

We would like to invite you to take part in our research study. Before you decide it is important for you to understand why the research is being done and what it would involve for you.

- Please take time to read the following information carefully and discuss it with others if you wish.
- Ask us if there is anything that is not clear or if you would like more information.
- Please take time to decide whether or not you wish to take part in the study.
- Thank you for reading this and considering taking part in our study.

Key points

- ✓ Who? Women overdue their smear
- ✓ What? An alternative test you can take yourself:
 - in private
 - no examination
 - no appointment

What is the purpose of this study?

Women who do not come regularly for cervical screening (smear tests) are more likely to develop cervical cancer. We want to find out if women who attend their GP surgery and are overdue their smear will take an alternative test which they can do themselves. The test is for human papillomavirus (HPV), a very common virus which can sometimes cause abnormal smears and even cancer. We have enclosed an HPV information leaflet in this pack in case you would like to read more.

We also want to find out if the women who have a positive test result will come for a follow up investigation.

Why have I been invited?

You have been invited to take part because you are at least 6 months overdue for your smear.

What will I have to do?

Firstly, please **complete** the lab request form, and check that your **contact details** are correct.

Next, you will need to take your sample following the instructions enclosed. The test is easy and painless to do and uses a vaginal swab (like a long cotton bud). You can choose to do it either in the bathroom at the GP surgery or at home.

You will need to return your sample **with** the lab request form for HPV testing (packaging instructions are enclosed). If you take your sample at the GP surgery, simply hand it to a staff member. If you take your sample at home, please put the sample in the freepost envelope provided and drop it in to any post box (no payment or stamps are needed).

Your test results will be sent to you (by the researcher) in the post within 2 weeks. A copy will also be sent to your GP.

If your test is negative you will not need to do anything further for the study. We would still encourage you to go for a smear but you can be reassured that your risk of having an abnormality on your cervix is low.



If your test is positive, you will be asked to go to your GP surgery for a standard cervical smear. If you have not attended for a cervical smear towards the end of the study, we will contact you with further advice and recommendations.

We would also like your permission to access your GP medical records. Only information relevant to the study will be accessed (eg the results of your cervical screening tests) and it will be collected using an automated electronic search.

What will happen to the sample I give?

After your sample has been tested and analysed it will be destroyed.

Do I have to take part?

It is up to you to decide whether or not you want to take part. If you do take part, you are free to withdraw at any time, without giving a reason. If you do not wish to take part, this will not affect your future care within the NHS.

What are the alternatives available?

The alternative is that you have a cervical smear taken by a doctor or nurse. This is a slightly better cervical screening test than the one used in this study.

What are the possible benefits of taking part?

Some women find it difficult to make an appointment for their smear because they or their GP surgeries are busy. Also, some women may find it uncomfortable or embarrassing to have a smear taken by a doctor or nurse. If you take part in this study you will be able to take a test yourself without the need to be examined or to make a GP appointment.

In other studies, some women who had not been for routine cervical screening and took a self-test were found to have abnormal cervical cells and were successfully treated.

What are the risks of taking part?

Women who have taken similar self-tests in studies performed by our research group have not reported any particular problems. However, it is important to know that the test alone does not protect you from cervical cancer. If your test result is positive we would recommend that you have a cervical smear taken by your GP or practice nurse.

What happens when the research project stops?

You will be asked to return your sample within a few days of being invited to the study. If you return your sample after the study ends, unfortunately we will not be able to test it. If you take part in the study and need to be followed up, your GP or the researchers will organise this for you.

What happens if there are problems?

This study has been reviewed and approved by the NRES Committee South East Coast - Brighton and Sussex Research Ethics Committee 13/LO/1441. If you have any concerns about the study, you should speak to the researchers who will do their best to answer your questions (0207 882 6154).

Is the information collected from me confidential?

All the information collected about you during the study will be kept strictly confidential.

What will happen to the results of the research study?

The results from this study will be used to help us plan a larger study of using this approach to screening in general practice. It is also hoped that we will publish the results in a medical journal to help increase knowledge.

If you would like to receive a copy of the study results, you can contact the study researcher Dr Anita Lim (see contact details overleaf) who will arrange this for you.

Who is organising and funding the research?

The study is being organised by the Centre for Cancer Prevention at Queen Mary University of London. It is funded by Cancer Research UK.

Contact details for further information

If you have any questions about the study or would like to find out more, please contact Dr Anita Lim:

Telephone	020 7882 6154
Email	a.lim@qmul.ac.uk.

Patient Information Sheet

Can we make cervical screening easier for you?

Human Papillomavirus (HPV) testing on self-collected samples to increase uptake of cervical screening in non-attenders: A pilot study within a primary care setting