

PrEP: Next Step?

PROUD, the UK study using daily Truvada (tenofovir/emtricitabine) as Pre-Exposure Prophylaxis, (PrEP) for HIV prevention is finding volunteers slow to come forward. Application for a larger (5,000 man) study of PROUD has been put on hold, to see if interest in the current pilot study picks up. According to the PROUD website, 500 HIV negative men who have sex with men (MSM) are required. Since recruitment started in November 2012, 147 have joined the study, but the team were hoping for 225 by the end of June. A lack of awareness of PrEP is cited as a stumbling block to recruitment - one of the aims of the trial is to assess the interest among gay men to use PrEP.

"Although recruitment has picked up, we are still substantially behind target," says Sheena McCormack one of the lead investigators for the study. "I worry that we will end up concluding PrEP is a tool of no interest when we haven't given it a fair shot. I firmly believe we can promote condoms and PrEP together in a responsible way, and if we don't rise to this challenge we are failing the breadth of the sexually active community in the long term, but especially gay men right now!"

The design of PROUD is that participants are randomly split into two groups - half of the men that enrol on the study will have access to PrEP immediately, the other half will not have access to PrEP for the first year of the two year study. Everyone will be given access to condoms and safer sex advice. (See the PROUD website www.proud.mrc.ac.uk for the full protocol). One of the major aims of the study is to see whether PrEP changes people's sexual activity and puts up their risk of HIV as a result.

Participants are asked to keep a short diary, fill out a monthly questionnaire online and attend a clinic every three months. Other studies have shown that PrEP is effective but not completely in preventing HIV transmission, with levels of protection varying generally according to adherence to the pills.

The reason for the study design, say investigators, is to check that PrEP can be used safely and responsibly in the UK. There are universal concerns expressed around PrEP promoting unsafe sex and a consequent increase in STIs - this can only be assessed when men know they are taking an active group, and by comparison to men who are not taking drug - hence the PROUD trial design. Community concerns and input are being continually sought to see if these are changing as the awareness and demand for PrEP grows..



Professor Sheena McCormack