

# Trial of financial incentives for preventing postpartum return to smoking

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<b>Registration date</b> 05/07/2019	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 23/08/2024	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Offering financial incentives is one of the most effective ways of helping women to stop smoking during pregnancy. Unfortunately, most pregnant women who stop smoking are likely to return to smoking within 12 months of the infant's birth. There is no evidence for methods that are effective at preventing these high rates of return to smoking. Financial incentives provided after the birth may help women to remain abstinent from tobacco use. The aim of this study is to assess the effectiveness and cost-effectiveness of offering financial incentives to help women who are abstinent from smoking at the end of pregnancy to avoid returning to smoking during the 12 months after the birth.

### Who can participate?

Women at the end of their pregnancy who are confirmed as having stopped smoking during their pregnancy

### What does the study involve?

Participants are randomly allocated to one of three groups: (i) no financial incentives to remain abstinent; (ii) financial incentives for the participant of £60 for remaining abstinent from smoking up to 3 months postpartum, plus a further payment of £60 to a nominated supportive person if both that person and the participant remain abstinent (total of £120), or (iii) incentives as for (ii) plus further incentives for the participant of £60 at 6, 9 and 12 months after the birth (total of £300). The smoking status of all participants is assessed at 3 and 12 months after giving birth. Interviews with participants and a focus group with stop smoking advisers collect the experiences of and views on the incentives intervention and trial processes.

### What are the possible benefits and risks of participating?

The results will inform national and international policy on interventions for preventing postpartum return to smoking. For those women who are offered shopping vouchers, this may help them avoid a return to smoking and will help their health and that of their baby, now and in the longer term. All the methods of support and assessment during the study are very safe. If the researchers telephone and leave a message, it's possible that someone else could hear the message and find out that they are taking part in the study. The researchers will not leave a message unless participants say they can.

Where is the study run from?  
Four NHS Trusts in Greater Manchester (UK)

When is the study starting and how long is it expected to run for?  
February 2018 to August 2024

Who is funding the study?  
Greater Manchester Combined Authority (UK)

Who is the main contact?  
Prof. Michael Ussher  
mussher@sgul.ac.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Michael Ussher

**ORCID ID**  
<https://orcid.org/0000-0002-0995-7955>

**Contact details**  
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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**ClinicalTrials.gov (NCT)**  
Nil known

**Protocol serial number**  
<https://doi.org/10.17605/OSF.IO/NCKJ9>

## Study information

**Scientific Title**  
Three-arm randomised controlled trial of Financial Incentives for Preventing Postpartum return to Smoking: the FIPPS trial

## **Acronym**

FIPPS

## **Study objectives**

There are three hypotheses:

1. That an intervention offering twelve months of postpartum financial incentives will be significantly more effective for aiding smoking cessation up to 12 months postpartum than a no incentives condition.
2. That an intervention offering three months of postpartum incentives will be significantly more effective for aiding smoking cessation up to 12 months postpartum than a no incentives condition.
3. That an intervention offering 12 months of postpartum incentives will be significantly more effective for aiding smoking cessation up to 12 months postpartum than an intervention offering three months of postpartum incentives.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Approved 31/02/2018, North West - Liverpool Central Research Ethics Committee (3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ; Tel: +44 (0)2071048234; Email: nrescommittee.northwest-liverpoolcentral@nhs.net), ref: 18/NW/0838

## **Study design**

Randomized controlled trial

## **Primary study design**

Interventional

## **Study type(s)**

Prevention

## **Health condition(s) or problem(s) studied**

Prevention of smoking relapse in women following the birth of a child

## **Interventions**

The three groups are:

1. No incentives – postpartum care will proceed as usual.
2. Incentives will be offered up to three months postpartum. There will be three incentive payments of a £20 voucher. Each voucher payment will be based on self-report of not smoking a single puff of a cigarette since the birth and on expired CO validated confirmation of smoking abstinence (<8 ppm) at 1, 2 and 3 months postpartum.  
Significant Other Supporter payments: Participating women will also be given the option to identify and recruit a 'Significant Other Supporter' (SOS) (a member of their community who agrees to support the woman to remain smoke-free, including attending smoking cessation validation visits). The women's SOS will be offered an incentive of £60 if the woman achieves CO validated abstinence (<8 ppm) at 3 months postpartum and the SOS is also confirmed as abstinent (CO <8 ppm). The total value of incentives offered to group 2, including those offered to the participant and the SOS is £120.

3. Incentives will be offered up to 12 months postpartum. In addition to the incentives received by group 2, those in this group can receive a £60 voucher at 6, 9 and 12 months postpartum. Again, voucher payments will be dependent on CO confirmation of self-reported abstinence. The total value of incentives offered to group 3, including those offered to the participant and SOS is £300.

(added 15/10/2020)

In instances where it is not possible to conduct CO validation, due to COVID-19 restrictions, smoking abstinence will be by self-report alone.

### **Intervention Type**

Behavioural

### **Primary outcome(s)**

Current primary outcome measure as of 15/10/2020:

Smoking status at 12 months postpartum. Self-reports of having not smoked a single puff of a cigarette since the woman's last quit date in pregnancy will be confirmed by an expired CO reading of <8 ppm, and also by saliva cotinine (only among those reporting not currently using e-cigarettes or NRT) at 12 months postpartum.

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Previous primary outcome measure:

Smoking status at 12 months postpartum. Self-reports of having not smoked a single puff of a cigarette since the birth of the baby will be confirmed by an expired CO reading of <8 ppm, and also by saliva cotinine (only among those reporting not currently using e-cigarettes or NRT) at 12 months postpartum.

### **Key secondary outcome(s)**

Current secondary outcome measure as of 27/02/2024:

Self-report of smoking status at 3 months post-partum. Report of having not smoked a single puff of a cigarette since the birth of the baby will be confirmed at this time by an expired CO reading of <8 ppm. Where a CO reading is not available, (e.g., due to COVID-19 restrictions), self-report alone will be assessed.

Self-reported and CO-validated smoking abstinence two plus years postpartum.

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Previous secondary outcome measure as of 15/10/2020 to 27/02/2024:

Self-report of smoking status at 3 months post-partum. Report of having not smoked a single puff of a cigarette since the birth of the baby will be confirmed at this time by an expired CO reading of <8 ppm. Where a CO reading is not available, (e.g., due to COVID-19 restrictions), self-report alone will be assessed.

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Previous secondary outcome measure:

Self-report of smoking status at 3 months post-partum. Report of having not smoked a single puff of a cigarette since the birth of the baby will be confirmed at this time by an expired CO reading of <8 ppm.

**Completion date**

14/08/2024

## Eligibility

**Key inclusion criteria**

Current inclusion criteria as of 20/11/2020:

1. Confirms having not smoked a single puff of a cigarette for at least four weeks
2. Is between 34 weeks gestation and two weeks postpartum
3. Expired carbon monoxide (CO) reading
4. Aged at least 16 years
5. Intends remaining abstinent from smoking after the birth
6. Able to speak and read English
7. If participant needs to use a single-person, self-administered carbon monoxide (iCO) monitor, she needs to have a device (e.g., phone) that is compatible with the monitor app
8. Willing and able to give written informed consent for participation in the study

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Previous inclusion criteria as of 15/10/2020:

1. At a time between 34 weeks gestation and 2 weeks postpartum, reports having not smoked a single puff of a cigarette since their last quit attempt in pregnancy
2. Reports having not smoked a single puff of a cigarette for at least four weeks
3. If the woman needs to use a Bedfont single-person, self-administered iCO monitor (e.g., during COVID-19 restrictions on face-to-face contact), has a device (e.g. phone) that is compatible with using the iCO monitor app
4. Expired carbon monoxide (CO) reading < 4 parts per million (ppm)
5. Aged at least 16 years
6. Intends remaining abstinent from smoking after the birth
7. Able to speak and read English
8. Willing and able to give informed consent for participation in the study

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Previous inclusion criteria:

1. At 36 weeks gestation reports having not smoked a single puff of a cigarette since beginning a quit attempt during pregnancy
2. Expired carbon monoxide (CO) reading < 4 parts per million (ppm)
3. Aged at least 16 years
4. Intends remaining abstinent from smoking after the birth
5. Able to speak and read English
6. Willing and able to give informed consent for participation in the study

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

16 years

**Sex**

Female

**Total final enrolment**

481

**Key exclusion criteria**

Current exclusion criteria as of 20/11/2020:

1. Reports having smoked even a single puff of a cigarette within the last four weeks
2. Is less than 34 weeks gestation or more than two weeks postpartum
3. Expired CO reading >3ppm
4. Does not intend to remain abstinent from smoking after giving birth
5. Insufficient understanding of spoken and written English
6. Needs to use single-person, self-administered iCO monitor and does not have a device (e.g., phone) that is compatible with using the iCO monitor app
7. Unwilling and or unable to give written informed consent for participation in the study

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Previous exclusion criteria as of 15/10/2020:

1. At a time between 34 weeks gestation and 2 weeks postpartum woman reports having smoked even a single puff of a cigarette since her last quit attempt in pregnancy
2. Reports smoking even a single puff of a cigarette in the last four weeks
3. Does not have a device (e.g. phone) that is compatible with using the iCO monitor app
4. Expired CO reading > 3 ppm
5. Does not intend to remain abstinent from smoking after giving birth
6. <16 years old
7. Insufficient understanding of spoken and written English

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Previous exclusion criteria:

1. At 36 weeks gestation reports having smoked even a puff of a cigarette since commencing a pregnancy quit attempt
2. Expired CO reading > 3 ppm
3. Does not intend to remain abstinent from smoking after giving birth
4. <16 years old
5. Insufficient understanding of spoken and written English

**Date of first enrolment**

01/02/2019

**Date of final enrolment**

31/08/2021

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre****The Pennine Acute Hospitals NHS Trust**

Research and Innovation Department, Salford Royal NHS Foundation Trust,  
Northern Care Alliance NHS Group, Summerfield House, 1st Floor,  
544 Eccles New Road, Salford  
Manchester  
United Kingdom  
M5 5AP

**Study participating centre****Tameside and Glossop Integrated Care NHS Foundation Trust**

Tameside General Hospital  
Fountain Street  
Ashton-under-Lyne  
United Kingdom  
OL6 9RW

**Study participating centre****Manchester University NHS Foundation Trust**

Cobbett House  
Oxford Road  
Manchester  
United Kingdom  
M13 9WL

**Study participating centre****Bolton NHS Foundation Trust**

The Royal Bolton Hospital  
Minerva Road  
Farnworth  
Bolton  
United Kingdom  
BL4 0JR

# Sponsor information

## Organisation

University of Stirling

## ROR

<https://ror.org/045wgfr59>

# Funder(s)

## Funder type

Government

## Funder Name

Greater Manchester Combined Authority

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Michael Ussher ([mussher@sgul.ac.uk](mailto:mussher@sgul.ac.uk)) once the main findings of the trial have been accepted for publication for up to 10 years. The researchers will decide whether to share data on an individual basis depending on the aims of the research and subject to a data sharing agreement. Data will be pseudo-anonymised i.e., it will include ethnicity, age and gender.

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		16/04/2024	18/04/2024	Yes	No
<a href="#">Protocol article</a>		02/08/2021	19/08/2021	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Protocol (other)</a>		26/02/2024	27/02/2024	No	No
<a href="#">Statistical Analysis Plan</a>		18/05/2022	12/04/2023	No	No