



Examining the impact on gay men of
using Pre-Exposure Prophylaxis (PrEP)



PROUD study interim analysis finds pre-exposure prophylaxis (PrEP) is highly protective against HIV for gay men and other men who have sex with men in the UK

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An interim analysis of the PROUD study data has shown that pre-exposure prophylaxis (PrEP) is highly protective against HIV for gay men and other men who have sex with men (MSM) at high risk of infection. On this basis, the PROUD Trial Steering Committee has announced that participants currently on the deferred arm of the study, who have not yet started PrEP, will be offered the opportunity to begin PrEP ahead of schedule.

PrEP involves HIV-negative people taking antiretroviral drugs (that are usually used to treat HIV) to reduce their risk of becoming infected if they are at high risk of exposure to the virus. Placebo controlled trials have already shown that PrEP works to protect against acquiring HIV and that protection is best when the daily tablet is taken consistently. Currently PrEP is only available in England through the PROUD study. There are still a number of outstanding questions about real-life effectiveness and the costs of implementing PrEP in the UK:

- Does PrEP reduce HIV, taking account of changes in risk behaviour and adherence?
- Are most-at-risk UK MSM interested in PrEP as additional protection against HIV?
- Will they take the tablets regularly enough to protect themselves?
- What effect will taking PrEP have on their sexual risk behaviour?
- Will resistance be a big problem in any breakthrough HIV infections?
- Will PrEP be cost-effective in the UK?

The PROUD study was designed as a pilot to find out if it would be feasible to conduct a larger study to answer these questions. The fact that the study has been able to address this question after enrolling only 545 MSM implies that PROUD recruited men at higher risk of HIV than expected, and the level of protection from PrEP was high.

The PROUD study includes HIV-negative gay men, other men who have sex with men, and transgender women, who reported having anal sex without condoms recently. Each participant was randomised to either start PrEP (a daily Truvada tablet) straight away (the immediate arm), or after 12 months in the study (the deferred arm). All participants are offered regular testing for HIV and sexually transmitted infections, condoms and safer sex support.

The exact number of HIV infections that PrEP prevented is not yet known. PROUD clinics are aiming to have follow-up visits (including HIV tests) with all trial participants by the end of the year, which means results will be available early in 2015. Participants who have lost touch with their clinics are urged to get back in contact. The Independent Data Monitoring Committee, who reviewed the interim data from the trial, is confident that this follow-up will not change the overall conclusion of the trial, but will provide greater accuracy in the results. Continued follow-up of participants will also allow the PROUD study to answer questions about longer-term adherence, changes to risk behaviour and drug resistance.

This result is a major step forward towards the control of HIV transmission in gay men in the UK. It shows that PrEP is highly effective at protecting against HIV, and is an exciting opportunity to engage men most-at -risk of HIV and turn the tide on the spread of this infection. The final results will provide evidence to support making PrEP available in the NHS. It also paves the way for future research to identify other PrEP regimens that may be even easier to adhere to or have even fewer side-effects.

If you require further information:

PROUD participants: please speak to your clinic

Media enquiries: MRC Press Office press.office@headoffice.mrc.ac.uk 020 7395 2345

Other enquiries related to PrEP: your local sexual health clinic can provide advice on how to reduce your risk of HIV