

DESIRE

Developing and Evaluating Short-acting
Innovations for Rectal Use

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Protocol Chair MTN-035

Agenda

- Choice?
- Description of MTN 035
- Recruitment Milestones
- What have we learned so far from the US?

What choice matters? To whom? When?

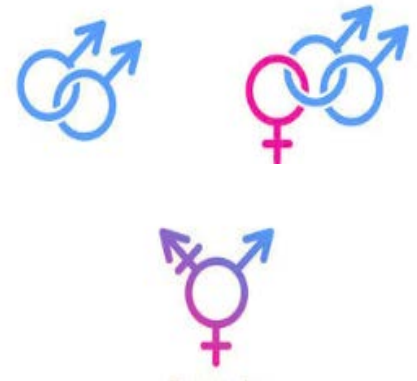
Choice and decision-making is not static

New approaches are needed

- Oral PrEP works, yet it may not be accessible, available or desired among certain population segments.
- Topical prophylaxis may have buy-in among young vulnerable populations who:
 - Have complex lifestyles
 - Experience risk seasonally
 - Find daily adherence challenging
 - Have poor/limited health access
 - Can't access/afford systemic prevention
 - Associate stigma with the use of ARV pills

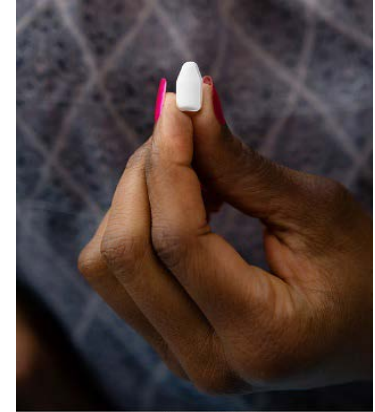
MTN 035

- First study to systematically examine the acceptability, tolerability and adherence of three placebo formulations in a sample of young cisgender MSM and Transgender People in 5 countries.
- Compare/contrast modalities based on product characteristics and participants' characteristics and contexts.
- Assess modality acceptability and tolerability, including best practices learned from participants' experiences, as MTN explores formulations.



Why a placebo study?

- Understand participants' acceptability and experiences with non-gel delivery vehicles (e.g., douche, insert, suppository).
- Learn from users about their experiences with these products in order to develop intervention strategies that promote adherence within a future drug trial.
- Plan and address foreseeable barriers and opportunities.



Credit: CONRAD



Design

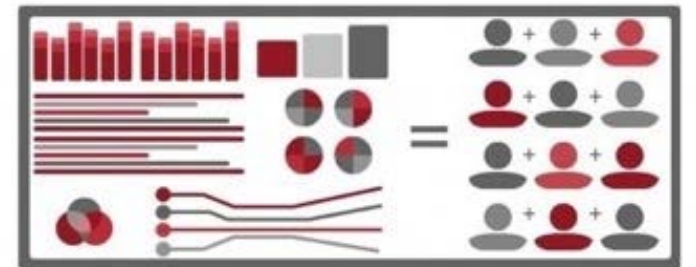
Sequence	N	Period 1 (4 weeks)	Washout period (~1 week)	Period 2 (4 weeks)	Washout period (~1 week)	Period 3 (4 weeks)
A	35	Insert	--	Douche	--	Suppository
B	35	Douche	--	Suppository	--	Insert
C	35	Suppository	--	Insert	--	Douche
D	35	Insert	--	Suppository	--	Douche
E	35	Douche	--	Insert	--	Suppository
F	35	Suppository	--	Douche	--	Insert



MTN 035 Recruitment (as of 2/10)

Site	Total Screened	Total Enrolled	Status
San Francisco	36	30	Follow-up completed
Birmingham	39	28	On-going recruitment
Pittsburgh	33	29	On-going recruitment
Peru	38	30	Completing follow-up
Chiang Mai	32	24	On-going recruitment
WRHI	25	17	On-going recruitment
Blantyre	13	4	On-going recruitment
Total	216	162/210 (77.1%)	

Data Collection



CONJOINT ANALYSIS

Data Collection



158 of 210
baseline surveys
completed!

Data Collection

309 of 630 PUEV
completed!

30 of 70 Exit
Interviews
completed!



Data Collection

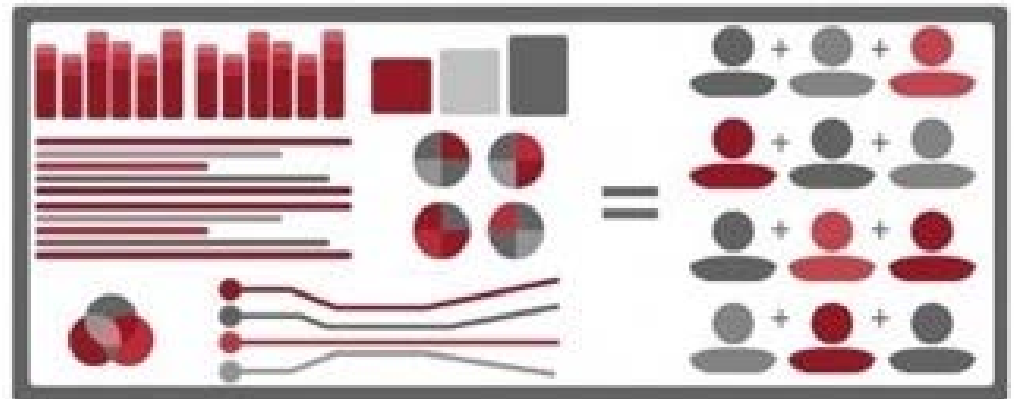
7,847 (Sent)

6,214 (Received)



Data Collection

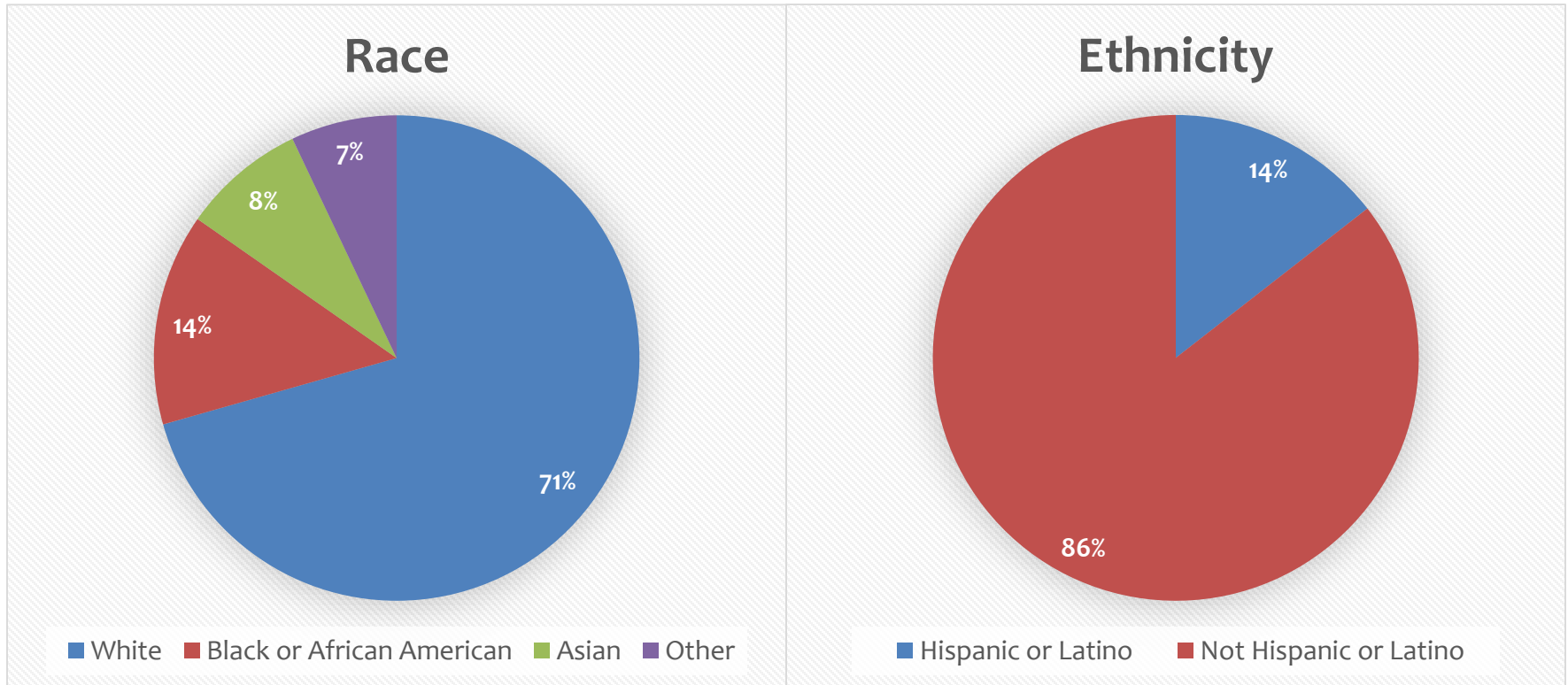
71 of 210 done!



CONJOINT ANALYSIS

MTN 035 Participants in the US

- Full age range: 18-35
- 11% identified as Trans



What have we learned from US sites?

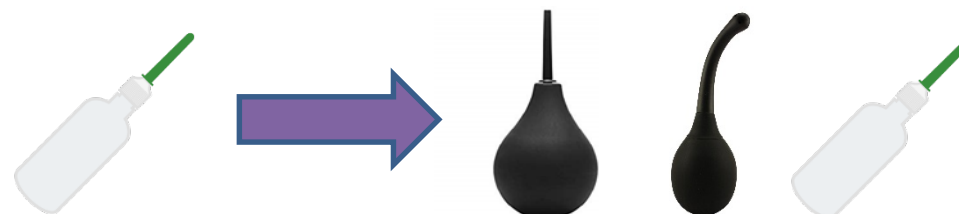
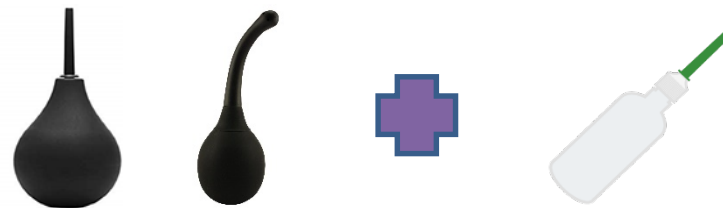
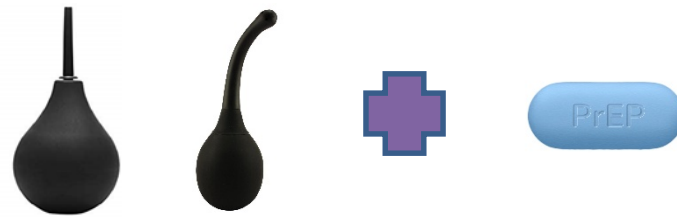
- Participants are open to testing products and are candid about their experiences
- Congruence: Practice vs Product
- Diversity in Desired Product Choice
- Product Choice and Relationships

Product vs Practice

- Douche:
 - **1:** A jet or current of liquid directed against or into a bodily part or cavity as an act of cleansing
 - **2:** a device for giving douches



Product + Practice



Behavioral Congruence

“I: Okay. You told me a little bit already about your experience using the suppository before sex and how it went; that it wasn’t really a problem. How did you feel that it affected the encounter in terms of spontaneity, or pleasure, or anything else?”

P: So I usually use a douche before every time I have sex, so usually spontaneity isn’t really a thing that happens, cuz I kind of have to get ready. So it didn’t really affect that much. I would say, it seemed like everything was the same. Maybe a little bit more time waiting for the suppository to melt but I think that was more just me wanting to just make sure it was gone.”

Product Choice Changes...

P: “I think that by the time I was using this product, I had started reducing the thoroughness of my douching. Like I said I have a boyfriend now and we’ve been having a lot more sex and like mainly its just been us two, but we obviously like sleep outside of it...

He’s just encourage- he just been very much lax about: “listen you don’t have to douche so much just like ya know if we get dirty we get dirty, we will just clean up.”

He’s been like very supportive about me like you don’t have to douche every single time it’s a lot of work for you and sometimes I want to have sex and I’m just like okay well if you’re cool with that.”

Diversity in Product Choice

- “Yeah, I wish it had come in a single use package like the suppository so that I could more easily carry it around.”
- “[Product] was easy to insert, I couldn’t feel it after I inserted it. Theoretically I could carry it around and have it easily concealed. I could travel with it.”



Acknowledgments



Acknowledgments

The MTN is funded by the National Institute of Allergy and Infectious Diseases (UM1AI068633, UM1AI06615, UM1AI106707), with co-funding from the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development and the National Institute of Mental Health, all components of the U.S. National Institutes of Health.





Short-Messaging Service (SMS)

What did we learn from MTN 017?

- Power & Internet outages
- Random spam texts & Automatic wrong keyword response triggered by spam
- SIM card failure or USB modem issues
- Physical malfunctions at remote sites
- Broken text in SMS messages
- Daylight saving time-induced system clock malfunction
- Participants without a functioning cell phones

How to prevent same issues?

- Only allow numeric responses. Anything else triggered a contact clinic staff prompt.
- Platform and Infobip are hosted in the United States with international capabilities allowing sites to avoid having to house cell phones.
- Used Unicode unformatted text.
- Set-up system to automatically update for DST.
- Some sites provide phones.

Short-Messaging Service (SMS)

What Actually Happened...

- All sites:
 - DST did not automatically update
 - API Failure
 - Messages appeared to go through but participants didn't receive
- Thailand: Do Not Disturb List
- South Africa: Initial local number didn't work in live environment, programming update
- Malawi: SMS does not work in country, WhatsApp solution
- Peru: Local phone number did not work

How solved?

- All sites:
 - DST was manually updated
 - API was extended to 2021
 - Participants notified to inform staff of missed messages.
- Thailand: Data collected in IDI
- South Africa: Reprogrammed from test environment to update in live.
- Malawi: WhatsApp as an alternative.
- Peru: Developed a short code for SMS