PrEP Impact Trial

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PARTICIPANT INFORMATION SHEET AND CONSENT FORM

PrEP Impact Trial: A Pragmatic Health Technology Assessment of PrEP and Implementation

We are inviting you to take part in a research project called the PrEP Impact trial. Before you decide whether to take part we would like 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.

- Part 1 tells you the purpose of this study and what will happen to you if you take part.
- Part 2 gives you more detailed information about the conduct of the study.

Ask us if there is anything that is not clear or if you would like more information.

Part 1

1. Why are we doing this study?

PrEP (HIV Pre-exposure Prophylaxis) is a medicine for HIV negative people. It can reduce the risk of catching HIV when taken as instructed. PrEP is made up of two drugs, Tenofovir and Emtricitabine.

Both these drugs have been widely used for many years to treat HIV. The drug has been used by several thousands of HIV negative people to reduce the risk of HIV.

PrEP is available in some countries. To plan a PrEP programme in England, NHS England and Local Authorities need to know how many people need PrEP, how many will want to take it and for how long. In order to find this out, we are conducting this research. Everyone who takes part will have access to PrEP.

The PrEP Impact trial will answer three important questions:

1. How many people attending sexual health clinics need PrEP?
2. How many of these start PrEP?
3. How long do they need PrEP for?

2. Why might I take part in this research?

You may benefit from PrEP as a way to reduce your risk of HIV. In order to take part you must be HIV negative.

You may not be able to take part if:

- You have an illness that could be due to HIV, you would need to wait until it has been confirmed that you do not have HIV.
- You are taking any other medication that might not interact well with PrEP.

3. What will I need to do if I take part?

During your first visit, you will have tests that are recommended for people who would benefit from PrEP. These tests include:

- HIV blood test
- Confirmation of your Hepatitis B status
- Blood and urine tests to check your kidney function
- STI and Hepatitis C screen
- Pregnancy test (if required)

Once the necessary tests have been completed, we will be able to prescribe up to 3 months' supply of PrEP

Some people will be able to take PrEP daily and some will be able to take PrEP less frequently. Your clinician will help you to make this decision and ensure you have the information you need to make the right choice for you.

If you are starting PrEP for the first time, the clinic may contact you within the first 4 weeks to see how you are getting on with the tablets. If you need to come back to the clinic for other reasons, this will be in-person. Otherwise a member of the clinic staff will contact you by phone or via email, whichever you prefer.

During the time you are taking PrEP you will need to visit the clinic every 3 months for an HIV test. At these visits it is likely that a test for other sexually transmitted infections is also needed. If you are still eligible to receive PrEP we can prescribe you up to a further 3 months' supply of tablets at each visit. If you have any concerns between visits about PrEP or your sexual health you are welcome to return to the clinic sooner.

After you have been taking PrEP for 12 months, you will also have a blood test to check your kidney function. The clinic staff will repeat this test every year whilst you are on PrEP.

You do not need to do anything more. All the information needed for the research (but not anything that could identify you) will be collected from routine reports and shared with the researchers. You will not have to make any extra visits to your clinic over and above those recommended for the care of PrEP users.

The research will go on for 3 years from when the first person starts. If you choose to take part in this research then you can continue to take part until the end.

You will have access to PrEP as long as you remain eligible i.e. you are at high risk of catching HIV. People's circumstances can change and your risk of catching HIV may change to. If you are no longer at a high risk of HIV, there is no benefit from PrEP. This does not mean you would be removed from the trial. The clinic staff would invite you to come back to the clinic at appropriate intervals so that your risk of HIV can be assessed. If your risk increases for whatever reason, you may be prescribed PrEP again to help reduce that risk.

4. What if I need to go to a different clinic?

If you need to go a different sexual health clinic for any reason, you should let the staff at the new clinic know that you are already enrolled on the PrEP Impact Trial. The staff will ask you for your trial ID, you can get this information from your copy of the consent form.

It is important that you do not enrol yourself at more than one sexual health clinic. There are limited places on the study, if you enrol more than once other potential participants may not be able to access PrEP.

5. Do I have to take part?

No. It is entirely up to you to decide. If you do not want to take part, that's OK. Your decision will not affect the quality of care you receive. There are other ways to help you to reduce your risk of HIV, and clinic staff will help you with this.

If you decide to take part you are free to withdraw at any time, without giving a reason, by letting the clinic staff know. It is very helpful to the research if you can give a reason, but you do not have to do this if you do not feel comfortable.

6. What are the possible disadvantages/risks?

The possible side-effects of the medicine you will be given will be explained by the clinic staff and are also provided in the information leaflet that comes with the medicine.

The majority of people taking PrEP do not report side effects. However, like all other medicines, PrEP has the potential to cause side effects. Mild nausea, diarrhoea, bloating and headache were reported in studies of PrEP in the first month by less than 1 in 10 people. These side effects then usually stop.

PrEP can also affect your kidneys which is why monitoring is important. In studies of PrEP, a small proportion of people taking PrEP developed reduced kidney function; these changes reversed on stopping PrEP. The risk is higher if you are older than 40 or if you already have reduce kidney function when you start PrEP.

PrEP can also reduce bone density (how much calcium and other minerals are in your bones) by 1-5% causing slight thinning of the bones. This loss reverses after PrEP is stopped. This side effect is more important if you already have low bone density related due to other factors. It might also be important if you are younger than 30 as your bones are still developing. So far there have not been any reports of bone fractures related to PrEP use.

Event based PrEP might reduce the risk of those side effects, though this has not been formally studied yet.

If you experience any unpleasant side effects, you should discuss these with the clinic staff and it may be that you need to interrupt or even stop PrEP. Your clinician will ask you if you take any other medicines to make sure they are safe to use with PrEP.

7. What are the possible benefits of taking part?

- Reducing your risk of catching HIV as a result of taking PrEP. The clinic staff will talk to you about other ways you could reduce your risk of HIV, as well as PrEP, and create an individual plan for you.
- The opportunity to contribute to the understanding of how PrEP can be best delivered in a public health programme.

8. What happens when the research stops?

At the moment, PrEP is not available on the NHS in England outside this study. We cannot provide further PrEP to participants after the trial stops. The findings from this study will help NHS England and Local Authorities make decisions about how PrEP could be provided in the future. It is anticipated that a national programme will be put in place and that PrEP will be available to all who are eligible.

9. Contact Details

You can ask the clinic staff any questions you may have about the study, or about taking PrEP. You can also access the study website which has further information and updates regarding the Impact study.

Local Study Doctor: **Dr Adele Wolujewicz**
Local Study Doctor Contact Details: **Adele.Wolujewicz@uhbw.nhs.uk**
Trial Website: www.PrEPImpactTrial.org.uk

Part 2

10. What if relevant new information becomes available?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, the clinic staff will tell you about it and it may influence your decision to stay on PrEP or to stay in the study.

11. What if there is a problem?

Complaints: If you have a concern about any aspect of this study, you should ask to speak with the study doctor or clinic staff who will do their best to answer your questions **(tel: 0117 342 6941).** If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital.

Compensation: If you suffer any injuries or complications as a result of this study, you should contact the study doctor or clinic staff as soon as possible and you will be assisted in arranging appropriate medical treatment. If you require any more information concerning the trial and your rights and obligations as a clinical trials participant you should contact the local Patient Advice and Liaison Services (PALS) team.

12. What will happen to the results of the research study?

The study results will be presented at international research conferences and published in research journals. The results will be reported in a Clinical Study report which will be sent to the Ethics Committee. You will not be identified in this report, if reference to you is made this will only be done using code numbers

A summary of the results of this research will be made available to all those taking part who would like to receive this. The results will be shared with your clinic and also made available on the research website. For further information or a lay summary on the results of the study, please contact the study doctor at your clinic.

13. Will my taking part in the study be kept confidential?

Yes, all records that identify you will be kept confidential.

If you consent to take part in the study, your medical records and data collected electronically may be looked at by authorised persons from the organisation sponsoring the research. They may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant; we will do our best to meet this duty. Your name will not be disclosed outside the hospital. You have the right to access your medical records if you would like to. For more information, please consult your study doctor.

This permission to share your personal health information for this study does not have an expiry date. If you no longer want to share your personal health information, you may cancel your permission at any time by writing to the study doctor/clinic staff

14. What will happen to information collected about me during the study?

Chelsea and Westminster Hospital NHS Foundation Trust is the sponsor for this study based in England, and is the Data Controller. The Data Controller is responsible for looking after your information and using it properly. We will be using your clinic number to collect coded information from your medical records in order to undertake this study, and a minimum of personal information (your date of birth and a code of your surname).

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 withdraw from the study, 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.

Public Health England collects data from sexual health clinics in England to help identify outbreaks, understand the amount of sexually transmitted infections in the population and better understand who is at risk of getting infections. These data are used to help plan services. This data does not include your name or address but it does include a clinic identification (ID) number so they know if the same person attends more than once.

If you consent to take part in this study, the researchers will use this data that is already submitted to Public Health England. This data will summarise the tests taken at each visit, the results, your gender and your date of birth. They will know which local authority you live in, but not your actual address. They will also know your sexual orientation and ethnic group. They will use this information and what we know about your PrEP use to understand how PrEP will be used in practice and to plan a national PrEP programme.

15. Who is organising and funding the research?

The trial is organised and sponsored by Chelsea and Westminster Hospital NHS Foundation Trust. They have legal responsibility for the trial.

Public Health England has partnered with Chelsea and Westminster Hospital NHS Foundation Trust and will be providing important information and expertise to help deliver the trial.

The research is funded by NHS England; they are also responsible for obtaining the drug for the trial.

16. Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a research ethics committee; this is to protect your rights, safety, dignity and well-being. This study has been reviewed and approved by the London - Hampstead Research Ethics Committee.

Thank you for reading this information sheet and for considering taking part in this research

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INFORMED CONSENT FORM

Study Title:	PrEP Impact: A Trial of Eligibility, Uptake and Duration		
Short Title:	Impact		
Sponsor	Chelsea and Westminster Hospital NHS Foundation Trust		
Protocol Number:	SSCR104		
Site Number:	RA7CQ	**Principal Investigator:**	Dr Adele Wolujewicz

Trial ID Number:	

Please initial box

1. I confirm that I have read and understand the information sheet (version 3.0,19 Jun 2018) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that relevant sections of any of my medical notes and data collected during the study may be looked at by responsible individuals from Chelsea and Westminster Hospital NHS Foundation Trust, Public Health England and NHS England, Research Ethics Committees or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐
4. I agree to take part in the above study. ☐
5. I understand that I will be given a signed copy of this document to keep. ☐

Name of Participant (print) _____

Signature _____ Date _____

Name of Healthcare Professional (print) _____

Signature _____ Date _____

When completed, three copies are to be obtained - 1 for participant; 1 for site file; 1 (original) to be kept in medical notes