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Trial of financial incentives for preventing postpartum return to smoking

Submission date 05/06/2019	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 05/07/2019	**Overall study status** Completed	[X] Statistical analysis plan [X] Results
Last Edited 23/08/2024	**Condition category** Other	[_] 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
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Contact information

Type(s)
Scientific

Contact name
Prof Michael Ussher

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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.

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.

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.

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
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United Kingdom
M13 9WL

Study participating centre
Bolton NHS Foundation Trust
The Royal Bolton Hospital
Minerva Road
Farnworth
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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) 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?
Results article		16/04/2024	18/04/2024	Yes	No
Protocol article		02/08/2021	19/08/2021	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol (other)		26/02/2024	27/02/2024	No	No
Statistical Analysis Plan		18/05/2022	12/04/2023	No	No