ISRCTN15236311 https://doi.org/10.1186/ISRCTN15236311

The smoking cessation in pregnancy incentives trial

Submission date
09/10/2017

Recruitment status
No longer recruiting

Registration date
13/10/2017

Overall study status
Completed

Last Edited
05/11/2024

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Current plain English summary as of 04/02/2019:
Background and study aims
Lifelong smokers lose 10 years of life. Smoking cessation by age 40 leads to a near normal lifespan. Eighty percent of women have a baby, most by age 40, making pregnancy an opportunity to help women quit before their health is irreversibly compromised. Few of the UK's current 130,000 pregnant smokers quit despite free counselling and Nicotine Replacement Therapy. Offering financial incentives for smoking cessation has worked in local single site trials including in Glasgow where the pilot study for this trial took place. The aim of this study is to examine the effectiveness and cost effectiveness of offering financial incentives in the form of shopping vouchers to pregnant smokers to engage with smoking cessation services, quit smoking during pregnancy and stay quit after pregnancy.

Who can participate?
Pregnant women (less than 24 weeks) aged 16 and older who smoke.

What does the study involve?
Participants are randomly allocated to one of two groups. All participants receive an offer to attend counselling sessions to help them stop smoking. Those in the first group receive a £50 shopping voucher if they provide data about their smoking late in their pregnancy and a £25 shopping voucher if they provide data six months after giving birth. Those in the second group receive the offer of up to £400 in shopping vouchers if they attend face-to-face counselling appointments and setting a quit smoking date. Participants are followed up to see if they have stopped smoking through questionnaires (confirmed by urine or saliva samples).

What are the possible benefits and risks of participating?
All the methods of support offered during the study have been shown to be very safe. Direct benefits of taking part include the 50% chance of receiving the financial incentive vouchers worth £400. However, only participants who manage to give up smoking will receive the vouchers. Giving up smoking will help the health of the woman and that of their baby in the short and longer term.

The results of the study will enable policy makers to determine whether financial incentives should be recommend for use in NHS smoking cessation services to help stop pregnant women from smoking.

Where is the study run from?
1. Wishaw General Hospital (UK)
2. Queen's University Belfast (UK)
3. Wessex England (UK) – Salisbury, Poole, Portsmouth, Isle of Wight, Dorchester

When is the study starting and how long is it expected to run for?
September 2017 to November 2020

Who is funding the study?
1. Cancer Research UK (UK)
2. Chest Heart and Stroke Northern Ireland (UK)
3. The Lullaby Trust (UK)
4. Public Health Agency for Northern Ireland (UK)
5. Scottish Government Chief Scientist Office (CSO) (UK)
6. Scottish Cot Death Trust (UK)

Who is the main contact?
Professor David M Tappin
david.tappin@glasgow.ac.uk

Previous plain English summary:
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5. Public Health Agency for Northern Ireland (UK)
6. Scottish Government Chief Scientist Office (CSO) (UK)
7. Yorkshire Cancer Research (UK)

Who is the main contact?
Professor David M Tappin
david.tappin@glasgow.ac.uk

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
CPMS 36323

Study information

Scientific Title
The Smoking Cessation in Pregnancy Incentives Trial: A multi-centre phase III randomised controlled trial

Acronym
CPIT III

Study objectives
The aim of this study is to conduct a pivotal phase III randomised controlled multi-centre trial to examine the effectiveness and cost effectiveness of offering financial incentives in the form of shopping vouchers to pregnant smokers to engage with smoking cessation services, quit smoking during pregnancy and stay quit after pregnancy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West of Scotland REC 4, 16/08/2017, ref: 17/WS/0173

Study design
Randomized; Interventional; Design type: Prevention, Other

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Smoking during pregnancy

Interventions
Current interventions as of 10/05/2018:
Participants are randomly allocated to either the intervention or the control group.

The intervention group and control group receive the offer of smoking cessation services support which includes a face to face counselling appointment (in some areas within individual trial sites, the face to face contact may be within pharmacy services). Participants in both groups receive a £50 shopping voucher if they provide data at the primary outcome time point (late pregnancy) and a £25 shopping voucher if they provide data at the secondary outcome time point (6 months post-partum). (If a participant does not provide primary outcome data, they are still able to receive a £25 shopping voucher if they provide secondary outcome data).

Intervention:
In addition, the intervention group receive the offer of up to £400 of shopping vouchers: £50 for

attending the first routine face-to-face counselling appointment at the smoking services support meeting and setting a quit smoking date, £50 if quit 4 weeks later verified by exhaled carbon monoxide (CO) at the accepted level for a non-smoker at the site, £100 if CO verified quit 12 weeks post quit date, £200 if CO verified quit at 34-38 weeks gestation.

Control group:
The control group receives the offer of smoking cessation services support which includes a face to face counselling appointment. They also receive a £50 shopping voucher if they provide data at the primary outcome time point (late pregnancy) and a £25 shopping voucher if they provide data at the secondary outcome time point (6 months post-partum).

Previous interventions:
Participants are randomly allocated to either the intervention or the control group.

The intervention group and control group receive the offer of smoking cessation services support which includes a face to face counselling appointment (in some areas within individual trial sites, the face to face contact may be within pharmacy services). Participants in both groups receive a £50 shopping voucher if they provide data at the primary outcome time point (late pregnancy) and a £25 shopping voucher if they provide data at the secondary outcome time point (6 months post-partum). (If a participant does not provide primary outcome data, they are still able to receive a £25 shopping voucher if they provide secondary outcome data).

Intervention:
In addition, the intervention group receive the offer of up to £400 of shopping vouchers: £50 for attending the first routine face-to-face counselling appointment at the smoking services support meeting and setting a quit smoking date, £50 if quit 4 weeks later verified by exhaled carbon monoxide (CO) <10 parts/million, £100 if CO verified quit 12 weeks post quit date, £200 if CO verified quit at 34-38 weeks gestation.

Control group:
The control group receives the offer of smoking cessation services support which includes a face to face counselling appointment. They also receive a £50 shopping voucher if they provide data at the primary outcome time point (late pregnancy) and a £25 shopping voucher if they provide data at the secondary outcome time point (6 months post-partum).

Intervention Type
Other

Primary outcome(s)
Self-reported abstinence from smoking for at least eight weeks prior to 34-38 weeks gestation verified by cotinine and/or anabasine in urine/saliva.

Key secondary outcome(s))
24/07/2020: Secondary outcome measures updated to include those items omitted in error at trial registration and thus correspond with the published protocol:
1. Engagement with smoking cessation services measured as having attended a first appointment with a Stop Smoking Service Advisor and setting a quit date before 26 weeks gestation
2. Biochemically validated (CO) self-reported abstinence from smoking at 4 weeks after quit date
3. Cotinine and/or anabasine verified self-reported continuous abstinence from smoking until 6 months after birth

4. Birth weight
5. Cost-effectiveness: incremental cost per late pregnancy quitter and cost per quality-adjusted life year (QALY) gained over the trial time horizon and lifetime using the EQ-5D as the measure of utility at baseline, primary and secondary outcome data collection follow-up time points
6. Process evaluation: barriers and facilitators to trial recruitment and future implementation of incentives in practice using a mixed methods longitudinal case study design informed by the realist evaluation approach
Data for the primary outcome and secondary outcomes 1, 2 and 4 will be combined with data from the feasibility trial in a meta-analysis

Previous secondary outcome measures listed:
Cotinine and/or anabasine verified self-reported continuous abstinence from smoking until 6 months after birth, birth weight, cost effectiveness (using the EQ-5D as the measure of utility) and process evaluation.

Completion date
30/11/2021

Eligibility

Key inclusion criteria
1. Self-reported smoker
2. >= 16 years
3. Pregnant less than 24 weeks
4. English speaking

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 years

Sex
Female

Total final enrolment
944

Key exclusion criteria
1. Non-smoker
2. <16 years
3. Pregnant > = 24 weeks
4. Non-English speaking

Date of first enrolment
01/02/2018

Date of final enrolment
04/04/2020

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Study participating centre
Wishaw General Hospital
50 Netherton Street
Wishaw
United Kingdom
ML2 0DP

Study participating centre
Queen's University Belfast
Royal Victoria Hospital
Grosvenor Road
Belfast
United Kingdom
BT12 6BJ

Study participating centre
NIHR Clinical Research Network, Wessex
C/O Amanda Pattie,
Assistant Portfolio Manager, amanda.pattie@nihr.ac.uk
University Hospital Southampton NHS Foundation Trust
Unit 7
Berrywood Business Village
Tollbar Way
Hedge End
Southampton
United Kingdom
SO30 2UN

Sponsor information

Organisation
NHS Greater Glasgow and Clyde

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Government

Funder Name
Cancer Research UK

Alternative Name(s)
CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
Northern Ireland Chest Heart and Stroke

Alternative Name(s)
Northern Ireland Chest Heart and Stroke’s (NICHS), Northern Ireland Chest Heart & Stroke, Northern Ireland Chest Heart & Stroke's, NI Chest Heart & Stroke's, Northern Ireland Chest, Heart and Stroke, nichestheartandstroke, NI Chest Heart & Stroke - Belfast, NICHS

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
Lullaby Trust

Alternative Name(s)
The Lullaby Trust, The Foundation for the Study of Infant Deaths, The Lullaby Trust Sales Limited, FSID

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
Public Health Agency

Alternative Name(s)
Public Health Agency (PHA), Public Health Agency (Northern Ireland), HSC Public Health Agency, publichealthni, PHA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Chief Scientist Office

Alternative Name(s)
CSO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Funder Name
Scottish Cot Death Trust

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. Trial participants give informed consent that the information collected about them will be used to support other research in the future and may be shared anonymously with other researchers. All the individual participant data collected during the trial, after de-identification, and the study protocol, SAP and data key describing each variable will be available. Other documents can be requested for consideration from the team. This data will be made available immediately following the main publications of the clinical effectiveness and cost-effectiveness findings with no end date. Requests may be made by researchers who provide a methodologically sound proposal for any purpose/analysis. Proposals should be directed to the Chief Investigators at David.Tappin@glasgow.ac.uk and linda.bauld@ed.ac.uk, and will be reviewed by the trial team. To gain access, data requestors will need to complete a data request form provided by York Trials Unit and sign a data confidentiality agreement.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		19/10/2022	20/10/2022	Yes	No
Protocol article		14/02/2020	17/02/2020	Yes	No
Protocol article		27/10/2020	21/09/2021	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Qualitative findings from a mixed-methods process evaluation	07/12/2022	06/01/2023	Yes	No
Other publications	Cost-effectiveness analysis and cost-utility analysis	15/03/2023	05/11/2024	Yes	No
Participant information sheet	version V1.4	01/08/2019	23/07/2020	No	Yes
Preprint results		22/06/2022	24/06/2022	No	No

Statistical Analysis Plan version 1.1	28/07/2021	21/09/2021	No	No	