Participant information sheet

TransRIHTS: Trans & Non-binary Reference Intervals while on Hormone Therapy Study

IRAS Number: 284892

Chief Investigator: Dr Michael Brady

PART 1

We'd like to invite you to take part in our research study. Joining the study is entirely up to you, before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through this information sheet with you, to help you decide whether or not you would like to take part and answer any questions you may have. We suggest this should take about 15 minutes. Please feel free to talk to others about the study if you wish.

The first part of the Participant Information Sheet tells you the purpose of the study and what will happen to you if you take part. The second part will give you more detailed information about the conduct of the study. Please ask if anything is unclear.

What is the purpose of the study?

The purpose of this study is to find out the normal results for common blood tests in trans and non-binary people who have been taking hormone therapy for a year or more. These normal results are also called "reference intervals". Finding these out may allow doctors to diagnose diseases more accurately.

Why have I been invited?

You have been invited to take part in the study because you're trans or non-binary, and because you have been on hormone therapy for a year or more. All service users attending cliniQ at The Caldecot Centre who have been taking hormone therapy for a year or more are being invited. In total approximately 240 people are expected to take part.

Do I have to take part?

No, it is up to you to decide. We will describe the study and go through this information sheet, which we will then give to you. You will be able to keep this information sheet and think about taking part. You are free to discuss the information with anyone you wish including your family and friends. If you agree, we will then ask you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive.

What will happen to me if I take part?

If you agree to take part we will ask you to read and sign a consent form. Then we will ask you to complete a questionnaire about your hormone therapy and your health. We will also ask to measure your height and weight and for you to collect a urine sample. Your appointment with the health care team will be the same as it is normally. Clinic staff will collect the blood samples normally used for hormone monitoring, and no extra blood samples will be required. The blood sample will be used for the tests that are normally performed for hormone monitoring, and some

extra tests will be performed using the left-over blood. When the clinic sends you your test results, they will send the results of the extra tests as well. This study requires only one visit, and it should take no more than one hour.

What are the alternatives?

If you do not take part in the study, you will receive the service you attended the clinic for as normal, and have any testing which is normally carried out to monitor hormone therapy.

What are the possible benefits of taking part?

There will be no direct benefit from taking part in this study. The information we get from this study may allow doctors to identify disease faster, helping to improve healthcare for trans and non-binary people who are on hormone therapy.

What are the possible disadvantages and risks of taking part?

The extra laboratory tests performed for the study could lead to the discovery of health problems, although the discovery of serious health problems is not expected. The doctor who monitors your hormone therapy will be sent the results of the extra laboratory tests so they can tell you about any abnormal findings and act on them.

Who is organising and funding this study?

The doctor in charge of this study is Dr Michael Brady, Consultant in Sexual Health and HIV. The study is sponsored by King's College Hospital NHS Foundation Trust, and it is funded by Viapath, a company that provides diagnostic tests to hospitals.

Who has reviewed this study?

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 favourable opinion by the Greater Manchester East Research Ethics Committee. It has also been approved by the Health Research Authority, and King's College Hospital has also give confirmation that the study can go ahead.

Expenses and Payments

There are no funds available for payments to those participating in this study.

This completes Part 1 of the Information Sheet.

If the Information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

PART 2

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

You are free to withdraw from the study for any reason, and at any time, up until the publication of the study results. If you decided to withdraw on the day you participate, please tell a member of the healthcare team. If you decide to withdraw after that day, please contact Devon Buchanan (devon.buchanan@nhs.net). It will not be possible to withdraw from the study after its results have been published. Your decision to withdraw from the study will not affect the care you receive.

If you withdraw your consent, all information about you will be removed from the study.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to an investigator, who will do their best to answer your questions. Contact the investigator Devon Buchanan (devon.buchanan@nhs.net) or the chief investigator Michael Brady (michaelbrady@nhs.net, 020 3299 4535).

If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints procedure by contacting your local Patient Advice Liaison Service (PALS) office. Details of your local office can be obtained by asking the clinic staff, asking your GP, telephoning your local hospital or looking on the NHS choices website http://www.nhs.uk/pages/home.aspx

Every care will be taken in the course of this study. However in the unlikely event that you are injured by taking part, compensation may be available.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against King's College Hospital NHS Foundation Trust, but you may have to pay your legal costs.

Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff or about any side effects (adverse events) you may have experienced due to your participation in the study the normal National Health Service complaints mechanisms are available to you. Please ask clinic staff if you would like more information on this.

Will my taking part be kept confidential?

The information about you in this study will be kept secure. Information which can identify you will be stored in a locked filing cabinet in the Sexual Health Clinic at King's College Hospital. Anonymised information about your health will be stored on the secure hospital computer network. The only people who will have access to either of these are the investigators, and people who are responsible for checking that the research is being carried out correctly.

Anonymised data from this study will be made publicly available. This will include the information you record on the health questionnaire, and your test results, but it will not include any information which could be used to identify you. Making this data publicly available is important because it allows other researchers to check the quality of this study, and it can support other researchers, policy makers and medical laboratories in improving healthcare for trans and non-binary people. This does mean the data could be re-used by others without further ethics committee approval, it

could be used by commercial companies, and it could be used in other countries where people's privacy is protected less than in the UK. Therefore, your confidentiality will be maintained in by removing any information which could be used to identify you.

The data controller for this study is the sponsor, King's College Hospital NHS Foundation Trust. They are legally responsible for the security and validity of the information held under the Data Protection Act. The data custodian is the chief investigator, Dr Michael Brady, who will manage access to data.

If you consent to take part in the research, any of the information collected about you may be inspected by the sponsor (including representatives of the sponsor). These inspections are solely for the purposes of the research and analysing the results. Your records may also be looked at by the regulatory authorities or ethics committees to check that the study is being carried out correctly.

The organisations listed above will keep information about you confidential and secure. Your name will not be used in any reports about the study and all data is stored in accordance with the principle of the Data Protection Act 2018.

What will happen to any samples that I give?

The samples that you give will be destroyed after 3–4 days.

Which tests will be performed?

The urine and blood samples will be used for tests which provide information about your kidneys, liver, bones, cholesterol, and sex hormones, and which can detect anaemia and inflammation.

What will happen to the results of my tests?

We will ask you for your consent to send the test results and the results of the extra investigations to your GP. If you are happy for us to do this, we will send you and your GP the test results. If you do not want us to do this, we will send you these results, which you can forward to the doctor who monitors your hormone therapy. If you have investigations for other reasons (for example, sexual health testing) they will be communicated to you as normal. Abnormal results from the extra investigations are not expected, but if any are found, you will be given advice about them by Dr Michael Brady, Consultant in Sexual Health and HIV.

The investigators will collect the results of your hormone therapy monitoring today, and the extra investigations. The investigators will not look at any other investigations, or at your previous results. The data collected will be used to calculate the normal results for trans and non-binary people on hormone therapy.

What will happen to the results of the study?

The results of the study will be published in a scientific journal, and the data collected during the study will also be anonymised and made publicly available to encourage more research to improve healthcare for trans and non-binary people. The results will also be used to create a website to help doctors use the results in their everyday practice.

The results of the study will also be summarised in plain English for participants, and emailed to those who request it. The participant consent form has space for you to write your email address if you want to receive the results of the study.

None of the information placed in the public domain will contain information which could be used to identify you.

How we will use your data

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

This information will include your name, date of birth, and the number used to identify you at the Caldecot Centre. People will use this information to do the research or to check your records to make sure that the research is being done properly.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

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 will keep information about you that we already have.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

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

You can find out more about how we use your information:

- on the Health Research Authority website https://www.hra.nhs.uk/information-about-patients/
- at our website https://www.kch.nhs.uk/about/corporate/data-protection
- by emailing our Data Protection Officer on kch-tr.dpo@nhs.net

Thank you for considering taking part and taking the time to read this information sheet. If you decide to take part in the study, we will give you a copy of the information sheet and a signed consent form to keep.

Further information and contact details

- Local contacts for this study: Devon Buchanan, Reference Biochemistry, First Floor, Bessemer Wing, King's College Hospital, Denmark Hill, SE5 9RS. E-mail: devon.buchanan@nhs.net
- Information about taking part in research: NIHR Be Part of Research. Website: https://bepartofresearch.nihr.ac.uk/
- King's College Hospital Research and Innovation Department
  e-mail: kch-tr.research@nhs.net Tel: 020 3299 1980
- Trans and non-binary people's wellbeing and sexual health:
  cliniQ, Caldecot Centre, 15-22 Caldecot Road, London SE5 9R
  Website: https://cliniq.org.uk/ e-mail: admin@cliniq.org.uk Tel: 07545 143797