Practice Questions

PRACINTRO1

Thank you for agreeing to complete this questionnaire for the MTN-024 Study.

Before you begin, there are a few practice questions for you to get used to how the system works. You may wish to experiment with your responses (try to leave certain fields blank, change your answers, etc.) to become more comfortable with the system. If you have any questions on how to use the computer, the clinic staff can assist you.

Click the "NEXT" button to go to the next screen.

PRACINTRO2

Good! You can always move to the next screen by clicking "NEXT," or to go to the previous screen, click the "PREVIOUS" button. If you refuse to answer the question, click on the grey box in the bottom corner. You will be asked to confirm that you wish to skip the question and go on to the next page.

Click the "NEXT" button to go to the practice questions.

| 1. | PRAC1 | (note: | examp | le of | a r | adio | button (| question |) |
|----|-------|--------|-------|-------|-----|------|----------|----------|---|
|----|-------|--------|-------|-------|-----|------|----------|----------|---|

This is an example of a question where one answer is allowed. It shows how to answer questions with buttons. Try answering the question below by moving the mouse arrow and clicking on the button that matches your answer. If you want to change your answer, simply click the new answer you want.

| Example question: | | | |
|-------------------|---------|--|--|
| Do you like | summer? | | |
| 0 | Yes | | |
| 0 | No | | |

2. PRAC2 (note: example of a radio table question)

You will also be asked to answer questions listed in a table. For each row, click on one of the columns. For example, in the question below, for each season, mark 'Yes' or 'No'.

Example question:

Please indicate whether or not you like the following seasons.

| | Yes | No |
|-----------|-----|----|
| a. Winter | 0 | 0 |
| b. Spring | 0 | 0 |
| c. Summer | 0 | 0 |
| d. Fall | 0 | 0 |

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3. **PRAC3** (note: example of a drop-down menu question)

You will be asked questions which involve selecting one answer from a drop-down menu. In order to answer these questions, click on the down arrow and select the appropriate answer.

Example question:

When was the last time you ate ice cream?

(drop-down menu will display these eight options)

- Today
- Yesterday
- 2 days ago
- 3 days ago
- 4 days ago
- 5 days ago
- 6 days ago
- 7 or more days ago
- **4. PRAC4**(note: example of a check-all-that-apply question)

Some questions will involve checking one or more boxes. You will be asked to mark <u>all</u> the boxes that are appropriate and you may mark several boxes. If you would like to select a response, click on the box beside the response. If you change your mind, you can de-select the response by clicking again on the checked box to remove the check.

Example question:

What type(s) of ice cream do you like to eat? Choose all that apply.

| None of the above |
|------------------------|
| Other, please specify: |
| Chocolate |
| Strawberry |
| Vanilla |

A few notes about this type of question:

- 1. If you select 'Other', be sure to fill in the space beside the response with the specific flavor of ice cream that you like. If you forget to fill this in, you will receive an error message.
- 2. If you select **None of the above**, you may not select any of the other boxes. If you select **None of the above** after checking any of the other boxes, the checks in the other boxes will disappear. Be sure to only check the last option if none of the other options are appropriate.

(Logic: At least one must be marked.)

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PRACEND

Thank you for completing the practice questions. If you had any problem answering any of them, let the study staff know about it. Otherwise, click "NEXT" to proceed to the questionnaire.

Behavioral Assessment

Thank you for coming to the clinic today, for the MTN-024 study. As part of the study, you will be asked questions about yourself, your sexual behavior and health. There is no right or wrong answer to any question we ask, and every answer is important. Please be as honest as you can. Some of the questions may seem very personal. We are using the computer to give you the most privacy possible. The study staff will not have access to your answers, and none of your answers will prevent you from participating in the study. All of your answers will be kept confidential. If at any time you have a question or a problem, please ask the study staff to help you. Let's begin.

| iviolivation to join stud | Motivation to j | ioin study |
|---------------------------|-----------------|------------|
|---------------------------|-----------------|------------|

| l. | Have you e | ver participated in a clinical trial or any other research study? |
|----|-------------|---|
| | 0 | Yes |
| | 0 | No |
| | | |
| 2. | Which is th | e main reason you joined this research study? |
| | 0 | To receive the financial reimbursement/compensation |
| | 0 | To be provided with free health care during the study, or to get higher quality health care |
| | 0 | To be tested for HIV |
| | 0 | To get educated or find out more about HIV |
| | 0 | To help test a product that may prevent women from getting HIV |
| | 0 | To contribute to scientific knowledge |
| | 0 | To satisfy my curiosity about participating in a study |
| | 0 | A friend/family member recommended that I join the study |
| | 0 | I am worried about getting infected with HIV |
| | 0 | My health care provider recommended that I join the study |
| | 0 | Other, please specify: |
| | | |

Demographics and background behavioral characteristics BDEMOINTRO

Next, we will ask you some questions about yourself.

- 3. Which of the following best describes where you currently live?
 - Own a house or apartment
 - o Rent a house or apartment

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|---------|-----|----|-----|--------|------|---|
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- o Rent a room in a group house
- Stay with partner/relatives/ family
- Stay with friends
- o Homeless or I do not have a regular place to live
- Other, please specify: _____
- 4. Please choose the response that best describes your sexual orientation.
 - Lesbian / gay / homosexual
 - Bisexual
 - Straight / heterosexual
 - o None of the above
- 5. How many times in your life have you been pregnant? Please include live births, still births, terminations/abortions, miscarriages and tubal pregnancies. _____ (Logic: If number of pregnancies=0 SKIP to question XXXSINTRO)
 - 5a. Please indicate how many of these pregnancies resulted in:
 - Vaginal delivery _ _
 - Caesarean delivery ___
 - Miscarriage___
 - Abortion__
 - Ectopic (tubal) pregnancy ___

(Logic: number of responses in 5a must = # of pregnancies in 5. ppt MUST provide a number 0 or more to each item a through e)

BDRUGINTRO

Now we will ask you some questions about your alcohol and drug use and other behaviors.

6. In the past 30 days, how many days did you drink alcohol?

__ days

- 7. How often do you have four or more drinks on one occasion?
 - Never
 - Less than monthly
 - Monthly
 - Weekly
 - Daily or almost daily
- 8. In the past 30 days, have you smoked, swallowed or snorted any kind of recreational drug?
 - o Yes
 - o No
- 9. Have you ever in your life injected any kind of recreational drug?
 - Yes

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o No

(Logic: If no, skip to Question 10 -- ever exchanged sex)

9a. In the past 30 days have you injected any kind of recreational drug?

- o Yes
- o No
- 10. Have you ever in your life exchanged sex for food, drugs, shelter or money?
 - Yes
 - o No
- 11. Have you ever in your life been diagnosed or treated for a sexually transmitted infection?
 - o Yes
 - o No

Sexual practice/Partner types

You will now be asked questions about your sexual behavior and health. There are no right or wrong answers to the questions and every answer is important. Please feel free to be completely honest.

We have listed below all the different types of sexual activities that we will ask you about.

| When we say: | We mean: |
|---------------------|---|
| Vaginal sex | When a man inserts his penis into your vagina |
| Anal sex | When a man puts his penis into your anus/butt |
| Receiving oral sex | When a partner puts his or her mouth or tongue on your vagina or |
| | anus/butt |
| Giving oral sex | When you put your mouth or tongue on your partner's penis, vagina |
| | or anus/butt |
| Finger sex | When you or a partner inserts finger(s) into your vagina or anus/butt |
| Non-penetrative sex | When you have any kind of sex with yourself or with a partner, |
| | without inserting something into your vagina or anus/butt (e.g. |
| | rubbing each other, mutual masturbation or self masturbation) |

Now, we would like to ask you some questions about your sex life.

- 12. In your **lifetime**, what type(s) of sexual activity have you had?
 - a. Vaginal sex
 - Yes
 - o No

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| | b. Anal | l sex | |
|-----------|-----------|-----------------------|---|
| | 0 | Yes | |
| | 0 | No | |
| | c. Rece | eiving ora | al sex |
| | 0 | Yes | |
| | 0 | No | |
| | d. Givii | ng oral s | ex |
| | 0 | Yes | |
| | 0 | No | |
| | e. Fing | | |
| | 0 | Yes | |
| | 0 | No | |
| | f. Non- | penetra | tive sex |
| | 0 | Yes | |
| | 0 | No | |
| | | 3: if Q12 last act | a=1 of vaginal sex that you had, was a condom used? |
| 0 | Yes No | | |
| - | | - | these if corresponding Q12 question=1 |
| L4. IN TI | | nal sex | , what type(s) of sexual activity have you had? |
| | a. vagi | Yes | |
| | | No | |
| | 0 | NO | |
| Pre-skip | : Ask if | Q14a=1, | , else go to Q14b |
| | | i. | In the past 30 days, how many times did you have vaginal sex? times |
| | b. Anal | l sex | |
| | 0 | Yes | |
| | 0 | No | |
| | | | |

o Man o Woman

| MTN 024 Bas | seline CASI Questionnaire |
|------------------|---|
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| c. Rece | eiving oral sex |
| 0 | Yes |
| 0 | No |
| d. Givi | ng oral sex |
| 0 | Yes |
| 0 | No |
| e. Fing | er sex |
| 0 | Yes |
| 0 | No |
| f. Non- | penetrative sex |
| | Yes |
| 0 | No |
| Now we would | d like to ask you some questions about your sex partners. |
| Pre-Skip on Q1 | 5: ask if any Q12, else go to Q17 |
| 15. Do you cur | rently have a primary sex partner? By primary sex partner we mean a person you haven a regular basis or who you consider to be your main partner. |
| | o Yes |
| | o No |
| Post-skip: go to | Q16 if Q15=2 |
| 15a.Do | pes your primary sex partner know that you are taking part in this study? |
| | o Yes |
| | o No |
| | o Don't Know |
| 15b. V | When did you start having sex with your primary sex partner? |
| | Month Year |
| 15c. Is | your primary sex partner a man or a woman? |

Other, please specify: _____

MTN 024 Baseline CASI Questionnaire Version 1.0 (30 July 2013) 15d. How old is your primary sex partner? _ _ years old 15e. Has your primary sex partner experienced difficulty in sexual performance in the past 3 months? (e.g. erectile problems, ejaculation difficulties, low arousal) Never Some of the time Most of the time All of the time 15f. In the past 3 months, has your primary partner used medications to enhance or improve sexual performance? Yes o No 16. In the past 3 months, have you used any medications to enhance or improve sexual performance? Yes o No Now, we would like to ask you about all of your sex partners. Pre-Skip: ask if Q12a, Q12b, or Q12e = 1, else go to Q19 17. How many sex partners have you had in your life? Please only count persons with whom you have had vaginal sex, anal sex, or finger sex, including your primary sex partner. ___ sex partners (range check: 1+)

Pre-Skip: ask if Q12a, Q12b, or Q12e = 1, else go to Q19

18. **In the past 3 months**, how many sex partners have you had? Please only count persons with whom you have vaginal sex, anal sex, or finger sex, including your primary sex partner.

```
___ sex partners (range check: 1+ if Q14a, Q14b, or Q14e = 1)
```

Pre-Skip: ask if Q12a=1, go to VAGINALPRACTICES

- 19. In the past 3 months, how often has vaginal sex been painful for you?
 - Never
 - o Some of the time
 - Most of the time
 - o All of the time

Post-skip:if Q19=1 then go to VAGINALPRACTICES

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19a How painful was it?

- o A little painful
- o Somewhat painful
- Very painful

vaginas. hese items. ising them ll not affect

| VAGINA | _PF | ACTICES |
|-----------|------|--|
| | | t questions, we will ask you about items that women sometimes insert into their |
| | | for personal hygiene or other reasons, and some women may not insert any of t |
| Please no | ote | that these questions are about putting items inside your vagina and not about u |
| outside y | ou/ | r vagina. You should feel free to tell us anything you have used. Your answers wil |
| your par | tici | pation in the study. |
| | | |
| 20. Have | yc | ou ever in your life used any of the following? |
| | a. | Male condom (Please mark 'Yes' if your partner used a condom.) |
| | | o Yes |
| | | o No |
| | b. | Female condom |
| | | o Yes |
| | | o No |
| | c. | Vaginal ring (such as NuvaRing, Estring, Femring) |
| | | o Yes |
| | | o No |
| | d. | Spermicidal sponge, cream or jelly |
| | | o Yes |
| | | o No |
| | e. | Cervical barrier (diaphragm, cervical cup, etc.) or menstrual cup |
| | | o Yes |
| | | o No |
| | f. | Douche or other personal hygiene products that are inserted inside the vagina |
| | | o Yes |
| | | o No |
| | g. | Tampon |
| | | o Yes |
| | | o No |
| | h. | Personal or sexual lubricant |
| | | o Yes |
| | | o No |

i. Vaginal medication in cream or gel form

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|-----------------|--------------|
| 0 | Yes |
| 0 | No |
| j. Otl | her |

o Yes, please specify:

o No

Pre-skip: Ask if Q20e=1

21. How many times did you douche vaginally in the past 3 months? times

BRINGINTRO

Now, we would like to ask you some questions about the vaginal ring used in this study ("the ring").

Some women may have **worries or concerns** about the ring. Please indicate the worries you are having **today** about using the ring.

- 22. How worried are you about having a vaginal ring inside of you every day for 3 months?
 - Very worried
 - Somewhat worried
 - Not at all worried

We are going to ask you a series of questions that can be answered with yes or no regarding all the worries you may have today about using the vaginal ring.

- 23. Are you worried about...
 - a. the ring being dirty?
 - Yes
 - o No
 - b. the ring coming out by accident?
 - Yes
 - o No
 - c. the ring not staying correctly in place?
 - o Yes
 - o No
 - d. the ring getting stuck inside your body?
 - Yes
 - o No
 - e. the ring coming out during sex?
 - o Yes
 - o No

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| f. | the ring feeling uncomfortable or painful during sex? O Yes O No |
|------|--|
| g. | your primary sex partner or other sex partner bumping into or feeling the ring during sex? O Yes No |
| h. | difficulty inserting the ring? o Yes o No |
| i. | difficulty removing the ring? o Yes o No |
| j. | the ring feeling uncomfortable or painful during normal daily activities? o Yes o No |
| k. | your primary sex partner or other sex partners not liking or approving of you wearing the ring? o Yes No |
| I. | a family member not liking or approving of you wearing the ring?YesNo |
| m. | the ring causing infection, genital problems, or other health problems? o Yes o No |
| n. | feeling sick from wearing the ring? o Yes o No |
| | anything else? O Yes, please specify: No |
| 1end | opause Rating Scale |

Now we would like to ask you some questions about any menopause symptoms you may feel.

24. Which of the following symptoms apply to you at this time? Please, mark the appropriate box for each symptom. For symptoms that do not apply, please mark 'none'.

| n None Mild Moderate Severe Very Severe | mptom | |
|---|-------|--|
|---|-------|--|

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| | | 0 | 1 | 2 | 3 | 4 |
|----|---|---|---|---|---|---|
| a. | Hot flashes, sweating (episodes of sweating) | | | | | |
| b. | Heart discomfort (unusual awareness of heart beat, heart skipping, heart racing, tightness) | | | | | |
| C. | Sleep problems (difficulty in falling asleep, difficulty in sleeping through, waking up early) | | | | | |
| d. | Depressive mood (feeling down, sad, on the verge of tears, lack of drive, mood swings) | | | | | |
| e. | Irritability (feeling nervous, inner tension, feeling aggressive) | | | | | |
| f. | Anxiety (inner restlessness, feeling panicky) | | | | | |
| g. | Physical and mental exhaustion (general decrease in performance, impaired memory, decrease in concentration, forgetfulness) | | | | | |
| h. | Sexual problems (change in sexual desire, in sexual activity and satisfaction) | | | | | |
| i. | Bladder problems (difficulty in urinating, increased need to urinate, bladder incontinence) | | | | | |
| j. | Dryness of vagina (sensation of dryness or burning in the vagina, difficulty with sexual intercourse) | | | | | |
| k. | Joint and muscular discomfort (pain in the | | | | | |

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| joints, rheumatoid | | | |
|-----------------------|--|--|--|
| complaints) | | | |

Urogenital Distress Inventory UDI-6

Now we would like to ask you some questions about any problems you may have with urination.

| Now we would like to ask you some questions about any problems you may have with dimation |
|---|
| 25. Do you usually experience frequent urination? ☐ Yes |
| \square No |
| Post-skip: If Q25=2 then go to Q26 |
| 25a. How much does this bother you? ☐ Not at all ☐ Somewhat ☐ Moderately ☐ Quite a bit |
| 26. Do you usually experience urine leakage associated with a feeling of urgency; that is, strong sensation of needing to go to the bathroom? ☐ Yes ☐ No |
| Post-skip: If Q26=2 then go to Q27 |
| 26a. How much does this bother you? ☐ Not at all ☐ Somewhat ☐ Moderately ☐ Quite a bit |
| 27. Do you usually experience urine leakage related to coughing, sneezing, or laughing? ☐ Yes ☐ No Post-skip: If Q27=2 then go to Q28 |
| 27a. How much does this bother you? ☐ Not at all ☐ Somewhat ☐ Moderately ☐ Quite a bit |
| 28. Do you experience small amounts of urine leakage (that is, drops)? ☐ Yes ☐ No |
| Post-skip: If Q28=2 then go to Q29 |

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| 28a. How much does this bother you? ☐ Not at all ☐ Somewhat ☐ Moderately ☐ Quite a bit | |
|---|--|
| 29. Do you experience difficulty emptying your bladder? ☐ Yes ☐ No Post-skip: If Q29=2 then go to Q30 | |
| 29a. How much does this bother you? Not at all Somewhat Moderately Quite a bit | |
| 30. Do you usually experience pain or discomfort in the lower abdomen or genital region? ☐ Yes ☐ No Post-skip: If Q30=2 then go to COMPLETE | |
| 30a. How much does this bother you? ☐ Not at all ☐ Somewhat ☐ Moderately ☐ Quite a bit | |
| 30b. Is your pain relieved after emptying your bladder? ☐ Yes ☐ No | |

COMPLETE

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.