The University of Manchester

Manchester University
NHS Foundation Trust

Alternative Cervical Screening (ACES) At Home

Participant Information Booklet

Alternative CErvical Screening

This study offers people who are overdue cervical screening the chance to be screened by urine or vaginal self-sampling.

You are being invited to take part in a research study looking at self-sampling for cervical screening. Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully before deciding whether to take part and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Contact details can be found at this end of this booklet. Thank you for taking the time to read this.

WHAT IS THE PURPOSE OF THIS RESEARCH STUDY?

This study will look at self-sampling as an alternative method for cervical screening. Cervical screening is also known as the 'smear test'.

Cervical screening can save lives from cervical cancer, yet only 7 in 10 people attend. People who do not attend screening regularly are at higher risk of cervical cancer.

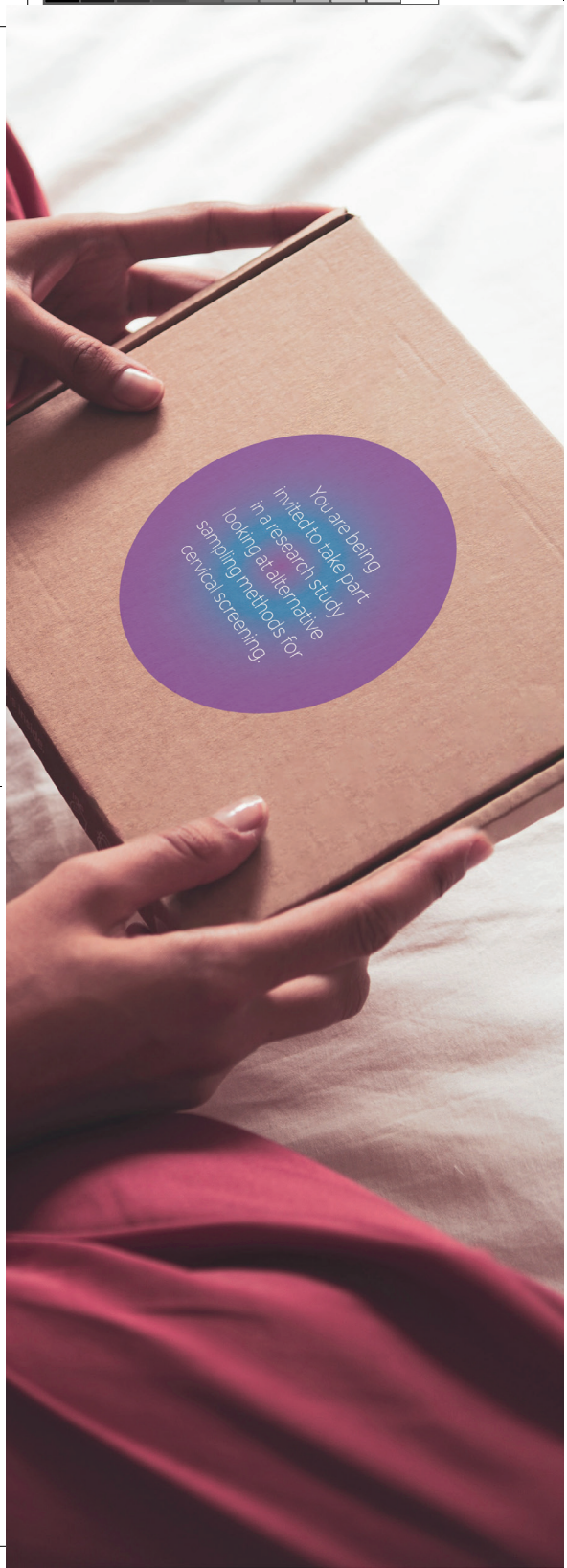
We are studying whether offering people the opportunity to take their own sample in the privacy of their home (known as self-sampling) will encourage more people to take up screening.

By taking part in this study, you will help us find out if self-sampling could be used in the NHS Cervical Screening programme in the future. Your participation could help prevent others from developing cervical cancer.

WHY AM I INVITED?

You are invited to take part because you are overdue cervical screening by six months or more.

Please DO NOT take part if you are up to date with cervical screening.



WHAT WOULD MY INVOLVEMENT IN THIS STUDY BE?

Taking part is entirely optional. If you take part, you will:

1

Request a self-sampling collection kit

You can choose between a urine or a vaginal self-sampling kit.
See page 8 for how to request a kit

2

Read and sign a consent form

to confirm you are happy to take part.

3

Collect a sample

in the comfort of your home.

4

Complete a questionnaire

about how you found the test, your previous experience of cervical screening and your background. The questionnaire is optional but would help us to understand how particular groups of people feel about cervical screening.

WHAT IS CERVICAL SCREENING?

Cervical screening, previously called 'a smear test' is a free health test available on the NHS as part of the national cervical screening programme. It helps prevent cervical cancer by checking for a virus called high-risk HPV. It is not a test for cancer.

80%

of people will get an HPV infection in their lifetime

WHAT IS HPV?

HPV (human papillomavirus) is a common virus. It is thought that 80% of people will have an HPV infection at some point in their lives. **HPV does not cause symptoms.** Most people will fight off HPV naturally (like we flight off a cold). However, sometimes, HPV can cause cells in your cervix to become abnormal and in some cases the abnormal cells can go on to develop into cancer.

WHY DO WE NEED SELF-SAMPLING?

Some people find having a sample taken at their GP practice a barrier to cervical screening. This can be for many reasons like embarrassment, discomfort, stress or lack of time. Self-sampling allows you to take a sample at your own pace in the comfort and privacy of your home and you can post the sample in any post box to the testing lab.

> **The results from this study will help the NHS decide whether home-based screening should become part of the cervical screening programme in future.**

IF I TAKE PART IN THIS STUDY SHOULD I STILL ATTEND CERVICAL SCREENING AT MY GP PRACTICE?

Yes. Taking part in this study does not replace cervical screening. In this study your sample will be tested for HPV for research purposes only. We will let you know the result, but we are not able to refer you for any further investigations. We encourage you to attend cervical screening at your GP practice after you have taken part in this study.

Taking part in this study will not affect your participation in the NHS cervical screening programme. You will still receive your screening invitations and you can attend as normal.

Cervical screening saves lives

HOW ACCURATE IS SELF SAMPLING?

Routine cervical screening picks up around 95 out of every 100 cervical pre-cancers. Vaginal self-sampling is already being used in some national screening programmes, including in Australia and the Netherlands. Urine self-sampling is a newer test and there is less evidence about how well it performs for cervical pre-cancer detection.

From what we know so far, vaginal and urine self-sampling may be slightly less accurate than routine cervical screening, picking up around 90 to 94 cervical pre-cancers out of every 100. Through ongoing research, we hope to understand the real world performance of the tests better and optimise the testing process to improve their accuracy.

No screening test is 100% effective. This is because HPV infection can sometimes be missed. If HPV is not found this does not guarantee that abnormal cells will never develop in the future.

Regardless of your research sample test result, we encourage you to go for routine cervical screening at your GP practice as this is currently the only way to get follow up treatment if needed.

HOW DO I TAKE PART IN THIS STUDY?

Taking part is easy!

The first step is to request a self-sampling collection kit.

Urine collection

Vaginal swab

You can choose between a urine or a vaginal collection kit which we will send to your home address.

The kit will include everything you need to collect a sample as well as a consent form, questionnaire and free return packaging.

To request a kit

you can complete the online request form. Scan the QR code.

You may also have received a paper request form which you can return to us using a pre-paid envelope.

HOW DO I TAKE THE SAMPLE?

If you choose a urine self-sampling kit, the sample would be collected by weeing into a funnel shaped container.

If you choose a vaginal self-sampling kit, the sample would be collected using a small swab, like a long cotton bud, which is inserted into the vagina and gently rotated for 10-30 seconds.

Most people find self-sampling easy and don't find it painful. Full instructions on how to collect the sample will be provided within the kit.

HOW DO I RETURN A SAMPLE?

You can return the sample using any Royal Mail post box. Pre-paid packaging is provided in the self-sampling kit.

You may receive a text, letter or email reminder if you have not requested a kit within 4 weeks of your invitation.

WHAT WILL HAPPEN TO THE SAMPLE I GIVE?

We will perform HPV DNA testing on your sample. The testing will take place at Manchester University NHS Foundation Trust. We will write to you and your GP with the results. The sample will be stored by Manchester University NHS Foundation Trust or in The University of Manchester laboratories until the end of the study under a unique study ID (not your name), after which time the sample will be securely destroyed. This study does not involve the use of laboratory animals.

HOW WILL YOU LET ME KNOW MY RESULTS?

We will write to you and your GP with the result of the HPV test. There are 3 possible results:

1

If your test is **negative,** it is unlikely that you carry HPV. However, as self-sampling is not officially recognised in the NHS cervical screening programme, we would still encourage you to book a routine cervical screening test with your GP.

2

If your test is **positive,** it means HPV has been detected and you may be at risk of cervical abnormalities. We would strongly encourage you to book a routine cervical screening test with your GP. This will confirm whether HPV is present, and a follow-up can be arranged to pick up and treat any abnormal cervical cells as soon as possible.

3

Occasionally a sample may be called **'inadequate'.** This may be due to a technical problem, for example, and does not mean your sample is abnormal. It is nothing to worry about. If this happens we will ask you to collect a second sample.

FREQUENTLY ASKED QUESTIONS

I AM PREGNANT CAN I TAKE PART?

If you are pregnant you cannot take part in this study. Please do not use the self-sampling kit.

I AM UP TO DATE WITH CERVICAL SCREENING, CAN I TAKE PART?

You cannot take part if you are up to date with cervical screening. Every woman or person with a cervix is invited for screening every 3 years (aged 25-49) or 5 years (aged 50-64).

HOW DO YOU GET HPV?

HPV is easy to catch. Many HPV types affect the throat, mouth and genital area. You can get HPV from vaginal, anal or oral sex; skin-to-skin contact of the genital area; and sharing sex toys. You may get HPV with your first or any subsequent sexual partner. It can stay in the body for a long time which means that you can still have an HPV infection even if you are not currently sexually active.

HOW DO WE PREVENT HPV?

Girls and boys are now offered the HPV vaccine as part of the school-based NHS vaccination programme. Vaccination does not protect against all the HPV types which cause cancer. Therefore, regular attendance at cervical screening is still recommended for those who have been vaccinated.

For more information on HPV, please visit: **https://www.nhs.uk/conditions/human-papilloma-virus-hpv/**

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

You will help us find out whether at home self-sampling is a good alternative to routine cervical screening, and whether it will encourage more people to be screened. Our results will help the NHS decide whether home-based screening should become part of the cervical screening programme. If you test positive for HPV, you may be more likely to attend cervical screening at your GP practice and if abnormal cells are identified, they can be treated to prevent cervical cancer.

WILL MY GP KNOW I AM TAKING PART?

Yes. We will inform your GP of the research sample test results.

WHAT ARE THE POSSIBLE DISADVANTAGES AND RISKS OF TAKING PART?

There are no expected disadvantages or risks of taking part. However, if you are worried about any aspect of the study, please contact the research team and we will be happy to discuss.

We advise that you keep the self-sample collection pack in a safe place, away from children.

Urine collection: If you choose the urine collection pack, the Colli-Pee® urine collection device included in the pack contains a small amount of preservative (liquid to protect the sample). You should not drink or pour out the liquid.

Vaginal sample collection: There is a very small chance that the swab could break while a person is taking the sample. However, this is very unlikely unless excessive force is applied to the swab. No one has reported this happening in any of our previous studies. In the unlikely event that the swab does break, it should be gently removed.

WILL I BE PAID ANY EXPENSES?

You will not receive any money for taking part in the study. We will cover the cost of posting your sample back to us by providing you with a pre-paid return package.

WHAT HAPPENS IF I DO NOT WANT TO TAKE PART OR IF I CHANGE MY MIND?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information booklet to keep and will be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time without giving a reason and without detriment to yourself. However, it will not be possible to remove your data from the project once it has been anonymised as we will not be able to identify your specific data. This does not affect your data protection rights. If you wish to withdraw, please get in touch with us using the contact details at the end of this booklet.

If you do not wish to take part after receiving your self-sampling kit, simply dispose of the collection kit with the household waste. The kit cannot be used by anyone else.

RESEARCH CONDUCT AND FUNDING

WHO WILL CONDUCT THE RESEARCH?

The research is sponsored by The University of Manchester. Professor Emma Crosbie, Dr Jiexin Cao and Dr Jennifer Davies-Oliveira from the Division of Cancer Sciences at The University of Manchester are leading the research in collaboration with Dr Alex Sargent at Manchester University NHS Foundation Trust.

WHO IS ORGANISING AND FUNDING THE RESEARCH?

This study is sponsored by The University of Manchester and funded by the National Institute for Health and Care Research, funder reference NIHR300650. The doctors and nurses involved in the study will not receive any payments for including you in the study.

WHAT IF SOMETHING GOES WRONG?

In the unlikely event that something goes wrong and you are harmed during the research you may have grounds for a legal action for compensation against The University of Manchester but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

WILL THE OUTCOMES OF THE RESEARCH BE PUBLISHED?

The result of this study will be published in a scientific journal, student dissertations and postgraduate theses. The research forms part of one or more student projects, including a MD thesis. We will share a summary with your GP practice to display on their websites where possible. You will not be identified in any publication. If you would like to obtain a summary of the result of this study, please get in touch.

WHO HAS REVIEWED THE RESEARCH PROJECT?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by London – Camberwell St Giles Research Ethics Committee, 24/LO/0385, IRAS project ID 321531.

DATA COLLECTION AND CONFIDENTIALTY

WHAT INFORMATION WILL YOU COLLECT ABOUT ME?

In order to participate in this research project we will need to collect information that could identify you, called "personal identifiable information". Specifically we will need to collect:

- Name, Address and Postcode – this is so we can send you a sample kit and the test results
- NHS number, date of birth and GP details – this is so we can inform your GP of the test results.

The above information is collected only if you complete the study consent form or request a kit. We will not use any identifiable data as part of the study analysis or in any publications.

We will also collect demographics: age, gender, sexual orientation, occupation, disability, ethnicity, deprivation score, education and the date of your last cervical screening test. This is collected so we can see what people from different backgrounds think of cervical screening.

This data will be stored under a unique ID number and not with your personal details. All data will be kept strictly confidential.

PEOPLE INVITED BY TEXT OR LETTER BY THE GP PRACTICE

If you have been invited to take part by your GP practice by letter or text, the GP practice will collect the following data: age (month and year of birth), postcode, ethinicity and date of your last cervical screening test. The data will be transferred securely to The University of Manchester. It will not include any identifiable data. Contact your GP if you do not wish your anonymous data to be shared.

UNDER WHAT LEGAL BASIS ARE YOU COLLECTING THIS INFORMATION?

We are collecting and storing this personal identifiable information in accordance with UK data protection law which protect your rights. These state that we must have a legal basis (specific reason) for collecting your data. For this study, the specific reason is that is is "a public interest task" and "a process necessary for research purpose".

WHAT ARE MY RIGHTS IN RELATION TO THE INFORMATION YOU WILL COLLECT ABOUT ME?

You have a number of rights under data protection law regarding your personal information. For example, you can request a copy of the information we hold about you. If this happens you will be informed by the research team. If you would like to know more about your different rights or the way we use your personal information to ensure we follow the law, please consult our Privacy Notice for Research. Link:

https://documents.manchester.ac.uk/display.aspx?DocID=37095

WILL MY TAKING PART IN THE STUDY BE KEPT CONFIDENTIAL AND MY PERSONAL IDENTIFIABLE INFORMATION BE PROTECTED?

In accordance with data protection law, The University of Manchester is the Data Controller for this project. This means that we are responsible for making sure your personal information is kept secure, confidential and used only in the way you have been told it will be used.

If you consent to take part, the study team will store your identifying information securely and separately from your study data. Your study data will be marked with an ID number and not your name. The key for linking your ID number to your identity will be accessible only to the small research team. Once all the data has been analysed, we will destroy the key, anonymising your data. At this point we will remove the ID number from your consent form using a secure, permanent redacting method. Your consent form and personal data (including your name and signature) will be retained separately for 5 years after the end of the study. Paper records are stored securely in locked filing cabinets on University premises. Electronic records are stored only in a secure restricted manner.

Your anonymised study data will be retained for 15 years. After this, the data will be destroyed in a secure manner. This includes data in both paper and electronic format.

Your study data will be analysed by statisticians at London School of Tropical Hygiene and Queen Mary London University who are collaborating with the project, but they will not be able to identify you.

Please also note that individuals from The University of Manchester, NHS Trust or regulatory authorities may need to look

at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data but all individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant.

With your consent your anonymised information will be shared with other researchers, here or at other organisation, in order to support additional research in accordance with the UK Policy Framework for Health and Social Care Research, https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/ This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of cancer prevention or gynaecological health, and cannot be used to contact you regarding any other matter. It will not be used to make decisions about future services available to you. If you would like more general information on how researchers use data about patients, please visit: www.hra.nhs.uk/information-about-patients/

WHAT IF I HAVE A COMPLAINT?

If you have a concern or complaint that you wish to direct to members of the research team, please use the contact details on the last page of this booklet.

If you wish to make a formal complaint to someone independent of the research team or if you are not satisfied with the response you have gained from the researchers in the first instance then please contact: Research Ethics Manager, Research Office, Christie Building, University of Manchester, Oxford Road, Manchester, M13 9PL. Email. **research.complaints@manchester.ac.uk** or Tel. **0161 306 8089**

If you wish to contact us about your data protection rights, please email **dataprotection@manchester.ac.uk** or write to the Information Governance Office, Christie Building, University of Manchester, Oxford Road, M13 9PL and we will guide you through the process of exercising your rights. You also have a right to complain to the Information Commissioner's Office about complaints relating to your personal identifiable information at **https://ico.org.uk/make-a-complaint/your-personal-information-concerns/** or Tel. **0303 123 1113**

CONTACT INFORMATION

For further study information please contact:

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