
6-2023

Does size matter? A randomized controlled trial to assess the impact of external diameter on adherence to 3 different intravaginal rings among 24 US couples

Irene Bruce
Population Council

Marlena Gehret Plagianos
Population Council

Jessica M. Sales

Jessica Atrio

Shakti Shetty

See next page for additional authors

Follow this and additional works at: https://knowledgecommons.popcouncil.org/hubs_cbr

How does access to this work benefit you? Click here to let us know!

Recommended Citation

Bruce, Irene, Marlena Gehret Plagianos, Jessica M. Sales, Jessica Atrio, Shakti Shetty, Caio Sant'Anna Marinho, Brady Zieman, Lisa Haddad, and Barbara Friedland. 2023. "Does size matter? A randomized controlled trial to assess the impact of external diameter on adherence to 3 different intravaginal rings among 24 US couples," presentation at the Adherence 2023 conference.

This Presentation is brought to you for free and open access by the Population Council.

Authors

Irene Bruce, Marlena Gehret Plagianos, Jessica M. Sales, Jessica Atrio, Shakti Shetty, Caio Sant'Anna Marinho, Brady Zieman, Lisa Haddad, and Barbara Friedland



Does size matter? A randomized controlled trial to assess the impact of external diameter on adherence to 3 different intravaginal rings among 24 US couples

Irene Bruce, Marlena Plagianos, Jessica M. Sales, Jessica Atrio, Shakti Shetty, Caio Sant'Anna Marinho, Brady Zieman, Lisa B. Haddad, Barbara A. Friedland

Adherence 2023 • June 11-13 • Puerto Rico



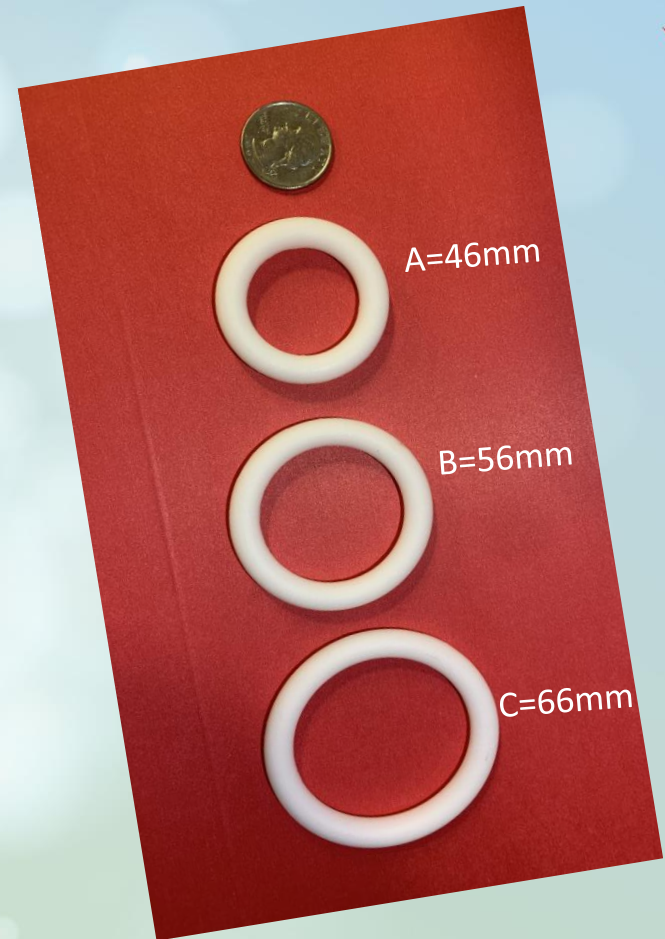
Rationale

- Women of reproductive age would benefit from a multipurpose prevention technology (MPT) that combines protection against pregnancy and HIV/STIs
- Intravaginal rings (IVRs) have been used for over 40 years and are a promising delivery system for MPTs
- No empirical data exists to support the current 54-58mm size as ideal
- Understanding the impact of IVR size on adherence is critical for developing a product that can be used correctly and consistently



Primary Objectives

- **Adherence**
 - To determine which of 3 non-medicated IVRs (A, B or C) each used continuously for ~30 days yields the highest adherence
- **Preference**
 - To assess which of 3 non-medicated IVRs (A, B or C), each used continuously for ~30 days, is preferred by women enrolled with their male partners



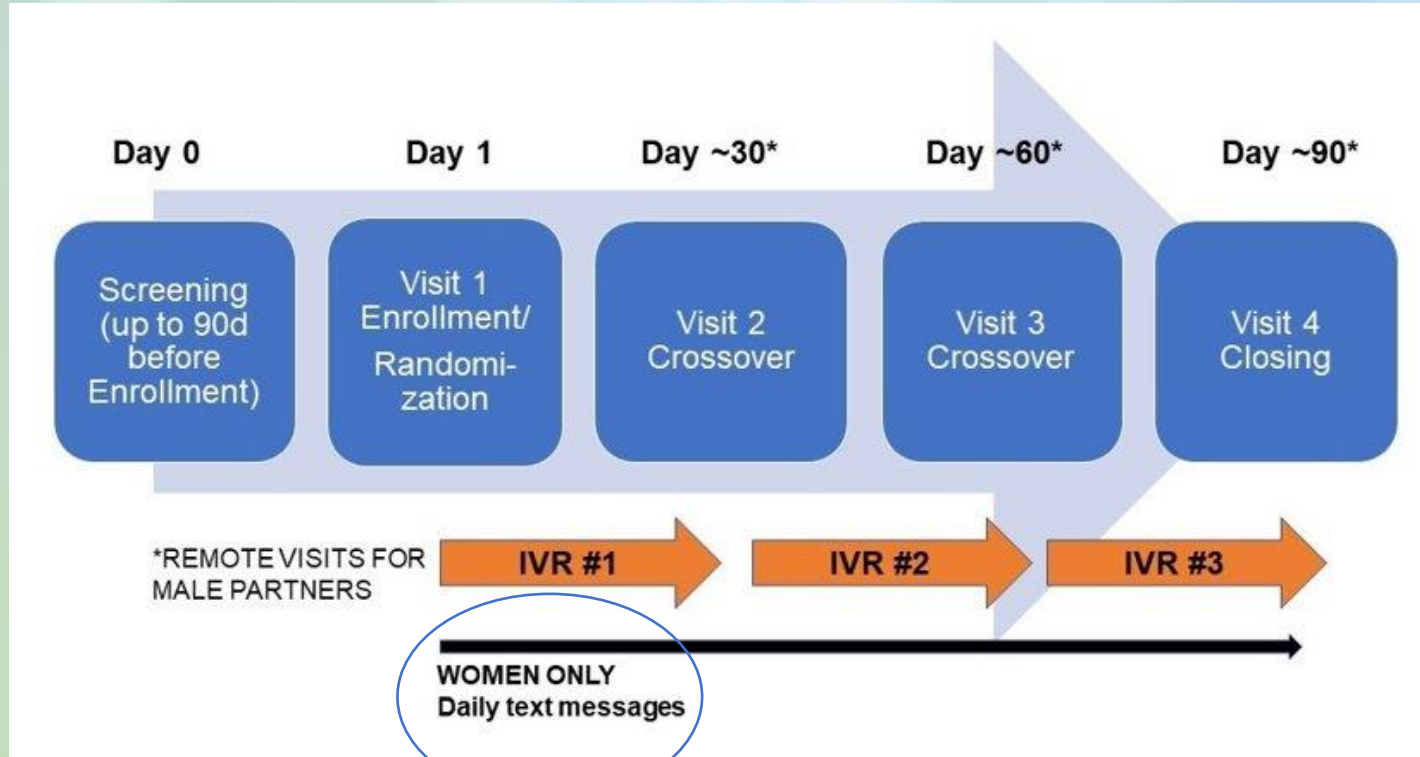


Study Design

- Randomized, open-label, parallel group, 3-way crossover
- Population: 24 healthy, HIV-seronegative couples (n=48)
 - Mutually monogamous, low-risk
 - Women 18-40 yrs
 - Males ≥ 18 yrs
 - Sexually active
- Sites
 - Albert Einstein College of Medicine, Bronx NY
 - Emory University, Atlanta GA
- Duration
 - 3 months per couple (one month per ring)
 - 16 months overall for data collection (Sept 2021-Dec 2022)

Study Schema

#ADHERENCE2023





Text message questions

Question 1:

In the past 24 hours, has the ring been out of your vagina? Enter the number corresponding to your answer:

1 = No, it was in place the entire time

2 = Yes, it was completely out of my vagina for the entire time

3 = Yes, it was out of my vagina for part of the time

Question 2:

In the past 24 hours, how did the ring come out?

1 = I removed it

2 = I felt like it was slipping/starting to come out, so I removed it

3 = It came out on its own (expulsion)

4 = I had already taken the ring out more than 24 hours ago and had not reinserted it

Question 3:

In the past 24 hours, about how long in total was the ring out of your vagina?

1 = less than ½ hour

2 = more than ½ hour, but less than an hour

3 = 1-2 hours

4 = more than 2 hours



Analysis methods

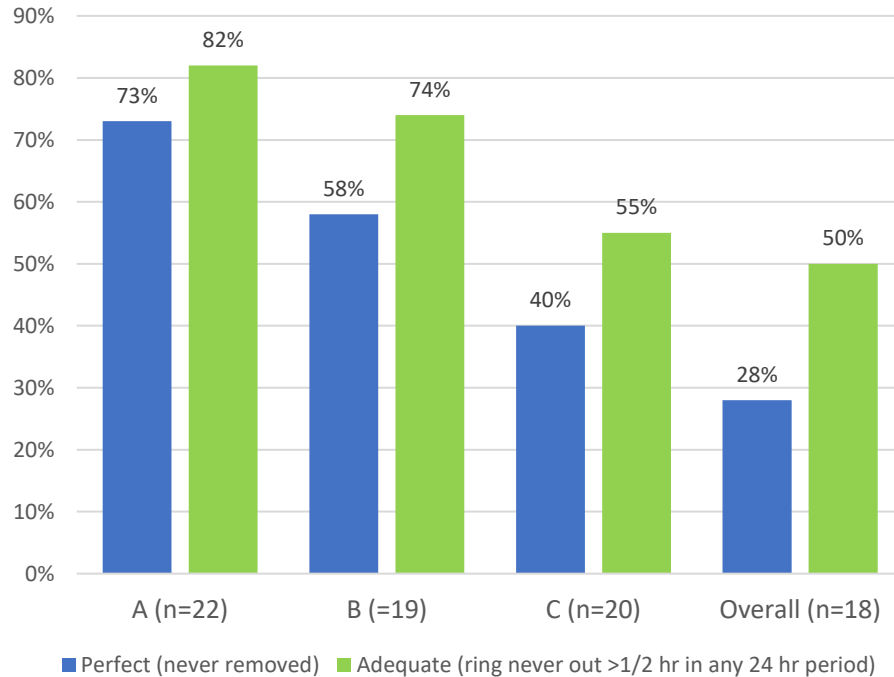
- We summarized the number of days the IVR was out at all, out all day, or expelled, and the proportion of women adherent to each IVR
- Mixed methods logistic regression models with random intercepts (per participant) compared the probability of each event happening per day of IVR use, per IVR

Results: Background Demographics, Females

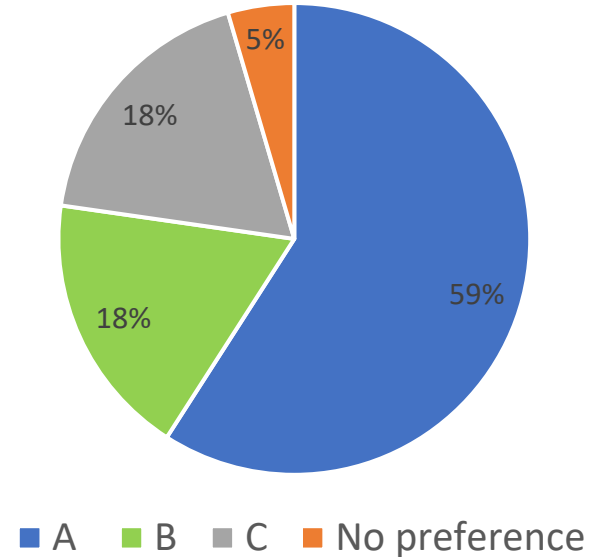
Characteristic	Bronx (n=12)	Atlanta (n=12)	Overall (n=24)
Mean Age (SD)	27(4.65)	26.3(2.84)	26.7(3.78)
Mean Age (Range)	25(23-40)	26(23-33)	25.5(23-40)
BMI			
18.5-<25	5 (42%)	6 (50%)	11 (46%)
25-<30	5 (42%)	4 (33%)	9 (38%)
≥ 30	2 (17%)	2 (17%)	4 (17%)
Race			
White	8 (67%)	7 (58%)	15 (63%)
Black/African	1 (8%)	2 (17%)	3 (13%)
Asian	2 (17%)	4 (33%)	6 (25%)
Other	1 (8%)	0 (0%)	1 (4%)
Ethnicity			
Hispanic	4 (33%)	1 (8%)	5 (21%)
Not Hispanic	8 (67%)	11 (92%)	19 (79%)
Born in the US	8 (67%)	10 (83%)	18 (75%)
Marital Status			
Married/Cohabiting	4 (33%)	1 (8%)	5 (21%)
Single	8 (67%)	11 (92%)	19 (79%)
Highest Level of Education			
Some College	0 (0%)	2 (17%)	2 (8%)
College Grad	12 (100%)	10 (83%)	22 (92%)
Parity			
Nulliparous	11 (92%)	11 (92%)	22 (92%)

Results: Adherence and Preference

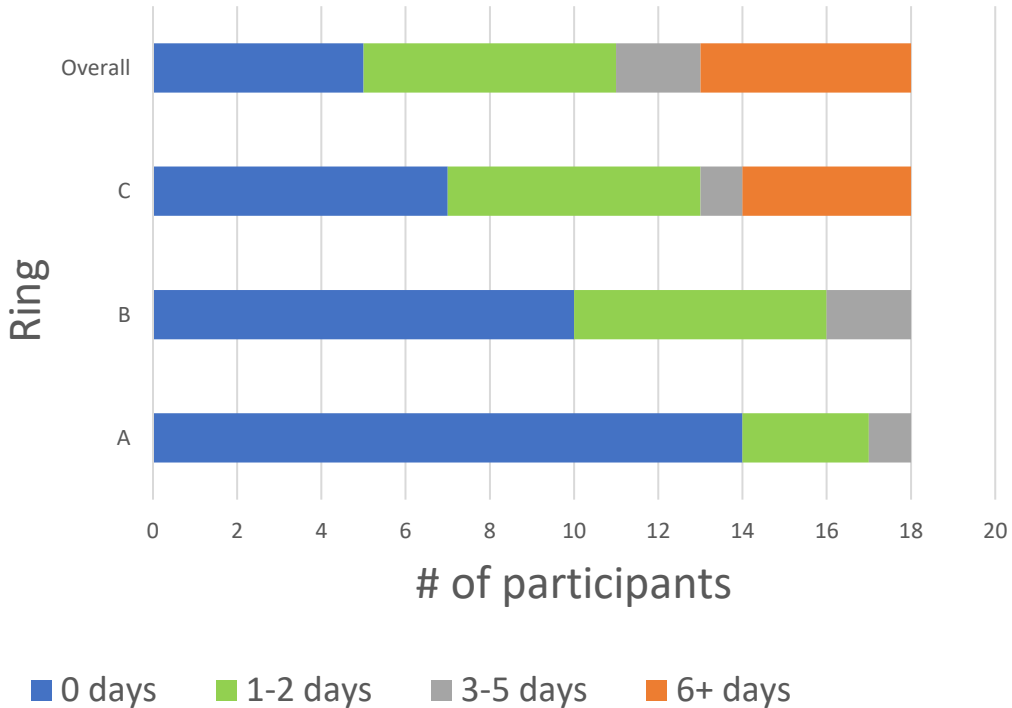
Adherence by Ring Type, Overall



Preference, Females End of Study (n=22)

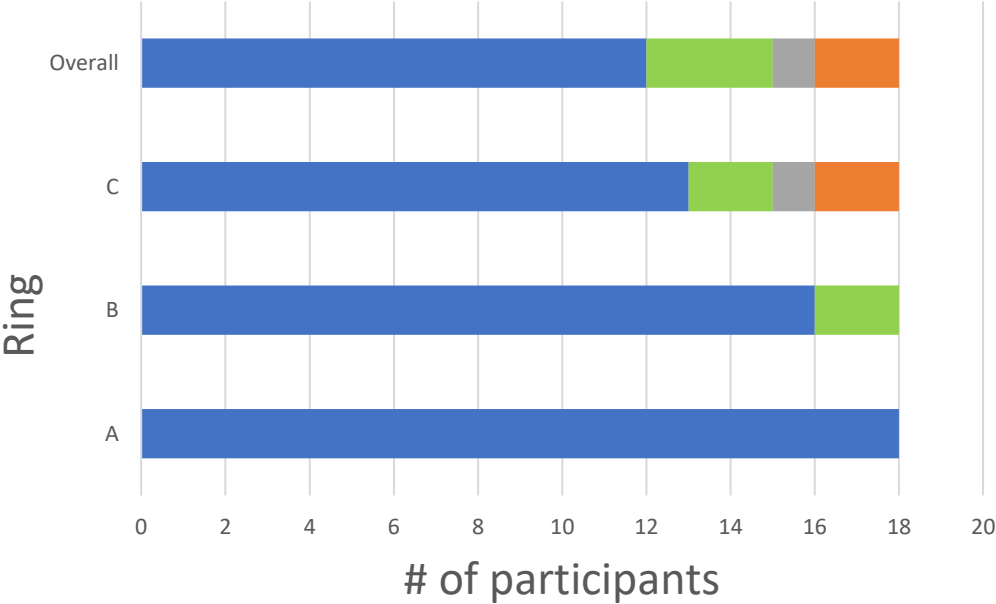


Number of participants with ring ever out by ring and overall (n=18)



A vs B; OR 0.56; 95% CI 0.21-1.44
C vs B; OR 6.92; 95% CI 3.65-13.1

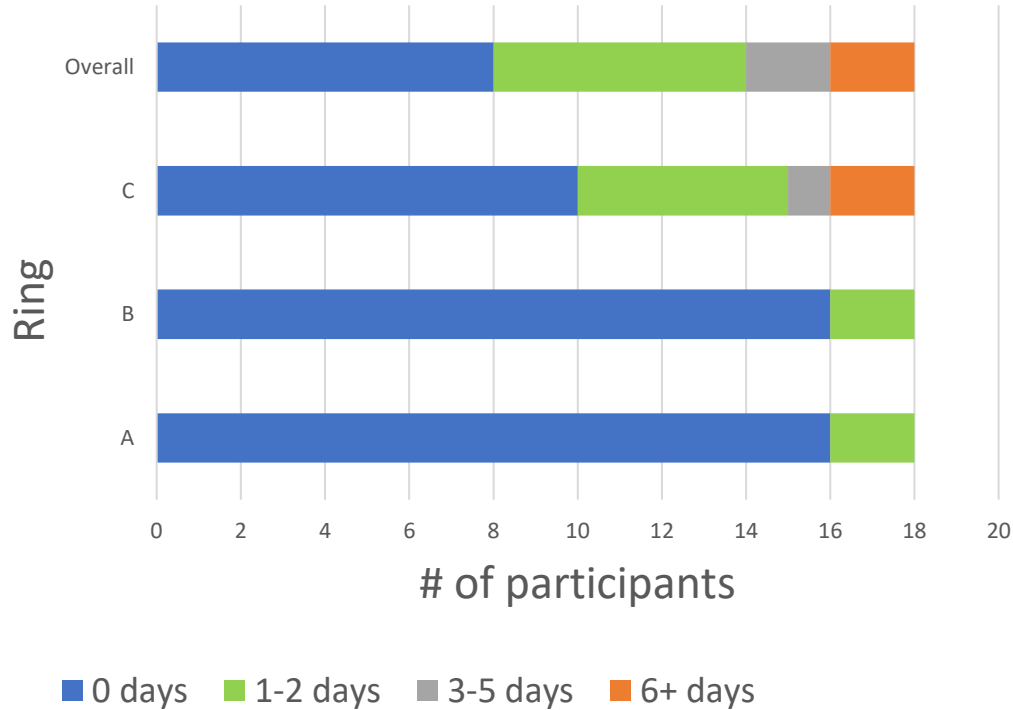
Number of participants with ring out all day by ring and overall (n=18)



C vs B; OR 16.4; 95% CI 3.79-71.3

(cannot calculate A vs B since no one had ring A out all day)

Number of participants with expulsions (partial or full) by ring and overall (n=18)



A vs B; OR 1.08 95% CI 0.15-7.8
C vs B; OR 27.8 95% CI 6.48-119



Summary

- Overall adherence (ring never out) was highest with the smallest ring (A, 46mm) and lowest with the largest ring (C, 66mm) but differences between the rings were not statistically significant
- The probability of expulsions was the highest with the largest ring (C, 66mm); there was no difference between ring A and ring B
- External diameter had an impact on adherence with 46mm and 56 mm performing better than the 66mm ring



Conclusions

- We only measured external diameter; other ring characteristics such as compressibility should be assessed and taken into consideration with ring development
- Adherence should not only be considered as a dichotomous endpoint; patterns of adherence over time and factors contributing to adherence should also be considered when developing IVRs
- A few women preferred ring C; developers should consider making rings in multiple sizes



Acknowledgements

Study Participants

Albert Einstein College of Medicine

Gabriella Alexandrou, Jessica Atrio, Nadia N. Douglas, Neva Morales-Grajales, Maritza Padin, Natasha Rambishun, Renee Rolston, Nicole Roselli, Caio Sant'Anna Marinho, Eleftheria Zias

Emory University

Michelle Nguyen, Marcia Peters, Evangelia Pitsoulakis, Aditi Ramakrishnan, Aimee Roller, Jessica Sales, Anandi Sheth, Shakti Shetty, Tina Taylor Tisdale

Population Council

Irene Bruce, Barbara A. Friedland, Lisa B. Haddad, Daniel Loeven, Ruth Merkatz, Marlena Plagianos, Craig Savel, Heather Sussman, Natalia Teleshova, Bruce Variano, Brady Zieman

Funding support from:

Research reported in this presentation was supported by the National Institute Of Allergy And Infectious Diseases of the National Institutes of Health under Award Number R01AI150360. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health



Thank you!

- For more information, please contact ibruce@popcouncil.org