



End-user research on Multipurpose Prevention Technologies (MPT) for HIV and pregnancy prevention: Young women's ratings of three delivery forms in a randomized, cross-over study in Kenya and South Africa

Alexandra Minnis^{1,2}, Sarah T. Roberts¹, Kawango Agot³, Rachel Weinrib¹, Khatija Ahmed⁴, Kgahliso Manenzhe⁴, Fredrick Owino³, Ariane van der Straten^{1,5}, on behalf of the TRIO Study Team

¹ Women's Global Health Imperative (WGHI) RTI International, San Francisco, USA; ² School of Public Health, UC Berkeley, USA; ³ Impact Research and Development Organization, Kisumu, Kenya; ⁴ Setshaba Research Centre, Soshanguve, South Africa; ⁵ Center for AIDS Prevention Studies, Dept. of Medicine, UCSF, San Francisco, USA

Background

Preventing HIV and unintended pregnancies are key health priorities for young women in sub-Saharan Africa (SSA).

- Rates of HIV infection are over 2x higher among women age 18-30, compared to men¹
- 59% of people living with HIV in SSA are women¹
- 40-60% of pregnancies in SSA are unintended²

A dual-purpose product may facilitate uptake, use and acceptability among at-risk women compared to a single indication product.

To inform the development of MPT products, we evaluated young women's opinions of three placebo MPTs in Kenya and South Africa.

1. UNAIDS 2014
2. Mc Phail ., BMC Med. 2007; Kott,A. Int Pers Sex R. H. 2011

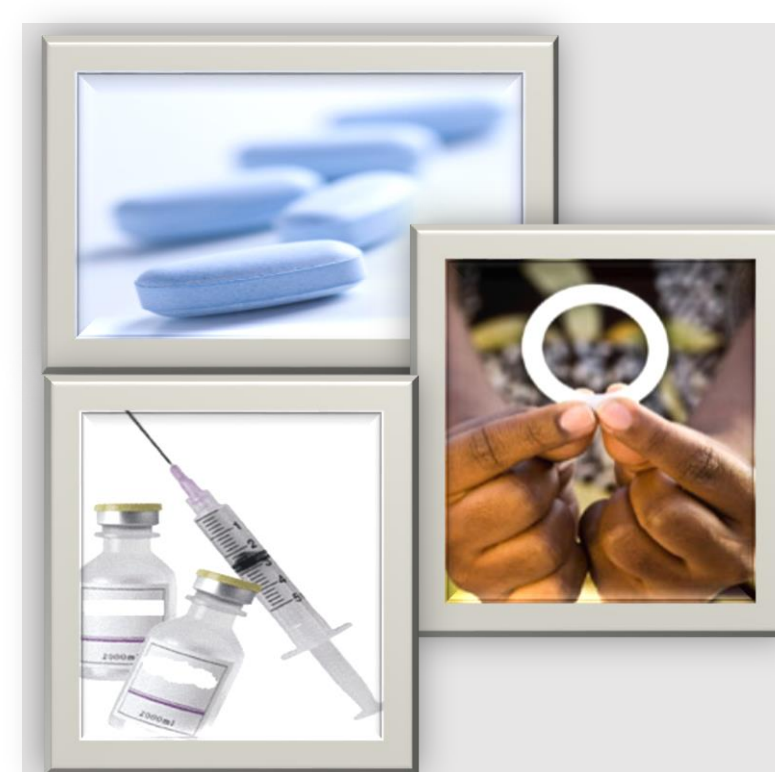
The TRIO study (2014-2017)

Objective: To improve understanding of young women's preferences among three potential MPTs.

Three placebo MPTs:

- Daily oral tablets
- Monthly vaginal ring
- Two monthly injections (one in each gluteal muscle)

Multi-component study; included a clinical acceptability study among young sexually active women.



TRIO clinical study



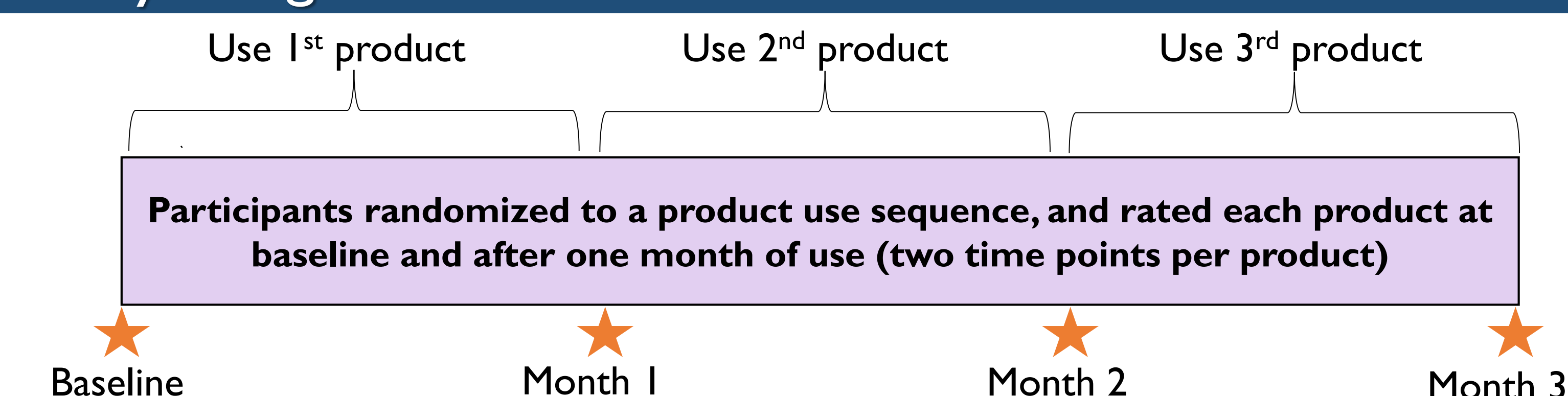
★ Kisumu, Kenya: N=130*
★ Soshanguve, South Africa: N=128*

Eligibility:

Female
HIV-negative
Sexually active
Non-pregnant
Aged 18-30 years
Microbicide and PrEP naive

*Includes all women with at least 1 product rating during follow-up

Study design



Objectives of this phase: to assess product satisfaction ratings after one month of use.

★ Time points contributing data to this analysis. In the final two months of follow-up (not shown here), women used the product of their choice, and those data are presented at IAS 2017 in abstract #WEPEC0978.

Methods

At baseline, participants watched a brief animated video introducing the products, and then rated how much they would like using each product for both HIV and pregnancy prevention on a 5-point Likert scale (1=low).



At each monthly follow-up visit, participants rated how much they liked the product they used for the past month, and provided opinions of product attributes. Response options for attribute questions ranged on a 4-point scale from very unacceptable to very acceptable.

Analysis:

- Paired t-tests to compare mean ratings for each product and changes over time.
- Multivariable linear regression to examine product attributes associated with ratings for each product, adjusting for age, site and product use sequence.

Study enrolment and retention

Total of 277 women enrolled.

- 258 (93%) contributed at least one month of follow-up.

- Loss to follow-up during crossover period was not associated with product sequence.
- Sample size for each product (number of total visits after one month of use):

	Tablets	Ring	Injections
	255	254	254

Table 1: Sample characteristics by country

		Soshanguve, South Africa (N=130)	Kisumu, Kenya (N=128)	Total (N=258)
AGE GROUP:	18-24	67%	67%	67%
	25-30	33%	33%	33%
Married or cohabiting		4%	48%	26%
Pregnancies >=1		78%	80%	79%
Completed secondary school		63%	40%	52%
LIVES WITH:	Parents/grandparents	79%	23%	53%
	Husband/boyfriend	8%	47%	28%
	Other	13%	30%	20%
FOOD INSECURITY:	Never	62%	29%	46%
	Rarely or sometimes	25%	54%	39%
	Often	13%	17%	15%
Has privacy in the home		93%	73%	83%

ACKNOWLEDGEMENTS: We are grateful to the TRIO Study participants for contributing to the research, the TRIO study staff, and the communities who partnered with us in this work.

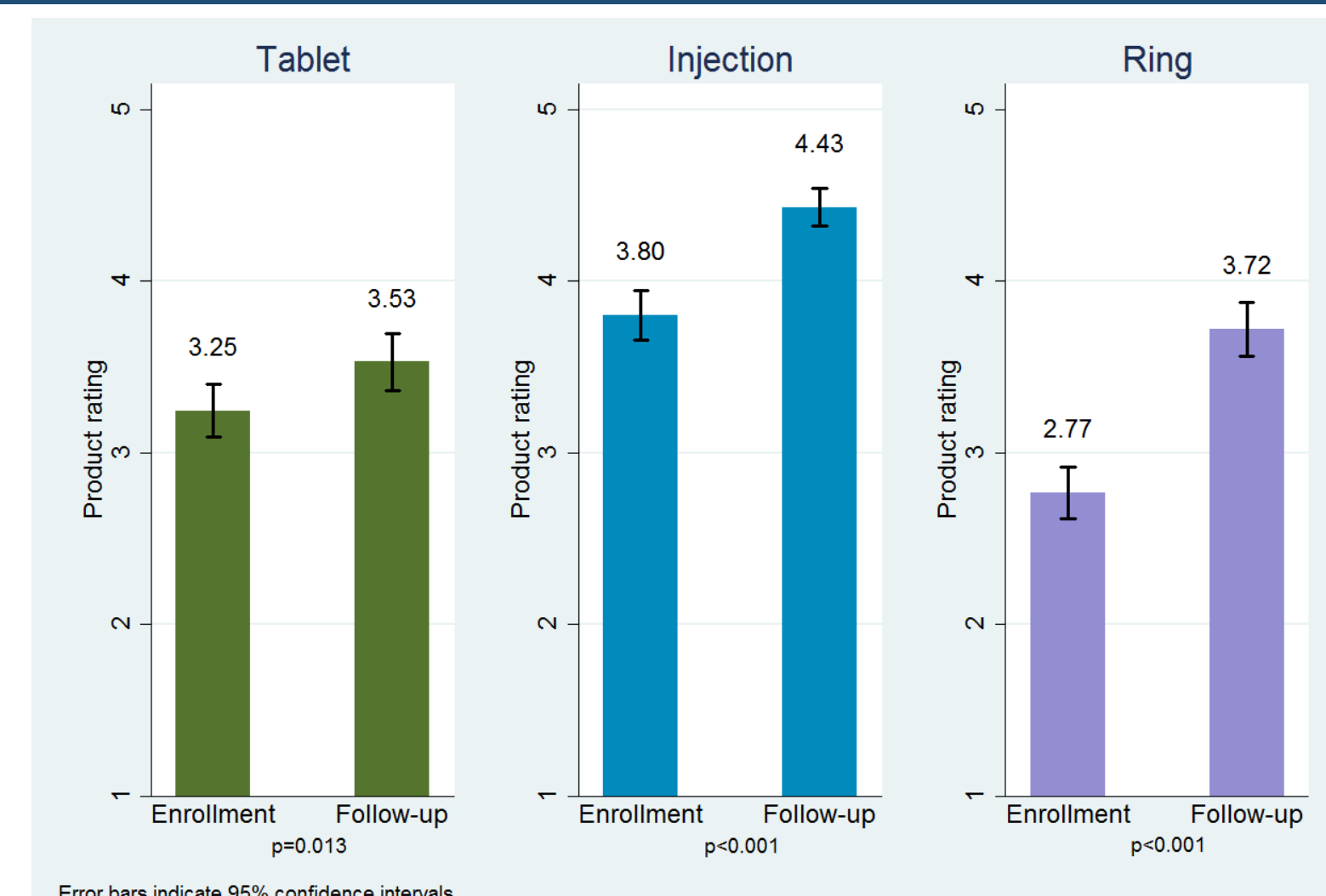
Placebo tablets were graciously provided by Gilead Sciences, Inc. Placebo rings were provided by the International Partnership for Microbicides (IPM).

Funding was provided by the Bill & Melinda Gates Foundation (Opp114942).

Change in MPT rating from baseline

"How much would you like using the [tablets/ring/injections] for both pregnancy and HIV prevention?"

For all products, rating increased after one month of use.



Product ratings after 1 month of use

- "Please rate how much you liked the [tablets/ring/injections] you used over the past month."
- Injection most highly rated product, followed by ring and then tablet.

Women in Kenya rated tablets higher and rings lower than women in South Africa.

	Soshanguve, South Africa (N=130)	Kisumu, Kenya (N=128)	Total (N=258)
Tablets**	2.74 (SD 1.27)	3.19 (SD 1.27)	2.96 (SD 1.29)
Injections	4.29 (SD 1.04)	4.23 (SD 0.95)	4.26 (SD 1.00)
Ring*	3.46 (SD 1.28)	3.10 (SD 1.44)	3.28 (SD 1.37)

*p<0.05; **p<0.01

Product attribute acceptability

Proportion of women indicating the attribute "acceptable" or "very acceptable" after 1 month of use.

	Tablets (N=255)	Injections (N=254)	Ring (N=254)
Product look	62%	88%	66%
Interference with normal activities	67%	91%	73%
Ease of use	58%	93%	74%
Felt product could be used without partner knowledge	69%	78%	63%
Felt product could be used without family knowledge	65%	73%	80%

Predictors of Tablet, Ring and Injection ratings

	β	95% CI
TABLETS		
Acceptability of General Product Attributes		
Product look	1.06***	0.72, 1.40
Ease of use	1.15***	0.85, 1.45
Interference with normal activities	1.16***	0.82, 1.49
Acceptability of Tablet-Specific Attributes		
Tablet color	0.70***	0.32, 1.08
How it felt to swallow the tablets	0.95***	0.64, 1.26
How stomach felt after taking tablets	0.92***	0.57, 1.27
Taking a tablet every day	1.32***	1.05, 1.6
How the tablet felt in hands	0.84***	0.48, 1.2
Size of tablets	0.64***	0.32, 0.95
INJECTIONS		
Acceptability of General Product Attributes		
Product look	1.11***	0.62, 1.59
Ease of use	1.10***	0.48, 1.73
Interference with normal activities	1.11***	0.55, 1.67
Acceptability of Injection-Specific Attributes		
Getting injections at the clinic	1.38***	0.76, 2.00
How the needle felt	0.43**	0.16, 0.70
Feeling at injection site 1 day later	0.79***	0.41, 1.18
Number of injections at a time	0.41**	0.11, 0.71
Having 2 injections in a month	0.55**	0.24, 0.86

	β	95% CI
RING		
Acceptability of General Product Attributes		
Product look	1.36***	1.02, 1.70
Ease of use	1.81***	1.47, 2.14
Interference with normal activities	1.45***	1.11, 1.79
Possible to use without partner knowledge	0.49**	0.14, 0.84
Acceptability of Ring-Specific Attributes		
Ring size	0.80***	0.46, 1.14
Inserting the ring	0.78***	0.41, 1.14
Removing the ring	0.53*	0.12, 0.94
How the ring felt during sex	1.36***	1.01, 1.7
How the ring felt during sex to partner	1.12***	0.74, 1.49
How the ring felt during sex to partner	0.93***	0.52, 1.34
Leaving the ring in for an entire month	1.68***	1.35, 2.00
How the ring felt in hands	0.58**	0.24, 0.93

Coefficients (βs) represent the mean difference in overall product rating between women who rated the attribute acceptable vs. unacceptable, adjusted for age, site, and product use sequence.

Note only significant associations listed in tables.

*p<0.05; **p<0.01; ***p<0.001.

Finding the following attributes acceptable increased mean rating by ≥ 1-unit.

Tablets	Ring	Injections
<ul style="list-style-type: none"> • Taking a tablet every day • Interference with normal activities • Ease of use • Product look 	<ul style="list-style-type: none"> • Ease of use • Leaving the ring in for an entire month • Interference with normal activities • Product look • How the ring felt during sex • How the ring felt during sex to partner 	<ul style="list-style-type: none"> • Getting injections at the clinic • Interference with normal activities • Product look • Ease of use

Limitations

- Use in TRIO may not fully reflect active product experiences, including side effects, lead-in and lead-out dosing (injections), and likely 3-month duration (ring).
- One month of use provides an opportunity to try the product but does not mimic sustained use period.

Conclusions

Injections were the most preferred product.

Rating of all three products increased after one month of use.

- Greatest increase in rating seen with the least familiar product: the ring.

Product attributes related to the burden of use were most influential on product ratings.

- **Tablets:** Ease of use and comfort with daily tablet-taking associated with highest increases in mean rating.
- **Ring:** Comfort with the ring during sex and with leaving the ring inserted for a month associated with the highest increases in mean rating.
- **Injections:** Acceptability of getting injections at the clinic and of the "product look" associated with highest increases in mean ratings.

PRESENTED AT THE 9TH IAS CONFERENCE ON HIV SCIENCE - PARIS, FRANCE

