

1 **Title**

2 Financial Incentives for Preventing Postpartum return to Smoking (FIPPS): study protocol for a  
3 three-arm randomised controlled trial

4

5 **Names protocol contributors**

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8 **Abstract**

9 **Background:** Financial incentives are an effective way of helping women to stop smoking during  
10 pregnancy. Unfortunately, most women who stop smoking at this time return to smoking within  
11 12 months of the infant's birth. There is no evidence for interventions that are effective at  
12 preventing postpartum smoking relapse. Financial incentives provided after the birth may help  
13 women to sustain cessation. This randomised controlled trial will assess the effectiveness and cost  
14 effectiveness of financial incentives to help women who are abstinent from smoking at end of  
15 pregnancy to avoid return to smoking up to 12 months postpartum.

16 **Methods:** This is a UK-based, multi-centre, three-arm, superiority, parallel group, individually  
17 randomised controlled trial, with 1:1:1 allocation. It will compare the effectiveness of two financial  
18 incentive interventions with each other (one intervention for up to three months postpartum  
19 offering up to £120 of incentives (£60 for the participant and £60 for a significant other support);  
20 the other for up to 12 months postpartum with up to £300 of incentives (£240 for the participant  
21 and £60 for a significant other support)) and with a no incentives/usual care control group. Eligible  
22 women will be between 34 weeks gestation and two weeks postpartum, abstinent from smoking  
23 for at least four weeks, have an expired carbon monoxide (CO) reading <4 parts per million (ppm),  
24 aged at least 16 years, intend remaining abstinent from smoking after the birth and able to speak

1 and read English.

2 The primary outcome is self-reported, lapse-free, smoking abstinence from the last quit attempt in  
3 pregnancy until 12 months postpartum, biochemically validated by expired CO and/or salivary  
4 cotinine or anabasine. Outcomes will be analysed by intention-to-treat and regression models  
5 used to compare the proportion of abstinent women between the two intervention groups and  
6 between each intervention group and the control group. An economic evaluation will assess the  
7 cost-effectiveness of offering incentives and a qualitative process evaluation will examine barriers  
8 and facilitators to trial retention, effectiveness and implementation.

9 **Discussion:** This pragmatic randomised controlled trial will test whether offering financial  
10 incentives is effective and cost-effective for helping women to avoid smoking relapse during the  
11 12 months after the birth of their baby.

12 **Trial registration:** International Standard Randomised Controlled Trial Number: 55218215.  
13 Registered retrospectively on 5<sup>th</sup> June 2019.

#### 14 **Keywords**

15 Intervention, randomised controlled trial, pregnancy, postpartum, smoking relapse prevention,  
16 smoking cessation, financial incentives

17

#### 18 **Administrative information**

19 **Note:** the numbers in curly brackets in this protocol refer to SPIRIT checklist item numbers. The  
20 order of the items has been modified to group similar items (see [http://www.equator-  
21 network.org/reporting-guidelines/spirit-2727-statement-defining-standard-protocol-items-for-  
22 clinical-trials/](http://www.equator-network.org/reporting-guidelines/spirit-2727-statement-defining-standard-protocol-items-for-clinical-trials/)).

Title {1}	Financial Incentives for Preventing Postpartum return to Smoking (FIPPS): study protocol for a three-arm randomised controlled trial
Trial registration {2a and 2b}.	International Standard Randomised Controlled Trial Number registry, No. 55218215  <a href="https://doi.org/10.1186/ISRCTN55218215">https://doi.org/10.1186/ISRCTN55218215</a>  Registered retrospectively on 5 <sup>th</sup> June 2019,
Protocol version {3}	V7.0, 16 <sup>th</sup> November 2020
Funding {4}	Greater Manchester Combined Authority
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Role of sponsor {5c}	The University of Stirling is the trial sponsor and has delegated all responsibility for the management of the trial and publication of the findings to the Chief Investigator and co-investigators. The sponsor played no part in study design; collection, management, analysis, and interpretation of data; writing of this or other reports or the decision to submit reports for publication.
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**Introduction**

**Background and rationale {6a}**

More women stop smoking during pregnancy than at any other time; around half of pregnant women who smoke are likely to cease smoking ‘spontaneously’ [1]. This presents a valuable opportunity to help women who stop smoking in pregnancy to stop permanently. Most women who stop smoking in pregnancy wish to remain abstinent after the birth [2]. However, up to three-quarters of spontaneous quitters return to smoking within six months of the birth [3], thereby increasing their risks of smoking-related illness, as well as their children’s risks of passive smoking [4,5] and of becoming smokers [6]. Behavioural support has been evaluated as an intervention for preventing postpartum relapse to smoking but there is no evidence for these interventions [7]. During pregnancy, offering financial incentives has been shown to be one of the most effective smoking cessation interventions [1, 8) and it is plausible that offering incentives in postpartum will reduce relapse to smoking.

1 Several studies have recruited women in early pregnancy and examined the combined effect of  
2 offering incentives in pregnancy and postpartum on postpartum rates of smoking abstinence.  
3 First, a trial that randomised women to incentives or a control group during pregnancy (N=43)  
4 showed that, when providing an incentive voucher of \$50 at one month and two months  
5 postpartum (contingent upon validated abstinence), around a third of women still relapsed by two  
6 months post-partum and the rate of relapse was similar in the control group [9]. Secondly, a non-  
7 randomised study (N=58) offered a \$20 incentive voucher (contingent upon abstinence) once  
8 weekly during the initial four weeks postpartum and then every other week for a further eight  
9 weeks [10]. In the incentives vs control group, rates of abstinence reduced between end-of-  
10 pregnancy (37% vs 9%) and 24-week postpartum assessment (27% vs 0%), in favour of the  
11 incentives group. A further trial, which randomised women to receive incentives or not in  
12 pregnancy (N=77), used the same intervention schedule as Higgins and colleagues [10] except that  
13 payments could escalate based on maintaining abstinence [11]. This study reported abstinence  
14 rates for incentives vs control at end-of-pregnancy of 41% vs 10% and at 24-week postpartum as  
15 8% vs 3%. Higgins and colleagues 2014 (N=118) [12] randomised women in pregnancy and  
16 included the same intervention as Heil and colleagues [11] as well as a revised condition which  
17 provided bonuses for those who could meet a more stringent biochemical validation criterion. The  
18 validated abstinence rates at end-of-pregnancy and 24 weeks postpartum, respectively, were:  
19 standard incentives 36% vs 15%, revised incentives 45% vs 18%, and control 18% vs 8%. In the  
20 largest study to date (N=1014), women who were randomised in early pregnancy were offered  
21 cash incentives of \$25–40 for each of four home visits at one, two, four and 6 weeks postpartum,  
22 \$20 for each of five post-birth counselling calls and \$40 for biochemically verified abstinence at  
23 one and six months postpartum [13]. At 6 months postpartum 15% were validated as abstinent in  
24 the incentives group and 9% in the control group. This study did not report abstinence at end-of-

1 pregnancy, therefore it was not possible to examine the relapse rates. Finally, a pilot study (N=60),  
2 randomising women in early pregnancy, used an app-based intervention and offered vouchers  
3 worth \$33 for each validated assessment conducted twice weekly during the first four weeks  
4 postpartum and once weekly during a further eight weeks postpartum [14]. At end-of -pregnancy,  
5 validated abstinence for the incentives vs control group was 37% vs 13%, while at 24 weeks  
6 postpartum it was 20% vs 7%.

7  
8 While these studies show some potential benefit of postpartum incentives, randomisation was  
9 early in pregnancy for women who were currently smoking; therefore, it was not possible to  
10 examine the separate effects of postpartum incentives on smoking cessation. Moreover, all the  
11 studies were conducted in the US and all, except the study by Baker and colleagues [13], were  
12 limited by small sample sizes. We are conducting a UK-based large randomised controlled trial  
13 (RCT), which is the first to examine the specific effect of postpartum financial incentives on rates  
14 of postpartum relapse to smoking, among women who received incentives in pregnancy, were  
15 confirmed as abstinent at end-of-pregnancy and at that time were randomised to receive  
16 incentives or no incentives.

17  
18 **Objectives {7}**

19 **Primary Objective**

20 The primary objective of this three-arm RCT is to assess the effectiveness of offering financial  
21 incentives to help women who are abstinent from smoking at end of pregnancy to avoid return to  
22 smoking up to 12 months postpartum.

23

24

## 1 **Hypotheses**

2 There are four hypotheses relating to the primary objective:

3 (i) That an intervention offering twelve months of postpartum financial incentives will be  
4 significantly more effective for aiding smoking cessation up to 12 months postpartum than a no  
5 incentives condition.

6 (ii) That an intervention offering three months of postpartum incentives will be significantly more  
7 effective for aiding smoking cessation up to 12 months postpartum than a no incentives condition.

8 (iii) That an intervention offering 12 months of postpartum incentives will be significantly more  
9 effective for aiding smoking cessation up to 12 months postpartum than an intervention offering  
10 three months of postpartum incentives.

11 (iv) That there will be a significant linear trend in smoking cessation across the three study groups,  
12 with rates of abstinence increasing from the no incentives group, to the three months incentives  
13 group, to the 12-month incentives group.

14

## 15 **Secondary Objectives**

16 The secondary objectives are:

- 17 • To assess the effectiveness of offering financial incentives to help women maintain smoking  
18 abstinence until at least three months after birth of the infant.
- 19 • To assess whether financial incentives are cost effective in terms of incremental cost per  
20 quitter at 12 months postpartum.
- 21 • To identify the effects of maternal characteristics (e.g., cigarette consumption before  
22 pregnancy) and type of smoking cessation services (i.e., midwife led or not) on the  
23 effectiveness of the intervention.

- 1 • To explore participant’s and intervention provider’s experiences of, and views on, the  
2 intervention and research procedures, in order to identify the barriers and facilitators to  
3 trial/intervention retention, effectiveness and implementation.  
4

5 **Trial design {8}**

6 This study is a multi-centre, three-arm, superiority, parallel group, individually randomised  
7 controlled trial, with 1:1:1 allocation, designed to test the effectiveness of offering financial  
8 incentives to help women, who are abstinent from smoking at end of pregnancy, to avoid  
9 returning to smoking up to 12 months postpartum. In addition, an economic evaluation will assess  
10 the cost-effectiveness of offering financial incentives, and a qualitative process evaluation will  
11 examine barriers and facilitators to trial retention, effectiveness and implementation.  
12

13 **Methods: Participants, interventions and outcomes**

14 **Study setting {9}**

15 Study participants will be recruited from stop smoking services (SSS) serving maternity hospitals in  
16 four UK National Health Service (NHS) hospital Trusts in Greater Manchester. All participating  
17 Trusts cover large areas of deprivation and include a city, several provincial towns, suburban and  
18 rural areas. This diversity facilitates recruitment of women from different socio-economic  
19 backgrounds. Each of these sites have different SSS configurations offering their own care  
20 pathway within the framework of the UK National Institute for Health and Care Excellence (NICE)  
21 guidance [15]. This includes NHS/local authority-run services, generic/specialist pregnancy  
22 services, midwifery/SSS advisor-led services, and represents most UK usual care pathways for  
23 smoking cessation in pregnancy. This also includes multiple care settings, from low risk midwifery  
24 led care to high risk tertiary units. The total deliveries per year at the four Trusts in 2019-2020 was



1 28, 270, ranging from 2230 births in the smallest Trust to 12,150 in the largest Trust. In these  
2 Trusts, again in 2019-2020, 10.7% of women were recorded as smokers at time of delivery, against  
3 an average across England of 10.4%.

4

## 5 **Eligibility criteria {10}**

### 6 **Site eligibility: Current routine care for smoking cessation in pregnancy**

7 Study sites are only eligible if they are currently offering the Smokefree Pregnancy Programme in  
8 Greater Manchester, which incorporates an offer of financial incentives for biochemically  
9 validated smoking abstinence through to the end of pregnancy. This section describes this routine  
10 smoking cessation care which is offered in Greater Manchester.

11

12 This programme includes 'BabyClear' [16], which implements UK guidance [15] around smoking in  
13 pregnancy, as well as linking NHS Trusts who provide antenatal care and community-based  
14 providers of smoking cessation support. Training is provided for maternity staff, smoking cessation  
15 advisors and administrators within smoking cessation services. Midwives are trained to use CO  
16 monitoring for all women at the first antenatal appointment, with routine opt-out referral for  
17 smoking cessation support for any woman with a CO recording above 3 (parts per million) ppm.  
18 Babyclear also includes an enhanced 'risk perception' intervention for women who continue to  
19 smoke at their first trimester ultrasound scan appointment, at around 12 weeks gestation.

20

21 Women who report currently smoking, or having stopped smoking in the last two weeks, and have  
22 an expired CO reading > 3ppm are offered regular (at least four weekly) support from a stop  
23 smoking advisor. Women can be referred by maternity services to receive this support or can self-  
24 refer. Expired CO is routinely tested at all smoking cessation appointments and stopping smoking

1 is facilitated at the earliest possible point in pregnancy, with routes back into support at any point  
2 of relapse.

3  
4 In addition to Babyclear, all the women in the pregnancy programme are offered a financial  
5 incentives scheme. This scheme is routine care and is not part of the intervention for the trial. For  
6 the first four weeks women are offered a £10 'Love2Shop' voucher (redeemable in many UK retail  
7 outlets) per week and then a £20 voucher each month, up to 36 weeks gestation. This is  
8 conditional on the woman reporting lapse free abstinence since their quit date and having an  
9 expired CO reading of <4ppm. Additionally, participating women are given the option to recruit a  
10 'Significant Other Supporter' (SOS) (a member of their community, including a close family  
11 member such as a partner, who agrees to support the woman to remain smoke free, including  
12 attending cessation support sessions) who is entitled to receive a £60 Love2Shop voucher if the  
13 woman remains quit at 36 weeks gestation and the SOS is also confirmed as abstinent (CO<8ppm).  
14 If a woman relapses to smoking and agrees to set a new quit, she can be re-recruited into the  
15 incentives scheme, up to 32 weeks gestation. If she relapses a second time she is no longer eligible  
16 to participate in the scheme and is offered support outside the scheme. The latest point at which a  
17 women can begin a quit attempt as part of the Smokefree Pregnancy Programme/Babyclear is at  
18 32 weeks gestation. If a woman is referred after 32 weeks she is offered routine support for  
19 smoking cessation in pregnancy without the offer of incentives (and is not eligible for the trial). In  
20 cases of miscarriage, premature birth or stillbirth the woman is no longer eligible for the  
21 incentives scheme and is offered cessation support outside of the scheme.

22  
23 All women provided with smoking cessation support in pregnancy are also given brief advice about  
24 maintaining abstinence postpartum and in the long-term.

## 1 **Participant eligibility**

2 Women who have undergone the above Smokefree Pregnancy Programme in Greater Manchester  
3 will be eligible to join the study if they meet the following inclusion criteria: are between 34 weeks  
4 gestation and two weeks postpartum, confirm having not smoked a single puff of a cigarette for at  
5 least four weeks, expired carbon monoxide (CO) reading < 4 ppm (piCO<sup>baby</sup>™ Smokerlyzer®, Bedfont  
6 Scientific Ltd), aged at least 16 years, intend remaining abstinent from smoking after the birth (or to  
7 continue remaining abstinent if recruited postpartum), able to speak and read English and be  
8 willing and able to give written informed consent for participation in the study. If the participant is  
9 required to use a single-person, self-administered carbon monoxide (iCO) monitor (i.e., during  
10 COVID-19 restrictions), they require a device (e.g., phone) that is compatible with the monitor  
11 app.

12  
13 *Rationale for CO cut-off of < 4ppm:* During pregnancy, when metabolism is higher and there are  
14 respiratory changes, a CO cut-off of <4ppm is recommended [17, 18]. Whereas out of pregnancy a  
15 cut-off of <8ppm is more standard [19]. Therefore, for eligibility we used a criteria of < 4ppm. It is  
16 not clear whether metabolism and respiratory function would have returned to non-pregnant  
17 levels during the first two weeks postpartum compared with pregnancy; therefore we will apply  
18 the CO cut-off of < 4ppm equally to women who are recruited in late pregnancy and to women  
19 who are recruited in the first two weeks postpartum.

20  
21 There is recent evidence that the iCO monitor can produce a slightly higher CO reading than more  
22 conventional CO monitors [20]. However, the iCO has not been compared with other monitors  
23 during pregnancy, therefore we retained the cut-off of <4ppm for the iCO during testing for  
24 eligibility.

1 **Who will take informed consent? {26a}**

2 All women confirmed as abstinent by their stop smoking service (SSS) advisor at around 36 weeks  
3 gestation (acceptable range: 34 weeks gestation to two weeks postpartum), and meeting other  
4 eligibility criteria, will be invited by their advisor to join the study. The SSS advisor will explain that  
5 we are running an RCT examining the effects of offering shopping vouchers on women's smoking  
6 cessation during the 12 months after their baby is born. If a face-to-face appointment is possible  
7 at this time, the SSS will ask women for their written informed consent to participate in the trial.  
8 They will also ask for their consent to be contacted after the 12 months follow-up to be invited to  
9 take part in an interview to discuss their experience of the trial. It will be made clear that women  
10 can participate in the trial without consenting to be interviewed and that this will not affect their  
11 participation in the trial or the usual care that they receive.

12

13 All women who are eligible and have provided consent to participate in the trial will be  
14 randomised to one of the three study groups. After women are randomised they will be given an  
15 additional participant information sheet (PIS) describing the specific study group they have been  
16 allocated to.

17

18 All SSS staff will attend a half-day session, delivered by a member of the research team, to be  
19 informed about the trial and to be trained in taking consent, delivering the intervention, and other  
20 research procedures.

21

22 *'Distanced' consent methods*

23 Due to COVID-19 restrictions on face-to-face contact, the following provisions have been made:

24 Potential participants can be contacted at around 32 weeks and 36 weeks gestation by phone, as

1 well as face-to-face. The participant information sheet and consent form can be sent to  
2 participants by post, email or via a web-link embedded within a text message. Women will be  
3 offered several 'distanced' methods for providing informed consent:

- 4 1. To post the completed written consent form to a researcher or SSS before being randomised.
- 5 2. To take a photo or scan of their completed written consent form and texting or emailing it to a  
6 researcher or SSS advisor.
- 7 3. To provide verbal consent to join the trial. During the call, potential participants will give explicit  
8 verbal consent to the statements on the consent form. An SSS advisor will then sign the  
9 participant's consent form and check a 'tick box' which notes on the consent form that consent  
10 was taken verbally by telephone.

11

#### 12 *Justification for distanced consent methods*

13 We believe it is ethical to use the 'distanced' consent methods described above and they have  
14 received ethical approval. If all participants are required to receive, sign and return signed consent  
15 forms, this will result in many women, who wish to join the trial, not returning signed  
16 confirmation. For example, women may be socially isolating and do not wish to leave their homes  
17 to post the consent form or they may not have the facility to transfer the completed form  
18 electronically. In this circumstance adequate recruitment and, hence, a robust evaluation would  
19 be difficult. Moreover, a 'hard-to-reach' group would lose the potential to benefit from  
20 participation in the trial.

21

#### 22 **Additional consent provisions for collection and use of participant data and biological specimens**

23 **{26b}**

24 No additional consent provisions are required.

1 **Interventions**

2 **Explanation for the choice of comparators {6b}**

3 Those in the ‘no incentives’ control group will receive postpartum care as usual, except, as for all  
4 participants, they will be offered a £20 voucher payment, at both 3 months and 12 months  
5 postpartum, as a gesture of thanks for completing a follow-up assessment. During pregnancy all  
6 women receive routine care for smoking cessation in pregnancy, including the offer of incentives,  
7 as described in section {10}. This includes brief advice about maintaining abstinence postpartum  
8 and in the long-term. Other than this, currently there is no routine, postpartum relapse prevention  
9 support offered to women or partners who have quit smoking before or during pregnancy.

10

11 **Intervention description {11a}.**

12 There are two intervention/incentive groups. The incentive payments are in the form of  
13 Love2Shop gift cards that can be redeemed in a wide variety of UK shops and that are used in the  
14 pregnancy incentives scheme that the women have participated in. Love2Shop vouchers have  
15 been used in a previous UK trial of incentives for smoking cessation in pregnancy [21].

16

17 **During COVID-19 restrictions on face-to-face contact** participants will attend appointments  
18 remotely, via telephone, rather than face-to-face and smoking cessation status will be assessed  
19 remotely. Also, vouchers will be posted to participants. See section {12} for details of ‘Assessing  
20 smoking cessation outcomes during COVID-19 restrictions on face-to-face contact’.

21

22 **Intervention group 1: Incentives are offered up to three months postpartum.**

23 This intervention is provided in addition to the usual care as received by the ‘no incentives’ group.

1 *Payments to participants:* Participants are offered a total of £60 of incentive payments. An  
2 incentive of £20 is offered at each of the visits at one, two and three months postpartum.  
3 Payments are conditional on self-report of not smoking a single puff of a cigarette since their last  
4 quit date in pregnancy and an expired CO reading of <8ppm. This intervention, including the  
5 amount of incentive, was chosen because it has been used previously in the UK, including in  
6 Greater Manchester, and has been shown to be acceptable to postpartum women and SSS  
7 advisors [22].

8  
9 *Payments to Significant Other Supporter:* Participants will also be given the option to identify a  
10 'Significant Other Supporter' (SOS) (a member of their community, including a close family  
11 member such as a partner, who agrees to support the woman to remain smoke free, including  
12 attending smoking cessation validation visits). The women's SOS will be offered an incentive of  
13 £60 if the woman achieves CO validated abstinence at three months postpartum and the SOS is  
14 also confirmed as abstinent (CO<8ppm), irrespective of whether the SOS has been a smoker.  
15 During the period of COVID-19 restrictions on face-to-face contact the SOS will be confirmed as  
16 abstinent based on self-report alone. Previously, SOS payments have been shown to be acceptable  
17 to postpartum women and their partners in the UK [22] and elsewhere [9].

18  
19 The total value of incentives offered to this group, including payments to the participant (£60) and  
20 the SOS (£60), is £120.

21  
22 **Intervention group 2: Incentives are offered up to 12 months postpartum.**

23 This intervention is provided in addition to the usual care as received by the 'no incentives' group.

1 In addition to all the incentives offered to group 1, participants in this group are offered £60 at  
2 each of the visits at six, nine and 12 months postpartum. The rationale for the amount of incentive  
3 offered in the 12-month condition was based on repeating the payment made to the participant at  
4 3 months (i.e., £60) at 3-month intervals (i.e., at 6, 9 and 12 months) up to 12 months. Again,  
5 payments are dependent on expired CO confirmation of self-reported abstinence. No additional  
6 incentive is offered to the SOS beyond that offered at 3 months.

7  
8 The total value of incentives offered to this group, including those offered to the participant  
9 (£240) and SOS (£60), is £300. This intervention was devised specifically for this study, in order to  
10 examine the potential benefit of continuing the offer of incentives, at three-month intervals, up to  
11 the primary end-point at 12 months postpartum.

12  
13 To our knowledge, neither of the incentive interventions has been previously tested in a research  
14 study. The level of incentives offered in the interventions are between the lowest level suggested  
15 by the general public that might be effective (£20 per month) and the highest acceptable level  
16 (£80 per month), for during pregnancy [23]. No such data on incentives is available for  
17 postpartum.

18  
19 **Behavioural support for intervention groups:** In both intervention groups the SSS advisor is  
20 instructed to provide only behavioural support that is integral to the incentives intervention. In  
21 total, the interventions include the following four behaviour change techniques (BCTs), as defined  
22 by a standard taxonomy of BCTs [24], and the numbering is that used in the taxonomy:  
23 10.1 *Material incentive (behavior)*: Inform that a financial incentive will be offered if the  
24 participant and SOS reports not smoking and has a CO < 8ppm.



1 1.3 Goal setting (outcome): Set a goal of not smoking a single puff of a cigarette until the next  
2 assessment.

3 2.6 Biofeedback: Inform the person of their expired CO reading.

4 10.4 Social reward: SSS congratulates person if they remain abstinent from smoking.

5 Adherence to the protocol for providing behavioural support will be explored in the interviews with  
6 smoking cessation advisors.

7

8 **Payments for attending assessments:** In addition, in order to maximise completion of follow-ups,  
9 all participants are offered a £20 voucher payment, for completing a follow-up assessment at both  
10 3 months and 12 months postpartum (i.e., £20 for each assessment).

11

#### 12 **Criteria for discontinuing or modifying allocated interventions {11b}**

13 There are no special criteria for discontinuing or modifying allocated interventions.

14 Participants may choose to stop attending appointments and receiving incentive payments for any  
15 reason.

16

#### 17 **Strategies to improve adherence to interventions {11c}**

18 None beyond the brief behavioural support described in {11a}.

19

#### 20 **Relevant concomitant care permitted or prohibited during the trial {11d}**

21 Trial participants are permitted to receive relapse prevention support, during postpartum, beyond  
22 that provided by the intervention and any additional support is recorded. The SSS conducting the  
23 research follow-ups are asked not to provide any relapse prevention support at the follow-ups beyond that  
24 defined as part of the intervention (for the description of the allowed support see: {11} Intervention

1 description/Behavioural support for intervention groups).

2

3 **Provisions for post-trial care {30}**

4 None, beyond standard care within the NHS.

5

6 **Outcomes {12}**

7 At the 3 and 12 months postpartum follow-ups, women will initially be assessed for smoking  
8 status over the phone (up to five attempts will be made to call them) by their stop smoking service  
9 (SSS) advisor or by a researcher. Those who report having not smoked a single puff of a cigarette  
10 since their last quit date in pregnancy will be asked to attend a face-to-face appointment with  
11 their SSS advisor to confirm their smoking status, or to confirm their smoking status by remote  
12 means (see section below 'Assessing smoking cessation outcomes during COVID-19 restrictions on  
13 face-to-face contact).

14

15 **Primary outcome measure**

16 The primary outcome is self-reported, lapse-free, smoking abstinence from the last quit attempt in  
17 pregnancy until 12 months postpartum, biochemically validated by an exhaled CO reading of  
18 <8ppm, and/or saliva cotinine or anabasine estimation. Where possible, both a CO reading and  
19 saliva sample will be collected and for a woman to be validated as abstinent both the CO reading  
20 and saliva test will need to confirm abstinence. Where both a CO reading and saliva sample cannot  
21 be collected, either a CO reading or a saliva test will be used to confirm abstinence. The  
22 proportion of abstinent women will be compared between the two intervention groups and  
23 between each intervention group and the control group. During pregnancy, due to physiological

1 changes including higher metabolism [25], a CO cut-off of <4ppm is recommended [17, 18].  
2 Whereas out of pregnancy a cut-off of <8ppm is more standard [19].  
3  
4 Where the expired CO reading is <8ppm, or a CO reading is not available, and the cotinine level is  
5 <10 ng/ml [26] the participant is defined as a biochemically verified as abstinent. Where the CO  
6 reading is <8ppm, or a CO reading is not available, and the cotinine level is  $\geq 10$  ng/ml and the  
7 participant reports use of nicotine replacement therapy, e-cigarettes or heat-not-burn products,  
8 then saliva samples will be also tested for anabasine. Where the anabasine result is <0.2ng/ml [27]  
9 then the participant will be defined as a biochemically verified as abstinent.

10 Since recruitment to the study is conducted between 34 weeks gestation and two weeks postpartum, it is  
11 possible that a few women may relapse after recruitment and before giving birth. In the analysis for the  
12 primary outcome these women will not be distinguished from those who have relapsed after the birth.  
13 However, we will report the numbers of women who relapsed before the birth, separately for the two  
14 study groups.

## 16 **Secondary outcome measures**

17 As a secondary outcome we will assess self-reported, lapse-free, smoking abstinence from the last  
18 quit attempt in pregnancy until three months postpartum, biochemically validated by an exhaled  
19 CO reading of <8ppm. Again, the proportion of abstinent women will be compared between the  
20 intervention and control groups. At both three and 12 months, for some women it may not be  
21 possible to conduct a test to biochemically validate self-reported abstinence (e.g., due to COVID  
22 restrictions). Therefore, as further secondary outcomes we will compare self-reported abstinence  
23 between the study groups at 3 and 12 months (including without biochemical validation as well as  
24 those with validation).

1 If a participant is recorded as having relapsed at three months postpartum, they will be  
2 automatically recorded as having relapsed for the primary outcome at 12 months postpartum, and  
3 will not be followed up at 12 months.

4

5 In addition, in order to understand any differences between study groups, we will assess the  
6 following measures at three and 12 months postpartum (see Table 1):

7 • Use of nicotine products:

8 Have you used any Nicotine Replacement Therapy (NRT) in the last week? Yes/No

9 If Yes, Which types of NRT have you mainly used? (tick all that apply)

10 Patch/Lozenge/Mouth Spray/Gum/Microtabs/Inhalator/Nasal Spray

11 Have you used an e-cigarette in the last week? Yes/No

12 Have you used a heat-not burn product in the last week (e.g., iQOS)? Yes/No

13 The assessment of use of nicotine products at 12 months postpartum also enabled us to consider  
14 the appropriateness of using a test of saliva cotinine vs anabasine, to determine smoking status, at  
15 this time.

16 • Smoking in the home: Does anyone living in your home smoke tobacco? Yes/No

17 • Partner smoking status: If you have a partner, does your partner smoke tobacco? Yes/No/

18 Not applicable

19 • Use of additional smoking cessation support beyond that provided in the trial:

20 Are you currently receiving any professional help with stopping smoking other than the help

21 you receive as part of this research study? Yes/No If Yes, which organisation is giving you

22 this help?

- 1 • Use of the iCO (single person use) monitor beyond that required for the research  
2 assessments:

3 Have you used your iCO carbon monoxide monitor at times other than when asked to do so by  
4 your stop smoking advisor? Yes/No If Yes, on how many days have you used the iCO in this  
5 way since your baby was born? (tick one box only) On one or two days/ On 3 to 5 days/ On 6  
6 to 10 days/ On 11 to 20 days/ On more than 20 days

7  
8 **Assessing smoking cessation outcomes during COVID-19 restrictions on face-to-face contact**

9 During COVID-19, for the three and 12-month postpartum outcomes for smoking cessation, if it is  
10 not possible to take an expired CO reading during a face-to-face visit, participants will take a CO  
11 reading using a self-administered/single person use device ((iCO™ Smokerlyzer, Bedfont Scientific  
12 Ltd.) [28] and send the CO reading to the stop smoking advisor via an app. There is recent  
13 evidence that the iCO monitor can produce a slightly higher CO reading than more conventional  
14 CO monitors [20]. However, the authors of this study recommend an optimal cut-off for the iCO of  
15 <6ppm, therefore we decided to retain our more liberal cut-off of <8ppm.

16  
17 If a participant joined the trial before the COVID-19 restrictions, and therefore was not sent a self-  
18 administered CO monitor when they were recruited and a face-to-face CO reading is not possible,  
19 then a CO reading will not be collected at 3 or 12 months follow-up; at 3 months, abstinence will  
20 be self-reported alone and at 12 months self-reported abstinence will be validated, where  
21 possible, by a saliva test. The participant will be sent a salivette and instructions to provide a saliva  
22 sample and will be advised how to take a saliva sample during the follow-up call with the stop  
23 smoking advisor. The participant will then be asked to post the saliva sample to a laboratory for  
24 analysis (ABS Laboratories, Hertfordshire, UK, <https://www.acmgloballab.com/about-us/our->

1 locations/europe-london-uk). The follow-up questionnaires will be administered by the  
2 participant's stop smoking advisor over the phone. When the COVID-19 restrictions have been  
3 lifted we will give participants the option of continuing with the above approach or they can  
4 choose to have face-to-face appointments.

#### 5 **Economic measures**

6 We will examine the incremental cost per quitter for the financial incentive interventions versus  
7 the no incentives group. We will collect resource and cost data (i.e., financial incentives, stop  
8 smoking service delivery) as well as considering rates of smoking cessation.

9

#### 10 **Process evaluation**

11 The process evaluation will collect quantitative data on recruitment and follow-up rates. In  
12 addition, qualitative data will be collected via a focus group with SSS advisors/managers delivering  
13 the intervention and through interviews with trial participants. This qualitative work will identify  
14 barriers and facilitators to trial recruitment and adherence and explore the acceptability of study  
15 processes and procedures. Full details of the process evaluation are reported in Additional file 1.

#### 16 **Baseline measures**

17 In a baseline questionnaire, administered by the SSS advisor before randomisation, we will assess  
18 measures which have been shown to predict postpartum smoking relapse [29] and which we  
19 would want to ensure are similar for the three study groups, as potential confounders of any  
20 effects on smoking cessation (see Table 1.). These measures are:

- 21 • Age
- 22 • Ethnicity
- 23 • Highest educational qualification
- 24 • Occupation

- 1 • Gestation
- 2 • Level of cigarette consumption before pregnancy
- 3 • Expired CO level in ppm
- 4 • Parity (i.e., number of previous pregnancies that have gone beyond 24 weeks)
- 5 • Assessment of any smoking in the home and of whether partner smokes
- 6 • Length of time since last smoking (Months/weeks)
- 7 • Self-efficacy: Rating of “How confident are you that you will continue not to smoke at least until
- 8 your baby’s first birthday?” (Not at all confident, Slightly confident, Moderately confident, Very
- 9 confident, Extremely confident) [30]
- 10 • Depression: Edinburgh Postnatal Depression Scale [31] (For the item “The thought of harming
- 11 myself has occurred to me” if women respond “Yes, quite often” or “sometimes” they will be
- 12 referred to their health visitor, Family Nurse Partnership or GP).
- 13 • Breastfeeding intent [32]
- 14 • Alcohol consumption: Alcohol Use Disorders Identification-Consumption (AUDIT-C) test [33,34]
- 15 • Use of support for smoking cessation beyond what is provided in the trial.
- 16 • Whether they recruited a significant other supporter (SOS) during their pregnancy.
- 17 • Use of nicotine replacement therapy (NRT) in the last week and main types of NRT used.
- 18 • Use of heat not burn products in the last week.
- 19 • Use of e-cigarettes in the last week.

20

21

22

23

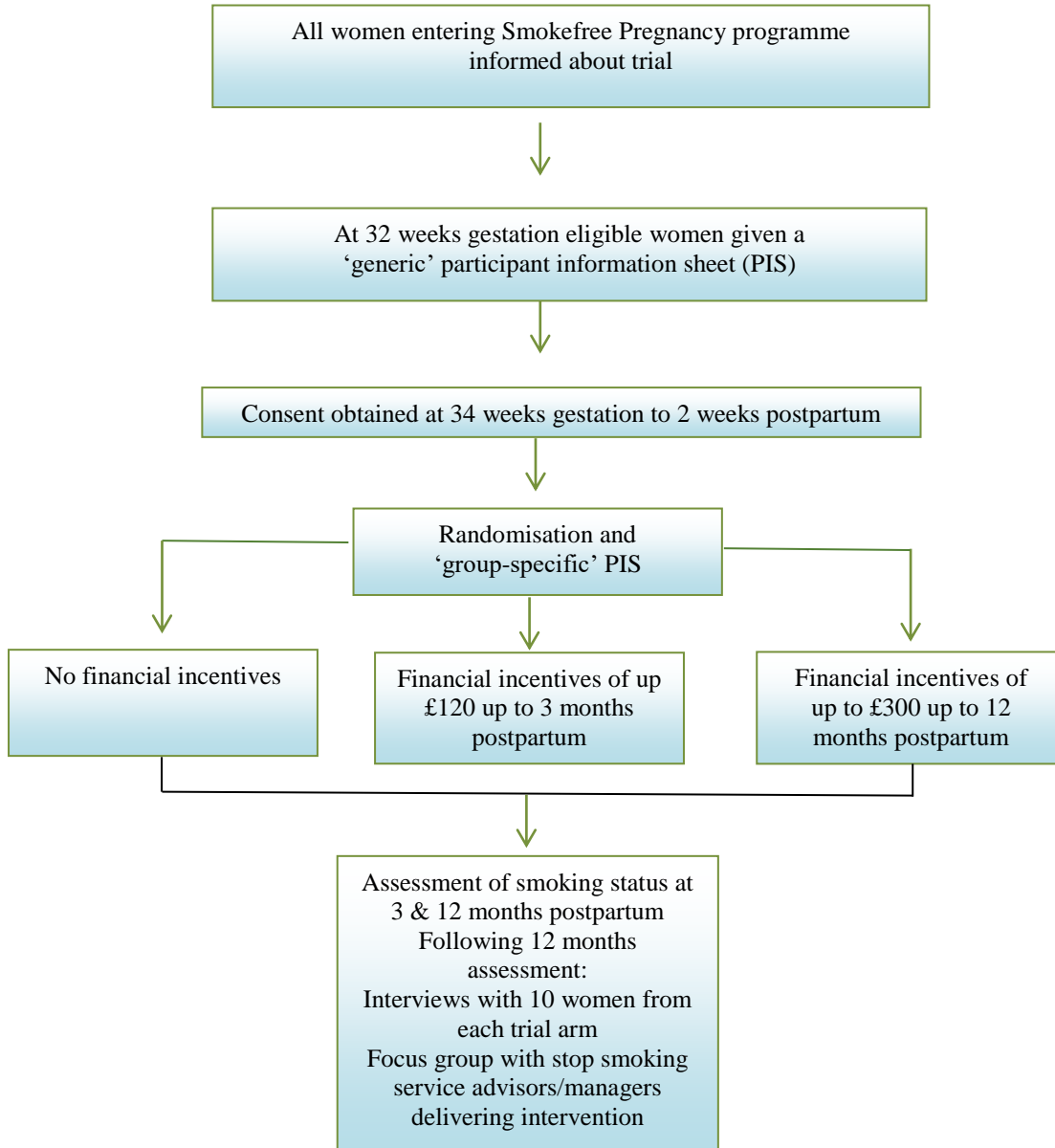
24

1 **Participant timeline {13}**

2

3 **Figure 1. Trial flow diagram**

4





1 **Sample size {14}**

2 We estimate that the proposed sample size of 900 women will give 90% power at an alpha  
3 threshold of 0.017 to detect a difference in abstinence rates across any two groups of 13.6% at 12  
4 month follow up. It is anticipated that the abstinence rate in the control group will be 9% at 12  
5 month follow up, that there will be 22.6% abstinence at 12 months follow up in the 3 month  
6 incentives group and 36.2% abstinence at 12 months follow up in the 12 months incentives group.  
7 The figure of 9% in the no incentives group is conservatively based on the assumption that over  
8 90% of women without incentives may relapse by 12 months postpartum [3]. The estimate of  
9 13.6% difference is based on the group difference found by Tappin and colleagues in a study of  
10 incentives during pregnancy [34]. The threshold for alpha is reduced to 0.017 to correct for  
11 multiplicity and allow comparisons across the three arms. This sample size will also give 100%  
12 power to detect a linear trend in abstinence across the three groups ( $p < 0.05$ ) from control to 12-  
13 month intervention.

14

15 **Recruitment {15}**

16 At the time that women join the Smokefree Pregnancy programme, which is most commonly  
17 following their first antenatal booking visit at 8-12 weeks gestation, they will be informed by their  
18 stop smoking service (SSS) advisor that those who are confirmed as abstinent from smoking at  
19 around 36 weeks gestation (acceptable range: 34 weeks gestation to 2 weeks postpartum) will be  
20 offered the opportunity to join a research study in which they may or may not be offered shopping  
21 vouchers to remain abstinent through 12 months postpartum.

22

23 Women confirmed as abstinent (CO <4ppm) by their SSS at around 32 weeks gestation will be  
24 given or sent a 'generic' PIS about the study. We decided to first provide a generic PIS, explaining

1 that incentives may or may not be offered, but not giving the specific details of the three study  
2 groups, in order to reduce potential dissatisfaction and dropout if women are not offered the  
3 highest value of incentives. It will be explained that if they are still confirmed as abstinent at their  
4 36-week appointment, and meet other eligibility criteria, they will have the opportunity to discuss  
5 the study and decide if they want to join. All women confirmed as abstinent at around 36 weeks  
6 gestation by their SSS (acceptable range: 34 weeks gestation to two weeks postpartum), and  
7 meeting other eligibility criteria, will be invited by their SSS advisor to join the study. If women  
8 give birth before their 36 week appointment they will still be eligible as long they join the study  
9 within two weeks of the birth of the baby and meet other eligibility criteria. The SSS advisor will  
10 explain that we are running an RCT examining the effects of offering shopping vouchers on  
11 women's smoking cessation during the 12 months after their baby is born and seek consent to  
12 participate. See {26a} for a description of the consent process.

13  
14 A screening form will be completed by the SSS advisor to record number of women approached,  
15 eligibility, number of women declining to take part or not eligible, and reasons for being ineligible  
16 or declining, if women are willing to provide this information.

17  
18 If a face-to-face visit and/or multiple use CO test is not possible (e.g., in order to maintain social  
19 distancing) the CO reading to determine eligibility will be taken by a single-person, self-  
20 administered CO monitor, posted to the woman following her appointment at 32 week's  
21 gestation, and used by the woman at home (iCO™ Smokerlyzer, Bedfont Scientific Ltd. [28]). The  
22 CO reading will be transferred to the SSS advisor using an app. Women who do not have a device  
23 (e.g., phone) that is compatible with this app will not be eligible to join the trial. The baseline  
24 questionnaire will be administered by the stop smoking advisor over the phone. When the COVID-

1 19 restrictions have been lifted we will give participants the option of continuing with the above  
2 approach or they can choose to have face-to-face appointments.

3 Details of those consenting to participate in the trial will be entered by the SSS advisor on to a  
4 secure University of Stirling online server which will generate a randomisation code. Some  
5 participants may be disappointed not to be allocated to one of the incentives groups and the SSS  
6 advisors will be trained to respond appropriately to this. Following randomisation, the  
7 participant's screening form, baseline questionnaire and consent form will be sent to the study  
8 principal investigator who will review this documentation and confirm eligibility.

9  
10 The patient's clinical care team (e.g., midwife, health visitor, GP) will already have been made  
11 aware that the woman is taking part in the Greater Manchester Smokefree Pregnancy  
12 programme, therefore we will not be sending a separate letter to patient's general physicians  
13 (GPs) when they join the trial.

14

15 **Assignment of interventions: allocation**

16 **Sequence generation {16a}**

17 Randomisation and allocation will be carried out by the trial statistician (CB) at the University of  
18 Stirling using STATA, with randomised permuted blocks and stratified by site (i.e., hospital trust).

19 Unit of randomisation will be individual participant, allocated in a ratio of 1:1:1 to the two  
20 intervention groups or control group. Following completion of the baseline questionnaire, details  
21 of women who consent to participate will be entered by the SSS advisor into a University of  
22 Stirling secure online server (i.e., randomisation date, participant birth date, participant initials  
23 and site). The SSS will then be automatically informed of the women's unique participant number  
24 and treatment allocation and this information will be given to the participant. Selection bias will

1 be minimised by ensuring all consenting women have equal opportunity of being allocated to each  
2 of the study arms.

3

4

5 **Concealment mechanism {16b}**

6 Randomisation will use a web-based randomisation system.

7

8 **Implementation {16c}**

9 SSS advisors at each site will enrol participants and request the group allocation.

10

11 **Assignment of interventions: Blinding**

12 **Who will be blinded {17a}**

13 Due to the nature of the intervention, participants and the SSS advisors delivering the intervention  
14 will not be blinded to the treatment received. Nor will SSS advisors or researchers who ascertain  
15 smoking status at three and 12 months postpartum be blinded; however, there is low risk of bias  
16 as smoking status is biochemically validated. Those involved in the data analyses will be blinded to  
17 the group allocation.

18

19 **Procedure for unblinding if needed {17b}**

20 Participants and SSS staff delivering the intervention are not blinded.

21

22 **Data collection and management**

23 **Plans for assessment and collection of outcomes {18a}**

1 Data will be collected via questionnaires at baseline and at three and 12 months postpartum.  
 2 Questionnaires will be either self-completed by participants or, during COVID-19 restrictions, will  
 3 be administered by SSS advisors over the telephone. Demographic information will be collected at  
 4 baseline via questionnaire. CO readings will be collected at baseline and at three and 12 months  
 5 postpartum during a face-to-face visit or, during COVID-19 restrictions, remotely via an app. For  
 6 those who report smoking abstinence at 12 months postpartum saliva, for cotinine/anabasine  
 7 testing, will be collected face-to-face or, during COVID-19 restrictions, saliva collection kits will be  
 8 posted to participants and participants will post the saliva sample to the laboratory.

9  
 10 **Table 1: Schedule of assessments**

<b>Assessment</b>	<b>Baseline</b>	<b>3 months postpartum</b>	<b>12 months postpartum</b>
Demographics: age, education, occupation, ethnicity	X		
Smoking status: self-reported	X	X	X
Time since last smoking	X		
Expired CO level in ppm	X	X	X
Use of iCO single person use CO monitor outside of assessments: self-reported		X	X
Cigarette consumption before pregnancy	X		
Self-efficacy for smoking cessation	X		
Use of nicotine products	X	X	X
Smoking in the home	X	X	X

Partner smoking status	X	X	X
Use of additional smoking cessation support	X	X	X
Whether they have a significant other supporter (SOS)	X		
Gestation	X		
Parity	X		
Breastfeeding intent	X		
Depression (Edinburgh Postnatal Depression Scale)	X		
Alcohol consumption: Alcohol Use Disorders Identification-Consumption (AUDIT-C) test	X		
Expired CO level in ppm	X	X	X
Saliva for cotinine/anabasine test			X

1

2 **Plans to promote participant retention and complete follow-up {18b}**

3 In order to maximise the number of participants who complete follow-ups, especially among those  
4 in the control group and those who have relapsed to smoking, all participants will be offered a £20  
5 voucher payment, for completing a follow-up assessment at both 3 months and 12 months  
6 postpartum (i.e., £20 for each assessment). The assessment includes completion of a  
7 questionnaire and biochemical assessment of smoking status. A previous UK trial of incentives for  
8 smoking cessation in pregnancy showed that such a payment motivates women to attend follow-  
9 ups [29]. Telephone contact for follow-up will be attempted on up to five occasions. If a  
10 participant has been asked to post a saliva sample to the laboratory and the saliva sample has not  
11 arrive the participant will be contacted and reminded to send the sample.

12

1 **Data management {19}**

2 All trial participants are given an individual trial number which will be used on all case  
3 report forms (CRF) for that participant. Researchers at the University of Stirling will enter data  
4 from CRFs into the secure trial database. To check for systematic errors, double data entry will be  
5 conducted for a random selection of 10% of CRFs. University of Stirling researchers will review  
6 CRFs and the database for range errors and for missing data.

7

8 **Confidentiality {27}**

9 All collected information will be kept strictly confidential and will be stored in accordance  
10 with the General Data Protection Regulation (GDPR) and the latest Directive  
11 on Good Clinical Practice (GCP). Confidentiality of patient's personal data is ensured by not  
12 collecting patient names on CRFs and limiting access to personal information held on the  
13 databases. At trial enrolment the participant will be issued a participant identification number and  
14 this will be the primary identifier for the participant, with secondary identifiers of month and year  
15 of birth and initials. Any paper copies of personal trial data will be kept at the participating site in  
16 a secure location with restricted access. Following consent, identifiable data will be kept in a  
17 secure database at each site and at the University of Stirling, to allow authorised members of the  
18 site team to contact participants in order to arrange appointments/assessments.

19 Any paper copies of consent form, with patient name and signature, will be kept securely at the  
20 trial site with a copy sent to the University of Stirling for monitoring purposes. Consent forms will  
21 not be kept with any additional patient data.

22

23

24

1 **Plans for collection, laboratory evaluation and storage of biological specimens for genetic or**  
2 **molecular analysis in this trial/future use {33}**

3 None

4

5 **Statistical methods**

6 **Statistical methods for primary and secondary outcomes {20a}**

7 The plan for statistical analysis is reported here in accordance with guidance for RCTS [35,36].

8 We will use descriptive statistics to present the baseline characteristics of the three study groups.

9 Descriptive statistics will also be used to report rates of recruitment, retention and follow-up at three

10 months and 12 months post-partum, and to report the numbers of women who relapsed before the birth

11 vs after the birth, separately for the two study groups. Again, descriptive statistics will be used to present

12 the following secondary outcomes at three and 12 months postpartum: use of nicotine products, smoking

13 in the home, partner smoking status, use of additional smoking cessation support beyond that provided in

14 the trial, and use of the iCO (single person use) monitor beyond that required for the research.

15

16 Analyses of smoking status, for primary and secondary outcomes, will be performed for the

17 intention-to-treat population and reported in accordance with the Consolidated Standards of

18 Reporting Trials (CONSORT) statement [37,38], including all women who are randomised and meet

19 the eligibility criteria. If ineligible persons are mistakenly randomised into the trial the

20 independent trial steering committee will review the case for removing the participant from the

21 analysis, such that this decision is unbiased and not influenced by events that occurred after

22 randomisation (and may therefore be affected by whether patients received experimental or

23 control treatment) [39].

24



1 Women lost to follow-up will be presumed to have returned to smoking [19]. This assumption is  
2 standard in the smoking cessation literature as the pattern of missingness is not random. We will  
3 compare differences in smoking cessation outcomes between all three treatment groups, using  
4 logistic regression adjusted for the random effect of site (i.e., NHS Trust), with statistical  
5 significance determined by the likelihood-ratio test, and with pairwise comparisons between  
6 treatment groups in accordance with the study objectives, using a p value of 0.017 adjusted for  
7 the three comparisons. The estimate of effect will be given as the odds ratio and 95% confidence  
8 interval for each of the three comparisons. We will also look for a linear trend in smoking  
9 cessation across the three groups, by examining the significance ( $p < 0.05$ ) of a linear contrast  
10 across the groups from control to 12-month intervention.

11

12 All outcomes will be analysed collectively following the completion of the final follow-up at 12  
13 months postpartum. A more detailed statistical analysis plan will be agreed to before the end of  
14 data entry and before the treatment code is broken.

15

#### 16 **Interim analyses {21b}**

17 There will be no interim analyses.

18

#### 19 **Methods for additional analyses (e.g. subgroup analyses) {20b}**

20 We will conduct a secondary-analyses adjusting for key baseline maternal variables that are  
21 predicted to be related to smoking status (i.e., socio-economic status, cigarette consumption  
22 before pregnancy, depression, and age) and type of smoking cessation service (midwife-led or not)  
23 [40]. We will also conduct sensitivity analysis to examine the effects of remote (i.e., during COVID-  
24 19) versus face-to-face consultations. We will also consider whether the women have been

1 supported by a significant other.

2

### 3 **Economic analysis**

4 An incremental cost-effectiveness analysis will be undertaken, following the NICE guidance for  
5 health-care evaluations [41,42], comparing the additional costs of the financial incentive  
6 interventions with those of the no incentives group, as well as the additional benefits, to give a  
7 cost per additional quitter. The economic evaluation will use resource and cost data (i.e., financial  
8 incentives, Stop Smoking Service delivery) as well as rates of smoking cessation.

9

10 We will document resources consumed that are related to each intervention, including the cost of  
11 personnel, staff training, materials, space, equipment, and administrative overheads, as well as  
12 the costs of the financial incentives. Data collection methods will include: (i) accounting for staff  
13 time using time and effort reports, (ii) accounting for computer time, mailing, and program costs  
14 using an accounting system that has been created to facilitate real-time aggregation of these  
15 costs, and (iii) using information gathered in the focus group with staff to determine the amount  
16 of time they devote to tasks related to the incentives intervention. All resources identified during  
17 the study will be valued using appropriate local and national unit cost data. The values used will be  
18 the most up to date at time of analysis, if unit cost data are obtained from more than one year  
19 then appropriate inflators will be used to transform costs into a common cost year.

20

21 The analysis will adopt a 'within trial' approach (i.e.; up to the 12 months follow-up point of the  
22 trial). The main outcome measure used in the economic analysis will be the study's primary  
23 outcome measure, lapse-free, biochemically validated smoking abstinence at 12 months  
24 postpartum. This will allow us to examine incremental cost per additional quitter. Multiple

1 imputation will account for missing data assuming data are missing at random, so that missingness  
2 can be predicted by other complete cases.

3

4 Costs and effects will be analysed using regression-based methods to allow for any differences in  
5 baseline characteristics. Incremental costs and effects will be reported. Additionally, if one group  
6 is more costly and more effective than the other we will report incremental cost-effectiveness  
7 ratios (ICERs). Non-parametric bootstrapping will be used to analyse uncertainty. Uncertainty  
8 inherent in the data will be represented by means of a cost-effectiveness acceptability curve  
9 (CEAC). Analyses will be performed using MS Excel, SPSS, and STATA.

10

#### 11 **Process evaluation analysis**

12 Full details of the process evaluation analysis are reported in Additional file 1.

13 The relationship between the quantitative and qualitative data will be examined [42].

14

#### 15 **Methods in analysis to handle protocol non-adherence and any statistical methods to handle** 16 **missing data {20c}**

17 We will use chi-squared tests to compare follow-up rates between the three study groups to  
18 establish whether there is differential drop out. We will then explore the effect of alternative  
19 assumptions about the pattern of missing data, through complete case analysis, and through using  
20 imputation methods [43].

21 We will report withdrawal from the intervention and from the study and reasons for withdrawal,  
22 where known.

23

24

1 **Plans to give access to the full protocol, participant level-data and statistical code {31c}**

2 This document is the full protocol. To access the participant-level dataset or statistical code.  
3 please contact the corresponding author (MU).

4

5 **Oversight and monitoring**

6 **Composition of the coordinating centre and trial steering committee {5d}**

7 The Chief Investigator (CI) will have overall responsibility for the study and its management. The  
8 Trial Management Group (TMG) at the University of Stirling, including the CI, a statistician, data  
9 manager and researcher, will be responsible for the day-to-day running of the trial, as well as  
10 overseeing data management and analyses. The TMG will meet as needed and will be supported  
11 by and report to a Trial Steering Committee (TSC). The TSC will have an independent chairperson  
12 and members but also include the TMG, other trial investigators and a representative of the  
13 funders. The TSC will meet every six months and more often if required. In addition, the site  
14 Principal Investigators (PIs) will meet with the Chief Investigator (CI) every three months to discuss  
15 progress. The CI will send a monthly newsletter, including recruitment and follow-up rates, to the  
16 TMG, to all co-investigators and to all site staff.

17

18 **Composition of the data monitoring committee, its role and reporting structure {21a}**

19 A separate Data Monitoring and Ethics Committee is not judged necessary, as we cannot envisage  
20 the intervention having the potential to harm participants.

21

22

23

24

1 **Adverse event reporting and harms {22}**

2 It is not considered necessary to record or report adverse events as the intervention being tested  
3 involves the offer of financial incentives (Loveshop vouchers) which could not be a contributory  
4 factor in adverse events.

5

6 **Frequency and plans for auditing trial conduct {23}**

7 The Trial Steering Committee will meet at least every six months to audit trial conduct and  
8 progress. This will include independent monitoring of: adherence to the study protocol; approving  
9 changes to the study protocol; reviewing quality assurance indicators; monitoring study  
10 recruitment and the overall timetable; advising, as required, on specific scientific items that may  
11 arise; compliance with legislation; adherence to research governance; reporting to funders; and  
12 approving publication and dissemination strategies.

13

14 **Plans for communicating important protocol amendments to relevant parties (e.g. trial  
15 participants, ethical committees) {25}**

16 Amendments will be approved by the research ethics committee and Health Research Authority.  
17 Funders, sponsors and NHS Research and Development Offices will be routinely informed of any  
18 amendments.

19

20 **Dissemination plans {31a}**

21 In addition to journal publications and conference presentations, we will develop a  
22 publication and dissemination policy and will discuss presentations and dissemination with  
23 relevant patient and clinical interest groups.

24

1 **Discussion**

2 At present, the majority of women who stop smoking in pregnancy return to smoking within 12  
3 months of the birth of their baby. In the UK, there is currently no standard offer of help to support  
4 relapse prevention and no interventions have been shown to be effective. Incentive payments to  
5 maintain abstinence from smoking may provide a substantial benefit by reducing harmful health  
6 consequences for the mother and child and thereby reducing long-term health care costs. The  
7 results of this definitive trial should provide sufficient data to determine whether it is effective to  
8 offer financial incentives to women to help them avoid relapse to smoking. This evidence will  
9 provide information required for NICE to consider recommending financial voucher incentive  
10 payments to support pregnant smokers across the UK to maintain abstinence from the smoking  
11 after the birth of their baby.

12  
13 **Trial status**

14 The FIPPS trial is currently recruiting in four UK centres/Hospital Trusts in Greater Manchester.  
15 Recruitment began in February 2019 and is due to end In August 2021, with follow-up completed  
16 by September 2022. The trial has a TSC which has convened five times. During COVID-19, due to a  
17 combination of lack face-to-face screening of women’s smoking status in pregnancy and reduced  
18 staffing due to illness or ‘shielding’, fewer women have joined the pregnancy cessation scheme  
19 than expected and therefore there has been a smaller pool of women to screen to join the trial.  
20 Thus, the trial is behind target and will not recruit the target of 900 women by August 2021. As of  
21 June 30<sup>th</sup> 2021, 424 participants have been recruited. Based on recent recruitment rates, we anticipate  
22 recruiting approximately 462 women by the end of August 2021. We do not have the resources to continue  
23 recruiting past this date. This has implications for the power calculations. Assuming N=154 in each of the

1 three study groups and effect sizes as estimated in the original sample size calculation, then the power for  
2 the three comparisons, all with an alpha threshold of 0.017, will be:  
3 60% power for 3-month incentives versus 12-month incentive group comparison  
4 82% power for the no incentives versus 3-month incentive group comparison  
5 100% power for the no incentives versus 12-month incentive group comparison

6  
7 The power for examining the significance ( $p < 0.05$ ) of a linear contrast across the three groups from  
8 control to 12-month intervention will be 100%.

9  
10 This article is based on protocol version V7.0, 16<sup>th</sup> November 2020. For the registered trial  
11 protocol and updates see <https://doi.org/10.1186/ISRCTN55218215>

### 13 **Abbreviations**

14 BCT: behaviour change technique; CEAC: cost-effectiveness acceptability curve; CI: Chief  
15 Investigator; CO: carbon monoxide; CONSORT: Consolidated Standards of Reporting Trials; CRF:  
16 case report form; GCP: Good Clinical Practice; GDPR: General Data Protection Regulation; GP:  
17 General Physicians; iCO: Bedfont single-person, self-administered carbon monoxide monitor;  
18 ICERs: cost-effectiveness ratios; NICE: National Institute for Health and Care Excellence; NHS:  
19 National Health Services; NRT: nicotine replacement therapy; PI: Principal Investigator; PIS:  
20 participant information sheet; ppm: parts per million; REC: Research Ethics Committee; RCT:  
21 randomised controlled trial; SOS: Significant Other Supporter; SSS: stop smoking service; TMT: trial  
22 management team; TSC: Trial Steering Committee (TSC);

23

24

1 **Declarations**

2 **Acknowledgements**

3 We would like to acknowledge Jane Coyne and Fran Franklin, representatives of the funders and  
4 managers of the Greater Manchester Smokefree Pregnancy programme, for their support and  
5 advice throughout the trial. We would also like to thank all local Principal Investigators and site  
6 staff for their commitment in recruitment for the FIPPS trial.

7

8 **Authors' contributions {31b}**

9 MU and LB conceived the study and were applicants for the funding. MU is the Chief Investigator.  
10 All authors contributed to the study design and to the development of the protocol. JM and MU  
11 led on process evaluation aspects of the protocol development. SL and CB are the trial statisticians  
12 and led the main analysis aspects of protocol development. All authors read and approved the  
13 final manuscript, adhere to the authorship guidelines of *Trials* and have agreed to publication.

14

15 **Funding {4}**

16 The trial was funded by the Greater Manchester Combined Authority (GMCA). The views and  
17 opinions expressed are those of the authors and do not necessarily reflect those of GMCA.

18

19 **Availability of data and materials {29}**

20 Any data required to support the protocol will be supplied on request to the CI (MU).

21

22 **Ethics approval and consent to participate {24}**

23 The trial has ethical approval from North West - Liverpool Central Research Ethics Committee,  
24 obtained on 11<sup>th</sup> January 2019 (18/NW/0838). Local NHS site recruitment approvals have all been



1 obtained. Written or verbal informed consent to participate will be obtained from all participants.

2

3 **Consent for publication {32}**

4 Not applicable

5

6 **Competing interests {28}**

7 On two occasions since 2008, TC has been paid to attend and present at symposia arranged by

8 Pierre Fabre Laboratories (PFL); PFL is a manufacturer of nicotine replacement therapy. All other

9 authors have no competing interests.

10

11 **Additional files**

12 Three Additional files are attached in PDF format:

13 Additional file 1: Details of the process evaluation.

14 Additional file 2: Award letter from the funder

15 Additional file 3: Letter of ethical approval

16

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