



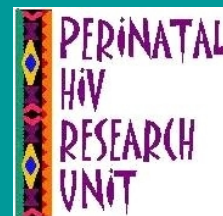
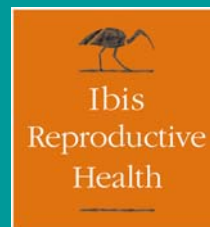
High Cohort Retention in a Phase III Trial of the Diaphragm and Lubricant Gel in Southern Africa

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Collaborative Research Programme

IAS 2007 Conference



Methods for Improving Reproductive Health in Africa (MIRA)

- Phase III randomized controlled trial to examine the effectiveness of the diaphragm and Replens® gel in preventing HIV acquisition in women



Background: The MIRA Trial

- n = 5045
 - UZ-UCSF = 2502
 - MRC = 1515
 - PHRU = 1028
- Five study clinics in Zimbabwe (Harare) and South Africa (Durban & Soweto)
- Sites were a mixture of rural, peri-urban and urban; with formal and informal settlements



Baseline participant characteristics

(n= 5045)

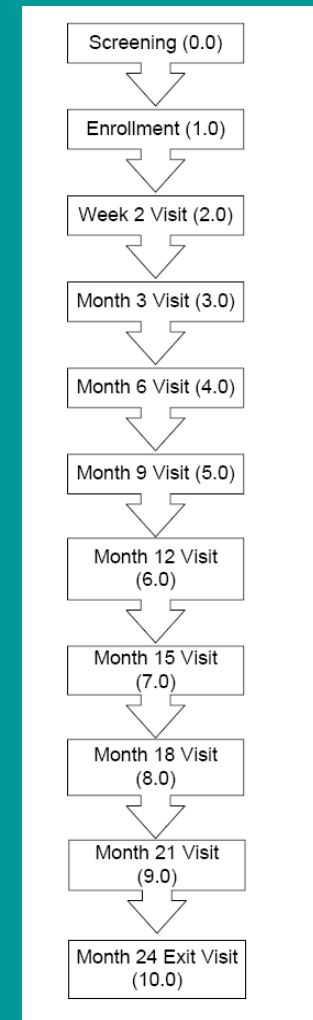
- Average age = 28 (range 18 - 50)
- 44% high school educated
- 23% employed
- 56% earned income in the past year
- 59% married
- 68% living with partner
- 94% Christian
- Average age at sexual debut = 18 (10-31)
- 22% had circumcised partner, 20% didn't know

Retention and LTFU considerations

- Protocol assumed 4-7% loss to follow-up (LTFU) per year over 3 years given an overall expected HIV incidence in the trial of 4%
- Minimizing LTFU is essential in clinical trials to ensure the validity of trial results
- Important not only to limit LTFU, but to ensure that LTFU is not different by study group
- “LTFU” defined as no closing visit with HIV endpoint data
- Sample size considerations - HIV incidence estimated as 4% across sites, therefore we aimed to limit LTFU to approximately this level

Follow-up schedule

- Screening visit
- Enrollment visit (2 weeks after screening visit; repeat screening visit conducted if > 2 weeks since first screening visit)
- Week 2 visit
- Quarterly follow up visits during between 12 and 24 months, depending on date of enrollment
- Closing visit at 12 - 24 months, depending on date of enrollment



Concerns about LTFU prior to implementation

- Migration
- Long follow-up period (24 months)
- Lack of perceived incentive to stay in study for control group?

Retention strategies prior to study implementation



- Initiation training
- Every staff member's responsibility
- Resources allocated and sites encouraged to hire many outreach workers
- Outreach workers given space in clinic
- Community launch activities
- **VERY DETAILED LOCATOR FORM**

Locator form information

- Home address and phone number, space to draw map
- Husband's name, work address and phone number
- School-going child's name, school name and address
- Parent or nearest relative's name, address and phone number
- Second contact after parent or relative
- Rural address of the participant
- For each, participant indicated and initialed whether it was okay to reach that contact person, by phone or by post, and whether it was okay to mention the study by name

Retention strategies during study implementation:

1. extensive follow-up

- Reminder letters sent prior to visits
- Phoning or home visits 24-hours after missed visits
- Peer educators used for outreach (MRC site)

2. improving customer service

- Offered Saturday Clinics and evening hours
- Created participant suggestion boxes
- Provided transport
- Appointed Client Liaison Officer to interface with participants regarding expected waiting periods
- Played family movies and served refreshments in waiting areas
- Provided childcare while women were in their visits

3. small gifts and competitions

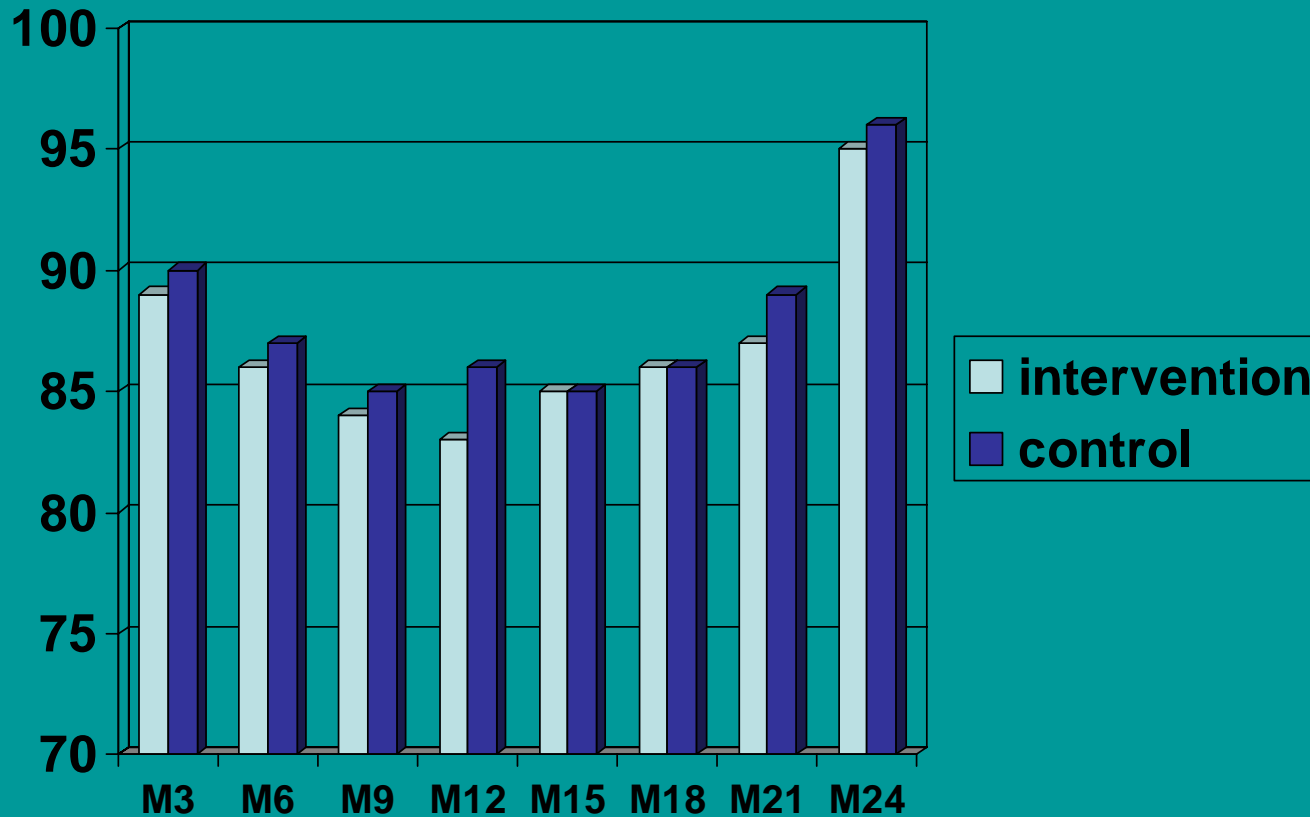
- All IRB approved
 - Token gifts at visit milestones (all < R15 each) given at 6 month intervals:
 - Purse/ clock
 - Umbrella
 - Sewing Kit
 - Tupperware set
 - Participant lottery – one voucher for every visit attended and quarterly draw for winners. Prize = grocery voucher
 - Incremental reimbursement scale for every follow-up visit completed

4. Focusing on hard to reach participants

- Rural outreach trips
- Closing visits done at homes
- Coordinators/ PIs visiting participants who repeatedly were “difficult to bring to the clinic”
- Fast-track provision for hard-to-reach or working participants
- “Final push” for 2 months after last scheduled visit

Results – Visit attendance

attended/ #expected



Results – final retention and LTFU

	Intervention Arm	Control Arm
Followed	2521 [†]	2518 [†]
Completed scheduled closing visit	2322 (92%)	2349 (93%)
Early withdrawals ^{††}	57 (2.3%)	42 (1.7%)
Lost to follow up	142 (5.6%)	127 (5.0%)

[†] Baseline sample

^{††} Withdrawals include participants who were discontinued due to death (23) or who came back to the study clinic and withdrew or were withdrawn early because of relocation (22), partner-related reasons (16), personal reasons (13), no time to participate (13) or other reasons (12)

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
- Many of our successful strategies were staff-driven, therefore it's important to involve all members of staff in retention discussions, and to share ideas across sites

THANK YOU!

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