MTN 027 EXIT Behavioral Survey

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PROGRAMMER: Logic checks are in *italics*. Skip patterns are in **CAPITALIZED BOLD**.

SECTION A. PSYCHOSOCIAL

A1. First we would like to ask you about your everyday emotions and experiences. **Since beginning this trial,** how often have you...

[Response options for A1a-k: 1=Never, 2=Almost never, 3=Sometimes, 4=Fairly often, 5=Very often]

- a. Been upset because of something that happened that you didn't expect?
- b. Felt nervous and "stressed out"?
- c. Found that you could not deal with all the things that you had to do?
- d. Gotten angry because of things that happened that were outside of your control?
- e. Felt that you had so many problems that you could not deal with them?
- f. Felt that you were able to successfully handle the important changes occurring in your life?
- g. Felt able to handle your personal problems?
- h. Felt that things were going your way?
- i. Been able to control hassles in your life?
- j. Felt that you were on top of things?
- k. Been able to control the way to spend your time?

	, , ,
A2. How m	any participants do you personally know in the MTN-027 study? participant(s) [IF A2=0, SKIP TO A4]
Δ3 Of thos	se [import A2 response] participants, how many are:
7.5. 01 11105	a. Friends
	b. Family members
	c. Women you met through clinic
	· ——
	d. Neighbors
	e. Other Please specify your relationship:
	The sum of responses for 3a-e must equal A2.
	han clinic staff, think of the 5 close/important people that you have talked to about MTN-027 and list them below.
(/ /	(List up to 5 people. If fewer than 5, leave rows blank. Please use only initials or a
	nickname/alias.)
	,
	a. Person 1:
	b. Person 2:
	c. Person 3:
	d. Person 4:
	e. Person 5:
	

PRE-SKIP: IF A4a-e ARE ALL BLANK, SKIP TO B1.

Please answer the following questions for each person listed.

A5. For each person named, please select the box that best applies

[Columns:]

- C1 Is this person male or female?
 - 1. Male
 - 2. Female
- C2 What is this person's relationship to you?
 - 1. Husband or wife
 - 2. Sexual partner other than husband or wife
 - 3. Other family member (e.g., sister or mother)
 - 4. Someone you met during the trial
 - 5. Neighbor
 - 6. Friend
 - 7. Co-worker
 - 8. Other, please specify: _____
- C3 Have they participated in MTN-027?
 - 1. Yes
 - 0. No
- C4 What is this person's opinion about the ring?
 - 1. Liked the ring
 - 2. Disliked the ring
 - 3. No opinion
 - 4. Don't know
- C5 How did this person respond to your use of the ring?
 - 1. Encouraged me to use the ring
 - 2. Discouraged me from using the ring
 - 3. Did neither

SECTION B. RING ACCEPTABILITY

The following questions are about your **overall experience with the ring used in this trial**.

- B1. Overall how easy or difficult was it to use the ring?
 - 1. Very difficult
 - 2. Difficult
 - 3. Easy
 - 4. Very easy
- B2. How difficult or easy was it to insert the ring?
 - 1. Very difficult
 - 2. Difficult
 - 3. Easy
 - 4. Very easy
 - 5. I did not insert the ring
- B3. How difficult or easy was it to take the ring out?
 - 1. Very difficult
 - 2. Difficult
 - 3. Easy
 - 4. Very easy
 - 5. I did not take the ring out
- B4. How often did you think about the ring being inside your body?
 - 1. Never
 - 2. Some of the time
 - 3. Most of the time
 - 4. All of the time
- B5. How often were you aware of the ring during your normal daily activities?
 - 1. Never
 - 2. Some of the time
 - 3. Most of the time
 - 4. All of the time
- B6. Overall, how did it feel to have the ring inside you every day?
 - 1. Very comfortable
 - 2. Comfortable
 - 3. Uncomfortable
 - 4. Very uncomfortable

The following questions are about changes in your vagina that you may have experienced while wearing the ring.

B7bd. How much has your vagina being drier bothered you?		
1. Not at all		
2. A little		
3. Somewhat		
4. Very much		
B7c. Overall, have you experienced any other changes in your vagina while wearing the ring?		
1. Yes, please specify:		
0. No [SKIP TO B8]		
B7cd. How much has this change bothered you?		
1. Not at all		
2. A little		
3. Somewhat		
4. Very much		
Very maon		
B8. How often did you feel the ring inside you when you had vaginal sex?		
1. Never [SKIP TO B10]		
2. Some of the time		
3. Most of the time		
4. All of the time		
5. I never had vaginal sex with the ring in [SKIP TO B10]		
B9. How much did it bother you to feel the ring inside you when you had vaginal sex?		
1. Not at all		
2. A little		
3. Somewhat		
4. Very much		
The next question will ask about your primary sex partner's reaction to you wearing the vaginal ring.		
Please respond even if your primary sex partner doesn't know you are taking part in this study.		

B7a. Overall, did you notice that your vagina was wetter?

B7ad. How much has your vagina being wetter bothered you?

B7b. Overall, did you notice that your vagina was drier?

0. No [SKIP TO B7b]

0. No **[SKIP TO B7c]**

1. Yes

1. Yes

Not at all
 A little
 Somewhat
 Very much

B10. If you were to have sex with the ring in, how important would it be for you that your primary sex partner does not feel the ring during sex?

- 1. Not at all important
- 2. Somewhat important
- 3. Very important
- 4. Extremely important

SECTION C. PRODUCT PREFERENCE

Now we would like to ask you about your experience with both the ring and male condoms.

- C1. Overall, how much do you like male condoms?
 - 1. Dislike very much
 - 2. Dislike
 - 3. Like
 - 4. Like very much
- C2. As a method to prevent HIV, which would you prefer to use—the ring or the male condom?
 - 1. Ring
 - 2. Condom
 - 3. Neither-I dislike both products
 - 4. Both–I like both products equally
- C3. What would your primary partner prefer—the ring or the male condom?
 - 1. Ring
 - 2. Condom
 - 3. Neither-dislikes both products
 - 4. Both-likes both products equally
 - 5. Don't know
 - 6. I don't have a primary partner

If in the future a vaginal ring was available that provided some protection against HIV, and it was similar to the one you will use in this study...

- C4a. Would you use it?
 - 1. Yes
 - 0. No

C4b. How likely would you be to keep it inserted in your vagina every day?

- 1. Very unlikely
- 2. Unlikely
- 3. Likely
- 4. Very likely

SECTION D. RING PROBLEMS

Now we would	like to ask you about any problems you experienced while wearing the ring.
physical discom	28 days that you were asked to use the ring, how many days did you experience any after because of the ring? day(s) [IF D1=0, SKIP TO D3]
D2. Overall, ho	w much did the physical discomfort bother you?
1.	Not at all
2.	A little
	Somewhat
4.	Very much
D3. During the because of the	28 days that you were asked to use the ring, how many days did you experience any pain ring?
	day(s) [IF D3=0, SKIP TO D5]
D4. Overall, ho	w much did the pain bother you?
1.	Not at all
2.	A little
3.	Somewhat
4.	Very much
was moving or	28 days that you were asked to use the ring, how many days did you feel that the ring not correctly in place?
	day(s) [IF D5=0, SKIP TO D7]
D6. Overall, ho	w much did the ring moving or being out of place bother you?
	Not at all
	A little
	Somewhat
4.	Very much
D7. During the	28 days that you were asked to use the ring, how many days did the ring cause you
	omfort such as worries, fears, guilt or any other unpleasant feelings? _ day(s) [IF D7=0, SKIP TO D9]
D8. Overall, ho	w much did this emotional discomfort bother you?
1.	Not at all
2.	A little
3.	Somewhat

4. Very much

_	28 days that you were asked to use the ring, how many days did the ring interfere with
your normal da	,
	day(s) [IF D9=0, SKIP TO D11]
D10. Overall, h	ow much did this interference with daily activities bother you?
1.	Not at all
2.	A little
3.	Somewhat
4.	Very much
D11. During the constipation?	e 28 days that you were asked to use the ring, how many days did you experience any
	day(s) [IF D11=0, SKIP TO D13]
D12. Overall, h	ow much did the constipation bother you?
1.	Not at all
2.	A little
3.	Somewhat
4.	Very much
D13. During the leakage?	e 28 days that you were asked to use the ring, did you experience any change in urine
_	Increase
2.	No change
3.	Decrease
4.	I never experienced urine leakage
D14. Were you	ever unable to remove the ring when you tried to take it out of your vagina?
1.	Yes
2.	No
3.	I never tried to remove the ring
	any other problem you had with the ring?
	Yes, please specify:
0.	No
	your preferences about wearing the ring every day?
	I prefer wearing it every day
	I prefer not wearing it everyday
3.	I don't have a preference
D17. Overall, h	ow much do you like the ring?
1.	Dislike very much
2.	Dislike

3. Like

4. Like very much

D18. How do you like the ring now compared to when you started the study?

- 1. I like it MORE now than when I started the study
- 2. I like it LESS now than when I started the study
- 3. I like it the SAME as when I first started
- 4. Not applicable, I do not like the ring

SECTION E. SEXUAL BEHAVIOR

The next set of questions will ask you about sexual behavior.

butt)

Let's briefly go over the definitions of some terms so that you understand what is being asked.

When I say: I mean:

Vaginal sex: When a man inserts his penis into your vagina

Receptive anal sex: When a man puts his penis into your anus (or butt)

Receiving oral sex: When a partner puts his or her mouth or tongue on your vagina or anus (or butt)

Giving oral sex: When you put your mouth or tongue on your partner's penis, vagina or anus (or

The next set of questions will be about your sexual behavior with men since beginning this trial.

E1. Since beginning this trial, how many male sexual partners have you had?

_____ male sexual partner(s) [IF E1=0, SKIP TO E9]

- E2. Since beginning this trial...
 - a. How many times did a male partner put his penis in your vagina?

_____ time(s) [IF E2a=0, SKIP TO E5]

b. How many times did a male partner put his penis in your vagina <u>without a condom</u>?
 time(s) [IF E2b=0, SKIP TO E5]

c. How many different men put their penises in your vagina without a condom?

_____ men [IF E2c > 1, SKIP TO E4]

- E3. You said that one partner put his penis in your vagina without a condom. Regarding this partner (please select one answer)...
 - 1. This partner told you he was HIV-negative and you had no reasons to doubt it
 - 2. You knew this partner was HIV-positive
 - 3. You were not completely sure of this partner's HIV status

PRE-SKIP: IF E2c=1, SKIP TO E5.

E4. You said that **[import answer E2c]** partners put their penises in your vagina without a condom. Of those men...

a.	How many had actually told you they were HIV-negative and you had no reasons to doubt it?
	partner(s)
b.	How many do you know to be HIV-positive?
	partner(s)
C.	How many were you NOT completely sure of their HIV status? partner(s)
Logic c	heck: Sum of responses for E4a-E4c must equal E2c.
	e to ask you about <u>receptive anal sex</u> . Remember, by receptive anal sex, I mean when a
man puts his pe	enis inside your anus or butt. Since beginning this trial
a.	How many times did a male partner put his penis in your rectum (or butt)?
	time(s) [IF E5d=0, SKIP TO E8]
b.	How many times did a male partner put his penis in your rectum (or butt) without a
	condom?
	time(s) [IF E5e=0, SKIP TO E8]
c.	How many different men put their penises in your rectum (or butt) without a condom?
	men [IF E5c > 1, SKIP TO E7]
	at one partner put his penis in your rectum (or butt) without a condom. Regarding this e select one answer)
1.	This partner told you he was HIV-negative and you had no reasons to doubt it
2.	You knew this partner was HIV-positive
3.	You were not completely sure of this partner's HIV status
PRE-SKIP: IF E5	c=1, SKIP TO E8.
E7. You said the condom. Of the	at [import answer E5c] partners put their penises in your rectum (or butt) without a ose men
a.	How many had actually told you they were HIV-negative and you had no reasons to doubt it?
	partner(s)
b.	How many do you know to be HIV-positive?partner(s)
C.	How many were you NOT completely sure of their HIV status? partner(s)

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Logic check: Sum of responses for E7a-E7c must equal E5c.

	a.	How many times did you put a man's penis in <u>your mouth</u> ? time(s) [IF E8a=0, SKIP TO E8d]
	b.	How many times did you put a man's penis in your mouth without a condom? time(s) [IF E5e=0, SKIP TO E8]
	C.	How many different men's penises did you put in your mouth without a condom? men's penises
	d.	How many times did a man put his mouth on <u>your vagina</u> ? time(s) [IF E5c > 1, SKIP TO E9]
	e.	How many different men put their mouths on your vagina? men
The next	t set of	questions will be about your sexual behavior with women since beginning this trial.
E9. Since	e begin	ning this trial, how many female sexual partners have you had?
		female sexual partners [IF E9=0, SKIP TO F1]
E10. Sind	ce begi	nning this trial
	a.	How many times did you and your female partner(s) share any toys or other objects (e.g., vibrators, dildos, etc.) to penetrate each other vaginally? time(s) [IF E10a ≤ 1, SKIP TO E10c]
	b.	How many <u>different women</u> did you share any toys or other objects (e.g., vibrators, dildos, etc.) with to penetrate each other vaginally? women
	C.	How many times did you and your female partner(s) share any toys or other objects (e.g., vibrators, dildos, etc.) to penetrate each other in the rectum? time(s) [IF E10c ≤ 1, SKIP TO E10e]
	d.	With how many <u>different women</u> did you share any toys or other objects (e.g., vibrators, dildos, etc.) to penetrate each other in the rectum? women
	e.	How many times did you put your mouth on a vagina or clitoris? time(s) [IF E10e ≤ 1, SKIP TO E10g]

E8. Now I'd like to ask you about <u>oral sex</u>. Since beginning this trial...

f.	How many women's vaginas or clitorises did you put your mouth on? women's vaginas/clitorises
g.	How many times did women put their mouth on your vagina? time(s) [If E10g ≤ 1, skip to F1]
h.	How many different women put their mouths on your vagina? women

SECTION F. MENSTRUATION

F1. Did you manage your period any differently than you usually do while participating in this trial?
1. Yes, I started using tampons
2. Yes, I started using sanitary pads or panty liners
3. Yes, I started using (Please specify:)
4. Yes, I stopped using tampons
5. Yes, I stopped using sanitary pads or panty lines
6. Yes, I stopped using(Please specify:)
7. No [SKIP TO G1]
F2. Why did you change?
[Open Response]

1. Yes	
0. No [SKIP TO H1]	
G2. What contraceptive method(s) do you use now? [Check all that apply]	
1. Male condom	
2. Female or internal condom	
3. Oral contraception ("The Pill")	
 Emergency contraception (Paragard IUD, Ella, Plan B One-Step, Next Choice, My Way, Levonorgestrel, or Yuzpe regimen) 	
5. The Patch (such as Ortho Evra or Xulane)	
6. Depo-Provera ("The Shot")	
7. Vaginal ring (such as Nuva Ring, Estring, Femring)	
8. Spermicidal sponge, foam, cream, or jelly	
9. Cervical barrier (diaphragm, cervical cup, etc.)	
10. Intra-uterine device or IUD (such as Mirena, Paragard, Skyla)	
11. Implant (such as Implanon or Nexplanon)	
12. Withdrawal or "pull-out" method	
 Fertility awareness-based methods or menstrual cycle tracking No contraceptives 	
15. Other (Please specify:)	
15. Other (Fleuse speen)	
G3. Why did you change? [Open Response]	
, , , , , , , , , , , , , , , , , , , ,	

SECTION H. VAGINAL DOUCHES, LUBRICANTS, AND OTHER PRODUCTS

The next set of questions is about vaginal products.

- H1. **During the 28 days that you were asked to use the ring,** did you use any of the following products? [Check all that apply]
 - a. Dessicants, that is, anything to make your vagina dry or tight, such as Tight Stuff
 - b. Female condoms, also called "Reality®"
 - c. Medications for yeast infections that you put in your vagina such as Monistat, Femstat, or Gyne-Lotrimin
 - d. Spermicides, that is, a foam, gel, film, suppository, or cream that kills sperm and prevents pregnancy

FOR ANY H1a-d=N0(0), SKIP CORRESPONDING QUESTION IN H2.

H2. During the 28 days that you were asked to use the ring	g, how many times did you use each of t	:he
following products?		

following pro	ducts?	
a.	Dessicants, that is, anything to make your vagina dry or tight, such as Tight Stuff time(s)	
b	Female condoms, also called "Reality®" time(s)	
C.	Medications for yeast infections that you put in your vagina such as Monistat, Femstat, or Gyne-Lotrimin time(s)	
d	Spermicides, that is, a foam, gel, film, suppository, or cream that kills sperm and prevents pregnancy time(s)	
H3. During the 28 days that you were asked to use the ring, did you use a vaginal lubricant?		
	Yes No [SKIP TO H5]	
H4. During th all that apply]	e 28 days that you were asked to use the ring, what types of lubricant did you use? [Check	
a.	Silicon-based (e.g., Eros, Wet Platinum, Gun Oil)	
b	Water-based (e.g., KY Jelly, Wet Original, Durex, ForFun, Love Lub, Aquasol, Astroglide, Gun Oil H20)	
C.	Oil-based (e.g., Crisco, lotion or cream, Vaseline, vegetable oil, fish oil, yogurt, butter)	
	Spit	
	Lubricated condoms	
f.	I don't need to use additional lubrication (i.e. my vagina lubricates enough)	
g.	Other (please specify:)	

_	28 days that you were asked to use the ring, how many times did you douche vaginally r or other personal hygiene product into your vagina)?
	time(s) [IF ZERO, SKIP TO I1]
	port H5 response] times you douched during the 28 days that you were asked to use the y times did you douche for each of the following reasons:
2. 3. 4. 5. 6. 7.	For general hygiene In preparation for sex After sex For pleasure After your period was finished While you were bleeding from your period Because your vagina felt itchy or uncomfortable Other (Please specify:)
	es [import H5 response] you douched during the 28 days that you were asked to use the y times did you use the following products:
b. c. d.	A hand-held hose or bidet Over-the-counter disposable douche product (e.g., Massengill® or Summer's Eve®) Re-usable bottle system Water and vinegar Other (Please specify:)

SECTION I. SUBSTANCE USE

The following questions refer to alcohol and drug use. Remember, your answers are confidential and will not be viewed by clinic staff.

11. Since beginning this trial, how often have you used each of the following substances?

GO DOWN "A" COLUMN FIRST. IF "0" FOR ANY SUBSTANCES, SKIP B FOR THOSE PARTICULAR SUBSTANCES. USE THE FOLLOWING RESPONSE CHOICES:

		[A]	[B]
		Number of times used in since beginning this trial	Number of times used before or during sex since beginning this trial
a.	Alcohol (beer, wine, liquor)	times	times
b.	Marijuana/hashish/pot/weed	times	times
c.	Ecstasy/MDMA	times	times
d.	Crystal Meth/amphetamines/ methamphetamines/speed/crank/ice	times	times
e.	Ketamine/special K	times	times
f.	GHB (Gamma hydroxybutyrate)	times	times
g.	Other hallucinogens/LSD/ mushrooms	times	times
h.	Poppers/amyl nitrate/butyl nitrate	times	times
i.	Crack	times	times
j.	Cocaine (not crack)	times	times
k.	Heroin	times	times
I.	Any other pharmaceutical drugs not prescribed to you by a physician	times	times
m.	Other, please specify:	times	times

PRE-SKIP: If I1a[A]=0, SKIP TO J1

- 12. Thinking about the times you used alcohol since beginning this trial, how much did you typically use?
 - 1. Too little to feel any effect
 - 2. Enough to feel it a little
 - 3. Enough to feel it a lot
 - 4. Enough to get drunk
 - 5. Enough to feel like you might pass out

SECTION J. ADDITIONAL COMMENTS

We are almost to the end of the interview.

- J1. Is there anything that we haven't asked that you think we should have? [Open response]
- J2. Is there anything else you would like to tell us about your experience with the ring **since beginning this trial**?

[Open response]

This is the end of the interview. Thank you for completing this questionnaire! Please click on 'Next' when you are ready to save your responses. After you do so, you will not be able to change your answers.