



Background

In 2015, there were 37 million people estimated to be



were used for comparing continuous data. All analyses were performed using Stata<sup>TM</sup> Version 12.

## Results

### Participant characteristics

In total, 284 men were screened and 150 then randomised to receive immediate ( $n = 75$ ) or deferred ( $n = 75$ ) vaccination (screen-to-enrol ratio = 1.89). The main reasons for non-enrolment were positive hepatitis B

S1), no difference was detected between retention in the two study arms (adjusted OR comparing DV to IV = 1.36;



self-reported questions, scoring themselves relatively high with condom use (IV 60 [88%] vs. DV 56 [85%]), number of partners (IV 65 [96%] vs. DV 58 [88%]) and sexual behaviour in general (IV 67 [89%] vs. DV 65 [98%]).

#### Acceptability

Of the study procedures assessed, more than 90% of participants rated questionnaire completion, repeated HIV testing and receipt of reimbursements as a 4 or 5 out of 5 (Table 4). Only 65% of the deferred group, however, gave high ratings for being randomised, compared to 90% of the immediate group ( $P=0.001$ ). By contrast, 92% of the DV group held favourable views on the informed consent processes, compared to 82% of the IV group ( $P=0.080$ ). The collection of blood and genital

specimens were viewed relatively unfavourably by both groups.

In terms of the clinical services and visits, in both groups, being examined by a male nurse was viewed as more acceptable than a female one. All men in the IV group liked being examined by a male nurse, while these views were not universal among men in the DV group (96%;  $P=0.075$ ). Other highly preferred aspects of the clinical services in both groups (>90% participants scored item as 4 or 5) were: clean clinic environment, clinic staff attitudes, free treatment and condoms, and counselling and health information, and the hepatitis B vaccine itself. Only 79% of the IV and 83% of the DV group scored travel time favourably ( $P=0.560$ ).

No associations were detected between the acceptability items and having attended all four study visits (Additional file 2: Table S2). Attendance levels among those who held less favourable views on the clinical services were high. Though differences were not significant, on 8 of the 10 measures of clinical services, those with less favourable views had a higher attendance than those with more favourable perceptions.

WTP in a future HIV vaccine trial was high in both groups (64/68, 94% in IV vs. 62/63, 98% in DV;  $P=0.200$ ). The main motivations for participation were potential HIV protection (81%), to help find a vaccine that works (75%), and to help others (68%). Interestingly, only 2% reported that reimbursements for study visits would motivate participation. Free HIV testing and treatment, and knowing someone with HIV were also not regarded as incentives for participation. No variations by study group were observed in these views. Almost all viewed side effects as a major concern for future trial participation (98%).

When asked about future use of an effective HIV vaccine, essentially all reported that they would accept this vaccine for themselves or their children. The most important attribute favouring vaccine acceptance was durability of protection (93/131, 70%). Few viewed ease of access (20/131, 15%), side effects (12/131, 9%), cost Q/9%,0.81331%

infections. This phenomenon raises the sample size required for demonstrating efficacy of an intervention [29]. Follow-up rates, approximately equal in both arms, were higher than in many previous vaccine preparedness studies among men [22].

In both study arms, the levels of WTP in an HIV trial were among the highest recorded among men in similar studies to date. In a review of 16 preparedness studies [22], willingness ranged from 40–99.4%, and was lower among men than women in most [22, 24, 30], but not all studies [31]. More generally, men are often less engaged in health care than women – which is commonly attributed to gendered social behaviours, occupational obligations and even a disinterest in their own health [32, 33] – and this may influence their decision to participate in trials. It was thus noteworthy to observe that the study population were highly motivated to enrol in future trials. Similar to other studies, altruistic motives often underlined this WTP, expressed as a desire to help find an efficacious vaccine and





14. Venables E, Stadler J. 'The study has taught me to be supportive of her': empowering women and involving men in microbicide research. *Cult Health Sex.* 2012;14(2):181–94.
15. Moodie Z, Metch B, Bekker LG, Churchyard G, Nchabeleng M, Misana K, Laher F, Roux S, Mngadi K, Innes C, et al. Continued follow-Up of phambili phase 2b randomized HIV-1 vaccine trial participants supports increased HIV-1 acquisition among vaccinated Men. *PLoS ONE.* 2015;10(9):e0137666.
16. Koblin BA, Avrett S, Taylor PE, Stevens CE. Willingness to participate in HIV-1 vaccine efficacy trials and the effect of media events among gay and bisexual men in New York City: project ACHIEVE. *J Acquir Immune Defic Syndr Hum Retrovirol.* 1997;15(2):165–71.
17. Metch B, Frank I, Novak R, Swann E, Metzger D, Morgan C, Lucy D, Dunbar D, Graham P, Madenwald T, et al. Recruitment of urban US women at risk for HIV infection and willingness to participate in future HIV vaccine trials. *AIDS Behav.* 2013;17(2):760–72.
18. Koblin BA, Heagerty P, Sheon A, Buchbinder S, Celum C, Douglas JM, Gross M, Marmor M, Mayer K, Metzger D, et al. Readiness of high-risk populations in the HIV network for prevention trials to participate in HIV vaccine efficacy trials in the United States. *AIDS.* 1998;12(7):785–93.
19. Harrer E, Harrer T, Barbosa P, Feinberg M, Johnson RP, Buchbinder S, Walker BD. Recognition of the highly conserved YMDD region in the human immunodeficiency virus type 1 reverse transcriptase by HLA-A2-restricted cytotoxic T lymphocytes from an asymptomatic long-term nonprogressor. *J Infect Dis.* 1996;173(2):476–9.
20. Jenkins RA, Torugsa K, Markowitz LE, Mason CJ, Jamroentana V, Brown AE, Nitayaphan S. Willingness to participate in HIV-1 vaccine trials among young Thai men. *Sex Transm Infect.* 2000;76(5):386–92.
21. McGrath JW, George K, Svilar G, Ihler E, Mafigiri D, Kabugo M, Mugisha E. Knowledge about vaccine trials and willingness to participate in an HIV/AIDS vaccine study in the Ugandan military. *J Acquir Immune Defic Syndr.* 2001;27(4):381–8.
22. Dhalla S. An update on human immunodeficiency virus vaccine preparedness studies. *J Med Microbiol.* 2015;64(7):731–8.
23. Gray GE, Allen M, Moodie Z, Churchyard G, Bekker LG, Nchabeleng M, Misana K, Metch B, de Bruyn G, Latka MH, et al. Safety and efficacy of the HVTN 503/Phambili study of a clade-B-based HIV-1 vaccine in South Africa: a double-blind, randomised, placebo-controlled test-of-concept phase 2b study. *Lancet Infect Dis.* 2011;11(7):507–15.
24. Ot wombe KN, Sikkema KJ, Dietrich J, de Bruyn G, van der Watt M, Gray GE. Willingness to participate in biomedical HIV prevention studies after the