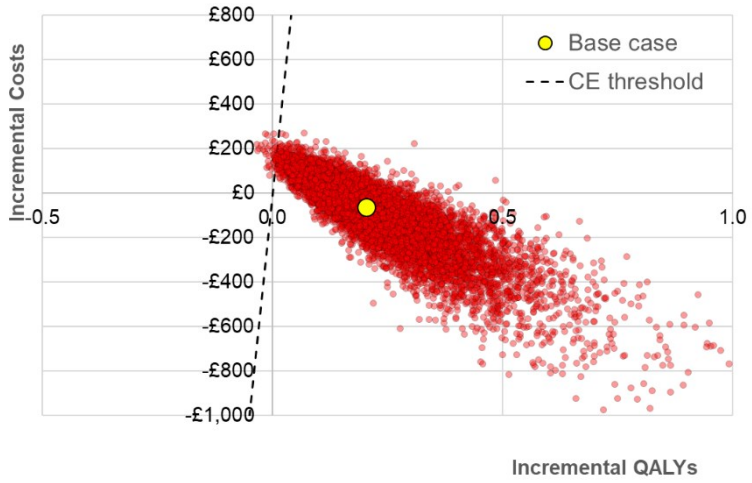
N.I. No incentives
a: Incentives and no incentives arm includes behavioural support and NRT l/s
b: Outcomes reported *per mother and child dyad*
c: Outcomes reported per mother only

The financial incentives intervention remained cost-effective across all DSAs which applied the following: upper and lower 95% confidence interval for the RR of smoking cessation vs. no incentives; limiting the time horizon to pregnancy, changing the age of the cohort to 21 and 38, increasing and decreasing intervention costs and increasing and reducing healthcare costs and QALYs.

In addition, a threshold analysis was conducted to address specific concerns from the PHAC regarding the effectiveness estimate. The pooled RR of cessation was (2.24 (1.75 to 2.88) but one study reported a much higher RR which was also highly uncertain (3.88(2.10 to 7.16)). The threshold analysis established the minimum number of quitters required for financial incentives to still be considered cost-effective. When considering maternal and child outcomes, financial incentives needed to result in at least 7 additional quitters per 1,000 to be considered cost-effective versus no financial incentives (or a RR=1.08). When considering maternal outcomes only, financial incentives needed to result in at least 33 additional quitters per 1,000 to be considered cost-effective versus no financial incentives (or a RR=1.38). The threshold is substantially less that the base case parameters where financial incentives resulted in 177 additional quitters per 1,000.

In the PSA, using the NICE threshold of £20,000/QALY as the criteria for cost effectiveness, the financial incentives intervention versus no incentives was cost effective in 99.7% of the 10,000 PSA iterations (see Fig 2).

Figure 2: PSA Results Financial Incentives



Summary of the evidence

Table 7: Evidence summary

Outcome	Summary	Confidence	GRADE profile
Abstinence from smoking (at longest follow-up)	Incentives were significantly associated with an increase in abstinence from smoking, compared with no incentives. (10 studies) *RR 2.24 (1.75 to 2.88)*	Low	1
Abstinence from smoking (at the end of pregnancy)	Incentives were significantly associated with an increase in abstinence from smoking, compared with no incentives. (7 studies) *RR 2.96 (2.22 to 3.93)*	Low	1

Outcome	Summary	Confidence	GRADE profile
Contingent rewards vs guaranteed payments (at longest follow-up)	Contingent rewards were significantly associated with an increase in abstinence from smoking, compared with guaranteed payments. (3 studies) *RR 4.39 (1.57 to 12.25)*	Moderate	2
Acceptability	Three studies (Butterworth 2014, Mantzari 2012, Morgan 2015) Mixed evidence of acceptability of incentives	Moderate	GRADE CERQual table
Incentives and deception	One study (Butterworth 2014) Concern over gaming and only abstaining on days that CO was being monitored	Low	GRADE CERQual table
Engagement with smoking cessation services	Two studies (Mantzari 2012, Morgan 2015) Women who received incentives had more motivation	Low	GRADE CERQual table
Providers views on the acceptability of incentives	One study (Morgan 2015) Mixed view on incentives	Low	GRADE CERQual table
Acceptability of voucher/cash incentives	One study (Morgan 2015) Vouchers were favoured over cash	Low	GRADE CERQual table
Acceptability of other types of incentives	Two studies (Butterworth 2014, Morgan 2015) Mother-based incentives were favoured over pregnancy or baby incentives	Low	GRADE CERQual table
Guaranteed rewards vs rewards contingent on a quit.	One study (Morgan 2015) Incentives should be given once smoking cessation have been verified	Low	GRADE CERQual table
Optimum monetary value of incentive	One study (Morgan 2015) There were mixed opinions on the optimum value of incentives	Low	GRADE CERQual table

Cost-effectiveness evidence statements

One cost-effectiveness analysis (Boyd, 2016) found that the use of financial incentives in the form of shopping vouchers, in combination with routine care (counselling and nicotine replacement therapy), resulted in a reduction in pregnant women who smoke by weeks 34 to 38 of the pregnancy, compared to routine care alone. The economic evaluation showed that whilst the financial incentive added £157 per smoking mother to the costs of smoking cessation support, when a lifetime perspective was taken to include maternal and birth outcomes, the incremental cost of routine care plus incentives versus routine care was £17. The cost per additional quitter was £1,127 over the trial time horizon and the cost per QALY gained using a lifetime Markov model was £482 per QALY gained. Probabilistic sensitivity analysis suggested a 72% likelihood that the incentives would be cost-effective at a willingness to pay threshold of £30,000 per QALY. The authors concluded that incentives would likely be more cost-effective (lower cost per QALY gained value and higher probability of being cost-effective) if health-related costs to the mother over her lifetime associated with

smoking had also been included. The analysis was assessed as directly applicable to the review question, with no limitations.

One directly applicable cost-utility analysis with minor limitations found that the financial incentives intervention was cost effective for the mother plus child analysis (dominant) and for the mother only analysis (ICER equal to £2,005). The results of the DSA showed the findings were robust with financial incentives remaining cost effective for all scenario analyses. The PSA showed no uncertainty in this finding with 97.7% of the 10,000 iterations being cost effective at the threshold of £20,000 per QALY.

The committee's discussion of the evidence

Interpreting the evidence

The outcomes that matter most

The committee agreed that the outcome that mattered the most for the effectiveness of incentive schemes was abstinence from smoking, which was the key outcome for the quantitative component of this review. Abstinence was reported at both the end of pregnancy and at the longest follow-up.

Confidence in the evidence

Quantitative evidence

The committee agreed that the evidence demonstrated that financial incentives offered to support smokers to quit during pregnancy are effective. They agreed that the evidence favoured the use of incentives for pregnant women and noted that this was supported by the results from the sensitivity analysis (at longest follow-up). The committee also acknowledged that all the included studies were randomised controlled trials, which establish causality between the intervention and outcome.

The committee discussed the evidence-base which included 1 large UK study (Tappin 2015) and agreed that they had reasonable confidence in this study, showing a positive effect of voucher incentives in increasing abstinence rates. The committee considered whether differences in the delivery and components of usual care between studies conducted in the USA and UK may impact the perceived effectiveness of the incentive intervention. The committee agreed whilst such differences are present, the combined delivery of incentives and usual care would likely be multiplicative in increasing abstinence rates, including in a UK context.

The committee discussed the evidence showing that contingent rewards are more effective than guaranteed rewards in relation to abstinence from smoking at the longest follow-up. The committee agreed that vouchers offered for cessation should be contingent on biochemically validated abstinence, and that this would help to reduce the likelihood of incentives being delivered to women who self-report abstinence but may still be smoking. The committee considered 1 study (Donatelle 2000a) which also incentivised a significant other supporter in tandem with the pregnant smoker and discussed that this may increase the likelihood of a woman successfully quitting.

Qualitative evidence

The committee agreed that the studies were generally well conducted and had no particular concerns about risk of bias. The committee noted that the evidence demonstrated that women and providers of care generally found voucher incentives acceptable and this reflected the type of rewards offered in incentive schemes already being implemented. They

also discussed how several women reported that they would like any incentive offered to be focused on the health and wellbeing of the mother. The committee agreed that recommendations should focus on voucher incentives for the mother and provide a choice of where to spend to ensure continual motivation. They also recommended that providers should ensure that vouchers cannot be redeemed in exchange for inappropriate items, such as cigarettes and alcohol, which would detract from any progress made to positively change their health behaviour. They discussed the evidence which demonstrated that some women admitting being tempted to abstain only for the carbon monoxide (CO) test to receive the incentive. The committee considered the impact of such gaming behaviour and whether this may have overestimated quit rates demonstrated in the quantitative evidence. They noted that 1 quantitative study (Tappin 2015) tested for such deception, which was found to be similar across both intervention and control groups, and therefore not likely to affect outcome assessments.

The committee also discussed suitable biochemical markers to validate self-reported cessation. They agreed that whilst urinary/salivary cotinine tests are a more reliable measure of smoking cessation over the past 7 days, they are expensive and sensitive to nicotine released from products designed to aid cessation. The committee agreed based on this that CO testing would be an appropriate measure, being less costly and more routinely available, with a cut-off of less than 4ppm being indicative of abstinence. They agreed that readings above 4ppm are indicative of exposure to tobacco smoke, and in such instances women should be automatically referred for stop smoking support via an opt-out pathway (aligns with the Saving Babies' Lives Care Bundle).

Benefits and harms

The committee agreed that any harms arising from the use of incentives would likely be minimal. They noted that various incentive schemes aimed at pregnant women are currently being implemented across NHS trusts. The committee considered that there are clear benefits to stopping smoking in pregnancy for both mother and baby, these benefits are substantial and therefore outweigh the possible concerns about using incentive schemes.

Cost effectiveness and resource use

The committee discussed evidence from 1 published cost effectiveness analysis based on a Phase II randomised controlled trial (RCT) and a cost-utility analysis using a life-time Markov model (Boyd, 2016). The study compared usual cessation support plus or minus financial incentives of up to £400 vouchers, contingent upon smoking cessation. The incremental cost per quitter at 34-38 weeks pregnant was £1127. The life-time model resulted in an incremental cost of £17 and a gain of 0.04 QALYs giving an ICER of £482/QALY. Probabilistic sensitivity analysis indicates uncertainty in the results, particularly regarding relapse after birth. The authors concluded that financial incentives for smoking cessation in pregnancy are highly cost-effective.

Although relapse was an important factor in determining the cost effectiveness of incentives the committee noted that the risk of relapse had to take extreme values – 80% in the intervention arm and 30% in the control arm – before the decision changed. Based on their expertise the committee thought this an unlikely scenario.

There were concerns that the study may have overestimated the impact of incentives because the intervention arm included multiple telephone contacts which may have been a contributing factor.

The committee were concerned about extrapolating a short term (6 month) quit outcome across a lifetime horizon although it transpires the model accounts for any relapse to

smoking post-trial; in the six month period following birth, and for up to eight years post quit. The committee thought this was an acceptable approach to take.

Variations in current practice led some of the committee to question the generalisability of the findings. However, they were reassured by feedback from other committee members about the study being replicated in other parts of the country including Greater Manchester and achieving positive results.

The results of the economic analysis showed the financial incentives intervention is highly cost effective. Of particular note to the committee was the finding of the PSA which showed no uncertainty in the probability of being cost effective. There was a concern among the committee that the results may have been inflated by a single study conducted in 2015 which had a very high RR of smoking cessation (3.88 (2.10 to 7.16)). However, the committee were reassured by the results of the threshold analysis which showed that the number of additional quitters would have to be substantially lower than the base case parameters in order for financial incentives to not be cost effective.

The committee agreed that whilst the provision of incentives would incur additional costs these would be more than offset by the health care savings that would arise from an increase in the number of pregnant women who quit smoking.

Overall, the committee discussed and agreed that the use of incentives in addition to usual smoking cessation support offers good value for money and will make an important contribution to achieving the smoking and pregnancy objectives set out in the long term NHS plan.

Other factors the committee took into account

The committee discussed whether there was a need to target incentive schemes to reduce inequalities caused by smoking in pregnant women. The committee agreed that based on the risks associated with smoking during pregnancy, incentive schemes should be targeted at all pregnant smokers.

The committee acknowledged that whilst women quitting at any stage of pregnancy is clearly a beneficial outcome of an incentive scheme, quitting at an earlier stage in pregnancy would provide the greatest benefit to both the mother and baby. They agreed that referral onto an incentive scheme should emphasise early pregnancy appointments to reduce the number of women entering a scheme at a later pregnancy stage. The committee discussed the duration of incentive provision and agreed that this should occur at least until the end of pregnancy (including pregnancies that do not progress), however that it wasn't clear whether provision would be beneficial in the post-partum period.

The committee agreed that there were further areas of uncertainty, including the optimum duration of incentive provision, the optimum value of the incentive and the effectiveness of additionally incentivising a significant other supporter.

Recommendations supported by this evidence review

This evidence review supports recommendations 1.20.12 to 1.20.14.

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Appendices

Appendix A – Review protocols

Review protocol for incentives during pregnancy.

ID	Field (based on PRISMA-P	Content
I	Review question	5.2a. Are incentives effective and cost effective for increasing smoking[3] cessation among women who are pregnant? 5.2b. Are incentives to increase smoking cessation acceptable to pregnant women who smoke and to healthcare providers who would deliver them? What are the barriers and facilitators to uptake of incentives?
II	Type of review question	Mixed methods
III	Objective of the review	Smoking during pregnancy is associated with a variety of health risks for mother and baby. New evidence is emerging about the use of incentives – financial and otherwise – to help pregnant women to quit. This review aims to establish which types of incentives are effective and cost effective, and whether they are acceptable.
IV	Eligibility criteria – population/disease/condition/issue/domain	**Included**: Women who are pregnant and who smoke. **Excluded**: Women who are trying to conceive or have recently given birth. Women who used to smoke habitually but who have since quit.

[3] Throughout, smoking refers to the use of all smoked tobacco products.

		Women who use other substances or smokeless tobacco products. **Setting** All settings.
V	Eligibility criteria – intervention(s)/exposure(s)/prognostic factor(s)	**Included:** Incentives offered to pregnant women with the aim of helping them to quit and to stay quit. Interventions which also offer incentives to a 'significant other supporter' (SOS) will be included. Types of incentives include: - Risk-based reward (e.g. lottery or raffle tickets) - Rewards contingent on a quit - Rewards not contingent on a quit - Participant's deposit returned **Excluded**: Interventions which only refund the cost of stop smoking support Interventions which only incentivise the partners or SOS of women who are pregnant or who have recently given birth to support the woman in her attempts to quit smoking. Incentives only to help partners or anyone other than the pregnant woman to stop smoking.
VI	Eligibility criteria – comparator(s)/control or reference (gold) standard	**Included**: No intervention

		Usual care, for example usual smoking cessation information and advice Other appropriate comparators, including active interventions.
VII	Outcomes and prioritisation	**Quantitative outcomes (5.2a)** Smoking status is the key outcome for this review. <u>Critical outcomes</u> Smoking status at longest available follow-up prior to birth, and longest total follow-up. Measured as: • Abstinence from smoking (relative risk) Where continued abstinence is presented, this is preferred over point-prevalence abstinence. Point prevalence measures will only be used where no continuous measure is reported. Where biochemically validated measures are available, these will be preferred to self-reported measures. <u>Important outcomes</u> • Adverse or unintended (positive or negative) effects (for example people who don't smoke enrolling; modified smoking to meet inclusion criteria; negative psychological effects of intervention). • Health-related quality of life (using validated patient-report measures, for example EQ-5D). **Qualitative outcomes (5.2b)** Qualitative evidence on incentives for pregnant women who smoke will be examined where available. Evidence should relate to views of pregnant women who smoke and healthcare providers who would deliver eligible interventions on:

		• The acceptability of the incentive for smoking cessation, including the source of the incentive and the type of incentive. • Barriers or facilitators to taking up or to delivering incentives for smoking cessation. **Cost/resource use associated with the intervention** The following outcomes will be extracted in reviews of the health economic evidence, where available: • cost per quality-adjusted life year • cost per unit of effect • net benefit • net present value • cost/resource impact or use associated with the intervention or its components
VIII	Eligibility criteria – study design	**Included study designs**: • Systematic reviews of included study designs • RCTs (including cluster RCTs) If no RCTs are identified, the following study designs will be considered, in this order. Otherwise, they will be excluded: • Non-randomised controlled trials • Controlled before-and-after studies <u>Economic studies</u>:

		• Cost-utility (cost per QALY) • Cost benefit (i.e. net benefit) • Cost-effectiveness (Cost per unit of effect) • Cost minimization • Cost-consequence <u>Qualitative studies:</u> • Focus groups, interview-based studies or surveys with open-ended responses. Must be related to incentives for cessation in pregnant women. **Excluded study designs**: • Cohort studies • Cross-sectional surveys (except for qualitative data) • Epidemiological studies • Correlation studies • Case control studies
IX	Other inclusion exclusion criteria	**Studies** This review is a result of a gap identified in PH26 by the 2015 review surveillance report. This is a new review for the Tobacco update. **Systematic Review**

		Relevant systematic reviews (SRs) identified from database searches will be citation searched. Highly relevant systematic reviews may be included as a primary source of data. These SRs will be assessed against the inclusion criteria for this protocol, and their quality will be assessed using the ROBIS tool. Where the SR is highly relevant and of high quality, details or data from the systematic review may be used. In addition to any SRs meeting the above criteria, other primary studies will be included if they were published after the publication date of the SR and meet the protocol inclusion criteria. Full economic analyses and costing studies identified from searches will be included. Costing data will not be used for the purpose of the effectiveness review. Health economics reviews and modelling will be conducted by the York Health Economics Consortium (YHEC). Only papers published in the English language will be included. Only studies carried out in OECD countries will be included (for effectiveness data) and in the UK (for qualitative data). Only studies published in 1998 onwards will be included. Only full published studies (not protocols or summaries even where they include some data) will be included.

X	Proposed sensitivity/sub-group analysis, or meta-regression	The following factors will be of interest in any meta-regression or subgroup analysis:
		
		• The total amount given in the incentive scheme
		  ○ total <£50 or equivalent vs £50+ or equivalent (prices will be inflated using the hospital and community health services index, and then converted using HMRC source)
		• Age of mother
		  ○ mothers <25 vs mothers 25+
		• Deprivation
		  ○ deprived vs not deprived, as defined by study

XI	Selection process – duplicate screening/selection/analysis	The review will use the priority screening function within the EPPI-reviewer systematic reviewing software.

		Double screening will be carried out for 10% of titles and abstracts by a second reviewer. Disagreements will be resolved by discussion. Inter-rater reliability will be assessed and reported. If below 90%, a second round of 10% double screening will be considered. The study inclusion and exclusion lists will be checked with members of the PHAC to ensure no studies are excluded inappropriately.
XII	Data management (software)	EPPI Reviewer will be used: • to store lists of citations • to sift studies based on title and abstract • to record decisions about full text papers • to order freely available papers via retrieval function • to request papers via NICE guideline Information Services • to store extracted data Cochrane Review Manager 5 will be used to perform meta-analyses. Any meta-regression analyses will be undertaken using the R software package. Qualitative data will be summarised using secondary thematic analysis. A matrix approach will be used to compare findings with quantitative evidence.
XIII	Information sources – databases and dates	The following methods will be used to identify the evidence: • the databases listed below will be searched with an appropriate strategy. • the websites listed below will be searched or browsed with an appropriate strategy. • studies included in the evidence reviews for PH26 which support the recommendations that are being updated and potentially meet the criteria for the current review will be added to the search results. • studies included in the surveillance reviews for PH26 will be added to the search results. • selected studies that are potentially relevant to the current review will be identified from the bibliography of any systematic reviews identified during the search process that are not being included in their own right. • forward citation searching and reference harvesting will be done using selected studies prioritised from the surveillance reviews, the studies included in PH26, scoping searches or any relevant systematic reviews identified in the search process. **Database strategies**

		The database strategy will be adapted as appropriate from the one used in PH26 in 2009, taking into account the resources available to this review, the subscriptions that NICE has, changes in indexing policies and the final scope for the current evidence review. The principal search strategy is listed in Appendix A. The search strategy will take this broad approach: (smoking OR tobacco OR cigarettes OR shisha) AND (pregnancy OR maternity services OR obstetrics OR midwifery) AND (incentives OR rewards) AND 1998-Current AND Limits Feedback on the principal database strategy will be sought from PHAC members. The principal search strategy will be developed in MEDLINE (Ovid interface) and then adapted, as appropriate, for use in the other sources listed, taking into account their size, search functionality and subject coverage. The databases will be: • British Nursing Index (BNI) via HDAS • Cochrane Central Register of Controlled Trials (CENTRAL) via Wiley • Cochrane Database of Systematic Reviews (CDSR) via Wiley • Cumulative Index to Nursing and Allied Literature (CINAHL) via HDAS • Embase via Ovid • Health Management Information Consortium (HMIC) via Ovid • MEDLINE via Ovid • MEDLINE-in-Process (including Epub Ahead-of-Print) via Ovid • PsycINFO via Ovid • Social Policy and Practice (SPP) via Ovid **Database search limits** Database functionality will be used, where available, to exclude: • non-English language papers • animal studies

		• editorials, letters and commentaries • conference abstracts and posters • registry entries for ongoing or unpublished clinical trials • duplicates. Sources will be searched from 1998 to current. The database search strategies will not use any search filters for specific study types. **Cost effectiveness evidence** A separate search will be done for cost effectiveness evidence. The following databases will be searched again with agreed study-type search filters applied to a strategy based on the one in Appendix A: • Embase via Ovid • MEDLINE via Ovid • MEDLINE-in-Process (including Epub Ahead-of-Print) via Ovid In addition, the following sources will be searched without study-type filters: • Campbell Collaboration via https://campbellcollaboration.org/library.html • EconLit via Ovid • HTA database via CRD https://www.crd.york.ac.uk/CRDWeb/ • NHS EED via CRD https://www.crd.york.ac.uk/CRDWeb The main website results will be rescanned to check if there are any results potentially relevant to cost effectiveness. **Web of Science** Forward citation searching and reference harvesting will be conducted using Web of Science (WOS) Core Collection. Only those references which NICE can access through its WOS subscription will be added to the search results. Only papers published in 1998-Current and in the English language will be included in the search results. Duplicates will be removed in WOS before downloading. **Websites** The following websites will be searched with an appropriate strategy: • Health Services/Technology Assessment Texts (HSTAT) https://www.ncbi.nlm.nih.gov/books/NBK16710

		• NICE Evidence Search https://www.evidence.nhs.uk The websites of relevant organisations, including the ones below, will be browsed: • Action on Smoking and Health (ASH) http://ash.org.uk/home • Local Government Association https://www.local.gov.uk • National Centre for Smoking Cessation and Training http://www.ncsct.co.uk • Northern Ireland Assembly http://www.niassembly.gov.uk/ • Public Health England https://www.gov.uk/government/organisations/public-health-england • Royal College of Midwives https://www.rcm.org.uk • Royal College of Nursing https://www.rcn.org.uk • Royal College of Paediatrics and Child Health https://www.rcpch.ac.uk/ • Royal College of Physicians https://www.rcplondon.ac.uk • Scottish Government https://www.gov.scot • Smoking Toolkit Study http://www.smokinginengland.info • UK Centre for Tobacco and Alcohol Studies http://ukctas.net/index.html • University of Bath Tobacco Control Research Group https://researchportal.bath.ac.uk/en/organisations/uk-centre-for-tobacco-control-studies • University of Stirling Centre for Tobacco Control Research https://www.stir.ac.uk/about/faculties-and-services/health-sciences-sport/research/research-groups/centre-for-tobacco-control-research/publications • Welsh Government https://gov.wales/?lang=en • World Health Organization Europe http://www.euro.who.int/en/health-topics/disease-prevention/tobacco The website results will be reviewed on screen and documents in English and published from 1998-Current that are potentially relevant will be listed with their title and abstract (if available) in a Word document. The initial screening decision will be made using this Word file. Any items selected for review at full text will be added to EPPI-Reviewer. **Quality assurance**

		The guidance Information Services team at NICE will quality assure the principal search strategy and peer review the strategies for the other databases. Any revisions or additional steps will be agreed by the review team before being implemented. Any deviations and a rationale for them will be recorded in the search history document. **Search results** The database search results will be downloaded to EndNote before duplicates are removed using automated and manual processes. The de-duplicated file will be exported in RIS format for loading into EPPI-Reviewer for data screening.
XIV	Identify if an update	This question is a new question for the Tobacco update.
XV	Author contacts	Please see the guideline development page
XVI	Highlight if amendment to previous protocol	For details please see section 4.5 of Developing NICE guidelines: the manual
XVII	Search strategy – for one database	For details please see appendix B.
XVIII	Data collection process – forms/duplicate	A standardised evidence table format will be used and published as appendix D (effectiveness evidence tables) or H (economic evidence tables).
XIX	Data items – define all variables to be collected	For details please see evidence tables in appendix D (effectiveness evidence tables) or H (economic evidence tables).
XX	Methods for assessing bias at outcome/study level	Standard study checklists will be used to critically appraise individual studies. For details please see Appendix H of Developing NICE guidelines: the manual The risk of bias across all available evidence will be evaluated for each outcome using an adaptation of the 'Grading of Recommendations Assessment, Development and Evaluation (GRADE) toolbox' developed by the international GRADE working group http://www.gradeworkinggroup.org/ GRADE will be used to assess confidence in the findings from quantitative evidence synthesis. GRADE-CERQual will be used to assess confidence in the findings from qualitative evidence syntheses.

XXI	Criteria for quantitative synthesis (where suitable)	For details please see section 6.4 of Developing NICE guidelines: the manual Non-randomised studies are at risk of confounding. These studies should adjust for confounders which are decided by the committee to have important potential to affect the result, or the allocation into intervention or control groups. These factors are: - Peer or family smoking - Baseline smoking status (where sample includes people who smoke) - Socioeconomic status Where adjusted results are provided, these will be used in analysis. Where no adjustment has taken place, this will be considered when assessing risk of bias.
XXII	Methods for analysis – combining studies and exploring (in)consistency	**Heterogeneity** Data from different studies will be pooled in a meta-analysis where they are investigating the same outcome and where the resulting meta-analysis may be useful for decision-making. Cluster and individual randomised controlled trials will be pooled. Randomised and non-randomised controlled studies investigating the same outcomes will be pooled. Results will be stratified by design (cluster, individual, randomised and non-randomised for a maximum of four groups stratified) and the P value of the interaction between study design and effect evaluated. A P value of <0.2 will be considered significant. If interaction is significant, results will be presented separately for each group, but if not, will be presented with one averaged effect estimate. It is anticipated that studies included in the review will be heterogeneous with respect to participants, interventions, comparators, setting and study design. Where significant between study heterogeneity in methodology, population, intervention or comparator is identified by the reviewer in advance of data analysis, random effects models will be used. If methodological heterogeneity is not identified in advance but the I^2 value is ≥50%, random effects models will also be used. If the I^2 value is above 50%, heterogeneity will be judged to be serious and so will be downgraded by one level in GRADE.

		If the I^2 value is above 75%, heterogeneity will be judged to be very serious and will be downgraded by two levels in GRADE. If the studies are found to be too heterogeneous to be pooled statistically, a narrative synthesis will be conducted. **Imprecision** No minimally important difference (MID) thresholds relevant to this guideline were identified from the COMET database or other published source. MIDs were agreed by committee. Uncertainty is introduced where confidence intervals cross the MID threshold. If the confidence interval crosses one lower MID threshold, this indicates 'serious' risk of imprecision. Crossing both MID thresholds indicates 'very serious' risk of imprecision in the effect estimate. Where the MID is 'any significant change' there is effectively only one threshold (the line of no effect), and so only one opportunity for downgrading. In this instance, outcomes will be downgraded again if they are based on small samples (<300 people). MIDs for outcomes will be included in the methods section of the individual reviews.
XXIII	Meta-bias assessment – publication bias, selective reporting bias	For details please see Appendix H of Developing NICE guidelines: the manual.
XXIV	Assessment of confidence in cumulative evidence	For details please see sections 6.4 and 9.1 of Developing NICE guidelines: the manual.
XXV	Rationale/context – Current management	For details please see the introduction to the evidence review.
XXVI	Describe contributions of authors and guarantor	A multidisciplinary committee will develop the guideline. The committee will be convened by Public Health Internal Guidelines Development (PH-IGD) team and chaired by Sharon Hopkins in line with section 3 of Developing NICE guidelines: the manual. Staff from Public Health Internal Guidelines Development team will undertake systematic literature searches, appraise the evidence, conduct meta-analysis where appropriate and draft the guideline in collaboration with the committee. Cost-effectiveness analysis will be conducted by YHEC where appropriate. For details please see Developing NICE guidelines: the manual.

XXVII	Sources of funding/support	PH-IGD is funded and hosted by NICE
XXVIII	Name of sponsor	PH-IGD is funded and hosted by NICE
XXIX	Roles of sponsor	NICE funds PH-IGD to develop guidelines for those working in the NHS, public health and social care in England.
XXX	PROSPERO registration number	[If registered, add PROSPERO registration number]

Appendix B – Literature search strategies

Search approach

The MEDLINE searches below were run after QA, peer review and consultation with the committee. The strategies were adapted as appropriate to the other databases listed in the protocol (see the sources tables below). The searches were done on 15 April 2019.

Additional search results were obtained from the surveillance review for PH26, studies included in the evidence reviews for PH26, scoping searches and from forwards citation searching and reference checking using Web of Science.

A joint search for grey literature was done for review questions on opt-out stop smoking support and incentives during pregnancy using the websites listed in the protocol. This was due to both review questions being closely related and overlap in the search terms.

Full details of all the search strategies are available in a separate document from the NICE guidance Information Services team.

Sources searched to identify the evidence

Database name	Date searched	Database Platform	Database segment or version	No. of records
British Nursing Index (BNI)	15/04/2019	HDAS	1992-present (provided by ProQuest)	126
Cochrane Central Register of Controlled Trials (CENTRAL)	15/04/2019	Wiley	Cochrane Central Register of Controlled Trials Issue 4 of 12, April 2019136	136
Cochrane Database of Systematic Reviews (CDSR)	15/04/2019	Wiley	Cochrane Database of Systematic Reviews Issue 4 of 12, April 2019	14
Cumulative Index to Nursing and Allied Literature (CINAHL)	15/04/2019	HDAS	1981-present (provided by Ebsco)	414
Embase	15/04/2019	Ovid	Embase 1974 to 2019 April 12	589
Health Management Information Consortium (HMIC)	15/04/2019	Ovid	Health Management Information Consortium 1979 to January 2019	50
MEDLINE	15/04/2019	Ovid	Ovid MEDLINE(R) 1946 to April 12, 2019	558
MEDLINE-in-Process (including Epub Ahead-of-Print)	15/04/2019	Ovid	Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations 1946 to April 12, 2019, Ovid MEDLINE(R) Daily Update April 12, 2019	77
PsycINFO	15/04/2019	Ovid	PsycINFO 1806 to April Week 2 2019	305
Social Policy and Practice (SPP)	15/04/2019	Ovid	Social Policy and Practice 201901	11
Forward citation searching	15/04/2019	Clarivate	Web of Science Core Collection (1990-present)	385
Surveillance	15/04/2019	-	-	1

Scoping searches	15/04/2019	-	-	21
Includes from PH26	15/04/2019	-	-	3

Database strategy– main search as run in MEDLINE and adapted for other sources

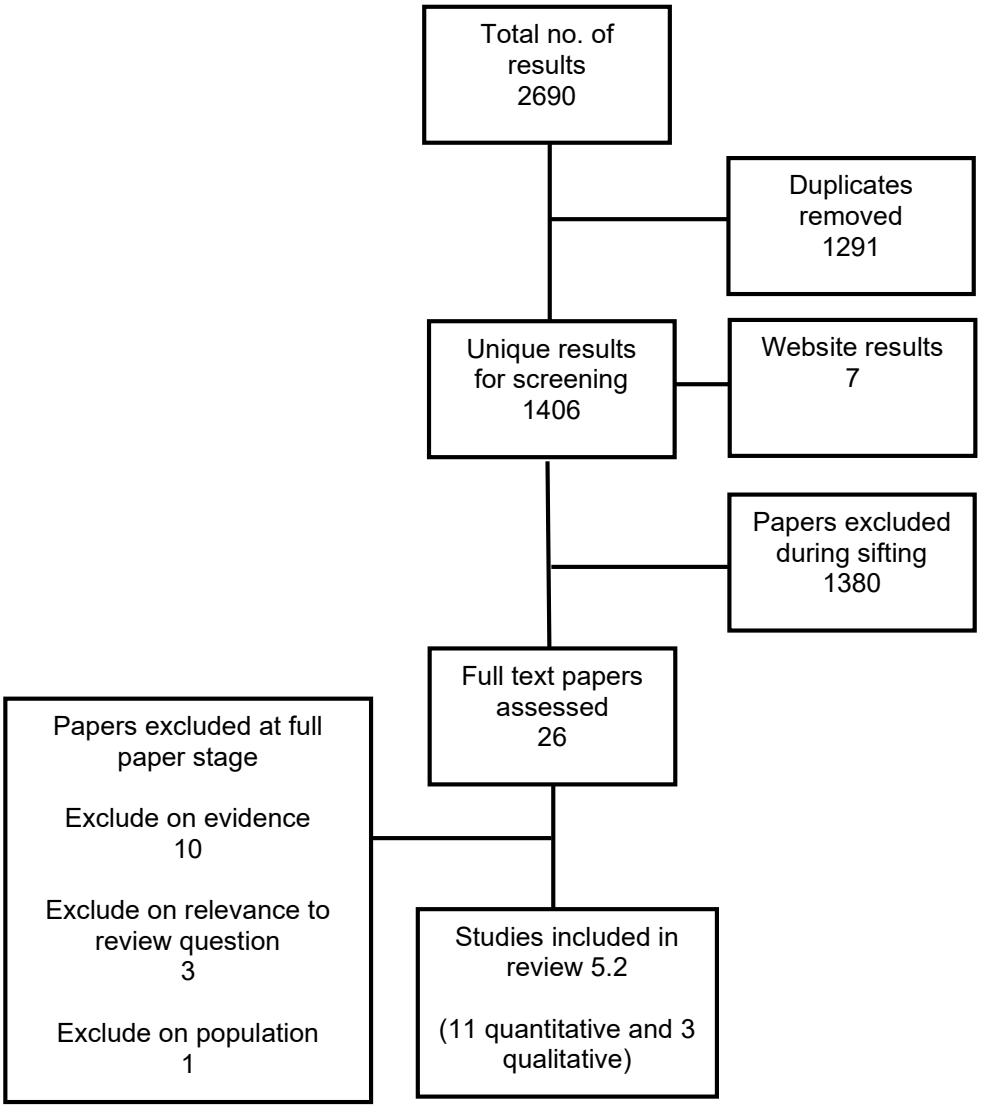
Database(s): **Ovid MEDLINE(R)** 1946 to April 12, 2019

Search Strategy:

#	Searches	Results
1	exp "tobacco use"/	2436
2	tobacco/	29440
3	"tobacco use disorder"/	10619
4	"tobacco use cessation"/	1064
5	"tobacco use cessation devices"/	1557
6	smoking/	135389
7	exp Pipe smoking/	87
8	smoking reduction/	23
9	"smoking cessation"/	26605
10	Smoking cessation agents/	32
11	nicotine/	24530
12	Smokers/	722
13	Ex-smokers/	13
14	exp Smoking Devices/	8351
15	(smoking* or smoker* or antismok* or anti smok* or anti-smok* or exsmoker* or ex-smoker* or "ex smoker*").ti,ab.	207251
16	(tobacco* or nicotin* or cigar* or cigs).ti,ab.	182809
17	(bidi or bidis or beedi or beedis or kretek* or hand roll* or handroll* or rollies).ti,ab.	484
18	(waterpipe* or water pipe* or dokha or dokhas or hookah or hookahs or hooka or hookas or shisha or shishas or sheesha or sheeshas).ti,ab.	1485
19	or/1-18	357695
20	exp Pregnancy/	858439
21	exp Pregnancy complications/	407712
22	Pregnant Women/	7377
23	exp Maternal Health Services/	45691
24	Midwifery/	18498
25	obstetrics/	21717

26	obstetric nursing/	2951
27	nurse midwives/	6951
28	pregnan*.ti,ab.	429409
29	(ante natal* or ante-natal* or antenatal* or pre natal* or pre-natal* or prenatal* or peri natal* or peri-natal* or perinatal*).ti,ab.	163299
30	(maternity* or maternal* or obstetric* or midwif* or midwiv*).ti,ab.	301268
31	or/20-30	1094593
32	19 and 31	24294
33	reward/	18782
34	motivation/	62683
35	health promotion/ec	2673
36	token economy/	922
37	reinforcement, social/	1042
38	Reimbursement, Incentive/	4148
39	"awards and prizes"/	16301
40	financial management/	16333
41	(incentive* or incentiviz* or incentivis* or reward* or prize* or voucher* or competition* or contest* or lotter* or raffle* or gift* or inducement* or motivat* or cash* or money* or monetar* or financ* or token* or reinforcement* or awards*).ti,ab.	359789
42	(deposit* adj3 (contract* or contingency* or contingent* or conditional* or return* or pay* or repay* or reimburs* or retain* or forfeit* or keep* or save* or saving* or system* or scheme* or program* or initiative* or intervention*)).ti,ab.	1512
43	((pay* or repay* or reimburs*) adj3 (contract* or contingency* or contingent* or conditional* or forfeit* or system* or scheme* or program* or initiative* or intervention*)).ti,ab.	9106
44	or/33-43	428474
45	32 and 44	781
46	Animals/ not (Animals/ and Humans/)	4536484
47	45 not 46	741
48	limit 47 to (letter or historical article or comment or editorial or news or case reports)	20
49	47 not 48	721
50	limit 49 to english language	663
51	limit 50 to yr="1998 -Current"	558

Appendix C – Public health evidence study selection



Appendix D – Public health evidence tables

Evidence tables have been produced for the Cochrane systematic review (Notley 2019[b]), 3 qualitative studies (Butterworth 2014, Mantzari 2012, Morgan 2015) and 1 quantitative paper (Glover 2015) not reported in Notley 2019[b]. Complete study characteristics of all other quantitative studies can be obtained from the Cochrane systematic review by Notley 2019[b].

Butterworth 2014

Bibliographic reference	**Butterworth Sarah J, Sparkes Elizabeth, Trout Alison, and Brown Katherine (2014) Pregnant smokers' perceptions of specialist smoking cessation services. Journal of Smoking Cessation 9(2), 85-97**	
Trial registration	Not reported	
Study type	Qualitative study- reports from the 2011 Solihull Primary Care Trust service development report (with a public involvement approach) aiming to inform changes to the existing smoking cessation in pregnancy service.	
Study dates	Not clear. Recruitment took place between January and May 2011.	
Aim	This research consults past, current and non-users of specialist smoking cessation services and reports pregnant women's views of smoking cessation delivery and potential service developments.	
Country/geographical location	Two postcodes in Solihull, West Midlands, UK- selected as demonstrated the highest rates of smoking at the time of delivery in the borough.	
Setting/School type	Focus groups were conducted in NHS North Solihull hospital wards, children's centres or central NHS You + Healthy Lifestyles Shop.	
Inclusion criteria	Women who were pregnant or who had given birth in the past 12 months, who had smoked for part or all of their pregnancy and lived within one of the two selected postcodes.	
Exclusion criteria	Not reported.	
Intervention	**TIDieR Checklist criteria**	**Details**
	Brief Name	Incentives for smoking cessation in pregnancy. Not all participants had experience of incentives.
Comparison	**TIDieR Checklist criteria**	**Details**
	Brief Name	No comparison
Follow up	Not applicable	
Qualitative methods	Research question(s)	
	Theoretical approach	Not reported
	Data collection	Focus groups were conducted and were guided by a semi-structured interview schedule. Demographic data was collected by questionnaire. Focus group discussions (42 to 72 minutes) were led by the researcher with support from either a specialist midwife (groups 1-4) or stop smoking in pregnancy advisor (group 5) who were able to offer clinical advice if needed. Participants in groups 1-4 were unknown to the attending specialist midwife, whilst 2 participants in group 5 were known to the stop smoking in pregnancy advisor,

<table>
<tr><th>Bibliographic reference</th><th colspan="2">Butterworth Sarah J, Sparkes Elizabeth, Trout Alison, and Brown Katherine (2014) Pregnant smokers' perceptions of specialist smoking cessation services. Journal of Smoking Cessation 9(2), 85-97</th></tr>
<tr><td></td><td></td><td>who left the room for part of the session to allow free discussion. Discussions were recorded and transcribed anonymously.</td></tr>
<tr><td></td><td>Method and process of analysis</td><td>Thematic analysis was used to identify, analyse and report themes within the data. A semantic and realistic approach was adopted whereby the researcher did not explore any further other than what the participant had said. A researcher conducted initial coding and theming, which was then analysed independently by a second researcher.</td></tr>
<tr><td></td><td>Population and sample collection</td><td>During recruitment 30 women who met the inclusion criteria were booked into a focus group, with 19 participants successfully recruited from both postcodes across 5 groups.
<u>Demographic data for pregnant/post-partum women</u>
<table>
<tr><th></th><th>n (%)</th></tr>
<tr><td>Age (years)
≤20
21-30
30+</td><td>
5 (26)
10 (53)
4 (21)</td></tr>
<tr><td>Ethnicity
Caucasian-British
Non-Caucasian/Caribbean</td><td>
18 (95)
1 (5)</td></tr>
<tr><td>Highest Completed compulsory education (CE)/ higher education (HE)
None
GCSEs (CE)
City and Guilds (1 year HE)
GNVQs (2 years HE)
A-levels (2 years HE)
Degree (5 years HE)</td><td>
4 (21)
6 (32)
2 (11)
5 (26)
1 (5)
1 (5)</td></tr>
<tr><td>Employment status
Home Carer
Unemployed/Never worked
Employed
Not stated</td><td>
4 (21)
11 (58)
3 (16)
1 (5)</td></tr>
</table>
<u>Participant smoking behaviour and pregnancy data</u>
<table>
<tr><th></th><th>n (%)</th></tr>
<tr><td>Current smoking status
Smoker
Ex-smoker</td><td>
14 (74)
5 (26)</td></tr>
<tr><td>Pregnancy gestation
Recently given birth
1st trimester (0-12 weeks)
2nd trimester (13-28 weeks)
3rd trimester (29-40 weeks)</td><td>
3 (16)*
5 (26)
5 (26)
6 (32)</td></tr>
</table>
*range 8-37 weeks</td></tr>
<tr><td>Results</td><td>Outcome</td><td>Acceptability of intervention</td></tr>
</table>

Bibliographic reference	**Butterworth Sarah J, Sparkes Elizabeth, Trout Alison, and Brown Katherine (2014) Pregnant smokers' perceptions of specialist smoking cessation services. Journal of Smoking Cessation 9(2), 85-97**		
	Population	Key themes	
	Pregnant/ post-partum women who smoke(d)	Initiatives to encourage participation – avoiding incentivising smoking cessation	All women felt that incentivising smoking cessation was unhelpful, and that self-satisfaction was more motivating than any financial incentive/reward. Most women felt that the rationale for quitting should not be centred on receiving a reward but to improve their own and unborn baby's health. Many women also stated that it would allow some people to abuse the system and receive rewards without abstaining. *"You're not doing it for a reward you're just doing it for your own self-worth aren't you? You're doing it for yourself. A pat on the back and someone telling you that you done really good is enough to make you feel good, you know." (Z, smoker)* Some women initially expressed that vouchers contingent on validated smoking cessation may aid recruitment to programmes, but later retracted from this as vouchers were often swapped or sold on the street for cigarettes. Additionally, women expressed that the financial value of any voucher would be less than the monetary savings of successfully quitting. Several women stated that if a reward was to be given, a special day out would be the most acceptable given that it was less likely to be sold and was not something that mothers would normally buy for themselves.
	Pregnant/ post-partum women who smoke(d)	Initiatives to encourage participation-perception of existing schemes to increase referrals and engagement with services	<u>Massage or beauty treatment reward</u> Women generally felt that earning these rewards after a continuous period of abstinence were not necessary, but believed if they had to be given then they could be motivating. *"Cos you think, stopping smoking you've got horrible skin haven't you through smoking and if you stop smoking for six months and you go there you go well done go to a spa. Not only does it make you feel better cos you give up smoking, it makes you feel better because you've gone, you've got pampered, you look better and you're not smoking." (T, smoker)* Women expressed that they were likely to continue smoking and abstain only for CO readings and to take the reward. As such, women expressed if such rewards were to be offered, a caveat was needed to implement more reliable monitoring methods. One woman stated that money saved from quitting smoking

Bibliographic reference	Butterworth Sarah J, Sparkes Elizabeth, Trout Alison, and Brown Katherine (2014) Pregnant smokers' perceptions of specialist smoking cessation services. Journal of Smoking Cessation 9(2), 85-97			
			would be enough to finance weekly beauty treatments.	
	Pregnant/ post-partum women who smoke(d)	Initiatives to encourage participation-perception of existing schemes to increase referrals and engagement with services	<u>Paying people to quit smoking</u> All women dismissed using financial incentives to encourage smoking cessation. Women expressed that it would be wrong to be rewarded for quitting, as "no-one paid them to start smoking" (smoker). Majority of women felt that people would attend stop-smoking sessions to receive money without this influencing their quit attempt and some women admitted that they may be inclined to do this themselves. *"I'll be honest with you right, if someone said to me now right come to the stop-smoking clinic I'll give you a tenner I'd go and get that tenner and I'd go and buy fags." (L, smoker)* Women also expressed that this may encourage participation from those who have no intention to quit and take away resources available for those with genuine intention to quit. One participant expressed that accepting a financial incentive would make her feel guilty if she later relapsed in her attempt to quit smoking: "*You've got to have that incentive yourself. For somebody doing it with money or things like that I wouldn't feel right going, just for the fact it would make me feel even worse if I failed. (Z, smoker)*	
Risk of bias	Item		Yes/No/Can't tell	Comments
	1. Was there a clear statement of the aim of the research?		Yes	To explore the views of current and past service users as well as non-users regarding existing smoking cessation services for pregnant women.
	2. Is a qualitative methodology appropriate?		Yes	Focus groups were conducted with service users and non-users regarding existing smoking cessation services for pregnant women.
	3. Was the research design appropriate to address the aims of the research?		Yes	Focus groups allowed discussion of key issues and produced insights which may not have been achieved through individual interviews. Discussions were guided with the use of a semi-structured interview schedule.
	4. Was the recruitment strategy appropriate to the aims of the research?		No	Participants were not recruited by purposive sampling or through a sampling frame. As such, this resulted in a lack of diversity in the sample.

Bibliographic reference	**Butterworth Sarah J, Sparkes Elizabeth, Trout Alison, and Brown Katherine (2014) Pregnant smokers' perceptions of specialist smoking cessation services. Journal of Smoking Cessation 9(2), 85-97**		
	5. Was the data collected in a way that addressed the research issue?	Yes	Group interviews were conducted, recorded and transcribed. Saturation of data not discussed.
	6. Has the relationship between researcher and participants been adequately considered?	Can't tell	Supporting healthcare professionals in focus groups were mainly unknown to participants, and where known left the room whilst discussions were taking place.
	7. Have ethical issues been taken into consideration?	Yes	Study notes that all procedures contributing to the research complied with ethical standards.
	8. Was the data analysis sufficiently rigorous?	Yes	Thematic analysis was used to identify, analyse and report themes within the data. Themes and codes were analysed independently by a second researcher.
	9. Is there a clear statement of findings?	Yes	Findings are explicit and report some views on the acceptability of financial incentives for smoking cessation. Findings link back to the original research question.
	10. Is the research valuable?	Can't tell	The views of pregnant women on the acceptability of incentives for quitting smoking is only a small proportion of the overall findings reported by the qualitative study. As such, there is limited discussion on the implications of offering financial incentives in this population. Focus groups were conducted in postcode areas with high deprivation, high unemployment and mainly Caucasian-British population, and results may not be generalisable to other areas in the UK.
Overall risk of bias	Moderate risk of bias		
Source of funding	No specific grant from any funding agency, commercial or not for profit sectors.		
Comments	Participants were provided with a shopping voucher for participation in focus groups.		

Glover 2015

<table>
<tr><td>Bibliographic reference/s</td><td>Glover Marewa, Kira Anette, Walker Natalie, and Bauld Linda (2015) Using incentives to encourage smoking abstinence among pregnant indigenous women? A feasibility study. Maternal and child health journal 19(6), 1393-9</td></tr>
<tr><td>Study name</td><td>Glover 2015</td></tr>
<tr><td>Registration</td><td>Not reported</td></tr>
<tr><td>Study type</td><td>Feasibility RCT</td></tr>
<tr><td>Study dates</td><td>Not clear. Recruitment took place between December 2012 and November 2013.</td></tr>
<tr><td>Objective</td><td>To determine the likely effectiveness of an incentives-based cessation trial among pregnant Māori women that smoked.</td></tr>
<tr><td>Country/ Setting</td><td>Auckland, New Zealand.</td></tr>
<tr><td>Number of participants / clusters</td><td>Twenty-four participants were recruited:
Intervention (voucher incentives): n=8
Intervention (product incentives): n=8
Control: n=8
As feasibility study, no sample size was calculated.</td></tr>
<tr><td>Attrition</td><td>Overall out of 24 participants who agreed to participate, 9 individuals completed the 8-week intervention (3 women withdrew and 12 women were not able to be contacted for 8 or more weeks after randomisation). Retention rate was 37.5%</td></tr>
<tr><td>Participant /community characteristics.</td><td>Demographics of pregnant women (n=24)
<table>
<tr><th></th><th>Control (n=8)</th><th>Product (n=8)</th><th>Voucher (n=8)</th><th>Overall (%)</th></tr>
<tr><td>Number of weeks pregnant n (%)
Mean
IQR</td><td>
17
10 (23.25)</td><td>
12
9.75 (16)</td><td>
18
13 (23.5)</td><td>
13</td></tr>
<tr><td>Education (highest level) n (%)
Primary (year 6)
Intermediate (year 8)
Secondary (year 11-12)
Trade or vocational training
Undergrad university degree
Postgraduate university degree
None</td><td>
0 (0)
0 (0)
3 (38)
5 (63)
0 (0)
0 (0)
0 (0)</td><td>
0 (0)
0 (0)
5 (63)
3 (38)
0 (0)
0 (0)
0 (0)</td><td>
0 (0)
0 (0)
4 (50)
2 (25)
1 (13)
0 (0)
1 (13)</td><td>
0
0
50
42
4
0
4</td></tr>
<tr><td>Number of cigarettes smoked per day n (%)
Mean
IQR</td><td>
6
4 (7.75)</td><td>
10
3.75 (12.5)</td><td>
12
10 (15)</td><td>
9</td></tr>
</table>
Financial environment of pregnant women (n=24)
<table>
<tr><th></th><th>n (%)</th></tr>
<tr><td>Employment status
Full-time paid employment</td><td>
2 (8)
1 (4)</td></tr>
</table></td></tr>
</table>

<table>
<tr><td>Bibliographic reference/s</td><td colspan="2">Glover Marewa, Kira Anette, Walker Natalie, and Bauld Linda (2015) Using incentives to encourage smoking abstinence among pregnant indigenous women? A feasibility study. Maternal and child health journal 19(6), 1393-9</td></tr>
<tr><td>Study name</td><td colspan="2">Glover 2015</td></tr>
<tr><td></td><td colspan="2">
<table>
<tr><td>Part-time/casual paid employment
Homemaker
Student
Unemployed</td><td>11 (46)
4 (17)
6 (25)</td></tr>
<tr><td>Community services card*
Yes
No
Don’t know</td><td>
16 (67)
7 (29)
1 (4)</td></tr>
</table>
*Proxy measure for low socioeconomic status
</td></tr>
<tr><td>Method of allocation</td><td colspan="2">Women were randomised in a 1:1 ratio to one of 3 arms (incentive voucher, incentive product or control) by envelope randomisation prepared by a statistician. Only researchers analysing the data were blinded to treatment allocation.</td></tr>
<tr><td>Inclusion criteria</td><td colspan="2">Women were eligible if they:
- were aged 16 or older
- self-identified as Māori
- resided in the Auckland region
- were 2-30 weeks pregnant
- were daily smokers</td></tr>
<tr><td>Exclusion criteria</td><td colspan="2">Women who were no longer smoking daily or participating in other smoking cessation trials.</td></tr>
<tr><td>Intervention</td><td>TIDieR Checklist criteria</td><td>Details</td></tr>
<tr><td></td><td>Brief Name</td><td>Incentive voucher group + usual care (as control group)</td></tr>
<tr><td></td><td>Rationale/theory/Goal</td><td>Not reported</td></tr>
<tr><td></td><td>Materials used</td><td>Not reported</td></tr>
<tr><td></td><td>Procedures used</td><td>Usual cessation support and a retail voucher for $25(NZ) was offered to women for each abstinent from smoking week to use at Farmers Trading Company (general department store that does not stock artificial infant food, cigarettes or alcohol). Women were not provided with any more incentives if they did not remain abstinent.</td></tr>
<tr><td></td><td>Provider</td><td>Research assistant</td></tr>
<tr><td></td><td>Method of delivery</td><td>Women were contacted by a research assistant weekly by phone, text or email to obtain self-reported smoking status and to provide stop smoking support. If women self-reported being abstinent from smoking for 2 weeks, the research assistant visited participant to biochemically validate smoking cessation (4 maximum visits = at baseline, 2 interim and one 8 weeks after randomisation). To minimise preparing for the validation test, visits took place at various times and dates and there were different durations between each visit (2-6 weeks apart). Participant and research assistant were not blinded to treatment allocation.</td></tr>
</table>

Bibliographic reference/s	**Glover Marewa, Kira Anette, Walker Natalie, and Bauld Linda (2015) Using incentives to encourage smoking abstinence among pregnant indigenous women? A feasibility study. Maternal and child health journal 19(6), 1393-9**	
Study name	Glover 2015	
	Location	Not clear where the incentive was provided. Smoking cessation was verified at a convenient location for the participant.
	Duration	8 weeks
	Intensity	Women could earn vouchers to the value of $200 (NZ) if they remained abstinent over 8 weeks.
	Tailoring/adaptation	NA
	Planned treatment fidelity	NA
	Actual treatment fidelity	NA
	Other details	None.
Intervention	**TIDieR Checklist criteria**	**Details**
	Brief Name	Incentive product group + usual care (as control group)
	Rationale/theory/Goal	Not reported
	Materials used	Not reported
	Procedures used	Usual cessation support and a choice of product pack (24 in total) was offered to women for each abstinent from smoking week. Product packs were valued at $25, $50, $75, $100 and $200 (NZ). Maximum value was $200 ($25/weekly). Women were not provided with any more incentives if they did not remain abstinent.
	Provider	Research assistant
	Method of delivery	As above for voucher incentive group
	Location	Not clear where the incentive was provided. Smoking cessation was verified at a convenient location for the participant.
	Duration	8 weeks
	Intensity	Women could earn products to the value of $200 (NZ) if they remained abstinent over 8 weeks. Women could choose a lower value weekly product pack or accumulate their incentive.
	Tailoring/adaptation	NA
	Planned treatment fidelity	NA
	Actual treatment fidelity	NA
	Other details	None.
Comparison	**TIDieR Checklist criteria**	**Details**
	Brief Name	Usual care- Women received usual smoking cessation support.
	Rationale/theory/Goal	Not reported.
	Materials used	Not reported.

<table>
<tr><td>Bibliographic reference/s</td><td colspan="2">Glover Marewa, Kira Anette, Walker Natalie, and Bauld Linda (2015) Using incentives to encourage smoking abstinence among pregnant indigenous women? A feasibility study. Maternal and child health journal 19(6), 1393-9</td></tr>
<tr><td>Study name</td><td colspan="2">Glover 2015</td></tr>
<tr><td rowspan="10"></td><td>Procedures used</td><td>Information provision on different smoking cessation services and products.</td></tr>
<tr><td>Provider</td><td>Research Assistant</td></tr>
<tr><td>Method of delivery</td><td>As above for voucher incentive group.</td></tr>
<tr><td>Location</td><td>Smoking cessation was verified at a convenient location for the participant.</td></tr>
<tr><td>Duration</td><td>8 weeks</td></tr>
<tr><td>Intensity</td><td>NA</td></tr>
<tr><td>Tailoring/adaptation</td><td>NA</td></tr>
<tr><td>Modifications</td><td>NA</td></tr>
<tr><td>Planned treatment fidelity</td><td>NA</td></tr>
<tr><td>Actual treatment fidelity</td><td>NA</td></tr>
<tr><td>Other details</td><td>NA</td></tr>
<tr><td>Follow up</td><td colspan="2">8-weeks</td></tr>
<tr><td>Data collection</td><td colspan="2">Demographic data and biochemical validation of smoking status collected by research assistant. Self-reported smoking status was collected weekly, and biochemical validation of smoking status was conducted monthly at face-to-face meeting. Biochemical validation was completed using a carbon monoxide (CO) breath test and tests were conducted at baseline to minimise the likelihood of recruiting non-smokers.
Women were considered to be smokers if they self-reported smoking during the previous week or had a CO reading of greater than 7ppm for 1 month or more. Women who dropped-out were assumed as being continuing smokers.</td></tr>
<tr><td>Critical outcomes measures and effect size. (time points)</td><td colspan="2"><u>Continuous abstinence from smoking at 8 weeks post-randomisation in those incentivised compared with control*</u>
<table>
<tr><td colspan="2" rowspan="2"></td><td colspan="2">Outcome – Abstinence from smoking***</td><td rowspan="2">Total</td><td rowspan="2">RR (95% CI)</td></tr>
<tr><td>Yes</td><td>No</td></tr>
<tr><td rowspan="3">Intervention-(voucher and product incentive)**</td><td>Yes</td><td>2</td><td>14</td><td>16</td><td rowspan="3">1.0 (0.1 to 9.4)</td></tr>
<tr><td>No</td><td>1</td><td>7</td><td>8</td></tr>
<tr><td>Total</td><td>3</td><td>21</td><td>24</td></tr>
</table>
*Based on intention to treat analysis and n=8 women in voucher, product and control groups. RR calculated by NICE review team.
** Incentive voucher and product groups have been combined. Quote “three participants (one from control and two from the product condition) were abstinent from smoking for all 8 weeks”, it has therefore been assumed that no women from the voucher group remained abstinent across the 8-week intervention.
*** Abstinence was weekly self-reported and monthly biochemically verified by CO test including 8 weeks after randomisation.</td></tr>
<tr><td>Important outcomes measures and effect size. (time points)</td><td colspan="2">None reported</td></tr>
</table>

Bibliographic reference/s	**Glover Marewa, Kira Anette, Walker Natalie, and Bauld Linda (2015) Using incentives to encourage smoking abstinence among pregnant indigenous women? A feasibility study. Maternal and child health journal 19(6), 1393-9**		
Study name	Glover 2015		
Statistical Analysis	Intention to treat analysis, no statistical analysis was conducted.		
Risk of bias (ROB) **Overall ROB**	**Outcome name: Abstinence from smoking**		
	Outcome	**Judgement (Low / High / some concerns)**	**Comments**
	Risk of bias arising from the randomisation process	Some concerns	Participants were randomised in a 1:1 ratio using envelope randomisation. Allocation sequence concealment unclear. Blinding to treatment allocation occurred only for the researchers analysing the data, and not participants or the research assistant collecting the outcome data.
	Risk of bias due to deviations from intended interventions (assignment)	Low risk	Participants and the research assistant were aware of their assigned intervention during the trial, and so controls may be more likely to drop out. Incentives were contingent on participants providing outcome data, which was then biochemically validated. As such, no apparent deviations from intended interventions.
	Missing outcome data (attrition bias)	High risk	Retention rate was 37.5%, participants with missing data for the critical outcome counted as smokers (ITT). For the critical outcome 9/24 individuals completed the 8-week intervention.
	Risk of bias in measurement of the outcome (detection bias)	Low risk	Smoking status was both self-reported weekly and CO verified monthly (including at the final visit 8 weeks after randomisation). Research assistant collecting the outcome data was not blinded to treatment allocation.
	Risk of bias in selection of the reported result	Some concerns	Results are not clearly reported, possibly due to the small sample size.
	Other sources of bias	None.	
	Overall Risk of Bias	High risk of bias	
	Other outcome details		
Source of funding	New Zealand Ministry of Health and the emerging issues fund of New Zealand's Tobacco Control Research Tūranga.		
Comments	- Ethics approval was granted by the Central Health and Disability Ethics Committee - All women were provided with a retention gift of $5 (NZ), for each face-to face visit, paid on the final visit.		

Bibliographic reference/s	**Glover Marewa, Kira Anette, Walker Natalie, and Bauld Linda (2015) Using incentives to encourage smoking abstinence among pregnant indigenous women? A feasibility study. Maternal and child health journal 19(6), 1393-9**
Study name	Glover 2015
	- Sample size was small as feasibility study. Results may not be generalisable to other settings due to focus of the study on indigenous pregnant Māori smokers who have a high smoking prevalence and slow rate of decline of smoking.
Additional references	None

Mantzari 2012

Bibliographic reference	**Mantzari Eleni, Vogt Florian, and Marteau Theresa M (2012) The effectiveness of financial incentives for smoking cessation during pregnancy: is it from being paid or from the extra aid? BMC pregnancy and childbirth 12, 24**	
Trial registration	Not reported.	
Study type	Qualitative study	
Study dates	Not clear. Women who were referred to NHS stop-smoking services between September 2009 and May 2010 were recruited.	
Aim	To identify differences between the experiences of pregnant smokers who were incentivised for cessation and of those who were not.	
Country/ geographical location	Birmingham, UK	
Setting/School type	UK Primary Care Trust	
Inclusion criteria	Participants were recruited if: -they were enrolled in a pilot scheme of incentivising smoking cessation run by the Birmingham East and North Primary Care Trust (BEN PCT) or -were eligible to be part of a comparison cohort, by living in comparison areas.	
Exclusion criteria	None reported	
Intervention	**TIDieR Checklist criteria**	**Details**
	Brief Name	Financial incentives- vouchers offered for quitting smoking.
	Rationale/theory/Goal	Not reported.
	Materials used	Not reported.
	Procedures used	Women who lived in the pilot areas were offered vouchers for quitting smoking, contingent on biochemically confirmed smoking cessation. Pilot areas were selected as those with the highest prevalence of smoking. Women were enrolled into the stop smoking services by the “call to quit” call-centre, being a telephone information line on local smoking cessation services.
	Provider	Women were referred to NHS stop smoking services by midwives. Incentive offered by BEN PCT as part of pilot scheme.
	Method of delivery	Stop smoking support initiated by phone.
	Location	Greater Birmingham area.

Bibliographic reference	**Mantzari Eleni, Vogt Florian, and Marteau Theresa M (2012) The effectiveness of financial incentives for smoking cessation during pregnancy: is it from being paid or from the extra aid? BMC pregnancy and childbirth 12, 24**	
	Duration	Vouchers were offered as fixed payments at set periods of time (time period not reported).
	Intensity	NA
	Tailoring/adaptation	NA
	Modifications	NA
	Planned treatment fidelity	NA
	Actual treatment fidelity	NA
	Other details	None.
Comparison	**TIDieR Checklist criteria**	**Details**
	Brief Name	Comparison cohort – not offered financial incentives for smoking cessation.
	Rationale/ theory/Goal	Not reported.
	Materials used	Not reported.
	Procedures used	Women in comparison cohort were not offered financial incentives for smoking cessation. Comparison areas were selected as similar geographical districts with equivalent rates of smoking in pregnancy as the pilot areas. Women were enrolled into the stop smoking services by the “call to quit” call-centre, being a telephone information line on local smoking cessation services.
	Provider	Women were referred to NHS stop smoking services by midwives.
	Method of delivery	Initial telephone support.
	Location	Greater Birmingham area.
	Duration	Not reported.
	Intensity	NA
	Tailoring/ adaptation	NA
	Modifications	NA
	Planned treatment fidelity	NA
	Actual treatment fidelity	NA
	Other details	None.
Follow up	Not applicable	

Bibliographic reference	**Mantzari Eleni, Vogt Florian, and Marteau Theresa M (2012) The effectiveness of financial incentives for smoking cessation during pregnancy: is it from being paid or from the extra aid? BMC pregnancy and childbirth 12, 24**		
Qualitative methods	Research question(s)	In pregnant women who smoke, what are their motivations to want to quit smoking and what are the factors they perceive as influencing and inhibiting their quit attempts?	
	Theoretical approach	Not reported	
	Data collection	Interviews were semi-structured, recorded and on average lasted 23 minutes. Interviews were conducted face-to-face and mainly took place in the women's home with the exception of 1 woman who was interviewed at her workplace.	
	Method and process of analysis	Interviews were anonymised and transcribed using framework analysis separately for each group. Themes were identified and compared between both groups.	
	Population and sample collection	Women were recruited through an opportunistic sampling frame, involving 115 pregnant smokers from the Birmingham area. Thirty-six participants were interviewed (n=20 from incentive group and n=16 from control group). Eleven women were interviewed post-partum (n=6 from the incentivised group, n=5 from the control group) and 1 participant had miscarried (from the incentivised group). Twenty-four women were still smoking at interview, whilst 12 women were smoke-free (n=8 in the incentivised group, n=4 from the control group). Mean age of participants in both groups was 28 years. Women were mainly White-British, 1 participant was of Indian decent (control group) and 1 participant originated from Hong Kong (incentivised group). Participants were mainly of a lower socio-economic class, with Index of Multiple Deprivation Scores of 42.35 for the incentivised group and 42.51 for the control group.	
Results	Outcome	Acceptability of intervention	
	Population	Key themes	
	Pregnant /post-partum women who smoke(d)	Reasons for wanting to quit smoking	Women in both groups reported similar reasons for wanting to quit smoking during pregnancy including: - Financial issues- expense of smoking and wanting to save money or wanting to receive the financial incentive as an added bonus. *"And then the vouchers give me incentive to, like, stop smoking" (incentivised)* *"…the vouchers and the incentives and I thought well, that's even better. That to me, was an added bonus that wasn't a reason quit, that was just like a reward for actually going to get them" (incentivised)*
	Pregnant /post-partum women who smoke(d)	Factors perceived as facilitating the quit attempt.	Women who were incentivised were more motivated to engage with smoking cessation services: *"I wouldn't have bothered going all the way to the doctors because at the beginning of your pregnancy and that you don't want to go out the house anyway because you're feeling sick and you're heavy and frumpy, and it just seems like a long way to go for nothing just to blow into a thing.*

Bibliographic reference	Mantzari Eleni, Vogt Florian, and Marteau Theresa M (2012) The effectiveness of financial incentives for smoking cessation during pregnancy: is it from being paid or from the extra aid? BMC pregnancy and childbirth 12, 24			
			With the vouchers it's like you're getting paid... rewarded to go there" (incentivised group) Women felt that financial incentives facilitated quitting attempts and provided a goal to resist smoking urges. *"the vouchers give me incentive to like stop smoking...So the vouchers have helped yeah because I'm thinking it's not that worth risking" (incentivised group)* *"I feel like I need another one [cigarette] I sort of sit there and think to myself well if I have this one it's going to mess me up getting my vouchers for my kids.... I won't because I'll just think well I've got the vouchers to look forward to" (incentivised group)* Women in the incentivised group reported monitoring was conducted routinely to confirm smoking status in order to attain vouchers, whereas women in the control group reported that monitoring was not consistently implemented. *"They don't really monitor you... They only do it, they only did it the once" (control group).* *"I think that was the most useful thing and knowing that you were going back the following week and that it had to be good because there was a quantifiable way of seeing if you'd been sticking to the routine." (control group).*
	Pregnant /post-partum women who smoke(d)	Factors perceived as inhibiting the quit attempt	Women reported encountering logistical problems with obtaining vouchers, which hindered their attempt to stop smoking. *"Well it didn't work very well because the first week we went my voucher came, but it didn't come to my address it came to another address and they sent it on. And then the next time I went to the chemist for the next test I didn't tell him that he hasn't got my address right, and my voucher never came.... that put me off then" (incentivised group)*	
Risk of bias	Item		Yes/No/ Can't tell	Comments
	1. Was there a clear statement of the aim of the research?		Yes	To compare the views and experiences of pregnant smokers who were either incentivised or not to quit smoking
	2. Is a qualitative methodology appropriate?		Yes	Interviews were conducted with pregnant smokers who were either incentivised or not to quit smoking.
	3. Was the research design appropriate to address the aims of the research?		Yes	Interviews were sufficient to obtain views and experiences. Interviews were semi-structured and were piloted to ensure information on

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			women's experiences of stopping smoking was elicited.
	4. Was the recruitment strategy appropriate to the aims of the research?	Yes	Participants were recruited through an opportunistic sampling frame and were matched in both groups based geographically to areas of equivalent smoking levels during pregnancy and comparable socio-economic position.
	5. Was the data collected in a way that addressed the research issue?	Yes	Face-to-face interviews were conducted, recorded and transcribed. Interviews were conducted until no new themes emerged.
	6. Has the relationship between researcher and participants been adequately considered?	Can't tell	No information.
	7. Have ethical issues been taken into consideration?	Yes	Women in both groups were informed about the research and their willingness to participate by the interviewer. Ethics approval was granted.
	8. Was the data analysis sufficiently rigorous?	Yes	Framework analysis was conducted to identify and compare themes from anonymised interviews between both groups. Data saturation for themes of interest was achieved in both groups.
	9. Is there a clear statement of findings?	Yes	Findings are explicit, and report both positive and negative views on the use of incentives from both groups. Findings link back to the original research question but it is not clear whether findings were validated by more than one researcher.
	10. Is the research valuable?	Can't tell	The views of pregnant women on the acceptability of incentives for quitting smoking is only a small proportion of the overall findings reported by the qualitative study. As such, there is limited discussion on the implications of offering financial incentives in this population. Several of the findings are in line with other studies on incentives, however these are not in pregnant smokers. Additionally, the effectiveness of the pilot incentive scheme was yet to be established and the interviews include views of women who had since stopped smoking.
Overall risk of bias	Low risk of bias		
Source of funding	Grant from the Wellcome Trust		

Bibliographic reference	**Mantzari Eleni, Vogt Florian, and Marteau Theresa M (2012) The effectiveness of financial incentives for smoking cessation during pregnancy: is it from being paid or from the extra aid? BMC pregnancy and childbirth 12, 24**
Comments	- Women received £20 for participating in the interview. - The incentives offered in this study were of much lower value than other trials assessing the effectiveness of incentives. - IMD scores were above average for the Birmingham area.

Morgan 2015

Bibliographic reference	**Morgan Heather, Hoddinott Pat, Thomson Gill, Crossland Nicola, Farrar Shelley, Yi Deokhee, Hislop Jenni, Moran Victoria Hall, MacLennan Graeme, Dombrowski Stephan U, Rothnie Kieran, Stewart Fiona, Bauld Linda, Ludbrook Anne, Dykes Fiona, Sniehotta Falko F, Tappin David, and Campbell Marion (2015) Benefits of Incentives for Breastfeeding and Smoking cessation in pregnancy (BIBS): a mixed-methods study to inform trial design. Health technology assessment (Winchester, and England) 19(30), 1-viii**	
Trial registration	Not reported	
Study type	Mixed methods study [known as the Benefits of Incentives for Breastfeeding and Smoking cessation in pregnancy study (BIBS)]. The Cessation in Pregnancy Incentives Trial (CPIT) ran alongside the BIBS study, qualitative data from CPIT were incorporated into the BIBS analysis towards the end of the study. Views on incentives for smoking cessation from providers and pregnant/post-partum women who smoke(d) is of relevance to this review.	
Study dates	February 2012 to October 2013.	
Aim	To investigate the mechanisms of action and interactions of incentives, a shortlist of incentive strategies and the unintended consequences of incentives.	
Country/ geographical location	Aberdeen, Lancashire for BIBS Greater Glasgow and Clyde for CPIT	
Setting/School type	Primary and secondary health services, local authority community and voluntary sector services (e.g. antenatal clinics, children and family centres, mother and baby groups).	
Inclusion criteria	Not reported for BIBS. For CPIT, pregnant women were self-reported as smokers at maternity booking appointment confirmed by CO test (≥7 parts per million), 16 years of age or older and less than 24 weeks gestation.	
Exclusion criteria	Not reported	
Intervention	**TIDieR Checklist criteria**	**Details**
	Brief Name	Incentives for pregnant women to quit smoking (CPIT)
	Rationale/ theory/Goal	Not reported
	Materials used	Not reported
	Procedures used	Women were offered a £50.00 voucher if they attended a face- to-face appointment, and set a quit date, and a further £50.00 voucher if they had quit at 4 week follow up, contingent on smoking status biochemically validated by CO breath test (<10 parts per million). Women were also offered routine stop smoking centre care including

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		face-to-face appointment for smoking cessation, setting a quit date and telephone support post quit date. Women who set a quit date were also offered free NRT provided by pharmacy services for up to 16 weeks after setting a quit date.
	Provider	Maternity services
	Method of delivery	Not reported how incentives were delivered.
	Location	Glasgow, UK
	Duration	Not reported.
	Intensity	Women were contacted at 12 weeks, and if still abstinent confirmed by CO testing, women were offered £100.00. Women were asked to self-report smoking status randomly between 24-38 weeks gestation, with women who had confirmed to quit by CO breath test were offered a final voucher of £200.00.
	Tailoring/ adaptation	NA
	Modifications	NA
	Planned treatment fidelity	NA
	Actual treatment fidelity	NA
	Other details	Primary outcome was self-reported quit at 34-38 weeks gestation, confirmed by either urine/saliva cotinine tests. Women were given a £25.00 voucher for providing primary outcome information.
Comparison	**TIDieR Checklist criteria**	**Details**
	Brief Name	No incentive offered for smoking cessation (CPIT)
	Rationale/theory/Goal	Not reported
	Materials used	Not reported
	Procedures used	Women were offered routine stop smoking centre care as for the intervention group.
	Provider	Maternity services
	Method of delivery	Face-to-face appointment and telephone support
	Location	Glasgow
	Duration	Not reported
	Intensity	NA
	Tailoring/adaptation	NA
	Modifications	NA

Bibliographic reference	**Morgan Heather, Hoddinott Pat, Thomson Gill, Crossland Nicola, Farrar Shelley, Yi Deokhee, Hislop Jenni, Moran Victoria Hall, MacLennan Graeme, Dombrowski Stephan U, Rothnie Kieran, Stewart Fiona, Bauld Linda, Ludbrook Anne, Dykes Fiona, Sniehotta Falko F, Tappin David, and Campbell Marion (2015) Benefits of Incentives for Breastfeeding and Smoking cessation in pregnancy (BIBS): a mixed-methods study to inform trial design. Health technology assessment (Winchester, and England) 19(30), 1-viii**	
	Planned treatment fidelity	NA
	Actual treatment fidelity	NA
	Other details	As above for intervention group
Follow up	Not applicable	
Qualitative methods	Research question(s)	To investigate the mechanisms of action and interactions of incentives, a shortlist of incentive strategies and the unintended consequences of incentives.
	Theoretical approach	Grounded theory approach was applied to develop an incentive taxonomy ("classification of incentive characteristics in relation to behavioural change strategies") and to understand the mechanism of action of incentives.
	Data collection	<u>BIBS</u> Data collection for BIBS started in April 2012 to August 2013. Qualitative interviews and focus groups were conducted with service users by 3 researchers. Participants were asked to "conceptualise incentives, what types of incentives may mean and where or not they were acceptable". Interviews were open ended, recorded and transcribed and varied from 15-100 minutes. Topic guides were used to ensure all key areas were covered. Intervention vignettes were used to facilitate discussion where appropriate. Three studies on smoking cessation were selected as vignettes: Gulliver 2004, Heil 2008 and Walsh 1997. <u>CPIT:</u> CPIT data collection occurred between April 2012 to October 2012. Semi-structured qualitative interviews and focus groups were conducted by 2 researchers in women participating in the trial and also professional stakeholders. Face to face interviews were conducted in participants home, whilst professional interviews mainly occurred at the workplace. Topic guides were used to aid data collection, and interviews covered views on the use of incentives to promote smoking cessation during pregnancy. Interviews were recorded and transcribed and lasted between 25-80 minutes.
	Method and process of analysis	Analysis was conducted using the framework method. Three researchers identified key themes and categories independently by reading transcripts and listening to the initial 4 participant and provider interviews. By further transcript reading and discussion, coding was agreed and further detailed analysis was conducted to ensure consistency. CPIT transcripts were then incorporated into the analysis.
	Population and sample collection	Summary of characteristics of women and partner participants are not presented separately. One hundred and thirty-six participants (38 pregnant women, 45 postnatal women and 53 providers) took part in 16 focus groups, 55 face-to face interviews and 19 telephone interviews.

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		<u>BIBS:</u> Purposive, snowball sampling strategy implemented over time to identify harder to reach, more disadvantaged participants. Sample included pregnant women and new mothers/partners/significant others from the first trimester until 6 months after birth, providers of care/stakeholders and experts/decision-makers. Views of service users (pregnant/post-partum women) and providers have been extracted in this evidence table. Providers would either deliver or receive incentives for introducing quitting or maintaining cessation (delivery of incentives of relevance to this review). <u>CPIT:</u> One hundred participants were approached to achieve target sample of 20 women, balanced over incentive intervention and control and age (>25 years and 25+ years). Sampling involved a 70/30 split roughly between Glasgow or Clyde area.	
Results	Outcome	Acceptability of intervention	
	Population	Key themes	
	Pregnant/ post-partum women who smoke(d)	Acceptability of financial incentives for quitting	Women were mixed in opinions on the use of financial incentives, with some women stating that "no-one should get paid for stopping smoking" to "that's a good idea". *"I think they should be doing it for the right reasons, for their health and if they want to stop smoking because you want to be healthy and things, that's fine. Don't just do it because you're going to get money and things out of it. I don't agree with that." (Pregnant woman, current smoker, no experience of being incentivised)* Several women suggested that providing incentives were motivating and enabled the process of change to be a "nicer experience" and provided something to "look forward to" or "recognition" and "acknowledgement" of their success. *"I suppose it's not about necessarily having £50.00 or the £100.00 or whatever, it's about the recognition that you've done something, that you've achieved something, it's not, it could have been anything I suppose". (Pregnant woman, quit during pregnancy, experience of smoking cessation incentives)* Some women who even favoured incentives expressed concern as to how the incentives would work, with some women being sure that they didn't think they would work. *"Because at the end of the day if you are going to succeed you'll succeed whether somebody hands you a Love to Shop voucher or not, if you are going to fail then you're going to have a cigarette whether*

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			or not somebody's going to give you a voucher or not". (Pregnant woman, quit during pregnancy, experience of smoking cessation incentives)
	Providers of care	Acceptability of incentives for smoking cessation	There were mixed views on the acceptability of offering incentives, although even where there was unsureness, providers felt that if incentives could help then they should be used and that it would be unethical to not explore all approaches to improving smoking cessation in pregnancy. *"From the smoking point of view obviously my biggest issue is obviously the babies because those babies- so I would agree to it with the smoking side of things because those babies…and even with the breastfeeding as well- but those babies are being put in a vulnerable position, aren't they? If we don't do anything to stop those women smoking and they're going to suffer long term with ill health, etc. and going to end up on the neonatal unit probably and have long-term health problems. So I do think we need to do something and that's where probably why I agree- it's difficult to say." (Focus group- public health practitioner and health education practitioner).* Some providers were strongly opposed to the provision of incentives and considered the use of them as "not just wrong, I'd say morally wrong". *"I think we're going right down the wrong route; I think that, you know, when we're enticing people with money and gifts just to do what's right for their health, you know. What else will we expect?" (Midwife)* Other providers felt that incentives may overshadow self-motivation and demoralise people and recognised the challenges faced by women who were more deprived which often present barriers to behaviour change. *"Efforts could possibly be better addressed – best spent – by addressing their circumstance rather than rewarding them for doing something they should be doing anyway". (Focus group- public health practitioner and health education practitioner).*
	Providers and pregnant/ post-partum women who smoke(d)	Acceptability of incentives contingent on verified outcomes	Some participants felt that risk-based rewards such as raffle tickets were acceptable as "everyone has a chance", whilst others felt that a guaranteed incentive was necessary for ensuring continual commitment and motivation. Several participants felt that incentives should only be given as rewards once smoking cessation had been verified, and not to reward deviant behaviour. *"Yeah, if I was going to go to something and thought, 'It's nice to go but I'm not going to do anything about*

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			it', it'd probably make me feel worse . . . Because then I'd think I should be giving up." (Pregnant woman, current smoker, no experience of being incentivised).
	Providers and pregnant/ post-partum women who smoke(d)	Acceptability of incentives for preparatory behaviours	Participants supported incentives for validated complete smoking cessation during pregnancy, in some women where quitting was unlikely, being incentivised to cut down was important and aided their well-being. "*Then to get pregnant and cut down and then knowing you've got a limit to smoke a day. Sometimes I can go over it; sometimes I cannot want a fag do you know what I mean. Sometimes I can light up a cigarette and then put it out and go no I don't want this it is making me feel sick. But I wish that had happened at the start, I wish that when I lit up a cigarette I would be sick or something so I wouldn't need to smoke". (Pregnant woman, current smoker, experience of smoking cessation incentives).* Incentives were considered to be useful in encouraging "meaningful discussions" and "a proper conversation", particularly for those that are "undecided" that could help to change a woman's attitude towards smoking cessation. *"I think, for me, it was about getting me into that first appointment. If you can get people into that first appointment and have someone like [smoking cessation adviser] talking you through it, for me that was where the real success was, because I came out of there like that, I need to do this". (Pregnant woman, quit during pregnancy, experience of smoking cessation incentives).* Several participants felt that offering incentives for those who engaged with support, irrespective of their smoking status, were justified as this indicated their willingness to try to change.
	Providers and pregnant/ post-partum women who smoke(d)	Incentive components: meaning and value	Some women found that shopping vouchers were the same as "bribery with money", whereas baby-related or personal well-being related items, which were more likely to be described as "gifts" or "more practical". Incentives seen as a "payment" to stop smoking, "you are getting paid to stop smoking" were often viewed negatively due to "giving money to the people to look after their own health". Women expressed mixed views on the optimum value of the incentive, and how this may determine how motivating an incentive may be and the probability of gaming. For some women, the financial value was less motivating, whereas for others a greater value was seen to be more motivating. The

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			financial situation of the recipient often was linked to the optimum financial value of the incentive, whereas others felt that intrinsic motivation was key to determining if an incentive offering large values of money was effective. *"I think if I was getting that much [£400-offered in CPIT] I'd be like, 'I'll stop smoking and I'll not go back on it'." (Pregnant woman, quit during pregnancy, experience of smoking cessation incentives).* *"I think if they'd said to me you'll get £2000.00 you know what I mean if you stop smoking then it maybe would have pushed me to it but I think in myself, you'd need to want to for yourself to stop smoking, not for money". (Pregnant woman, current smoker, experience of smoking cessation incentives).*
	Providers and pregnant/ post-partum women who smoke(d)	Acceptability of vouchers and cash incentives	Most participants felt that vouchers were equivalent as cash, based on the fact that most vouchers were redeemable in many retail shops. Choice of where to spend the voucher was key to the motivating nature of the voucher incentive, as "the money is theirs to spend how they like" or to "treat yourself". Vouchers were seen as a "reward" that heightened feelings of wellbeing and were a "boost" to continue. *"I was over the moon with it. I was. I was really happy with it and just receiving my wee £100.00 one there, I was really quite chuffed". (Pregnant woman, quit during pregnancy, experience of smoking cessation incentives).* *"So whether it's money or whether it's a token but it should be for something that they want, not something we think they should have as kind of middle-class professionals." (GP, provider)* Most participants preferred vouchers to "hard cash", as the latter may encourage women to either waste it or spend it on inappropriate items such as cigarettes or alcohol.
	Pregnant/ post-partum women who smoke(d)	Acceptability of maternal well-being incentives	Women expressed a desire for an incentive to be focused on the mother who they felt was often forgotten about with the focus on, the baby, the incentive aimed at "pampering them and making a fuss". These incentives were described as a "morale booster" and helped with coping with the challenges of new behaviours. Personal gifts were considered to be motivating, and more useable than vouchers in that they didn't require recall or access to retail shops.
	Providers and pregnant/	Acceptability of baby and pregnancy related incentives	There were mixed views on the acceptability of baby and pregnancy related incentives such as maternity clothes, bibs, nappies and car seats. Some women felt that such items should be considered necessities whereas other women and providers felt that the

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	post-partum women who smoke(d)		incentive should be "niceties, the luxuries that people can't generally afford", that add value to the woman's well-being as well as encouraging them to stop smoking.	
	Providers and pregnant/ post-partum women who smoke(d)	Acceptability of health-related incentives	There were mixed views on the acceptability of health-related incentives such as vouchers for fruit and vegetables or access to sport and leisure facilities. Some women were doubtful about the motivating effects of this type of incentive, whilst other providers felt that incentives provided for changing health behaviour should promote health. *"If it's something positive and it's going to be related to improving the whole, you know, family health, you know. I think it should be health-related benefits because we are, you know, it's the health service rather than just here's some money." (Hospital midwife)*	
Risk of bias	Item		Yes/No/ Can't tell	Comments
	1. Was there a clear statement of the aim of the research?		Yes	To investigate the mechanisms of action and interactions of incentives, a shortlist of incentive strategies and the unintended consequences of incentives.
	2. Is a qualitative methodology appropriate?		Yes	Interviews/focus groups were conducted with pregnant/post-partum women, including those who smoke(d) and providers of care who either had experience of smoking cessation incentives or not.
	3. Was the research design appropriate to address the aims of the research?		Yes	Interviews/focus-groups were sufficient to obtain views and experiences. Interviews were semi-structured and included topic guides to ensure all areas were covered.
	4. Was the recruitment strategy appropriate to the aims of the research?		Yes	Participants were recruited in the BIBS study by purposive, snowball sampling strategy. Participants were recruited in the CPIT study to achieve target sample size, balanced over incentive intervention and control and age groups. Geographic areas across both studies were selected due to diverse sociodemographic characteristics and their different incentive cultures for smoking cessation in pregnancy.
	5. Was the data collected in a way that addressed the research issue?		Yes	Face-to-face and telephone interviews were conducted, recorded and transcribed. Intervention vignettes were used for some participants to frame the incentives. No information on data

Bibliographic reference	**Morgan Heather, Hoddinott Pat, Thomson Gill, Crossland Nicola, Farrar Shelley, Yi Deokhee, Hislop Jenni, Moran Victoria Hall, MacLennan Graeme, Dombrowski Stephan U, Rothnie Kieran, Stewart Fiona, Bauld Linda, Ludbrook Anne, Dykes Fiona, Sniehotta Falko F, Tappin David, and Campbell Marion (2015) Benefits of Incentives for Breastfeeding and Smoking cessation in pregnancy (BIBS): a mixed-methods study to inform trial design. Health technology assessment (Winchester, and England) 19(30), 1-viii**		
			saturation. Data was collected by 5 researchers, in different locations, over a prolonged period of time.
	6. Has the relationship between researcher and participants been adequately considered?	Can't tell	Some participants appeared to expect the researchers to be pro incentives, without researchers conveying any information or evidence to this effect.
	7. Have ethical issues been taken into consideration?	Yes	Ethics approval was obtained. In addition, ethical approval for incorporating the qualitative transcripts from the CPIT into the BIBS study was granted.
	8. Was the data analysis sufficiently rigorous?	Yes	Framework analysis was conducted to identify and compare themes from transcribed interviews. Three researchers identified themes independently and coding was agreed. Further detailed analysis was conducted to ensure consistency. CPIT transcripts were incorporated into the analysis, to minimise bias of interpretation.
	9. Is there a clear statement of findings?	Yes	Findings are explicit, and report both positive and negative views on the use of incentives from both women and providers groups. Findings link back to the original research question and were validated by the wider research team.
	10. Is the research valuable?	Can't tell	Findings are in line with other qualitative studies for smoking cessation incentives in pregnancy. The study also incorporates views on incentives for improving breastfeeding (BF) outcomes (not of relevance to this review), with it often being difficult to separate the views of participants based on whether they were referring to smoking cessation or BF incentives. Similarly, views for women and providers were often grouped together with the views of partners and experts, if comparable. Providers views may have related to delivering or receiving incentives for introducing quitting or maintaining cessation.
Overall risk of bias	Low risk of bias		
Source of funding	HTA programme, National Institute for Health Research (NIHR).		
Comments	Participants in the CPIT study were offered £20.00 cash for participating in the qualitative interview part of the study.		

Notley 2019

Bibliographic reference	**Notley C, Gentry S, Livingstone-Banks J, Bauld L, Perera R, Hartmann-Boyce J. Incentives for smoking cessation. Cochrane Database of Systematic Reviews 2019, Issue 7. Art. No.: CD004307. DOI: 10.1002/14651858.CD004307.pub6[b]**
Review question	Cochrane review to determine the long-term effect of incentives and contingency management programmes for smoking cessation. (This updated review is a modified version of a previous Cochrane review by Cahill 2015. The review included studies from a mixed population setting and also studies in pregnant smokers, which were analysed separately and are the focus for this review).
Study design	Inclusion: - RCTs/Cluster RCTs which allocate individual/groups of adult women to an intervention (incentive scheme) or control conditions
Population	Pregnant adult women who smoke
Intervention	Incentive scheme to reward pregnant women for validated cessation and abstinence. Interventions which offered risk-based rewards alongside guaranteed incentives were included, but interventions which only offer risk-based rewards were not included (as covered in another Cochrane review).
Comparison	Usual care- smoking cessation intervention (practical smoking cessation support) without incentives
Location/setting	9 studies in USA and 1 study in UK Setting included antenatal clinics, obstetric practices and community antenatal programmes. One study in methadone-maintained pregnant women was conducted in the Center for Addiction and Pregnancy in Baltimore.
Search strategy	Literature searches were conducted on 30 July 2018. The Cochrane Tobacco Addiction Group Specialised Register was searched, which included grey literature, hand searching of specialist journals and individual studies identified by searching multiple databases including CENTRAL, MEDLINE, Embase, PsychINFO. Authors of included studies were contacted when necessary, such as Donatelle 2002 which reported interim results, in this instance review authors report that no response were elicited.
Included studies	33 RCTs in mixed population, 10 RCTs in pregnant women (n =2,571) 10 RCTs in pregnancy women included in this review; - Baker 2018, Donatelle 2000a, Donatelle 2000b, Donatelle 2002, Harris 2015, Heil 2008, Higgins 2014, Ondersma 2012, Tappin 2015a, Tuten 2012
Study quality	Quality assessment criteria (using Cochrane Collaboration's tool) included: • Random sequence generation (selection bias) • Allocation concealment (selection bias) • Blinding of outcome assessment/biochemical validation of abstinence (detection bias) • Incomplete outcome data (attrition bias) • Other potential risks of bias Performance bias was not assessed on the basis that blinding of participants was not possible due to the nature of the incentive intervention. For pregnancy studies (10 studies): Random sequence generation;

Bibliographic reference	**Notley C, Gentry S, Livingstone-Banks J, Bauld L, Perera R, Hartmann-Boyce J. Incentives for smoking cessation. Cochrane Database of Systematic Reviews 2019, Issue 7. Art. No.: CD004307. DOI: 10.1002/14651858.CD004307.pub6[b]**
	• Studies that reported the methods for randomisation and rated as low risk; Baker 2018, Harris 2015, Ondersma 2012, Tappin 2015a • Studies rated as unclear; Donatelle 2000a, Donatelle 2000b, Donatelle 2002, Heil 2008, Higgins 2014, Tuten 2012 Allocation concealment; • Studies that were rated as low risk; Ondersma 2012, Tappin 2015a • Studies rated as unclear; Baker 2018, Donatelle 2000a, Donatelle 2000b, Donatelle 2002, Harris 2015, Heil 2008, Higgins 2014, Tuten 2012 Blinding of outcome assessment; • Studies that were rated as low risk; Baker 2018, Donatelle 2000a, Donatelle 2000b, Donatelle 2002, Harris 2015, Heil 2008, Higgins 2014, Ondersma 2012, Tappin 2015a, Tuten 2012 Incomplete outcome data; • Studies that were rated as high risk; Donatelle 2000a • Studies that were rated as low risk; Baker 2018, Harris 2015, Heil 2008, Ondersma 2012, Tappin 2015a, Tuten 2012 • Studies rated as unclear; Donatelle 2000b, Donatelle 2002, Higgins 2014 Other potential risks of bias; • Studies that were rated as unclear risk; Baker 2018
Outcomes measures and effect size	Results for mixed populations not reported in this evidence table Smoking cessation outcomes were extracted at the closest follow up to the end of pregnancy, and also at longest follow up post-partum if reported. <u>Individual study details and effect sizes</u> **Baker 2018, RCT**

Participants	Total n= 1,014, intervention n= 505; control, n= 509
Setting	Private and community antenatal clinics, Wisconsin, USA.
Inclusion	Smoking daily within the last 6 months, 18+ years
Intervention	Cash incentive Smoking cessation counselling USD 25/visit for any pre-birth visit (up to 6), USD 25/attendance at post birth visits 2 and 3, USD 20/call for completion of 5 post-birth calls, USD 40/visit for biochemically confirmed abstinence at post birth visits 1 and 4. Could receive up to USD 500 for meeting all criteria
Control	Smoking cessation counselling

Bibliographic reference	Notley C, Gentry S, Livingstone-Banks J, Bauld L, Perera R, Hartmann-Boyce J. Incentives for smoking cessation. Cochrane Database of Systematic Reviews 2019, Issue 7. Art. No.: CD004307. DOI: 10.1002/14651858.CD004307.pub6[b]

	USD 40 for study registration, USD 40/visit for attendance at post birth visit 1 and 4. Could receive up to USD 120
Outcomes (biochemically validated)	7-day PPA at 6 months post-birth, carbon monoxide (CO) <7 parts per million (ppm). Biochemically confirmed abstinence at post-birth week 1 visit.
Other outcomes	Number of post-birth home visits and phone calls taken, self-reported smoking at 2 and 4-month visits
Follow-up	6 months post-birth
Effect size for abstinence at longest follow-up (95% CI)	RR 1.59 (1.12 to 2.24)

Donatelle 2000a, RCT

Participants	Total n= 220; intervention n=112; control n=108, 207 participants in primary analysis (intervention n =105, control n =102)
Setting	4 Women, Infants, and Children programme sites, Oregon, USA
Inclusion	≥15 years, ≤28 weeks gestation
Intervention	USD 5 participation voucher at each of 3 assessments. Participant was phoned monthly to self-report smoking status, for up to 10 months. If self-reported quit and verified, received USD 50 voucher monthly. Verbal and written advice on smoking cessation + quit kit Social supporter who was also eligible for vouchers if participant quit (USD 50 for first quit month, USD 25 for other quits months, USD 50 for final quit month).
Control	USD 5 participation voucher at each of 3 assessments. Verbal and written advice on smoking cessation +quit kit. Baseline advice and monthly calls to determine smoking status
Outcomes (biochemically validated)	7-day PPA, 8 months gestation and 2 months post-partum Biochemical salivary cotinine <30ng/ml, salivary thiocyanate <100mg/ml
Other outcomes	None
Follow-up	8-months gestation and 2-months post-partum
Effect size for abstinence at longest follow-up (95% CI)	RR 3.63 (1.54 to 8.58)

Donatelle 2000b, RCT

Participants	Total 186; intervention 1; n= 67; intervention 2; n=59; control n=60

Bibliographic reference	Notley C, Gentry S, Livingstone-Banks J, Bauld L, Perera R, Hartmann-Boyce J. Incentives for smoking cessation. Cochrane Database of Systematic Reviews 2019, Issue 7. Art. No.: CD004307. DOI: 10.1002/14651858.CD004307.pub6[b]

Setting	8 Women, Infants and Children programme sites, Oregon, USA
Inclusion	Similar to Donatelle 2000a, pregnant smokers
Intervention 1	5 A's intervention (Ask, Advise, Assess, Assist, Arrange) USD 25 voucher for each month validated abstinence.
Intervention 2	5 A's intervention (Ask, Advise, Assess, Assist, Arrange) USD 25 voucher for achieved abstinence and immediate feedback on risks to the foetus associated with CO results (CO ≤ 5ppm confirmed monthly abstinence).
Control	5 A's intervention (Ask, Advise, Assess, Assist, Arrange)
Outcomes (biochemically validated)	Abstinence at the end of pregnancy. Biochemically validated, salivary cotinine <30ng/ml. CO <5ppm monthly
Other outcomes	None
Follow-up	End of pregnancy
Effect size for abstinence at longest follow-up (95% CI)	RR 1.66 (0.71 to 3.89) (intervention 1 versus control)

Donatelle 2002, RCT

Participants	Total enrolled n=298; intervention 1; n=102; intervention 2; n= 96; control n=95 (results for n=293)
Setting	9 private practice antenatal clinics, Oregon, USA
Inclusion	Predominantly low-income, high risk pregnant women. Smoking (even a puff) in the last 7 days. <29weeks gestation, age ≥15 years
Intervention 1	5 A's intervention (Ask, Advise, Assess, Assist, Arrange), a copy of a guide to quit smoking, a local cessation resource guide. USD 25 voucher for each month achieving validated abstinence.
Intervention 2	As above but USD 75 for achieved abstinence.
Control	5 A's intervention (Ask, Advise, Assess, Assist, Arrange), a copy of a guide to quit smoking, a local cessation resource guide.
Outcomes (biochemically validated)	Abstinence at 8-months gestation and phone call post-partum. Salivary cotinine for self-reported non-smokers. Biochemically validated; salivary cotinine <30ng/ml; CO <5ppm at monthly tests.
Other outcomes	None
Follow-up	8 months gestation

Bibliographic reference	**Notley C, Gentry S, Livingstone-Banks J, Bauld L, Perera R, Hartmann-Boyce J. Incentives for smoking cessation. Cochrane Database of Systematic Reviews 2019, Issue 7. Art. No.: CD004307. DOI: 10.1002/14651858.CD004307.pub6[b]**

Effect size for abstinence at longest follow-up (95% CI)	Not stated- results are in interim analysis

Harris 2015, pilot RCT

Participants	Total n= 17, intervention n=7; control n=10
Setting	Rural Appalachia Ohio and Kentucky antenatal clinics, USA
Inclusion	Pregnant, ≥18 years, daily smokers (verified by breath CO and urinary cotinine)
Intervention	6-week web-based contingency management (CM) programme with 2 follow up sessions, occurred after the 6-week programmes ended before birth. CM programme used to verify breath CO measurements. 6-week programme of 5 stages (baseline, shaping, abstinence, thinning, return to baseline). During each phase – submitted video recordings and breath samples. Could earn vouchers with major retailers for breath samples based on programme phase. For abstinence – required to have breath CO 4ppm to earn vouchers. Escalating pay schedule, started at USD 1, increasing by USD 0.25 for each consecutive negative breath sample, with a USD 5 bonus for every 6 consecutive negative samples. If sample did not meet abstinence criteria, participant didn't receive incentive and voucher was reset back to baseline value. If reset required value went back to start point, 3 valid consecutive tests restored to previous level. Could earn a maximum of USD 800 during study. In addition, 2 spot checks during remaining months of pregnancy following programme end – if abstinent received USD 100 in cash.
Control	Phone-delivered counselling; 5 calls from a registered nurse, as many as 5 check-in calls.
Outcomes (biochemically validated)	PPA at end of pregnancy verified by urinary cotinine (cut-off not defined).
Other outcomes	Smoking reduction (time line follow-back method). Stages of change ladder, modified Fagerström test for nicotine dependence, post-treatment assessments measured birth outcomes and smoking-related variables
Follow-up	Until the end of pregnancy
Effect size for abstinence at longest follow-up (95% CI)	RR 0.48 (0.06 to 3.69)

Heil 2008, RCT

Bibliographic reference	Notley C, Gentry S, Livingstone-Banks J, Bauld L, Perera R, Hartmann-Boyce J. Incentives for smoking cessation. Cochrane Database of Systematic Reviews 2019, Issue 7. Art. No.: CD004307. DOI: 10.1002/14651858.CD004307.pub6[b]

Participants	Total n= 82, intervention n= 40, control n=37 (5 withdrawals for termination or foetal death). 77 participants in primary analysis.
Setting	4 Obstetric practices and the Women, Infants, and Children programme, Burlington, USA.
Inclusion	Gestational age ≤20 weeks, smoked at all in the previous 7 days
Intervention	Standard care from their clinic and leaflet. Contingent vouchers for proven abstinence during first 5 days. From 2nd week vouchers for urine cotinine ≤80ng/ml. Started at USD 6.25 to a maximum of USD 45, where they stayed until a missed visit or positive test. If reset required value went back to start point, 2 valid tests restored to previous level.
Control	Standard care from their clinic and leaflet. Vouchers independent of smoking status, USD 15 per visit antepartum, USD 20 per visit post-partum. Would average the mean payments earned in the other group.
Outcomes (biochemically validated)	Abstinence at the end of pregnancy, 12 and 24-weeks post-partum. Biochemically validated, urine cotinine <80ng/ml, apart from CO ≤6ppm for first week
Other outcomes	Foetal growth, baby health and total voucher earnings
Follow-up	End of pregnancy, 12 and 24-weeks post-partum
Effect size for abstinence at longest follow-up (95% CI)	RR 3.24 (0.35 to 29.82)

Higgins 2014, RCT

Participants	Total n= 130, intervention 1; n=44, intervention 2; n=44, control n=42 (12 women further withdrawn due to termination or foetal death). 118 participants in primary analysis (intervention 1; n=39, intervention 2; n=40, control; n=39)
Inclusion	Pregnant, smokers
Setting	Obstetric practices and the Women, Infants, and Children programme, Burlington, USA.
Intervention 1	Standard antenatal care for smoking (counselling). First 5-day week validated by CO, after by urine cotinine. Vouchers based on valid biotesting. Vouchers began at USD 6.25 increased by USD 1.25 to a max of USD 45. Missed or positive results, schedule was reset, 2 passes reset the schedule to former point.
Intervention 2	Standard antenatal care for smoking (counselling). Same pattern as intervention 1, but with potentially USD 296.25 available in weeks 1 to 6 by maintaining ≤4ppm breath CO in week 1, testing cotinine negative on 2nd Monday for an additional USD 87.50, and thereafter testing negative twice a week to week 6. The 2nd test each

Bibliographic reference	Notley C, Gentry S, Livingstone-Banks J, Bauld L, Perera R, Hartmann-Boyce J. Incentives for smoking cessation. Cochrane Database of Systematic Reviews 2019, Issue 7. Art. No.: CD004307. DOI: 10.1002/14651858.CD004307.pub6[b]

	week increased by USD 15.50 if it was negative and the first had also been negative. This was meant to reinforce early continuous abstinence.
Control	Standard antenatal care for smoking (counselling). USD 15 per antepartum and USD 20 per post-partum visit, irrespective of smoking status. Total available earnings comparable across 3 groups.
Outcomes (biochemically validated)	7-day PPA at baseline, 1 month, end of pregnancy, 2, 4, 8, 12- and 24-weeks post-partum. Biochemically validated; CO ≤4ppm or 6ppm, and urine cotinine ≤80ng/ml.
Other outcomes	Foetal growth, birth outcomes
Follow-up	To 24 weeks post-partum
Effect size for abstinence at longest follow-up (95% CI)	RR 2.27 (0.63 to 8.17) (intervention 2 versus control)

Ondersma 2012, pilot RCT

Participants	Total n=110; intervention 1; n= 26, intervention 2; n=28, intervention 3; n=30; control n= 26 94 participants included in primary analysis (intervention 1; n= 23, intervention 2; n=22, intervention 2; n=26, control n=23)
Setting	4 antenatal clinics, Detroit, USA
Inclusion	≥18 years, gestation <27 weeks
Intervention 1	CD-5A's: 5A's (Ask, Advise, Assess, Assist, Arrange) or 5 R's (Relevance, Risks, Rewards, Roadblocks, Repetition) for those unwilling to set a quit date. Professional video and testimonials.
Intervention 2	CM-lite. Relied on participant to request verification of smoking status. Testing offered at antenatal visits. Eligible for unlimited incentivisation attempts, only 5 reinforcement retail gift vouchers available (worth USD 50)
Intervention 3	Combination of CD-5A's and CM-lite
Control	Treatment as usual
Outcomes (biochemically validated)	7-day PPA, 30-day CA, validated by CO<4ppm, urinary cotinine <100ng/ml
Other outcomes	Mean number of samples submitted, modal number of negative samples, mean amount of gift vouchers earned, mean amount earned among those submitting a sample, help-seeking behaviour
Follow-up	10-weeks (end of pregnancy)
Effect size for abstinence at longest follow-up (95% CI)	RR 3.35 (0.44 to 25.68) (intervention 2 and 3 combined versus control)

Bibliographic reference	**Notley C, Gentry S, Livingstone-Banks J, Bauld L, Perera R, Hartmann-Boyce J. Incentives for smoking cessation. Cochrane Database of Systematic Reviews 2019, Issue 7. Art. No.: CD004307. DOI: 10.1002/14651858.CD004307.pub6[b]**

Tappin 2015a, RCT, Cessation in Pregnancy Incentives Trial (CPIT)

Participants	Total n=612; intervention n=306; control n= 306 609 participants included in primary analysis (intervention n = 306, control n=303)
Setting	Large health board area, Greater Glasgow and Clyde, UK
Inclusion	≥16 years, gestation ≤24-weeks, exhaled CO >7ppm
Intervention	Standard care – as control group Up to GBP 400 vouchers for engagement, quitting or both. GBP 50 for attending 1hr face-to-face and setting a quit date (engagement). At 4 weeks, phone check-up, if self-reported no smoking for past 2-weeks had a researcher visit and CO breath test, if <10ppm, passed and received another GBP 50 voucher. 12-weeks, phone call and CO test, if validated receive voucher GBP 100. Contacted between 34 and 38 weeks, researcher visit for self-reported quitters for CO and cotinine, GBP 200 for confirmed quitters. At final follow-up GBP 25 voucher for reporting smoking status.
Control	Standard care – referral to NHS stop smoking services. Included initial 1-hour session to discuss cessation, 4 weekly phone calls to provide support and 10 weeks free NRT available. SSS contact occurred at 4 and 12-weeks (if quit at 4), 34-38 weeks gestation and 6-months post-birth (if quit at 34-38 weeks)
Outcomes (biochemically validated)	Abstinence for 4-weeks (2-week PPA, CO <10ppm). 12-weeks, if quit at 4-weeks, intervention only (4-week PPA, CO <10ppm) 34 to 38 weeks, all participants (<5 cigarettes in past 8 weeks, CO <10ppm, cotinine (urine <44.7ng/ml; saliva <14.2ng/ml), if self-report quit) 6-months post-natal for confirmed quitters at 34 to 38 weeks: still quit or <5 cigarettes since quit date, cotinine confirmed.
Other outcomes	Adverse events (miscarriage and stillbirth), engagement, birth weight and cost- effectiveness.
Follow-up	Up to 6-months post-birth.
Effect size for abstinence at longest follow-up (95% CI)	RR 3.88 (2.10 to 7.16)

Tuten 2012, feasibility RCT

Participants	Total n= 102, intervention 1; n= 42; incentive 2; n= 28; control, 32
Setting	Center for addiction and pregnancy, Baltimore, USA

Bibliographic reference	**Notley C, Gentry S, Livingstone-Banks J, Bauld L, Perera R, Hartmann-Boyce J. Incentives for smoking cessation. Cochrane Database of Systematic Reviews 2019, Issue 7. Art. No.: CD004307. DOI: 10.1002/14651858.CD004307.pub6[b]**

Inclusion	≥18 years, ≤30 weeks gestation, nicotine-dependent or smoking 10+ cigarettes per day.
Intervention 1	Treatment as usual. Contingent behavioural incentives; 12-weeks eligibility for rewards contingent on reduction or abstinence. Incentives for each negative breath test on Mondays, Wednesdays and Fridays. Week 1, any reduction Weeks 2 to 4, 10% reduction Weeks 5 to 7, 25% reduction Weeks 8 to 9, 50% reduction Weeks 10 to 11, 75% reduction Week 12 – delivery, abstinence (CO <4ppm) Voucher started at USD 7.50, increased USD 1/day up to USD 41.5. If a negative sample missed through the 12 weeks, reset to USD 7.50, if 5 consecutive negative tests, voucher value restored to former level.
Intervention 2	Treatment as usual. Non-contingent behavioural incentives Told behaviour did not determine rewards received, they would receive incentives in line with previously established schedule. Had to give breath and urine samples to receive incentives – eligible for 12-weeks or until delivery.
Control	Treatment as usual
Outcomes (biochemically validated)	Abstinence at end of 12-weeks programme and 6-weeks post-partum. Cessation was PPA, biochemically validated (CO <4ppm; urinary cotinine <300ng/ml)
Other outcomes	Mean cigarettes per day
Follow-up	End of 12-week programme (end of pregnancy) and 6-weeks post-partum
Effect size for abstinence at longest follow-up (95% CI)	RR 20.72 (1.28 to 336.01) (intervention 1 and control)

Critical outcome

For both meta- analyses, a Mantel-Haenzel random effects model was used. I^2 statistic was used to assess heterogeneity.

- Abstinence from smoking at the end of pregnancy in pregnant women receiving incentives compared with no incentives; **RR 2.79 (95% CI 2.10 to 3.72)**

The pooled estimate included 7 studies (n = 1,244): Donatelle 2000a, Donatelle 2000b, Heil 2008, Higgins 2014, Ondersma 2012, Tappin 2015a, Tuten 2012. I^2 statistic was 0.0%.

<table>
<tr><td>Bibliographic reference</td><td colspan="3">Notley C, Gentry S, Livingstone-Banks J, Bauld L, Perera R, Hartmann-Boyce J. Incentives for smoking cessation. Cochrane Database of Systematic Reviews 2019, Issue 7. Art. No.: CD004307. DOI: 10.1002/14651858.CD004307.pub6[b]</td></tr>
<tr><td></td><td colspan="3">• <u>Smoking cessation at longest follow-up in pregnant women receiving incentives compared with no incentives</u>; RR 2.38 (1.54 to 3.69)

The pooled estimate included 9 of the 10 studies (n =2,273), due to one study (Donatelle 2002) not being included in the meta-analysis as only interim results were reported.
I^2 statistic was 41%.

<u>Other outcomes reported</u>

• <u>Effectiveness of contingent rewards compared with guaranteed payments on abstinence from smoking in pregnant women;</u>
RR 3.33 (0.97 to 11.38)

The pooled estimate included 3 studies (n=225): Heil 2008, Higgins 2014, Tuten 2012.
I^2 statistic was 18%.</td></tr>
<tr><td>Statistical analysis</td><td colspan="3">- For the outcome smoking cessation at longest follow-up, sensitivity analysis was conducted removing 1 study at high risk of bias (Donatelle 2000a), which resulted in a RR 2.22 (1.37 to 3.59) with the same I^2 statistic.

- Meta-regression was not able to be conducted comparing incentive amount to effect estimate due to insufficient data.</td></tr>
<tr><td>Risk of bias (ROB)
Overall ROB</td><td>Domain</td><td>Concerns (Low / High / unclear)</td><td>Rationale for concern</td></tr>
<tr><td></td><td>Study eligibility criteria</td><td>Low concern</td><td>The authors clearly specify the objectives of the review, the review question and the eligibility criteria. The updated review notes post-hoc changes to the original protocol, which still align with the objectives of the review.</td></tr>
<tr><td></td><td>Identification and selection of studies</td><td>Low concerns</td><td>An appropriate range of databases were searched as well as grey literature. A full search strategy is available and studies have not been restricted on language or to full text papers. RCT and related filters were used, but appropriate to the review question. Additional attempts were made to contact authors for ongoing and included studies when required. Titles and abstracts and were screened by 2 independent reviewers, and again at full paper stage. The review is likely to have identified and included a high proportion of relevant studies.</td></tr>
</table>

Bibliographic reference	**Notley C, Gentry S, Livingstone-Banks J, Bauld L, Perera R, Hartmann-Boyce J. Incentives for smoking cessation. Cochrane Database of Systematic Reviews 2019, Issue 7. Art. No.: CD004307. DOI: 10.1002/14651858.CD004307.pub6[b]**		
	Data collection and study appraisal	Low concerns	All relevant study characteristics and results were extracted, and the methods section details how results were transformed to risk ratios. Data extraction occurred by 2 independent review authors using a tailored data extraction form. Risk of bias was assessed using Cochrane Collaboration's tool for assessing risk of bias. Performance bias was not assessed due to blinding of participants not being feasible. Risk of bias was also assessed by two independent authors.
	Synthesis and findings	Low concerns	Review addresses heterogeneity appropriately in their analysis and uses a random effects model with no substantial heterogeneity. Risk of bias of individual studies was considered in a sensitivity analysis, removing one study at high risk of bias (pregnancy studies). Publication bias not able to be assessed due to insufficient studies (pregnancy studies).
	Overall Risk of Bias	Low risk of bias	
	Other details: None		
Source of funding	National Institute for Health Research (NIHR), via Cochrane Infrastructure and Cochrane Programme Grant funding to the Cochrane Tobacco Addiction Group.		
Comments	- One study included in the NICE evidence review (Glover 2015) was excluded from this systematic review due to being 8 weeks duration and not necessarily to the end of pregnancy or beyond - Intention to treat analysis was used where possible. Participants who dropped out or were lost to follow up after randomised, were assumed as being continuing smokers. - The update excluded 1 study (Higgins 2014) included in the previous version of the review, due to the study being non-randomised.		

Data and analyses from 10 studies in review I.i. were obtained from a Cochrane review (Notley 2019[b]) where the risk of bias was assessed using Cochrane's collaborative tool.

Using the assessments made in Notley 2019[b], the risk of bias of these studies was re-evaluated in this evidence review using the Cochrane's *Risk of Bias* tool, as outlined in the NICE manual.

Baker 2018

Risk of bias (ROB) Overall ROB	**Outcome**	**Judgement (Low / High / some concerns)**	**Comments**

	Risk of bias arising from the randomisation process	Some concerns	Participants were randomised using randomisation tables. Study reports: "Separate computer determined randomisation tables were created based on race (white/non-white) and county with proportional randomisation (1:1) into the incentive and control conditions". No information on allocation concealment.
	Risk of bias due to deviations from intended interventions (assignment)	Low risk	Participants not blinded to intervention and so controls may have been more likely to drop out. Incentives were contingent on participants providing outcome data, which was then biochemically validated. As such, no apparent deviations from intended interventions.
	Missing outcome data (attrition bias)	Low risk	Notley 2019[b] reports: "For the primary outcome, 316 of 509 (37.9%) control condition participants had missing data; 145 of 505 (28.7%) incentive condition participants had missing data. Participants with missing data for the primary outcome were counted as smoking ITT). "
	Risk of bias in measurement of the outcome (detection bias)	Low risk	Smoking status was CO verified.
	Risk of bias in selection of the reported result	Some concerns	Notley 2019[b] reports: "6-month follow-up stated for primary outcomes, but Table 2 results reports 4-6 months follow-up".
	Other sources of bias	None.	
	Overall Risk of Bias	Some concerns	
	Other outcome details: None		

Donatelle 2000a

Risk of bias (ROB) Overall ROB	**Outcome**	**Judgement (Low / High / some concerns)**	**Comments**
	Risk of bias arising from the randomisation process	Some concerns	No information reported on randomisation process or allocation concealment.
	Risk of bias due to deviations from intended interventions (assignment)	Low risk	Participants not blinded to intervention and so controls may have been more likely to drop out. Incentives were contingent on participants providing outcome data, which was then biochemically validated. As such, no apparent deviations from intended interventions.
	Missing outcome data (attrition bias)	High risk	Notley 2019[b] reports "Relatively high, but comparable with non-participants attenders at the WIC clinic. Losses: Intervention: 32% at 8 months gestation, 36%

			at 2 months post-partum; Control: 51.5% at 8 months gestation,52% at 2 months post-partum."
	Risk of bias in measurement of the outcome (detection bias)	Low risk	Abstinence was biochemically verified.
	Risk of bias in selection of the reported result	Low risk	No apparent selective reporting of results
	Other sources of bias	None.	
	Overall Risk of Bias	High risk of bias	
	Other outcome details: None		

Donatelle 2000b

Risk of bias (ROB) Overall ROB	**Outcome**	**Judgement (Low / High / some concerns)**	**Comments**
	Risk of bias arising from the randomisation process	Some concerns	No information reported on randomisation process or allocation concealment.
	Risk of bias due to deviations from intended interventions (assignment)	Low risk	Participants not blinded to intervention and so controls may have been more likely to drop out. Incentives were contingent on participants providing outcome data, which was biochemically validated. As such, no apparent deviations from intended interventions.
	Missing outcome data (attrition bias)	Some concerns	No information available.
	Risk of bias in measurement of the outcome (detection bias)	Low risk	Abstinence was biochemically verified.
	Risk of bias in selection of the reported result	Some concerns	Limited information to make assessment.
	Other sources of bias	None.	
	Overall Risk of Bias	High risk of bias	
	Other outcome details: None		

Donatelle 2002

Risk of bias (ROB) Overall ROB	Outcome	Judgement (Low / High / some concerns)	Comments
	Risk of bias arising from the randomisation process	Some concerns	No information reported on randomisation process or allocation concealment.
	Risk of bias due to deviations from intended interventions (assignment)	Low risk	Participants not blinded to intervention and so controls may have been more likely to drop out. Incentives were contingent on participants providing outcome data, which was biochemically validated. As such, no apparent deviations from intended interventions.
	Missing outcome data (attrition bias)	Some concerns	No information available. Notley 2019[b] reports "298 reported enrolled, but results given for only 293."
	Risk of bias in measurement of the outcome (detection bias)	Low risk	Abstinence was biochemically verified.
	Risk of bias in selection of the reported result	Some concerns	No information to make assessment
	Other sources of bias	None.	
	Overall Risk of Bias	High risk of bias	
	Other outcome details: None		

Harris 2015

Risk of bias (ROB) Overall ROB	Outcome	Judgement (Low / High / some concerns)	Comments
	Risk of bias arising from the randomisation process	Some concerns	Participants were randomised using an internet based random-number generator. No information on allocation concealment.
	Risk of bias due to deviations from intended	Low risk	Participants not blinded to intervention and so controls may have been more likely to drop out. Incentives were contingent on participants providing outcome data, which

	interventions (assignment)		was biochemically validated. As such, no apparent deviations from intended interventions.
	Missing outcome data (attrition bias)	Low risk	Notley 2019[b] reports “All participants reported as followed up”.
	Risk of bias in measurement of the outcome (detection bias)	Low risk	Abstinence was biochemically verified.
	Risk of bias in selection of the reported result	Low risk	No apparent selective reporting of results
	Other sources of bias	None.	
	Overall Risk of Bias	Some concerns	
	Other outcome details: None		

Heil 2008

Risk of bias (ROB) Overall ROB			
	Outcome	**Judgement (Low / High / some concerns)**	**Comments**
	Risk of bias arising from the randomisation process	Some concerns	Study reports: “randomization was stratified based on the clinic where participants received their pre-natal care”. Participants “were assigned randomly”. No information on allocation concealment.
	Risk of bias due to deviations from intended interventions (assignment)	Low risk	Participants not blinded to intervention and whilst controls were provided incentives irrespective of smoking status, they may have been more likely to drop out. Incentives were contingent on participants providing outcome data for the intervention group, which was biochemically validated. As such, no apparent deviations from intended interventions.
	Missing outcome data (attrition bias)	Low risk	Notley 2019[b] reports “Relatively high compliance (83% to 95%) with assessment schedules, and no differences between groups. Withdrawals only for termination or foetal death. 3 intervention and 2 control participants removed from the denominators”.
	Risk of bias in measurement of the outcome (detection bias)	Low risk	Abstinence was biochemically verified

	Risk of bias in selection of the reported result	Low risk	No apparent selective reporting of results
	Other sources of bias	None.	
	Overall Risk of Bias	Some concerns	
	Other outcome details: None		

Higgins 2014

Risk of bias (ROB) Overall ROB			
	Outcome	**Judgement (Low / High / some concerns)**	**Comments**
	Risk of bias arising from the randomisation process	Some concerns	No information on randomisation process, study reports that participants were "randomly assigned". No information on allocation concealment.
	Risk of bias due to deviations from intended interventions (assignment)	Low risk	Participants not blinded to intervention and whilst controls were provided incentives irrespective of smoking status, they may have been more likely to drop out. Incentives were contingent on participants providing outcome data for intervention groups, which was biochemically validated. As such, no apparent deviations from intended interventions.
	Missing outcome data (attrition bias)	Some concerns	Notley 2019[b] reports: "Losses not reported, apart from withdrawals and foetal demise, but ITT analyses conducted"
	Risk of bias in measurement of the outcome (detection bias)	Low risk	Abstinence was biochemically verified
	Risk of bias in selection of the reported result	Low risk	No apparent selective reporting of results
	Other sources of bias	None.	
	Overall Risk of Bias	Some concerns	
	Other outcome details: None		

Ondersma 2012

Risk of bias (ROB) Overall ROB	Outcome	Judgement (Low / High / some concerns)	Comments
	Risk of bias arising from the randomisation process	Low risk	Randomisation was conducted for the CD-5A's or control by computer (1:1) and research assistants were blind to computer-delivered intervention group. Then a second step used an online random number generator to randomise half the participants for the CM component.
	Risk of bias due to deviations from intended interventions (assignment)	Low risk	Participants not blinded to intervention and so those not incentivised may be more likely to drop out. Incentives were contingent on participants providing outcome data for intervention groups, which was biochemically validated. As such, no apparent deviations from intended interventions.
	Missing outcome data (attrition bias)	Low risk	Notley 2019[b] reports: "CD-5As: 3/26 lost; CM-Lite 6/28 lost; CD-5As+CM-Lite 4/30 lost; TAU 3/26 lost. All participants included in ITT analyses".
	Risk of bias in measurement of the outcome (detection bias)	Low risk	Abstinence was biochemically verified
	Risk of bias in selection of the reported result	Low risk	No apparent selective reporting of results
	Other sources of bias	None.	
	Overall Risk of Bias	Low risk of bias	
	Other outcome details: None		

Tappin 2015

Risk of bias (ROB) Overall ROB	Outcome	Judgement (Low / High / some concerns)	Comments
	Risk of bias arising from the randomisation process	Low risk	Study reports "The Glasgow clinical trials unit embedded the randomisation in the trial database using randomised permuted blocks, with a block length of four". Study reports "Allocation was concealed from staff and clients until consent and recruitment". "The helpline…contacted

			women, confirmed that all selection criteria had been met, enrolled participants using telephone consent, and conducted concealed random allocation".
	Risk of bias due to deviations from intended interventions (assignment)	Low risk	Participants not blinded to intervention, whilst staff who ascertained the primary outcome were blind to allocation. Incentives were contingent on participants providing outcome data, which was biochemically validated. As such, no apparent deviations from intended interventions. Those not incentivised may be more likely to drop out.
	Missing outcome data (attrition bias)	Low risk	Notley 2019[b] reports: "Attrition equal across groups: 43/303 (14%) control, 46/306 (15%) incentives. ITT analysis assumed all lost to follow up were continuing smokers, and cross-checked this where possible by residual blood samples".
	Risk of bias in measurement of the outcome (detection bias)	Low risk	Smoking status was biochemically verified
	Risk of bias in selection of the reported result	Low risk	No apparent selective reporting of results
	Other sources of bias	None.	
	Overall Risk of Bias	Low risk of bias	
	Other outcome details: None		

Tuten 2012

Risk of bias (ROB) Overall ROB			
	Outcome	**Judgement (Low / High / some concerns)**	**Comments**
	Risk of bias arising from the randomisation process	Some concerns	No information on random sequence generation or on allocation concealment. Study reports "participants were assigned randomly".
	Risk of bias due to deviations from intended interventions (assignment)	Low risk	Participants not blinded to intervention and so controls may be more likely to drop out. Incentives were contingent on participants providing outcome data for one of the intervention groups, which was biochemically validated. A second intervention group received a schedule of incentives irrespective of smoking status. As such, no apparent deviations from intended interventions.
	Missing outcome data (attrition bias)	Low risk	Notley 2019[b] reports: "CBI: 8/42 lost; NCBI 4/28 lost; TAU 7/32 lost, but all included in ITT analyses".

	Risk of bias in measurement of the outcome (detection bias)	Low risk	Abstinence was biochemically verified
	Risk of bias in selection of the reported result	Low risk	No apparent selective reporting of results
	Other sources of bias	None.	
	Overall Risk of Bias	Some concerns	
	Other outcome details: None		

Appendix E – Forest plots

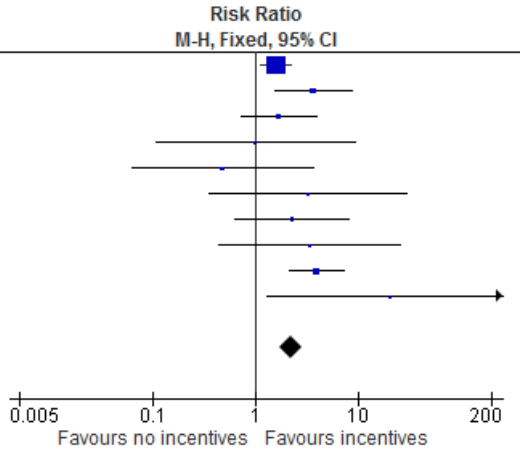
RQ I.i.

Incentives compared with no incentives for smoking cessation in pregnant women

Figure 1: Abstinence from smoking at longest follow-up (with the addition of Glover 2015)

Study or Subgroup	Incentives Events	Incentives Total	No incentives Events	No incentives Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Baker 2018	74	505	47	509	57.1%	1.59 [1.12, 2.24]
Donatelle 2000a	22	103	6	102	7.4%	3.63 [1.54, 8.58]
Donatelle 2000b	13	67	7	60	9.0%	1.66 [0.71, 3.89]
Glover 2015 (1)	2	16	1	8	1.6%	1.00 [0.11, 9.44]
Harris 2015	1	7	3	10	3.0%	0.48 [0.06, 3.69]
Heil 2008	3	37	1	40	1.2%	3.24 [0.35, 29.82]
Higgins 2014 (2)	7	40	3	39	3.7%	2.27 [0.63, 8.17]
Ondersma 2012	7	48	1	23	1.6%	3.35 [0.44, 25.68]
Tappin 2015a (3)	47	306	12	303	14.7%	3.88 [2.10, 7.16]
Tuten 2012	13	42	0	32	0.7%	20.72 [1.28, 336.01]
Total (95% CI)		**1171**		**1126**	**100.0%**	**2.24 [1.75, 2.88]**
Total events	189		81			

Heterogeneity: Chi² = 14.03, df = 9 (P = 0.12); I² = 36%
Test for overall effect: Z = 6.37 (P < 0.00001)

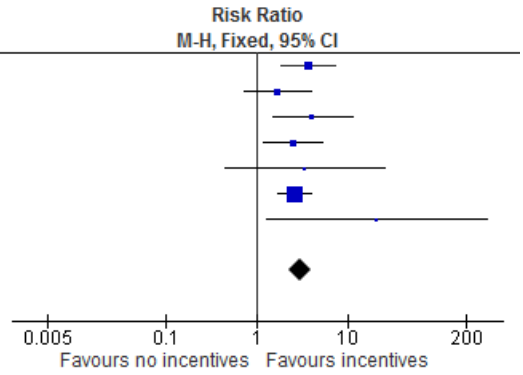


Footnotes
(1) Continious abstinence based on product and voucher condition groups combined
(2) Based on revised contingent voucher incentive group
(3) 12 months post-quit date

Figure 2: Abstinence from smoking at end of pregnancy

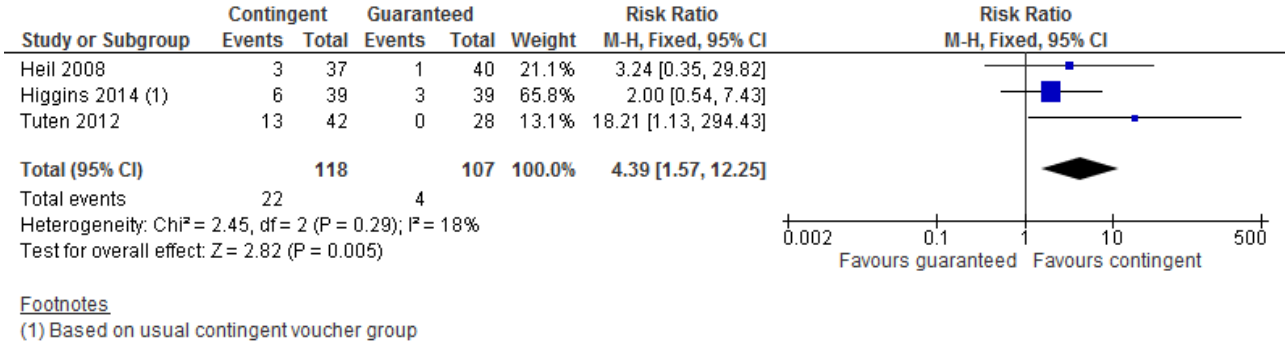
Study or Subgroup	Incentives Events	Incentives Total	No incentives Events	No incentives Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Donatelle 2000a	34	105	9	102	16.5%	3.67 [1.85, 7.26]
Donatelle 2000b (1)	13	67	7	60	13.3%	1.66 [0.71, 3.89]
Heil 2008	15	37	4	40	6.9%	4.05 [1.48, 11.11]
Higgins 2014 (2)	18	40	7	39	12.8%	2.51 [1.18, 5.33]
Ondersma 2012 (3)	7	48	1	23	2.4%	3.35 [0.44, 25.68]
Tappin 2015a	69	306	26	303	47.1%	2.63 [1.72, 4.01]
Tuten 2012 (4)	13	42	0	32	1.0%	20.72 [1.28, 336.01]
Total (95% CI)		**645**		**599**	**100.0%**	**2.96 [2.22, 3.93]**
Total events	169		54			

Heterogeneity: Chi² = 4.90, df = 6 (P = 0.56); I² = 0%
Test for overall effect: Z = 7.47 (P < 0.00001)



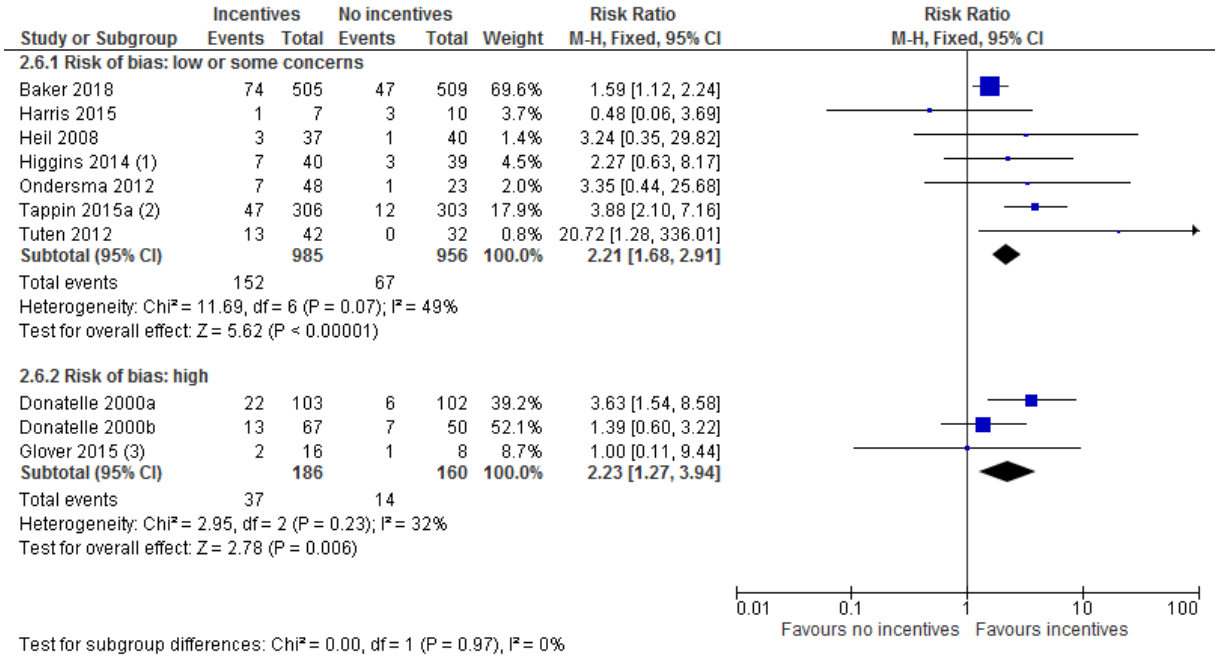
Footnotes
(1) Extrapolated from %
(2) Based on revised contingent voucher incentive group
(3) Results reported only to end of 10-wk programme (end of pregnancy)
(4) Results reported only to end of 12-wk programme (end of pregnancy)

Figure 3: Effectiveness of contingent rewards vs guaranteed payments on abstinence from smoking at longest follow-up



Footnotes
(1) Based on usual contingent voucher group

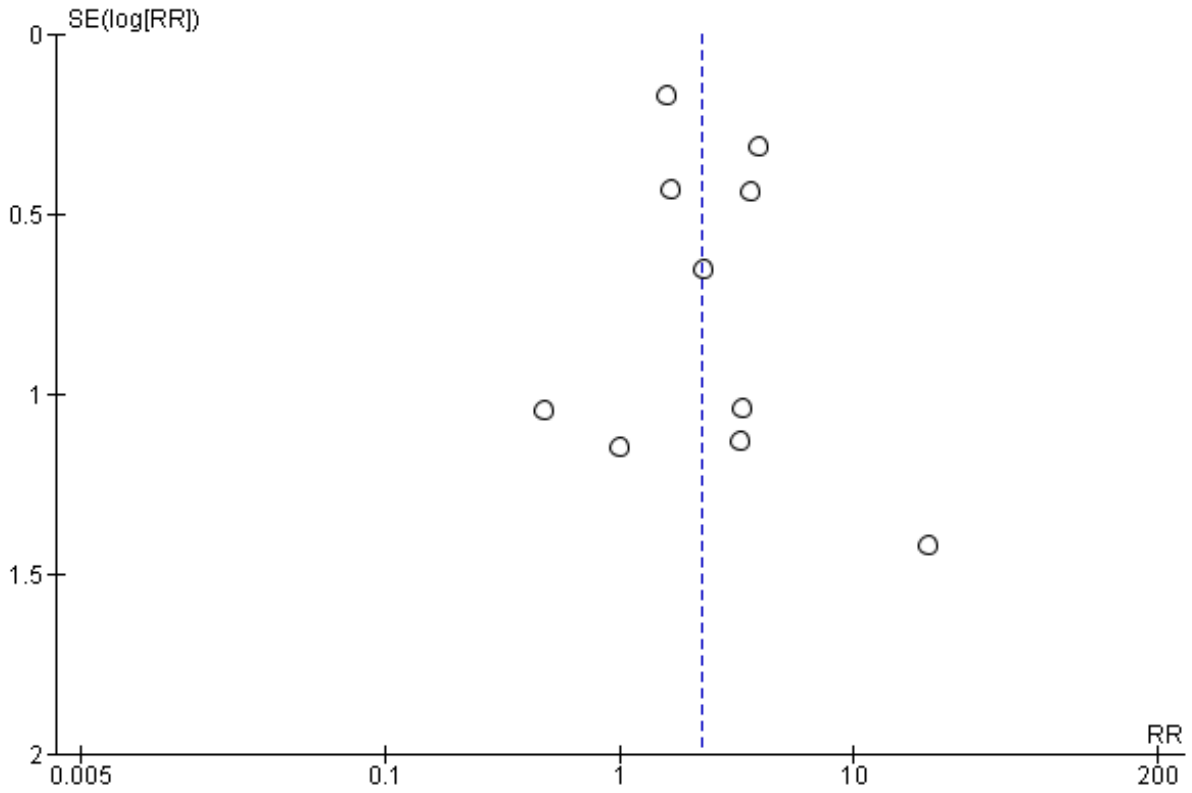
Figure 4: Sensitivity analysis for abstinence from smoking at longest follow-up, by risk of bias



Test for subgroup differences: Chi² = 0.00, df = 1 (P = 0.97), I² = 0%

Footnotes
(1) Based on revised contingent voucher incentive group
(2) 12 months post-quit date
(3) Continious abstinence based on product and voucher condition groups combined

Figure 5: Funnel plot for the outcome abstinence from smoking at longest follow-up (linked to Figure 1)


SE(log[RR])
0
0.5
1
1.5
2
0.005
0.1
1
10
200
RR

Appendix F – GRADE tables

Profile 1: Abstinence from smoking

Quality assessment							No of patients		Effect		Confidence
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Incentives in pregnant women	Control	Relative (95% CI)	Absolute	
Smoking cessation at longest follow-up (follow-up 8-24 weeks post-partum[1]; biochemically validated)											
10 a- j	randomised trials	very serious[2]	no serious inconsistency	no serious indirectness[3]	no serious imprecision	None	189/1171 (16.1%)	81/1126 (7.2%)	RR 2.24 (1.75 to 2.88)	89 more per 1000 (from 54 more to 135 more)	⊕⊕OO LOW
Abstinence at end of pregnancy[4] (biochemically validated)											
7 b-c, e-f, h-j	randomised trials	very serious[5]	no serious inconsistency	no serious indirectness	no serious imprecision	None	169/645 (26.2%)	54/599 (9%)	RR 2.96 (2.22 to 3.93)	177 more per 1000 (from 110 more to 264 more)	⊕⊕OO LOW

[1] One study reports abstinence at 12-months post-quit date.

[2] Three studies judged to be at high overall risk of bias. Five studies judged to have some concerns of overall risk of bias.

[3] One study included pregnant women who were smoking daily at some time point within the last 6 months

[4] In two studies results are reported to end of intervention programme (end of pregnancy)

[5] Two studies judged to be at high overall risk of bias. Three studies judged to have some concerns of overall risk of bias.

a) Baker 2018
b) Donatelle 2000a
c) Donatelle 2000b
d) Harris 2015
e) Heil 2008
f) Higgins 2014
g) Glover 2015
h) Ondersma 2012
i) Tappin 2015
j) Tuten 2012

Profile 2: Contingent rewards vs guaranteed payments at longest follow-up

Quality assessment							No of patients		Effect		Confidence
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Contingent rewards	Guaranteed payments	Relative (95% CI)	Absolute	
Contingent rewards vs guaranteed payments (follow-up 12-24 weeks post-partum; biochemical validated)											
3 e-f, j	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	None	22/118 (18.6%)	4/107 (3.7%)	RR 4.39 (1.57 to 12.25)	127 more per 1000 (from 21 more to 421 more)	⊕⊕⊕O MODERATE

[1] Three studies judged to have some concerns of overall risk of bias

a) Baker 2018
b) Donatelle 2000a
c) Donatelle 2000b
d) Harris 2015
e) Heil 2008
f) Higgins 2014
g) Glover 2015
h) Ondersma 2012
i) Tappin 2015
j) Tuten 2012

GRADE CERQual tables

Summary of review finding	Studies contributing to the review finding	Methodological limitations	Coherence	Adequacy	Relevance	CERQual assessment of confidence in the evidence
1. Women's acceptability on the use of incentives for cessation Many women stated that the motivation for wanting to quit should be to want to improve their health and that of their unborn baby, and not to be rewarded for stopping smoking. Several women expressed that any incentive offered would be less than any	Butterworth 2014, Mantzari 2012, Morgan 2015	Minor concerns (unclear reflexivity in all studies, 1 study did not include purposive sampling)	No or very minor concerns (there is a good fit between the studies and the review finding)	Moderate concerns (data is moderately rich for descriptive data but only includes three studies)	No or very minor concerns (data is of direct relevance and generally covers the population of interest, although does include several post-partum women	Moderate confidence 3 studies with minor methodological limitations. Moderately rich data, but only from 3 studies. Data is of direct relevance. No or very minor

Summary of review finding	Studies contributing to the review finding	Methodological limitations	Coherence	Adequacy	Relevance	CERQual assessment of confidence in the evidence
monetary savings of quitting smoking. Some women believed that incentives provided acknowledgement of their success and were an added boost to wanting to quit smoking.					and women who have quit smoking during pregnancy).	concerns about coherence.
Supporting quotations: <u>Positive perception of incentives</u> "…the vouchers and the incentives and I thought well, that's even better. That to me, was an added bonus that wasn't a reason quit, that was just like a reward for actually going to get them" (incentivised) "I suppose it's not about necessarily having £50.00 or the £100.00 or whatever, it's about the recognition that you've done something, that you've achieved something, it's not, it could have been anything I suppose". (Pregnant woman, quit during pregnancy, experience of smoking cessation incentives) "the vouchers give me incentive to like stop smoking...So the vouchers have helped yeah because I'm thinking it's not that worth risking" (incentivised group) "I feel like I need another one [cigarette] I sort of sit there and think to myself well if I have this one it's going to mess me up getting my vouchers for my kids.... I won't because I'll just think well I've got the vouchers to look forward to" (incentivised group) <u>Negative perception of incentives</u> "You're not doing it for a reward you're just doing it for your own self-worth aren't you? You're doing it for yourself. A pat on the back and someone telling you that you done really good is enough to make you feel good, you know." (Z, smoker) "You've got to have that incentive yourself. For somebody doing it with money or things like that I wouldn't feel right going, just for the fact it would make me feel even worse if I failed. (Z, smoker) "I think they should be doing it for the right reasons, for their health and if they want to stop smoking because you want to be healthy and things, that's fine. Don't just do it because you're going to get money and things out of it. I don't agree with that." (Pregnant woman, current smoker, no experience of being incentivised) "Because at the end of the day if you are going to succeed you'll succeed whether somebody hands you a Love to Shop voucher or not, if you are going to fail then you're going to have a cigarette whether or not somebody's going to give you a voucher or not". (Pregnant woman, quit during pregnancy, experience of smoking cessation incentives)						
<u>2. Incentives and deception</u> Several women expressed concerns of gaming and admitting	Butterworth 2014	Minor concerns (unclear reflexivity and study did not	No or very minor concerns	Serious concerns (data is moderately rich	No or very minor concerns	Low confidence 1 study with minor methodological

Summary of review finding	Studies contributing to the review finding	Methodological limitations	Coherence	Adequacy	Relevance	CERQual assessment of confidence in the evidence
that they may be influenced to abstain only for the carbon monoxide (CO) reading to take the reward. Many women expressed that a caveat was needed to implement more reliable monitoring methods, and to not take away resources from those with genuine intention to quit.		include purposive sampling)	(there is a good fit between the studies and the review finding)	for descriptive data but only includes one study)	(data is of direct relevance and generally covers the population of interest, although does include several post-partum women and women who have quit smoking during pregnancy).	limitations. Moderately rich data, but only from 1 study. Data is of direct relevance. No or very minor concerns about coherence.
Supporting quotations: "I'll be honest with you right, if someone said to me now right come to the stop-smoking clinic I'll give you a tenner I'd go and get that tenner and I'd go and buy fags." (L, smoker)						
<u>3. Engagement with smoking cessation services</u> Women who were incentivised reported to be more motivated to engage with smoking cessation services and underwent routine monitoring to determine smoking status, compared with those who were not incentivised.	Mantzari 2012, Morgan 2015	Minor concerns (unclear reflexivity)	No or very minor concerns (there is a good fit between the study and the review finding)	Serious concerns (data is moderately rich for descriptive data but only includes two studies)	No or very minor concerns (data is of direct relevance and generally covers the population of interest, although does include several post-partum women and women who have quit smoking during pregnancy)	Low confidence 2 studies with minor methodological limitations. Moderately rich data, but only from 1 study. Data is of direct relevance. No or very minor concerns about coherence.
Supporting quotations:						

Summary of review finding	Studies contributing to the review finding	Methodological limitations	Coherence	Adequacy	Relevance	CERQual assessment of confidence in the evidence
"I wouldn't have bothered going all the way to the doctors because at the beginning of your pregnancy and that you don't want to go out the house anyway because you're feeling sick and you're heavy and frumpy, and it just seems like a long way to go for nothing just to blow into a thing. With the vouchers it's like you're getting paid... rewarded to go there" (incentivised group) "I think, for me, it was about getting me into that first appointment. If you can get people into that first appointment and have someone like [smoking cessation adviser] talking you through it, for me that was where the real success was, because I came out of there like that, I need to do this". (Pregnant woman, quit during pregnancy, experience of smoking cessation incentives). "They don't really monitor you... They only do it, they only did it the once" (control group). "I think that was the most useful thing and knowing that you were going back the following week and that it had to be good because there was a quantifiable way of seeing if you'd been sticking to the routine." (control group).						
<u>4. Providers views on the acceptability of incentives</u> Some providers considered that it would be unethical to not explore the use of incentives to improve smoking cessation in pregnancy, whilst others felt they were morally wrong. Several providers felt that incentives may overshadow self-motivation and may demoralise people. Other providers recognised the challenges faced by those who were more deprived, presenting barriers to behaviour change.	Morgan 2015	Minor concerns (unclear reflexivity)	No or very minor concerns (there is a good fit between the study and the review finding)	Serious concerns (data is moderately descriptive data but only includes one study)	Minor concerns (data is of direct relevance and generally covers the population of interest, although data may relate to incentives either delivered to women and/or providers for initiating cessation. Data may refer to incentives for smoking cessation and breast-feeding).	Low confidence 1 study with minor methodological limitations. Moderately rich data, but only from 1 study. Data is of direct relevance. No or very minor concerns about coherence.
Supporting quotations: <u>Positive perception of incentives</u> "From the smoking point of view obviously my biggest issue is obviously the babies because those babies- so I would agree to it with the smoking side of things because those babies…and even with the breastfeeding as well- but those babies are being put in a vulnerable position, aren't they? If we don't do anything to stop						

Summary of review finding	Studies contributing to the review finding	Methodological limitations	Coherence	Adequacy	Relevance	CERQual assessment of confidence in the evidence
those women smoking and they're going to suffer long term with ill health, etc. and going to end up on the neonatal unit probably and have long-term health problems. So I do think we need to do something and that's where probably why I agree- it's difficult to say." (Focus group- public health practitioner and health education practitioner). <u>Negative perception of incentives</u> "I think we're going right down the wrong route; I think that, you know, when we're enticing people with money and gifts just to do what's right for their health, you know. What else will we expect?" (Midwife) "Efforts could possibly be better addressed – best spent – by addressing their circumstance rather than rewarding them for doing something they should be doing anyway". (Focus group- public health practitioner and health education practitioner).						
5. <u>Acceptability of voucher/cash incentives</u> Most people thought vouchers were equivalent to cash incentives but more acceptable, as there was less chance for vouchers to be spent on inappropriate items such as alcohol or cigarettes. The choice of where to spend the voucher and being redeemable in many retail shops was key to the motivating nature of the voucher incentive.	Morgan 2015	Minor concerns (unclear reflexivity)	No or very minor concerns (there is a good fit between the study and the review finding)	Serious concerns (data is moderately descriptive data but only includes one study)	No or very minor concerns (data is of direct relevance and generally covers the population of interest, although does include post-partum women and women who have quit smoking during pregnancy)	Low confidence 1 study with minor methodological limitations. Moderately rich data, but only from 1 study. Data is of direct relevance. No or very minor concerns about coherence.
Supporting quotations: "I was over the moon with it. I was. I was really happy with it and just receiving my wee £100.00 one there, I was really quite chuffed". (Pregnant woman, quit during pregnancy, experience of smoking cessation incentives). "So whether it's money or whether it's a token but it should be for something that they want, not something we think they should have as kind of middle-class professionals." (GP, provider)						
<u>6. Acceptability of other types of incentives</u>	Butterworth 2014, Morgan 2015	Minor concerns	No or very minor concerns	Serious concerns	Minor concerns	Low confidence

Summary of review finding	Studies contributing to the review finding	Methodological limitations	Coherence	Adequacy	Relevance	CERQual assessment of confidence in the evidence
Women expressed a desire for an incentive to be focused on the mother who they felt was often forgotten about. Several women thought that a special day out would be the most acceptable reward as it would less likely to be sold. There were mixed views on the acceptability of baby and pregnancy related incentives which were often considered as necessities rather than luxuries to encourage smoking cessation. Some women were doubtful about the motivating effects of health-related incentives, whilst other providers felt that incentives provided for changing health behaviour should be health promoting.		(unclear reflexivity and 1 study did not include purposive sampling)	(there is a good fit between the studies and the review finding)	(data is moderately rich for descriptive data but only includes two studies)	(data is of direct relevance and generally covers the population of interest, although does include post-partum women and women who have quit smoking during pregnancy. Data may refer to incentives for smoking cessation and breast-feeding).	2 studies with minor methodological limitations. Moderately rich data, but only from 2 studies. Data is of direct relevance. No or very minor concerns about coherence.
Supporting quotations: "Cos you think, stopping smoking you've got horrible skin haven't you through smoking and if you stop smoking for six months and you go there you go well done go to a spa. Not only does it make you feel better cos you give up smoking, it makes you feel better because you've gone, you've got pampered, you look better and you're not smoking." (T, smoker) "If it's something positive and it's going to be related to improving the whole, you know, family health, you know. I think it should be health-related benefits because we are, you know, it's the health service rather than just here's some money." (Hospital midwife)						
<u>7. Guaranteed rewards vs rewards contingent on a quit.</u> Several participants felt that incentives should only be given	Morgan 2015	Minor concerns (unclear reflexivity)	No or very minor concerns (there is a good fit between the	Serious concerns (data is moderately descriptive but	Minor concerns (data is of direct relevance and generally covers	Low confidence 1 study with minor methodological limitations.

Summary of review finding	Studies contributing to the review finding	Methodological limitations	Coherence	Adequacy	Relevance	CERQual assessment of confidence in the evidence
once smoking cessation had been verified. Others felt that offering incentives for those who had engaged with support, irrespective of smoking status, were justified as this indicated their willingness to try to change. Some women/providers felt that guaranteed rewards were more acceptable for ensuring continual motivation, rather than risk-based rewards.			study and the review finding)	only includes one study)	the population of interest, although does include post-partum women and women who have quit smoking during pregnancy. Data may also include the views of partners and experts).	Moderately rich data, but only from 1 study. Data is of direct relevance. No or very minor concerns about coherence.
Supporting quotations: "Yeah, if I was going to go to something and thought, 'It's nice to go but I'm not going to do anything about it', it'd probably make me feel worse . . . Because then I'd think I should be giving up." (Pregnant woman, current smoker, no experience of being incentivised). "Then to get pregnant and cut down and then knowing you've got a limit to smoke a day. Sometimes I can go over it; sometimes I cannot want a fag do you know what I mean. Sometimes I can light up a cigarette and then put it out and go no I don't want this it is making me feel sick. But I wish that had happened at the start, I wish that when I lit up a cigarette I would be sick or something so I wouldn't need to smoke". (Pregnant woman, current smoker, experience of smoking cessation incentives)						
8. Optimum monetary value of incentive There were mixed opinions on the optimum value of the incentive offered and how this may impact it's motivating effect, often depending on the financial situation of the recipient. Some women felt intrinsic motivation was an important factor to determine if an incentive of large monetary value was effective.	Morgan 2015	Minor concerns (unclear reflexivity)	No or very minor concerns (there is a good fit between the study and the review finding)	Serious concerns (data is moderately descriptive data but only includes one study)	No or very minor concerns (data is of direct relevance and generally covers the population of interest, although does include post-partum women and women who have quit	Low confidence 1 study with minor methodological limitations. Moderately rich data, but only from 1 study. Data is of direct relevance. No or very minor concerns about coherence.

Summary of review finding	Studies contributing to the review finding	Methodological limitations	Coherence	Adequacy	Relevance	CERQual assessment of confidence in the evidence
					smoking during pregnancy).	

Supporting quotations:

"I think if I was getting that much [£400-offered in CPIT] I'd be like, 'I'll stop smoking and I'll not go back on it'." (Pregnant woman, quit during pregnancy, experience of smoking cessation incentives).

"I think if they'd said to me you'll get £2000.00 you know what I mean if you stop smoking then it maybe would have pushed me to it but I think in myself, you'd need to want to for yourself to stop smoking, not for money". (Pregnant woman, current smoker, experience of smoking cessation incentives).

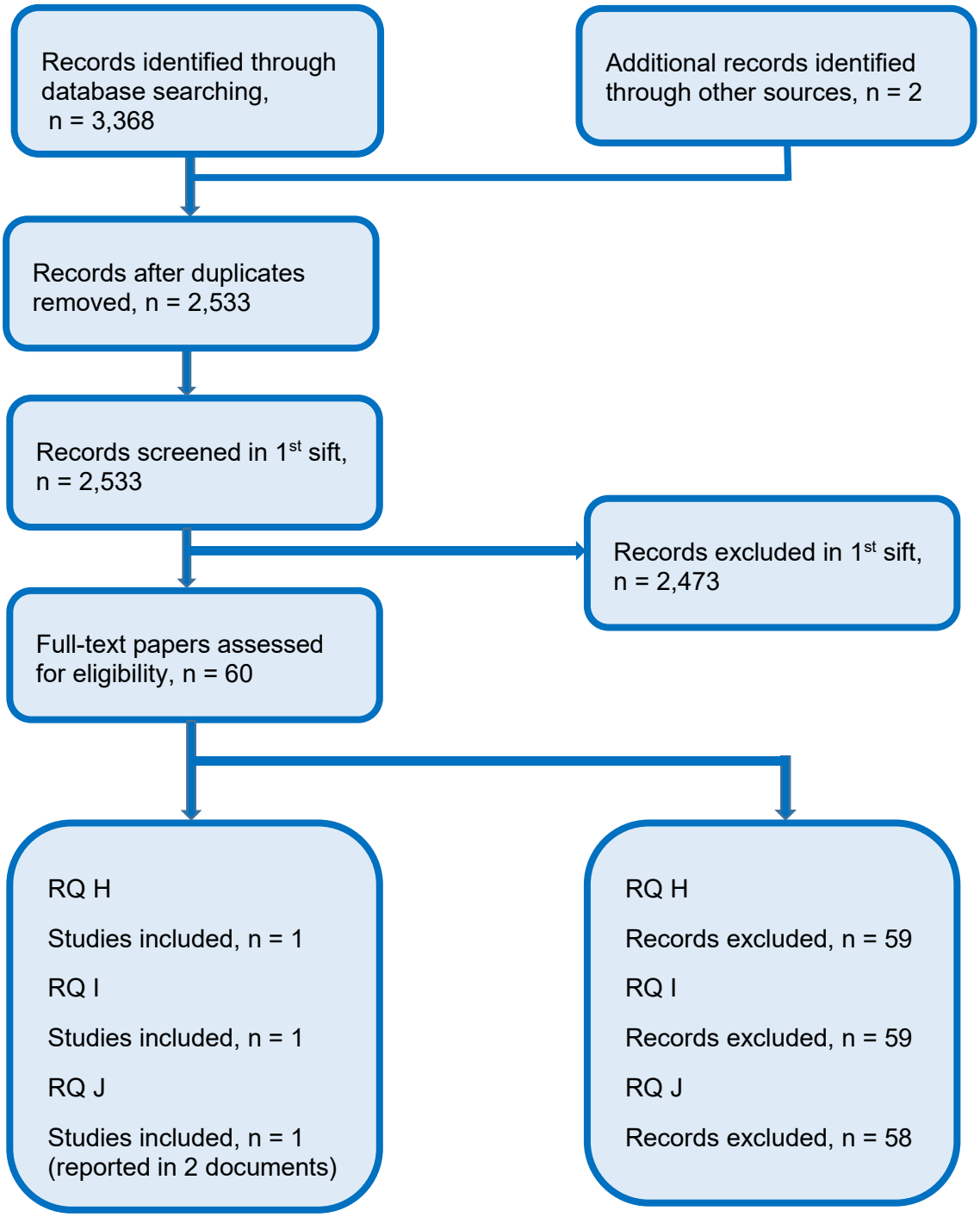
Matrix for integration of qualitative and effectiveness evidence

Quantitative outcomes	Related GRADE profile	Narrative exploration of qualitative review findings in relation to outcome
Abstinence from smoking	1	The clear effectiveness of the intervention at increasing abstinence from smoking could be due to several of the qualitative review findings which included **some** women reporting: • Motivating effect of incentives for promoting smoking cessation during pregnancy, including those who may have been undecided about quitting. • Intrinsic motivation for wanting to quit to reduce harm to self and baby, with incentives being an added boost. • Increased engagement with stop smoking services and positive perception of consistent monitoring to validate smoking status and receive incentive. • Abstaining only for carbon monoxide reading to obtain the reward (so quit rates may have been overestimated). • Positive perception of vouchers often seen as equivalent to cash if redeemable at many retail outlets. • The value of the incentive being a motivating factor depending on financial situation of recipient. However, the studies do not include sufficient information to determine whether these findings are linked to the evidence identified for this outcome.

Appendix G – Economic evidence study selection

The following flowchart shows the record selection process for all three review questions.

Figure 6: Flow chart of economic evidence study selection for the guideline



Appendix H – Economic evidence tables

See health economic evidence profiles in appendix I

Appendix I – Health economic evidence profiles

Table 8: Health economic evidence profile of study included in the economic evidence review on incentives for smoking cessation PICO inclusion

Study	Boyd 2016 (UK)			
Study details	**Population & interventions**	**Costs**	**Health outcomes**	**Cost-effectiveness**
Economic analysis: Cost effectiveness analysis (CEA) and cost utility analysis (CUA) **Study design:** RCT with results used in a lifetime Markov model **Approach to analysis:** Quit rates were taken from the Cessation in Pregnancy Incentives Trial and used in a Markov model of lifetime costs and outcomes from smoking which included relapse rates. Costs were drawn from the trial and from published sources. Future health outcomes associated with smoking and utility values for smokers and non-smokers were taken from the literature. In the	**Population:** Self-reported smokers pregnant for less than 24 weeks and aged 16 years or over in Glasgow with a carbon monoxide (CO) reading of at least 7 parts per million Sample size: 609 commenced the trial **Intervention:** Routine care (see comparator) plus financial incentives. £400 shopping vouchers were offered: • £50 for attending the first class • £50 for a 4-week CO validated quit • £100 for a 12-week CO validated quit	**Total costs (per participant)** Within trial period Routine care plus financial incentives [b]: £243 Routine care: £85 Lifetime horizon Routine care plus financial incentives: £1,282 Routine care: £1,265 **Cost savings** None reported **Currency & cost year:** GBP £, 2013 **Cost components incorporated:** Direct costs: Cessation support, NRT and incentives, cost of low	**Late pregnancy quit rate** Routine care plus financial incentives: 0.23 Routine care: 0.09 **Lifetime QALYs** Routine care plus financial incentives: 19.137 Routine care: 19.101	**Cost effectiveness ratios** The routine care plus financial incentives intervention cost an additional £157 per smoking mother with an additional 0.14 late pregnancy quitters, giving an ICER of £1,127 per late pregnancy quitter. Over a lifetime, the routine care plus financial incentives intervention cost an additional £17 with an additional 0.036 QALYs giving an ICER of £482 per QALY. **Analysis of uncertainty** Scenario analysis explored uncertainty in all key parameters. Probabilistic sensitivity analysis (PSA) suggested that there was a 72% likelihood that the routine care plus financial incentives intervention would be cost-effective at a willingness to pay threshold of £30,000 per QALY. Scenario analysis suggested that higher incentives than those offered may also be cost-effective.

Study	Boyd 2016 (UK)			
Study details	**Population & interventions**	**Costs**	**Health outcomes**	**Cost-effectiveness**
base case no health related costs from smoking to the mother were included, but the likelihood and costs of having a low birth weight baby depending on smoking status were included. **Perspective:** NHS **Time horizon:** Trial period (up to week 38 of pregnancy) and lifetime **Treatment effect duration:** Relapse rates were taken from published literature and clinical advice **Discounting:** In the lifetime model, 3.5% per annum for costs and benefits	• £200 for a 34 to 38 week CO validated quit **Comparator:** Routine care: routine referral to NHS Stop Smoking Services [a]	birthweight babies. The cost of smoking related deaths was explored in scenario analysis.		
Data sources				
Health outcomes: Cessation in Pregnancy Incentives Trial and published sources. **Quality-of-life weights:** Published sources (Kind et al. 1999). **Cost sources:** Costs were taken directly from the trial and from published sources (PSSRU, Scottish Information Services Division, Tappin et al 2015).				
Comments				
Source of funding: Scottish Government, Glasgow Centre for Public Health, Glasgow and Clyde Health Board. **Limitations:** Author-recognised limitations: only a phase II study, only one geographical location, uncertainty in data on relapse post birth **Other:** None				
Overall applicability: Directly applicable **Overall quality:** No limitations				
Abbreviations: CEA: cost-effectiveness analysis; CO: carbon monoxide; CUE: cost-utility analysis; ICER: Incremental Cost Effectiveness Ratio; PSA: probabilistic sensitivity analysis; QALY: quality-adjusted life-year; RCT: randomised controlled trial				

Study	Boyd 2016 (UK)			
Study details	**Population & interventions**	**Costs**	**Health outcomes**	**Cost-effectiveness**
a) *Specialist pregnancy cessation advice via a 1 hour face-to-face appointment, followed by four weekly telephone support calls and 'free to the user' Nicotine Replacement Therapy (NRT) via local pharmacies for 10 weeks.* b) *Including administration costs of the financial incentives*				

Appendix J – Health economic analysis

See separate full modelling report (evidence review P)

Appendix K – Excluded studies

Public health studies

Study Citation	Reason for excluding
Borland Tracey, Babayan Alexey, Irfan Saeeda, and Schwartz Robert (2013) Exploring the adequacy of smoking cessation support for pregnant and postpartum women. BMC public health 13, 472	**Exclude on relevance**; not of direct relevance to review question.
Cahill K, Hartmann-Boyce J, and Perera R (2015) Incentives for smoking cessation. Cochrane Database of Systematic Reviews (5),	**Exclude on evidence;** study is a systematic review
Chamberlain C, O'Mara-Eves A, Porter J, Coleman T, Perlen S M, Thomas J, and McKenzie J E (2017) Psychosocial interventions for supporting women to stop smoking in pregnancy. Cochrane Database of Systematic Reviews (2),	**Exclude on evidence;** study is a systematic review
Donatelle Rebecca, Hudson Deanne, Dobie Susan, Goodall Amy, Hunsberger Monica, and Oswald Kelly (2004) Incentives in smoking cessation: status of the field and implications for research and practice with pregnant smokers. Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco 6 Suppl 2, S163-79	**Exclude on evidence;** study is a systematic review
Gulliver Suzy Bird, Colby Suzanne M, Hayes Kerri, and Raffa Susan D (2004) Tobacco cessation treatment for pregnant smokers: incorporating partners and incentives. Medicine and health, and Rhode Island 87(1), 9-12	**Exclude on relevance**; study focuses on partner support rather than incentives
Hand Dennis J, Ellis Jennifer D, Carr Meagan M, Abatemarco Diane J, and Ledgerwood David M (2017) Contingency management interventions for tobacco and other substance use disorders in pregnancy. Psychology of Addictive Behaviors 31(8), 907-921	**Exclude on evidence;** study is a systematic review
Herxheimer Andrew (2015) Including partners in trials of financial incentives for smoking cessation in pregnancy. BMJ : British Medical Journal (Online) 350, n	**Exclude on evidence;** editorial letter does not fit study design criteria
Higgins Stephen T, Washio Yukiko, Heil Sarah H, Solomon Laura J, Gaalema Diann E, Higgins Tara M, and Bernstein Ira M (2012) Financial incentives for smoking cessation among pregnant and newly postpartum women. Preventive medicine 55 Suppl, S33-40	**Exclude on evidence;** study is a systematic review
Higgins Stephen T, Heil Sarah H, Solomon Laura J, Bernstein Ira M, Lussier Jennifer Plebani, Abel Rebecca L, Lynch Mary Ellen, and Badger Gary J (2004) A pilot study on voucher-based incentives to promote abstinence from cigarette smoking during pregnancy and postpartum. Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco 6(6), 1015-20	**Exclude on evidence;** study does not randomly allocate all participants.
Hoddinott Pat, Thomson Gill, Morgan Heather, Crossland Nicola, MacLennan Graeme, Dykes Fiona, Stewart Fiona, Bauld Linda, and Campbell Marion K (2015) Perspectives on financial incentives to health service providers for increasing breast feeding and smoking quit rates during pregnancy: a mixed methods study. BMJ open 5(11), e008492	**Exclude on target group;** incentive is for providers and not for pregnant women.
Lynagh Marita, Bonevski Billie, Symonds Ian, and Sanson-Fisher Rob W (2011) Paying women to quit smoking during pregnancy? Acceptability among pregnant women. Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco 13(11), 1029-36	**Exclude on relevance**; not of direct relevance to review question
Rose Davis, Danielle , Solomon Laura J, and Higgins Stephen (2017) A review of recent developments (2012–15) on the use of financial incentives with pregnant smokers. Drug & Alcohol Dependence	**Exclude on evidence;** no full text available

Su Anny, and Buttenheim Alison (2014) Maintenance of Smoking Cessation in the Postpartum Period: Which Interventions Work Best in the Long-Term?. Maternal & Child Health Journal 18(3), 714-728	**Exclude on evidence;** study is a systematic review
Wilson Sarah M, Newins Amie R, Medenblik Alyssa M, Kimbrel Nathan A, Dedert Eric A, Hicks Terrell A, Neal Lydia C, Beckham Jean C, and Calhoun Patrick S (2018) Contingency Management Versus Psychotherapy for Prenatal Smoking Cessation: A Meta-Analysis of Randomized Controlled Trials. Women's health issues : official publication of the Jacobs Institute of Women's Health 28(6), 514-523	**Exclude on evidence;** study is a systematic review

Economic studies

Reference	Reason for exclusion
Antonopoulos MS, Bercume CM. Varenicline (Chantix): A new treatment option for smoking cessation. P and T. 2007;32(1):20.	Ineligible patient population
Askew DA, Guy J, Lyall V, Egert S, Rogers L, Pokino L-A, et al. A mixed methods exploratory study tackling smoking during pregnancy in an urban Aboriginal and Torres Strait Islander primary health care service. BMC Public Health. 2019;19(1):343.	Ineligible study design
Ayadi MF, Adams EK, Melvin CL, Rivera CC, Gaffney CA, Pike J, et al. Costs of a smoking cessation counseling intervention for pregnant women: comparison of three settings. Public Health Rep. 2006;121(2):120-6.	Ineligible intervention
Barker DC. III. Maternal smoking cessation: a cost effective strategy for managed care. Introduction. Tob Control. 2000; 9(Suppl 1): i60. Available from: https://tobaccocontrol.bmj.com/content/9/suppl_1/i60	Ineligible study design
Bauld L, Graham H, Sinclair L, Flemming K, Naughton F, Ford A, et al. Barriers to and facilitators of smoking cessation in pregnancy and following childbirth: literature review and qualitative study. Health Technol Assess. 2017;21(36):1-158.	Ineligible study design
Bell R, Glinianaia SV, Waal Zvd, Close A, Moloney E, Jones S, et al. Evaluation of a complex healthcare intervention to increase smoking cessation in pregnant women: interrupted time series analysis with economic evaluation. Tob Control. 2018;27(1):90-98.	Ineligible intervention
Berlin N, Goldzahl L, Bauld L, Hoddinott P, Berlin I. Public Acceptability of Financial Incentives to Reward Pregnant Smokers Who Quit Smoking: A United Kingdom-France Comparison. Eur J Health Econ. 2018;19(5):697-708.	Ineligible patient population
Boucher J, Konkle ATM. Understanding inequalities of maternal smoking-bridging the gap with adapted intervention strategies. IJERGQ. 2016;13(3):282.	Ineligible study design
Buchanan C, Nahhas GJ, Guille C, Cummings KM, Wheeler C, McClure EA. Tobacco Use Prevalence and Outcomes Among Perinatal Patients Assessed Through an "Opt-out" Cessation and Follow-Up Clinical Program. Matern Child Health J. 2017;21(9):1790-97.	Ineligible study design
Canadian Agency for Drugs and Technologies in Health. Smoking cessation interventions for pregnant women and mothers of infants: a review of the clinical effectiveness, safety, and guidelines. Ottawa: CADTH; 2012. Available from: https://www.cadth.ca/smoking-cessation-interventions-pregnant-women-and-mothers-infants-review-clinical-effectiveness.	Ineligible outcomes
Chamberlain C, O'Mara-Eves A, Oliver S, Caird JR, Perlen SM, Eades SJ, et al. Psychosocial interventions for supporting women to stop smoking in pregnancy. (CD001055). London: Cochrane	Ineligible study design

Reference	Reason for exclusion
Collaboration; 2013. Available from: https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD001055.pub5/full.	
Cluss PA, Levine MD, Landsittel D. The Pittsburgh STOP program: disseminating an evidence-informed intervention for low-income pregnant smokers. Am J Health Promot. 2011;25(5 Suppl):S75-81.	Ineligible study design
Cohen D, Barton G. The cost to society of smoking cessation. Thorax. 1998;53(Suppl 2):S38-42.	Ineligible patient population
Coleman T, Cooper S, Thornton JG, Grainge MJ, Watts K, Britton J, et al. A randomized trial of nicotine-replacement therapy patches in pregnancy. N Engl J Med. 2012;366(9):808-18.	Ineligible study design
Cooper S, Lewis S, Thornton JG, Marlow N, Watts K, Britton J, et al. The SNAP trial: A randomised placebo-controlled trial of nicotine replacement therapy in pregnancy - Clinical effectiveness and safety until 2 years after delivery, with economic evaluation. Health Technol Assess. 2014;18(54):1-128.	Ineligible intervention
Crossland N, Thomson G, Morgan H, Dombrowski SU, Hoddinott P. Incentives for breastfeeding and for smoking cessation in pregnancy: An exploration of types and meanings. Soc Sci Med. 2015;128(March):10-17.	Ineligible outcomes
Dornelas EA, Magnavita J, Beazoglou T, Fischer EH, Oncken C, Lando H, et al. Efficacy and cost-effectiveness of a clinic-based counseling intervention tested in an ethnically diverse sample of pregnant smokers. Patient Educ Couns. 2006;64(1-3):342-9.	Ineligible intervention
Emery JL, Coleman T, Sutton S, Cooper S, Leonardi-Bee J, Jones M, et al. Uptake of Tailored Text Message Smoking Cessation Support in Pregnancy When Advertised on the Internet (MiQuit): Observational Study. J Med Internet Res. 2018;20(4):e146.	Ineligible intervention
Ershoff DH, Quinn VP, Boyd NR, Stern J, Gregory M, Wirtschafter D. The Kaiser Permanente prenatal smoking-cessation trial: when more isn't better, what is enough? Am J Prev Med. 1999;17(3):161-8.	Ineligible intervention
Essex HN, Parrott S, Wu Q, Li J, Cooper S, Coleman T. Cost-Effectiveness of Nicotine Patches for Smoking Cessation in Pregnancy: A Placebo Randomized Controlled Trial (SNAP). Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco. 2015;17(6):636-42.	Ineligible intervention
Fitzgerald EM. Evidence-based tobacco cessation strategies with pregnant Latina women. Nurs Clin North Am. 2012;47(1):45-54.	Ineligible study design
Flemming K, Graham H, Heirs M, Fox D, Sowden A. Smoking in pregnancy: a systematic review of qualitative research of women who commence pregnancy as smokers. J Adv Nurs. 2013;69(5):1023-36.	Ineligible patient population
Gamble J, Grant J, Tsourtos G. Missed opportunities: a qualitative exploration of the experiences of smoking cessation interventions among socially disadvantaged pregnant women. Women and Birth. 2015;28(1):8-15.	Ineligible study design
Giatras N, Wanninkhof E, Leontowitsch M, Lewis B, Taylor A, Cooper S, et al. Lessons learned from the London Exercise and Pregnant (LEAP) Smokers randomised controlled trial process evaluation: implications for the design of physical activity for smoking cessation interventions during pregnancy. BMC Public Health. 2017;17(1):85.	Ineligible intervention
Halpern MT, Dirani R, Schmier JK. The cost effectiveness of varenicline for smoking cessation. Manag Care Interface. 2007;20(10):18-25.	Ineligible patient population
Hebert R. What's new in nicotine & tobacco research? Nicotine Tob Res 2007;9(10):983-86.	Ineligible patient population
Higgins ST, Solomon LJ. Some Recent Developments on Financial Incentives for Smoking Cessation Among Pregnant and Newly Postpartum Women. Curr Addict Rep. 2016;3(1):9-18.	Ineligible study design

Reference	Reason for exclusion
Higgins ST, Washio Y, Lopez AA, Heil SH, Solomon LJ, Lynch ME, et al. Examining two different schedules of financial incentives for smoking cessation among pregnant women. Prev Med. 2014;68:51-7.	Ineligible study design
Hoekzema L, Werumeus Buning A, Bonevski B, Wolke L, Wong S, Drinkwater P, et al. Smoking rates and smoking cessation preferences of pregnant women attending antenatal clinics of two large Australian maternity hospitals. Aust N Z J Obstet Gynaecol. 2014;54(1):53-8.	Ineligible study design
Jessup MA. Organizational change in a perinatal treatment setting: Integration of clinical practice and policies on tobacco and smoking cessation. J Psychoactive Drugs. 2007;39(4):461-72.	Ineligible study design
Jones M, Lewis S, Parrott S, Coleman T. Systematic critical review of previous economic evaluations of smoking cessation during pregnancy. BMJ Open. 2015;5(11):e008998.	Ineligible study design
Lando HA, Valanis BG, Lichtenstein E, Curry SJ, McBride CM, Pirie PL, et al. Promoting smoking abstinence in pregnant and postpartum patients: a comparison of 2 approaches. Am J Manag Care. 2001;7(7):685-93.	Ineligible intervention
Levine MD, Cheng Y, Cluss PA, Marcus MD, Kalarchian MA. Prenatal smoking cessation intervention and gestational weight gain. Womens Health Issues. 2013;23(6):e389-93.	Ineligible study design
Likis FE, Andrews JC, Fonnesbeck CJ, Hartmann KE, Jerome RN, Potter SA, et al. Smoking cessation interventions in pregnancy and postpartum care. Washington, D.C.: Agency for Healthcare Research and Quality; 2014. Available from: https://www.ncbi.nlm.nih.gov/books/NBK190501/pdf/Bookshelf_NBK190501.pdf.	Ineligible study design
McCallum DM, Fosson GH, Pisu M. Making the case for medicaid funding of smoking cessation treatment programs: an application to state-level health care savings. J Health Care Poor Underserved. 2014;25(4):1922-40.	Ineligible study design
Mejdoubi J, van den Heijkant SCCM, van Leerdam FJM, Crone M, Crijnen A, HiraSing RA. Effects of nurse home visitation on cigarette smoking, pregnancy outcomes and breastfeeding: a randomized controlled trial. Midwifery. 2014;30(6):688-95.	Ineligible intervention
Melvin CL, Dolan-Mullen P, Windsor RA, Whiteside HP, Jr., Goldenberg RL. Recommended cessation counselling for pregnant women who smoke: a review of the evidence. Tob Control. 2000;9(Suppl 3):III80-4.	Ineligible intervention
Miyazaki Y, Hayashi K, Imazeki S. Smoking cessation in pregnancy: Psychosocial interventions and patient-focused perspectives. Int J Women Health. 2015(7):415-27.	Ineligible study design
Moore L, Campbell R, Whelan A, Mills N, Lupton P, Misselbrook E, et al. Self help smoking cessation in pregnancy: Cluster randomised controlled trial. BMJ. 2002;325(7377):1383-86.	Ineligible intervention
Muchowski K, Paladine H. An ounce of prevention: The evidence supporting periconception health care. J Fam Pract. 2004;53(2):126-33.	Ineligible study design
Mullen PD. Maternal smoking during pregnancy and evidence-based intervention to promote cessation. Prim Care. 1999;26(3):577-89.	Ineligible study design
Murthy P, Subodh BN. Current developments in behavioral interventions for tobacco cessation. Curr Opin Psychiatry. 2010;23(2):151-6.	Ineligible intervention
National Institute for Health and Care Excellence. Smoking cessation services in primary care, pharmacies, local authorities and workplaces, particularly for manual working groups, pregnant women	Ineligible study design

Reference	Reason for exclusion
and hard to reach communities. London: NICE; 2008. Available from: https://www.nice.org.uk/guidance/PH26.	
Ockene JK, Ma Y, Zapka JG, Pbert LA, Valentine Goins K, Stoddard AM. Spontaneous cessation of smoking and alcohol use among low-income pregnant women. Am J Prev Med. 2002;23(3):150-59.	Ineligible intervention
Oncken C, Dornelas E, Greene J, Sankey H, Glasmann A, Feinn R, et al. Nicotine gum for pregnant smokers: a randomized controlled trial. Obstet Gynecol. 2008;112(4):859-67.	Ineligible study design
Parker DR, Windsor RA, Roberts MB, Hecht J, Hardy NV, Strolla LO, et al. Feasibility, cost, and cost-effectiveness of a telephone-based motivational intervention for underserved pregnant smokers. Nicotine Tob Res 2007;9(10):1043-51.	Ineligible intervention
Patnode CP, Henderson JT, Thompson JH, Senger CA, Fortmann SP, Whitlock EP. Behavioral counseling and pharmacotherapy interventions for tobacco cessation in adults, including pregnant women: a review of reviews for the U.S. Preventive Services Task Force. Washington D.C.: Agency for Healthcare Research and Quality; 2015. Available from: https://www.ncbi.nlm.nih.gov/books/NBK321744/pdf/Bookshelf_NBK321744.pdf.	Ineligible study design
Ruger JP, Emmons KM. Economic evaluations of smoking cessation and relapse prevention programs for pregnant women: a systematic review. Value Health. 2008;11(2):180-90.	Ineligible intervention
Ruger JP, Emmons KM, Kearney MH, Weinstein MC. Measuring the costs of outreach motivational interviewing for smoking cessation and relapse prevention among low-income pregnant women. BMC Pregnancy Childbirth. 2009(9):46.	Ineligible intervention
Ruger JP, Weinstein MC, Hammond SK, Kearney MH, Emmons KM. Cost-effectiveness of motivational interviewing for smoking cessation and relapse prevention among low-income pregnant women: a randomized controlled trial. Value Health. 2008;11(2):191-98.	Ineligible intervention
Sedgwick P. Measuring the benefit of treatment: number needed to treat. BMJ. 2015; (350): h2206. Available from: https://www.bmj.com/content/350/bmj.h2206	Ineligible outcomes
Sloan M, Campbell KA, Bowker K, Coleman T, Cooper S, Brafman-Price B, et al. Pregnant Women's Experiences and Views on an "Opt-Out" Referral Pathway to Specialist Smoking Cessation Support: A Qualitative Evaluation. Nicotine Tob Res 2016;18(5):900-05.	Ineligible study design
Tappin D, Bauld L, Purves D, Boyd K, Sinclair L, MacAskill S, et al. Financial incentives for smoking cessation in pregnancy: Randomised controlled trial. BMJ. 2015; (350): h134. Available from: https://www.bmj.com/content/350/bmj.h134	Ineligible outcomes
Tod AM. Barriers to smoking cessation in pregnancy: a qualitative study. Br J Community Nurs. 2003;8(2):56-64.	Ineligible intervention
Ussher M, Lewis S, Aveyard P, Manyonda I, West R, Lewis B, et al. The London Exercise And Pregnant smokers (LEAP) trial: a randomised controlled trial of physical activity for smoking cessation in pregnancy with an economic evaluation. Health Technol Assess. 2015;19(84):vii-135.	Ineligible intervention
Vaz LR, Coleman T, Fahy SJ, Cooper S, Bauld L, Szatkowski L, et al. Factors associated with the effectiveness and reach of NHS stop smoking services for pregnant women in England. BMC Health Serv Res. 2017;17(1):545.	Ineligible intervention
Washio Y, Cassey H. Systematic Review of Interventions for Racial/Ethnic-Minority Pregnant Smokers. J Smok Cessat. 2016;11(1):12-27.	Ineligible study design

Reference	Reason for exclusion
Wisborg K, Henriksen TB, Secher NJ. A prospective intervention study of stopping smoking in pregnancy in a routine antenatal care setting. Br J Obstet Gynaecol. 1998;105(11):1171-6.	Ineligible intervention
Yunzal-Butler C, Joyce TJ, Racine AD. Maternal Smoking and the Timing of WIC Enrollment. Cambridge MA: National Bureau of Economic Research; 2009. Available from: https://www.nber.org/papers/w14728.	Ineligible study design

Appendix L – Research recommendations

No research recommendations were made for review I.