MOPE 0295

Changes in Barrier Method Use after an HIV Prevention Trial in Zimbabwe

Ariane van der Straten[1,2]; Helen Cheng[1]; Alexandra Minnis[1,3]

1. Study Site

2. Background

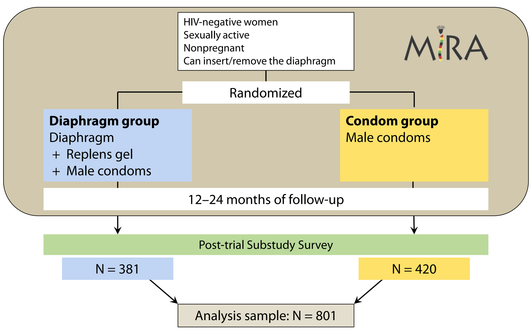
- Male condom use is intensively promoted in all biomedical HIV prevention trials, including those of female-initiated methods (FIM).
- The long-term (post-trial) effects of such condom promotion are mostly unknown.[1]
- Post-trial use of approved FIM under investigation in Phase III trials has not been studied previously.

Study Objective:

To examine change in male condom and diaphragm use after MIRA trial completion in Zimbabwe (MIRA: a Phase III diaphragm trial for HIV/STI prevention)

[1] Wong et al. Use of Male Condoms During and After Randomized, Controlled Trial Participation in Cameroon. *Sexually Transmitted Diseases 2005*, 32(5):300–307.

3. Study Design and Flow



4. Trial Products and Use Instructions

- Ortho All-Flex diaphragm (diaphragm group)
  - Diaphragm inserted at any convenient time; removed 6–24 hours after sex
  - Gel applied in dome prior to insertion + in vagina <1 hour prior to sex
- Replens® gel (diaphragm group)
  - Noncontraceptive vaginal moisturizer
  - 14-dose tube and reusable applicator
- Male condoms
  - Provided to women in both study groups
  - To be used for every sex act

5. Trial Exit Procedures

- All participants received free male condoms.
- In the diaphragm group, women could elect to keep the diaphragm and receive a year's supply of gel.
- In the condom group, women could elect to get fitted with a diaphragm and receive a year's supply of gel.
- All participants who elected to take a diaphragm received an educational session and a comprehension quiz to demonstrate full understanding that diaphragms are not a proven method for disease prevention or contraception (without a spermicide).
- Participants could return to the clinic for resupply of products or for advice, as needed.

6. Research Question

Between last MIRA study visit and post-trial visit, were there changes in:

- Male **condom use** at last sex?
- **Diaphragm use** at last sex?
- Use of any **barrier method** (diaphragm, male or female condom) at last sex?

7. Methods

Outcome Measures: Self-report of product use at last sex act (yes/no):

- Asked at baseline and quarterly ACASI interviews during MIRA
- Asked at one post-trial visit (by ACASI or face-to-face interview; no difference by mode)
  - Data collected on the following products at each time point:
    - Male condoms
    - Diaphragms
    - Female condoms
- Note: Female condoms were not provided by the study, but use information was collected throughout the trial.
- **Analysis:** Multivariable random effects logistic regression to assess within-participant change in method use between last MIRA visit and post-trial visit.
  - Separate models were run for each product and for each study group.

8. Tables and Figure

Table 1. Sample Characteristics (N = 801)

Age group	18–24	33%	
	25–34	47%	
	35+	20%	
One lifetime sexual partner		78%	
Cohabitates with partner		97%	
Less than high school		56%	
Sex ≤3 times/week		53%	
Median number of MIRA quarterly visits (range)		8	(1–8)
Kept the diaphragm at MIRA exit (diaphragm group n = 381)		97%	
Took the diaphragm at MIRA exit (condom group n = 420)		50%	
Median months between MIRA exit and post-trial visit (range)		9	(2–20)

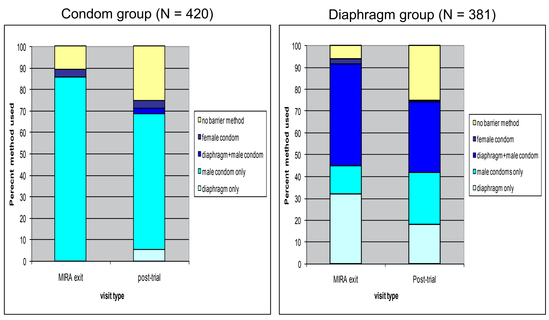
Table 2. Within-Individual Change in Method Use between Trial Exit and Post-Trial Visit

Condom group (N = 420)	MIRA Exit Visit %	Post-trial Visit %	AOR	95% CI	p-value
Male condom use at last sex	86	67	0.20	0.12–0.33	<.0001
Diaphragm use at last sex	0	7	-	-	
Any barrier method*	89	74	0.21	0.12–0.35	<.0001
Diaphragm group (N = 381)					
Male condom use at last sex	61	56	0.77	0.55–1.09	0.14
Diaphragm use at last sex	79	50	0.18	0.12–0.28	<.0001
Any barrier method*	94	75	0.15	0.08–0.27	<.0001

*Any barrier method = male or female condoms or diaphragms

All multivariable models control for age, post-trial interview mode, time since MIRA exit, and number of MIRA follow-up visits.

Figure 1. Last Sex Act by Barrier Method Used and Visit Type



9. Conclusions

- High condom use levels achieved during the trial were not sustained post-trial in the condom group.
- Providing a mix of methods may encourage more protected acts.
- Post-trial diaphragm use remained relatively high in the diaphragm group (given its unknown effectiveness), but was very low in the condom group.
- Introducing "new" methods for HIV prevention may require time and user skills before they get adopted.

Author Affiliations

[1] RTI International, San Francisco, CA, United States

[2] Center for AIDS Prevention Studies, University of California San Francisco, United States

[3] University of California, Berkeley, United States

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Contact Information

***Presenting author:** Ariane van der Straten

Phone: 415-848-1324 · **Email:** ariane@rti.org

RTI International, 114 Sansome Street, Suite 500, San Francisco, CA 94104-3812

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