ABSTRACT TEXT

Background:
The Africa Centre for Health and Population Studies conducted the Microbicides Development Programme (MDP) pilot study to optimise study procedures in preparation for a phase III randomized, double-blind, placebo-controlled microbicide clinical trial in the Umkhanyakude district. In a previous feasibility study, the site’s 3 month retention rate was 63%. In an attempt to improve this we evaluated the benefit of proactive participant retention techniques in the pilot study.

Methods:
147 women were screened for the study. 79 women met all eligibility criteria and were invited back for enrolment within a week. Eligible women not returning for enrolment were not tracked as this was considered a part of the informed consent process. Of the 79 eligible women, 51 (65%) returned for enrolment. Locator information was collected from all women including physical address and contact phone number. 78% provided a contact number. The participant retention team confirmed visits by phone, if a contact number had been provided, at least 2 days before the scheduled visit.

Results:
We have currently analysed 77 out of the total 153 scheduled appointments. Of these, 46 (60%) appointments were successfully confirmed. We were unable to confirm 31 (40%) either due to a lack of an available contact number or being unable to reach the person on the phone. Of those confirmed, 73% of women returned for the scheduled appointment, with the other 27% returning a mean of 2 days late (range 1-7 days). Of the unconfirmed appointments, 65% of women returned on time with 35% returning a mean of 3 days late (range 1-8 days). Although the difference is not statistically significant (p=0.484), it is logistically important. During a tracking visit, one woman withdrew from the study due to no longer being sexually active. The overall retention rate at the end of the pilot study (6 weeks) was 98%.

Conclusion:
Proactive participant retention methods appear to improve compliance with visit schedules. This will be an important factor in the management of large numbers of participants with monthly visits in the microbicide trial. The benefits versus human resource costs need further evaluation during the clinical trial.

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