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The cessation in pregnancy incentives trial

Submission date
21/07/2011

Recruitment status
No longer recruiting

Registration date
01/09/2011

Overall study status
Completed

Last Edited
25/07/2017

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
7 in 10 women have at least one baby, making pregnancy an opportunity to help most female smokers to quit before their own health is damaged. However less than 1 in 10 pregnant smokers make use of the offer of available support and only 1 in 30 smokers quit during pregnancy. Smoking can lead to:
1. 1 in 3 miscarriages and still births
2. Children who are less intelligent
3. Children who are more likely to have asthma
4. Children who have attention deficit hyperactivity disorder (ADHD)
5. Children who are more likely to develop cardiovascular disease as adults

Four trials in the USA have shown promising results and the use of incentives in Dundee, Scotland has led to an increase in the number of pregnant women accessing the smoking cessation (quit smoking) support available.

The results from this study will be used to design a larger study to confirm that financial incentives lead to increased uptake of smoking cessation services and/or more women quitting smoking during pregnancy. The larger study will also assess if the benefits to child and mother outweigh the extra cost of incentive voucher payments.

Who can participate?
All women who:
1. Self report as current smokers when routinely asked at maternity booking
2. Have a carbon monoxide breath test level greater than 6 parts per million
3. Are booked for maternity care in NHS Greater Glasgow and Clyde

What does the study involve?
This study will offer pregnant smokers:
1. Standard care (control group) which includes the offer of face to face support from a trained smoking cessation adviser followed by telephone support plus the offer of free nicotine replacement therapy (like nicotine gums, patches) provided by pharmacy services for up to 12 weeks to support a quit attempt.
2. Standard care plus the offer of voucher incentives (intervention group) to take part in cessation services and to quit. If smokers arrive for a face to face appointment with a cessation

adviser and set a quit date they will receive £50. If they have not smoked 4 weeks later (confirmed by a breath test) they will receive £50 and a further £100 if they have not smoked after 12 weeks. If they have not smoked when they are 34 to 38 weeks pregnant / near the end of pregnancy (confirmed by urine test) they will receive a final payment of £200.

What are the possible benefits and risks of participating?
Benefits:
1. Up to £400 in monetary vouchers
2. £1000 savings on cigarettes plus the health benefits to the mother and her unborn baby

Risks:
There are no risks to the participants

Where is the study run from?
The study will take place in the West of Scotland, United Kingdom

When is study starting and how long is it expected to run for?
Approximate start date will be late 2011 and the study will last approximately 2 years

Who is funding the study?
1. Chief Scientist Office Scottish Government
2. Glasgow Centre for Population Health
3. Yorkhill Children's Foundation
4. Royal Samaritan Endowment Fund
5. Director of Public Health Research and Teaching Endowment Fund

Who is the main contact?
Professor David Tappin
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Contact information

Type(s)
Scientific

Contact name
Prof David Tappin

Contact details
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Additional identifiers

Protocol serial number

V17.1

Study information

Scientific Title
The Cessation in Pregnancy Incentives Trial (CPIT): a phase II randomised controlled trial

Acronym
CPIT

Study objectives
By offering financial incentives to pregnant smokers more will engage with smoking cessation services and more will quit smoking during pregnancy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West of Scotland Research Ethics Committee 2, 25/05/2011, ref: 11/AL/0204

Study design
Phase II individually randomised parallel-group controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Smoking addiction

Interventions
The intervention group:
The offer of incentive payments for cessation during pregnancy will be delivered by the specially trained NHS Smoking Helpline staff towards the end of the second trial consent telephone contact call to participants who have been randomly allocated to the intervention group. A £50 store voucher will be sent by registered post if participants arrive for their first face to face appointment with the NHS Smokefree Pregnancy Service adviser and set a quit date; a further £50 voucher will be sent if they are self report abstinent 4 weeks after quit date corroborated by a routinely collected carbon monoxide breath test routinely taken by pharmacy services prior to dispensing of further Nicotine Replacement Therapy (NRT); a further £100 voucher will be sent if they are self report abstinent 12 weeks after quit date corroborated by either a routinely collected carbon monoxide breath test taken by pharmacy services prior to dispensing of further NRT; or a carbon monoxide test specially collected either in the Clinical Research Facility or by the research nurse at home; a final £200 store voucher will be given if the intervention client when contacted by NHS Smoking Helpline at 34-38 weeks gestation (about 6 months after their quit date) self report as abstinent and they then attend an appointment with the trial research nurse who collects a urine/saliva sample which is negative for cotinine, a nicotine metabolite. The intervention group will also receive the offer of standard smoking cessation support

starting with face to face support from an NHS Smokefree Pregnancy Service adviser followed by pharmacy dispensed Nicotine Replacement Therapy for women who decide to set a quit date and quit smoking.

The control group:
The control group will receive the offer of standard smoking cessation intervention with face to face support from an NHS Smokefree Pregnancy Service adviser followed by pharmacy dispensed Nicotine Replacement Therapy for women who set a quit date and quit smoking.

Intervention Type
Other

Phase
Phase II

Primary outcome(s)
Cotinine verified cessation at 34-38 weeks gestation towards the end of pregnancy

Key secondary outcome(s))
The cost effectiveness of the incentives intervention strategy. This phase II trial will examine the literature related to incentives for lifestyle change, develop data collection measures and systems for this phase II trial and then test them within a trial format. This will establish data collection systems so that cost effectiveness if present can be demonstrated with appropriate confidence in a future phase III trial

Other secondary outcomes
1. Engagement - 0-4 weeks after enrolment
1.1. If the participant arrives for a face to face appointment with the NHS Smokefree Pregnancy Service adviser and sets a quit date for smoking this will be marked 'yes'
1.2. If participant does not arrive at scheduled appointment or does not set a quit date will be marked 'no'
2. Quit at 4 weeks 4-9 weeks after enrolment
3. Available from routine 4 week telephone follow-up with the NHS Smokefree Pregnancy Service adviser
3.1. Answer yes I haven't smoked when asked not smoked even a single puff on a cigarette in the past 2 weeks. This will be marked as yes on the database
3.2. Not available for telephone follow-up. This will be marked as Not Available.
3.3. When asked not smoked even a single puff on a cigarette in the past 2 weeks answer no I have smoked. Database entry to quit at 4 weeks will be marked as no.
4. Birth weight of baby - The best methods to gather this data efficiently will be examined and tested.

Completion date
31/12/2013

Eligibility

Key inclusion criteria
1. 16 years and above
2. Female
3. Pregnant

4. English speaking
5. Referred to NHS Smokefree Pregnancy Service in Greater Glasgow and Clyde
6. Successfully contacted by NHS Smoking Helpline
7. Less than 24 weeks gestation at maternity booking
8. Carbon monoxide (CO) level 7ppm or greater at maternity booking
9. Self reported smoker at maternity booking
10. Permission given at first telephone contact to pass information to the Listening Company (NHS Smoking Helpline) for further discussion about the trial

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Not pregnant
2. Unable to provide informed consent
3. Non-English speaking
4. Not living in Greater Glasgow and Clyde catchment area or referred to Greater Glasgow and Clyde Obstetric Services
5. Referred pregnant smokers who cannot be contacted by NHS Smoking Helpline
6. CO level less than 7ppm at maternity booking
7. Not self reported smoker at maternity booking
8. Permission refused at first telephone contact to pass information to the Listening Company (NHS Smoking Helpline) for further discussion about the trial

Date of first enrolment
01/09/2011

Date of final enrolment
31/12/2013

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
PEACH Unit
Glasgow

United Kingdom
G3 8SJ

Sponsor information

Organisation
NHS Greater Glasgow and Clyde (UK)

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office (CZH/4/594)

Alternative Name(s)
CSO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Funder Name
Glasgow Centre for Population Health (UK)

Funder Name
Director of Public Health Education and Research Endowment Fund Greater Glasgow & Clyde Health Board (UK)

Funder Name
Yorkhill Children's Foundation (UK)

Funder Name
Royal Samaritan Endowment Fund (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	27/01/2015		Yes	No
Results article	results	26/08/2016		Yes	No
Results article	results	20/07/2017		Yes	No
Protocol article	protocol	20/07/2012		Yes	No