



Chelsea and Westminster Hospital 
NHS Foundation Trust



Participant Information Sheet for the PROUD Study: New Information about treatment being studied

Pre-exposure Option for reducing HIV in the UK: an open-label randomisation to immediate or Deferred daily Truvada for HIV negative gay men.

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PARTICIPANT-RELATED INFORMATION

PARTICIPANT INFORMATION SHEET (PIS) REGARDING NEW INFORMATION AND EXTENDED FOLLOW-UP

ACRONYM (or Short Title of Trial)	PROUD
Protocol Version	1.3
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PIS Version	1.0
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Thank you for taking part in the PROUD study!

In the participant information leaflet that you were given before you joined the study, we explained that the PROUD study is looking at whether using a daily tablet can reduce the risk of HIV transmission for gay and other men who have sex with men. It also looks at how taking a daily tablet may affect other risks and behaviour. Everyone in the study is supported to reduce their risk of HIV in other ways. On joining the study, some people were asked to take a tablet from the start, and others after 12 months.

New information has come to light which has an impact on the design of the study. As a result, we would like to offer all participants daily oral Truvada to use as pre-exposure prophylaxis through to the end of the study.

This information sheet is supplemental to the original information sheet you signed at the start of the study.

Part 1: The new information

1. A reminder of the aim of this study

This study is looking at a new way to reduce the risk of catching HIV.

This involves HIV negative men taking a daily tablet that includes two drugs commonly used to treat HIV. Taking a tablet to reduce risk of infection is called Pre-Exposure Prophylaxis, or PrEP. Prophylaxis refers to doing something to prevent an illness or infection.

Studies in other countries have already shown that PrEP significantly reduces the risk of catching HIV when taken consistently. This is the first study of PrEP for gay men in the UK.

Although PrEP helps to reduce the risk of HIV, this study also looks at other factors that could be important, including:

- Whether people using PrEP change the number of partners they have sex with
- Whether people using PrEP change how often they use condoms
- Whether the impact of PrEP on sexual behaviour leads to higher rates of other sexually transmitted infections (STIs).

This information on changes in sexual activity is one of the most important aspects of the study, because we do not know what happens to people's sexual activity when they know they are taking PrEP. **It's possible that the changes may increase the overall risk of catching HIV, so that PrEP is less effective.** To find out if this is the case we need to be able to compare a group that is taking PrEP to a group that is not taking PrEP. This is why half the participants in PROUD were offered PrEP from the beginning (immediate PrEP) and half were offered if after they have been followed up for 12 months (deferred PrEP).

At the outset we anticipated that a very large study of about 5,000 men would be needed to find out the impact of PrEP on sexual behaviour and HIV infection. The main aim of the PROUD pilot study was to find out if it would be feasible to conduct a much larger study in the UK.

2. Progress of the study and new information

Although the study was slow to recruit in the first six months, 545 participants were enrolled by 30 April 2014 when the study closed to enrolment. Two committees have been reviewing progress during the study, the Trial Steering Committee and an Independent Data Monitoring Committee.

The Independent Data Monitoring Committee is the only group that can compare the HIV infections between the 'immediate PrEP' and 'deferred PrEP' groups.

Following a review on the 6th October, this committee observed that Truvada is highly effective against HIV and has recommended that PrEP be offered to participants in the deferred PrEP group as soon as possible, and that every effort be made to provide continued access for all participants until the end of the study.

3. What does this mean for me?

If you are in the deferred PrEP group and still in your first 12 months of follow-up, you will be offered PrEP. You do not have to start PrEP if you do not want to, and if you do start there is no obligation to continue taking it. For example, your circumstances may change and you may no longer feel you need this additional risk reduction option.

We will ask everyone to continue to have three monthly checks of HIV and for sexually transmitted infections including hepatitis C in the annual screen. These can be conducted at any clinic in the sexual health network, at your convenience. The study team will need to know the results before they can issue a prescription for PrEP and you will only be able to collect PrEP from the study clinic. Some clinics may be able to post drug to you, but only in exceptional circumstances. You will need to physically attend a study visit at least once a year.

It is important that we check your kidney function. We will do this at the annual study visit, but inbetween we would like to know if there is any protein in your urine when it is tested in clinic, as this may mean that you need further investigation.

We will collect an additional blood sample (approximately 5-10ml) from some participants to measure levels of the PrEP drugs. We will give you these results to give you an idea of the level of active drug in your blood. We may also store these samples for testing later.

Participants who are already using the online database to complete diaries and monthly questionnaires can continue. However, many participants have experienced technical difficulties or found it difficult to remember to go online. As a result we will be collecting the questionnaires in clinic from everyone when they visit. If you do not physically attend the study visit, then we will ask you to complete the questionnaire when you collect your drugs and put it in the envelope provided.

Remember that PrEP is only one of the ways to reduce HIV risk.

The study teams will encourage you to focus on the things you would like to change to protect your health, and organise referrals for additional support where this is needed.

This plan could include a combination of:

- * Individual, couple or group counselling at a local clinic or community organisation. This is where you can talk to a trained health worker about things in your life that are related to the decisions you take about your health.
- * Motivational interviews or psychotherapy, in person, or possibly online. This is where you can talk about ways to help stick to goals and why this is often difficult.

4. Do I have to continue in the study?

Whether you decide to continue in the study is entirely your choice. You may withdraw your consent to participate at any time without giving any reason and without affecting your future care. If you are happy to tell us the reason, this could help us to improve the study. If you choose not to continue to take part then your doctor will explain the best standard treatment available.

Whether or not you continue the study will not affect your medical care, although PrEP may not be available outside the study because it is not yet available in the NHS. If you leave the study, we hope you will still continue with the HIV testing and screening for STIs.

You can also remain in the study but decide to no longer take PrEP. This would be something to consider if your circumstances change and you stop being at risk for catching HIV. In this case, you would still remain in the study and continue to fill in the questionnaires on sexual activity and have HIV testing and screening for STIs. At each clinic visit, your clinician will discuss your

circumstances with you in case you would like to recommence taking PrEP. Continuing to provide your data for the study is valuable to the analysis, even if you have stopped taking PrEP.

5. Will I still get PrEP after the study ends?

At the moment PrEP is not available on the NHS outside this study. A policy group has been established and the PROUD result provides very strong evidence to support PrEP provision. We cannot promise you will be able to access PrEP in clinic at the end of the study but we are working hard towards this goal and we will keep you up to date with developments via the study website and when you come to clinic.

6. Who should I talk to if I have more questions?

If you have any other questions your doctor or the researcher at the clinic should be able to answer them.

Some community organisations provide confidential information services to talk about whether a study is right for you.

These include:

- THT direct: 0808 802 1221
- i-Base treatment information phoneline: 0808 800 6013

Once you have asked any questions you want to ask, you will be asked to confirm, by signing a new consent form, that you have received this information, and whether or not you are happy to continue in the study.

Thank you for taking the time to read this information sheet and considering continued follow-up in the PROUD study.