

Quitting smoking in pregnancy with the help of shopping vouchers

Information Sheet

We would like to invite you to take part in our research study. Before you decide if you want to take part, it's important that you understand why we're doing the research and what's involved. Please read this sheet and, if you want, talk to others before you decide.

If anything isn't clear or you want to know more, just ask. Our contact details are at the end of this sheet, and a study team advisor will call you in few days to answer any questions you might have.

What is the study about?

As you may know, the NHS can help people who want to give up smoking. Stop smoking services offer this help to everyone, including pregnant women who smoke.

However, only a small number of pregnant women take up this offer to help them stop smoking. The number of women who manage to give up smoking while they are pregnant is even smaller.

Research studies in the past have shown that pregnant women might be more likely to use stop smoking services if these services could offer people rewards like shop vouchers for giving up smoking. We call these rewards financial incentives. These studies also showed that using financial incentives might help more women to give up smoking while they are pregnant.

This study will try to find out how true this is by offering financial incentives to one group of pregnant women and comparing them to a second group who have not been offered incentives. We're hoping that just over 900 women will join the study.

Who is doing the research?

Researchers from the University of Glasgow and the University of Stirling, together with researchers from other UK universities.

NHS Greater Glasgow and Clyde (NHS GG&C) is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical record in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. NHS GG&C will keep identifiable information about you for 10 years after the study has finished.

Who is paying for the study?

Cancer Research UK
The Lullaby Trust
Scottish Cot Death Trust

Health and Social Care Northern Ireland
Chest, Heart and Stroke Northern Ireland
Chief Scientist Office Scotland

What treatment are you testing?

We are testing the offer of financial incentives to pregnant women to stop smoking. The financial incentives will take the form of shopping vouchers up to £400.

Why have you invited me?

Because you said at your maternity clinic appointment that you're a smoker.

Do I have to take part?

No, it's up to you if you want to take part or not. Taking part in a research study does not affect your rights in any way.

How do I take part?

Just wait until the study team telephones you . They will call you from 0800 376 9444. You may wish to store this number on your phone. The person who contacts you will explain all parts of the study and answer any questions you have. They will then take consent from you and enrol you into the study.

What will happen if I take part? What will I have to do?

After you have given your consent to take part you will then be placed into one of the two groups, the incentive group or the control group. The computer will select the groups randomly, so no one can choose which group you go into. You will have a 1 in 2 (50%) chance of being in the incentive group.

The study team will call you at certain points during your pregnancy and around 6 months after your baby is born to ask if you have managed to stop smoking.

If you have managed to stop smoking and are in the incentives group we will ask you to have a breath test, for carbon monoxide that comes from smoking cigarettes, each time before we can give you any vouchers. We will also ask you to give a small saliva or urine sample, or perhaps both, for the study nurse to test for chemicals from cigarette smoke. This will happen six months after you join the study, and six months after your baby is born.

If you have managed to stop smoking and are in the control group we will ask you to have a breath test for carbon monoxide that comes from smoking cigarettes and give a small saliva or urine sample, or perhaps both, for the study nurse to test for chemicals from cigarette smoke. This will happen six months after you join the study, and six months after your baby is born.

The shopping vouchers we will offer to each group are:

Incentive group

£50 voucher if you attend the first meeting with a smoking advisor and set a date to quit

£50 voucher if you are not smoking after 4 weeks, and this is confirmed by a breath test

£100 voucher if you are still not smoking after 3 months, and this is confirmed by a breath test

£200 voucher if you are not smoking in late pregnancy, and this is confirmed by a breath test

£50 voucher at the end of pregnancy to thank you for being in the study, whether or not you have quit smoking

£25 voucher six months after giving birth to thank you for being in the study, whether or not you have quit smoking

Control group

£50 voucher at the end of pregnancy to thank you for being in the study, whether or not you still smoke

£25 voucher six months after having the baby to thank you for being in the study, whether or not you still smoke

When you join the study we will ask if we can look at blood samples left over from other tests that you have as part of your normal pregnancy care. We call these residual routine blood samples, and we would like to use them to test if you have given up smoking or not if we can't contact you later on.

We will ask you to give your consent to us testing your blood in this way because it would give us better results, but you can still take part in the study if you don't want to do this.

How can we learn what you really think about the current study?

We would also like to contact you by telephone to find out what you feel about financial incentives and your experiences with the study itself. We will ask your permission to contact you by phone to discuss these issues. So that we can understand your views, we would like to audio-record the telephone discussions. If you decide you do not want to be contacted in this way we understand this completely. Not agreeing to this part of the study will not affect you taking part in the rest of the study or any other support you receive from the NHS stop smoking staff or the rest of the study team.

Who should I phone if I don't want any contact?

If you don't want us to contact you please telephone Lesley Sinclair, Trial Manager or Margaret McFadden, Research Nurse, at the Central Study Team number below.

Can I still get help to stop smoking if I don't take part in the study?

Yes. If you want to give up smoking you will be offered an appointment with an advisor from the [Click here to enter local stop smoking service](#). The advisor will help you with regular support and counselling, and talk about help like Nicotine Replacement Therapy.

Could taking part cause me any problems or risks?

If you take part it will use up some of your time.

If we telephone and leave a message, it's possible that someone else could hear the message and find out that you are taking part in a stop smoking study when you don't want them to. We will not leave a message unless you say we can. If you don't want us to leave any messages we will try calling again.

All the methods of support offered during the study have been shown to be very safe.

Could I benefit from taking part?

There is a 50% chance that we will be able to offer you financial incentive vouchers worth £400 if you manage to give up smoking during this pregnancy. Giving up smoking will help your health and that of your baby, now and in the longer term.

If I take part, will it be confidential?

NHSGG&C will use your name and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from NHSGG&C and regulatory organisations may look at your medical and research records to check the accuracy of the research study. [NHS site] will pass these details to NHSGG&C along with the information collected from you. The only people in NHSGG&C who will have access to information that identifies you will be people who need to contact you in relation to your care or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, or contact details.

NHSGG&C will keep identifiable information about you from this study for 10 years after the study has finished.

We will keep all information collected about you strictly confidential. This information will be stored in locked offices and on secure, password-protected databases that meet NHS

security standards. Some data will be collected and stored with the study contact centre outside the NHS. This will include your contact details in order to send you vouchers.

Authorised study team members will look at the information collected about you to carry out the research. Some of this information you will have told us and some will be collected from your hospital and NHS records. Authorised people from NHSGG&C (who is overseeing the study) may also look at the information to check that we are carrying out the study properly. Anyone who looks at your information will have a duty of confidentiality to you.

We will share your contact details and some personal information with the NHS stop smoking services. We will look at information that the NHS keeps about your pregnancy, and information kept by stop smoking services in the NHS and in pharmacies. We will use this information to work out the costs of different treatments, but this will not include your name or contact details. If you agree, we will let your GP know that you're taking part in the study.

If you consent we will store any left-over routine blood samples at the approved [Insert name of local Bio-repository]. We will also ask you for consent to look at routine information that the NHS collects about you and your baby in the future. You do not have to agree to either of these things. You can still be part of the study if you don't.

All the information we collect during the study will be stored at the University of Glasgow for 10 years after the end of the study and in line with relevant legislation. The information will be stored in a way that stops anyone from finding out who you are.

We will destroy all digital voice recordings at the end of the study. We will store typed copies of the recordings in a secure archive for five years, with names and personal details removed.

What if I change my mind after the study has started?

You can leave the study at any time without giving a reason.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you do decide to leave we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information by contacting the study Team – details below.

If you are not sure if you want to stay in the study please call the [Click here to enter local stop smoking service](#) and an advisor will speak to you.

What will happen when the study ends?

If you don't manage to stop smoking during the study you can still get help from NHS stop smoking services after it ends.

We would like to contact you after the study ends to see how you and your child are getting on. We will ask you about this when we call you. You can still take part in the study even if you don't want to be contacted after it ends.

What will happen to the results of the study?

At the end of the study we will publish the results of our research. No one will be able to identify you in any report or publication. Our findings will help the NHS and government to decide on the best way to support pregnant women who smoke.

Who has reviewed the study?

All research in the NHS is looked at by a Research Ethics Committee, an independent group of people who look out for your safety, rights, wellbeing and dignity during a study.

The West of Scotland Research Ethics Committee 4 has looked at this study and come back with a favourable opinion.

What if there's a problem or I need further information?

If you have concerns about any part of the study please contact a member of the study team – their contact details are at the end of this sheet. If you are still unhappy and want to speak to someone who's not part of the study, please contact:

Mrs Karyn Cooper
Unit Administrator
School of Medicine, Dentistry and Nursing
Queen Elizabeth University Hospital
1345 Govan Road
Glasgow, G51 4TF

Tel: 0141 451 5841

Email: karyn.cooper@glasgow.ac.uk

Or

[Click here to enter local NHS complaints team contact details \(please don't go over the page\)](#)

Contact details

Local study team

[Click here to enter name and title of local site co-ordinator](#)

Telephone: [Click here to enter site co-ordinator number.](#)

Email: [Click here to enter site co-ordinator email](#)

[Click here to enter name & title of local research nurse](#)

Telephone: [Click here to enter nurse number.](#)

Email: [Click here to enter nurse email](#)

Central study team

Professor David Tappin, Professor of Clinical Trials for Children, University of Glasgow

Professor Linda Bauld, Bruce and John Usher Chair in Public Health, University of Edinburgh

Lesley Sinclair, Trial Manager, University of Edinburgh

Margaret McFadden, Research Nurse, NHS Greater Glasgow & Clyde

Helen Tilbrook, Trial Co-ordinator, York Trials Unit

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Thank you for taking the time to read this information sheet

