

Oral Abstract Session: Female Initiated HIV Prevention Technology

TUAC104 - Achieving a 95% cohort retention rate in a phase III trial of the diaphragm and gel in Southern Africa

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Objectives: Minimizing loss to follow up (LTFU) is essential in clinical trials to ensure the validity of trial results. In 2006, we completed a multi-site randomized trial of the diaphragm and Replens® lubricant gel in Southern Africa (the MIRA study). As part of trial design, we estimated an HIV incidence rate of 4% across sites, and aimed to limit LTFU to approximately this level.

Methods: Participants were followed quarterly for 12-24 months, depending on time of enrollment. The importance of retention was continuously emphasized to all staff during training and throughout the trial. While outreach workers played a critical role, retention was defined as every staff member's responsibility. During study implementation: outreach workers visited participants to remind about visit and the day after visit was missed. Sites shared strategies on regular conference calls, including: participant suggestion boxes, lottery and small gifts, evening and Saturday clinics, provision of transport, childcare, rural outreach, caseload management follow-up systems, peer educators, posting and phoning visit reminders, and competitions among outreach teams.

Results: The MIRA study (n=5045) was conducted at five study clinics in Zimbabwe and South Africa. Sites were a mixture of rural, peri-urban and urban; with formal and informal settlements. Study participants were on average 28 years of age, had over 9 years of education, and about 20% overall were employed. At last scheduled follow-up visit, on October 4, 2006, 89% of enrolled participants had a closing visit. After another 2 months of intensive follow-up and tracking, the study achieved an overall retention rate of 95%, LTFU rates ranged from 3-8% across the five clinics.

Conclusions: Pre-emptive planning and continuous monitoring of retention rates, combined with additional tracking time ensured high return of participants. Achieving high retention is resource intensive and requires proper allocation of financial, administrative and human resources.

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