Participant ID:

Participant Information Sheet

UMON: Understanding the Human Papillomavirus and microbial environment in transgender and non-binary people with neovaginas; a feasibility study

You are invited to take part in a research study. To help you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Contact us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

Introduction

We would like to invite you to take part in a study that will help us better understand the anogenital health of transgender and non-binary people who have had vaginal construction procedures
Before you decide whether to take part it is important for you to understand the background to the study and why you have been asked to take part and what it involves (as detailed in this information leaflet).
In order to take part in the study we ask that you are able to understand the information in this leaflet and provide your consent by signing an informed consent form. We are looking to recruit a total of 20 people to this study.

What is the purpose of the study?

Microbes (including bacteria and viruses) infect the genital tract. Human Papillomavirus is an extremely common virus that usually clears naturally and it is thought that 80 in 100 people will get it in their life time. However, sometimes, persistent infection can cause abnormal changes to cells. We also know that certain bacteria provide a beneficial effect on the genital tract by preventing other viruses and bacteria, that can cause health care issues, from growing. We know a lot about the microbes that are present in the genital tract of cis-women. Comparatively, this information is lacking in trans and non-binary people who have had vaginal construction procedures (sometimes referred to as “neovaginas”). Also, we need more research to tell us what the best way of sampling neovaginas to detect microbes is.

This study aims to

- See if trans and non-binary people with neovaginas would be willing to take part in this type of research now and in the future
- Determine if a self taken sample is as good as a sample taken from a health care worker when trying to detect microbes in neovaginas

The study could help us understand and improve the health of future generations. It would

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also provide important information to help us design future, longer term studies that monitor the anogenital health of trans and non-binary people over time.

Why have I been invited to take part?

You have been invited because you access gender identity services as part of your standard care or have seen the study advertised by another organisation you are in contact with. The study is focussed on trans and non-binary people with neovaginas. If you decide not to take part we may ask you how you came to your decision but it's up to you if you want to tell us or not

Do I have to take part?

No, 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 sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive, or your legal rights.

What will happen if I take part?

We are trying to approach potential participants in different ways, a member of the clinical team may have contacted you by text and/or phone call to ask if you are interested in participating in the study; this will give you an opportunity to ask further questions about it**.** Alternatively a health care worker may have given you this leaflet when you attended a clinic. Finally you may have seen this study advertised via an organisation you interact with. You will be given enough time to decide on whether you would like to take part

If you do decide to participate, on the day of your next clinic:

1. a health care worker would ask you to complete and sign a consent form (you and the health care worker would go through this together)
2. a health care worker would take a vaginal swab from you , please note this would **not** require a speculum (a speculum is a device used to open up the vaginal canal)
3. you would be asked to take a self taken vaginal sample (a private bathroom facility would be made available for this).
4. you would be asked to complete a brief questionnaire which will include your opinions regarding studies like this
5. please note that half of the participants would be asked to take the self taken vaginal sample first. For the remaining half of the participants the first sample would be taken by the health care worker

Other than providing the samples and completing the questionnaire there is nothing else that will be asked of you. This is a "one visit" study. The study procedures should take no more than 10 minutes

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Is there anything I need to do or avoid?

It won't be possible to participate in the study if you have not had a vaginal construction procedure, you have had a vaginal construction procedure in the last 3 months, or if you have participated in another research project in the last 30 days

What will happen to my samples during the study?

Your samples will be transferred to an experienced laboratory team at the Royal Infirmary of Edinburgh and University of Edinburgh for processing and testing. The laboratory team would perform a Human Papillomavirus (HPV) test on the samples as well as tests that provide information on other bacteria that can colonise the vagina and those that can assess the quality of the material captured. Results between the sample taken by the health care worker and the self taken sample would be compared. The team at the laboratory would not have access to your personal information as your samples will be labelled with a study number rather than your name.

We will keep the results from your sample so we can analyse and report the findings. We would like, with your permission, to store any remaining sample that is not used for this study for future research around microbes in the vagina. To help us do this, we would store your remaining sample in an approved tissue bank. Your sample would only be used for additional research, not directly related to the study, if an independent committee approves the research. The samples would be stored without your name. Also, you can take part in the main study but opt out of your samples being stored for future research- in which case your samples would be destroyed.

What are the possible benefits of taking part?

You will not receive any direct benefit from taking part in the research. However, we hope that the information we get from the study will help trans and non-binary people in the future and help us improve methods of sample-taking.

What are the possible disadvantages of taking part?

The swab is soft tipped and should be gently rotated in the vagina so it is unlikely you will feel discomfort, but not impossible. Remember, participation in this is entirely voluntary so if you feel taking the swab would be challenging to take then there is no need to take part. As mentioned, this is a single visit study and the total time taken to provide the swabs and complete the questionnaire should be no more than ten minutes

What if there are any problems?

If you have a concern about any aspect of this study please contact Dr Kate Cuschieri: Kate.Cuschieri@nhs.scot who will do their best to answer your questions.

In the unlikely event that something goes wrong and you are harmed during the research

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and this is due to someone's negligence then you may have grounds for a legal action for compensation against NHS Lothian but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

What will happen if I don't want to carry on with the study?

If you originally agree to take part in the study and then decide to withdraw consent we will destroy the samples you provided for the project. If you consented for your samples to be biobanked we would ensure your samples were withdrawn from the biobank.

What happens when the study is finished?

The results are experimental and will be used only for the study; they will not and cannot influence or affect your care in any way. Therefore we will not provide participants with their results individually, however if you are concerned about your vagina then speak to the health care worker who will advise you. Also we will produce a study report which contains overall findings (please note this report could not identify you in any way) that we would be delighted to share with you.

We will keep the results from your sample so we can analyse and report the findings, samples and associated information would be stored in NHS premises for 5 years

We would like, with your permission, to store any remaining sample that is not used for this study for future research around microbes in the vagina. To help us do this, we would store your remaining sample in an approved tissue bank. Your sample would only be used for additional research, not directly related to the study, if an independent committee approves the research. The samples would be stored without your name. *Als*o, **you can take part in the main study but opt out of your samples being stored for future research- in which case your samples would be destroyed.**

Will my taking part be kept confidential?

All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard your privacy at every stage.

Your identity will be known to the local study investigators and team who will be supporting your care. However, no identifiable information (such as your name or date of birth, etc.) will be shared with anyone outside NHS Lothian. If you agree to your sample being stored for future research; it would not be stored with your name.

We hope to present the results at scientific meetings and in scientific journals, but no publication/report will ever contain information that could identify you.

How will we use information about you?

We will need to use information from your medical records for this research project.

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We will collect your Community Health Index (CHI) number or NHS number. Note that the CHI is a population register, used in Scotland for health care purposes. The CHI number uniquely identifies a person on the index and is personal identifiable information. Your CHI number or NHS number is being collected to check your records to make sure you are eligible for the study

In order to approach you to see if you are interested in taking part in the study the care team will collect some other personal identifiable information including name and date of birth. Name and date of birth will also be on the consent form which we will keep a copy of. If you wish to be contacted by the care team then we will collect your preferred means of contact (which may be postal address / post code/ telephone number / e-mail address). People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a study number assigned instead.

We will keep all information about you safe and secure in NHS Lothian

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we may keep information about you that we already have so that our records are accurate.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from **www.hra.nhs.uk/patientdataandresearch**
- by asking one of the research team
- by ringing us on 0131 242 6039

What will happen to the results of the study?

We hope to present the results at scientific meetings and in scientific journals

We will also create a summary report on the overall findings which we would be delighted to share with you

Please note that you will **not** be identifiable from any report or publication

Who is organising and funding the research?

This study has been organised by teams in **NHS Lothian** and **University of Edinburgh,** and sponsored by **them.**

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The study is being funded by **Chief Scientist Office (CSO).**

Who has reviewed the study?

The study proposal has been reviewed by the Chief Scientist Office

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. A favourable ethical opinion has been obtained from **West Midlands – Solihull Research Ethics Committee, REC No: 24/WM/0114**. NHS Management Approval has also been given.

Researcher Contact Details

If you have any further questions about the study please contact Dr Kate Cuschieri on 0131 242 6039 or email on: Kate.Cuschieri@nhs.scot

Independent Contact Details

If you would like to discuss this study with someone independent of the study please contact John Reynolds-Wright (email: John.Reynolds-Wright@ed.ac.uk)

Complaints

If you wish to make a complaint about the study please contact:

Patient Experience Team
2 – 4 Waterloo Place, Edinburgh, EH1 3EG
feedback@nhslothian.scot.nhs.uk
0131 536 3370