

**MTN 035 Product Use End Visit Behavioral Survey
Rectal INSERT**

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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 you last completed this survey**, how often have you...

[Response options for 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?

SECTION B. Insert Use & Adherence

The following questions refer to your use of the rectal Insert over the past 4 weeks.

B0. Thinking about your experience during these past four weeks, how many weeks did you miss a rectal insert application?

1. 0 weeks
2. 1 week
3. 2 weeks
4. 3 weeks
5. 4 weeks [SKIP TO B4B]

During this 4-week period you were asked to apply the rectal insert in your rectum before anal sex or to use it once per seven-day period if you didn't have sex during that seven-day period. However, for different reasons, many people have difficulties doing this.

B1. How many times did a partner put a penis in your rectum during the past 4 weeks? _____

[IF B1 = 0, GO TO B4]

B2. **Of those [B1] times**, how many times did you use the study-provided rectal Insert BEFORE receptive anal sex?

(If you did not use the rectal insert prior to receptive anal sex, please enter '0'.)

__ time(s) [IF 0, SKIP TO B3]

B2a. Typically, how long before **receptive anal sex** did you apply the rectal **insert**?

1. Less than 15 minutes
2. Between 15 minutes and 30 minutes
3. Between 30 minutes and 1 hour
4. Between 1 and 2 hours
5. Between 2 and 3 hours
6. Between 3 and 4 hours
7. 4 hours or more

B2b. Did you use more than one rectal insert before engaging in receptive anal sex?

1. Yes
2. No

B2c. When you used a rectal insert before receptive anal sex, how often did you use also use a rectal douche/enema before sex?

1. Never
2. Rarely
3. Sometimes
4. Often
5. Always

B2d. When you used a rectal insert before receptive anal sex, how often did you use a rectal lubricant before applying the Insert?

1. Never
2. Rarely
3. Sometimes
4. Often
5. Always

B2e. What motivated you to use the study provided **rectal Insert BEFORE receptive anal sex**? *Indicate all that apply*

1. To follow the study procedures
2. I usually use an insert before receptive anal sex
3. I wanted to have a bowel movement
4. My sex partner suggested that I use an insert before sex
5. Other, *please specify*: _____

B2f. **[IF B2 ≠ B1]** Which of the following prevented you from using the rectal insert before sex? (Check all that apply).

- I forgot
- I did not have the rectal insert with me
- I didn't have enough time to use the rectal insert before anal sex
- My sexual partner did not want me to use the rectal insert
- I did not have the privacy needed to use the rectal insert
- I did not like the rectal insert
- The rectal insert made me feel ill
- I was drinking or using drugs
- There was a change in my regular routine
- I felt like people judged me for using a rectal insert
- Other, specify _____

B3. Of those [B1] times that a partner put a penis in your rectum over the past 4 weeks, how many times did you use the study-provided rectal Insert AFTER receptive anal sex?

(If you did not use the Insert AFTER anal sex, please enter '0'.)

__ time(s) **[IF 0, SKIP TO B4]**

B3a. Typically, how long after **receptive anal sex** did you use a **rectal Insert**?

1. Less than 15 minutes
2. Between 15 minutes and 30 minutes
3. Between 30 minutes and 1 hour
4. Between 1 and 2 hours
5. Between 2 and 3 hours
6. Between 3 and 4 hours
7. 4 hours or more

B3b. Typically, how many rectal inserts did you use after receptive anal sex?

1. One Insert
2. Two Inserts
3. Three or more Inserts

B3c. What made you use a **rectal Insert AFTER receptive anal sex**? *Indicate all that apply*

1. I usually use an Insert after receptive anal sex
2. I wanted to have a bowel movement
3. My sex partner suggested that I use an Insert after sex
4. Other, *please specify*: _____

B4. During the past 4 weeks, how many times did seven days go by in which you did NOT have receptive anal sex? _____ **[IF B4 = 0, GO TO B5]**

B4a. During those [B4] weeks, how many times did you use the rectal Insert at least once per week? _____

B4b. **[IF B0=5 OR B4a ≠ B4]** Which of the following prevented you from using the rectal Insert? (Check all that apply).

- I forgot
- I did not have the rectal insert with me
- My sexual partner did not want me to use the rectal insert
- I did not have the privacy needed to use the rectal insert
- I did not like the rectal insert
- The rectal insert made me feel ill
- I was drinking or using drugs
- There was a change in my regular routine
- My work/school schedule got in the way
- I was worried about the long-term effects of the rectal insert on my health
- I was worried my friends would find out that I was using a rectal insert
- I was worried my family would find out that I was using a rectal insert
- I was worried my sexual partners would find out I was using a rectal insert
- I felt like people judged me for using a rectal insert
- Other, specify _____

B5. Besides the rectal Insert, did you use any other rectal products (e.g., douche/enemas, suppositories) over the past 4 weeks?

1. Yes
2. No [GO TO B6]

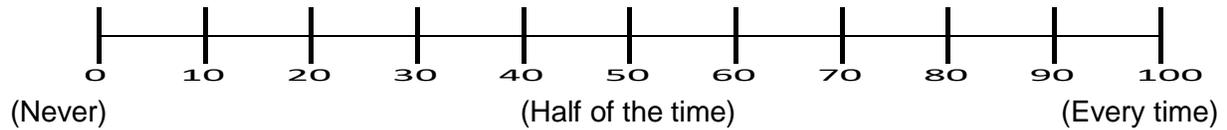
B5a. [If B5=1] Which of the following products did you use? (Check all that apply)

- Over-the-counter disposable enema product (e.g., Fleet®)
- A vaginal douche (e.g., Summer's Eve®) in your rectum
- A non-disposable douche or enema bag system (neoprene or rubber bag, rubber hose, plastic clamp, and plastic or rubber nozzle)____ ____
- A shower head hose and nozzle

- A “sinker”, a portable rubber or vinyl hose that attaches to a sink or bidet
- Re-useable bulb enema
- Suppositories (e.g., for hemorrhoids)
- Other (please specify:_____)

B5b. [IF B2 > 0 AND/OR B4a > 0] What percentage of time did you use another rectal douche?

Visual Analog Scale:



B6. Typically, how far into your rectum was the rectal insert placed?

1. up to 1 inch
2. between 1 and 2 inches
3. between 2 and 3 inches
4. more than 3 inches

B7. Where did you use the rectal insert?

1. Toilet
2. Shower/tub
3. Sink
4. Bidet
5. Bathroom Floor
6. Other, *please specify*: _____

B8. In what position did you prefer to use the rectal insert?

1. Kneeling
2. Laying on side
3. Standing
4. Squatting or seated over toilet/tub
5. Other, *please specify*: _____

B9. How often did you need to apply lubricant before using the rectal insert?

1. Never
2. Rarely
3. Sometimes
4. Often
5. Always

B10. When you use a rectal insert, how long does it usually take you before you have a bowel movement?

1. Occurs immediately
2. 1-5 minutes
3. More than 5 minutes
4. I did not have a bowel movement after using the rectal insert

B13. Did you give the rectal Insert to another person to use?

1. Yes
2. No [GO TO NEXT SECTION]

B14. How many rectal inserts did you give to another person? _____

B15. I gave the rectal insert to (check all that apply)

- 1. A family member
- 2. A friend
- 3. A partner
- 4. A person who wanted to buy it
- 5. A person who has HIV
- 6. Other (please specify: _____)

B16. Why did you share the insert with another person?

SECTION C. Rectal Insert ACCEPTABILITY

The following questions are about your overall experience with the rectal insert.

C1. **Overall**, how much did you like the rectal insert used as part of this study?

1—2—3—4—5—6—7—8—9—10

Disliked
Very Much

Liked Very Much

C1a. How much did you like the color of the rectal insert?

1. Disliked very much
2. Disliked
3. Liked
4. Liked very much

C1b. How much did you like the taste of the rectal insert?

1. Disliked very much
2. Disliked
3. Liked
4. Liked very much
5. Don't know, I did not taste the rectal insert

C1c. How much did you like the smell of the rectal insert?

1. Disliked very much
2. Disliked
3. Liked
4. Liked very much
5. Don't know, I did not smell the rectal insert

C1d. How much did you like the consistency of the rectal insert (how thick or thin it was)?

1. Disliked very much
2. Disliked
3. Liked
4. Liked very much

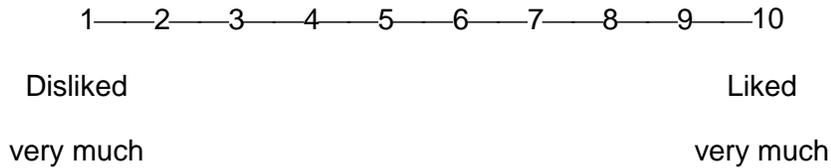
C1e. How much did you like how the rectal insert felt inside your rectum immediately after inserting it?

1—2—3—4—5—6—7—8—9—10

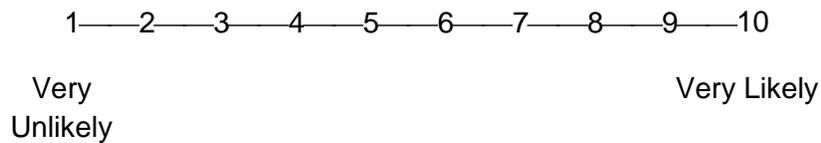
Disliked
very much

Liked
very much

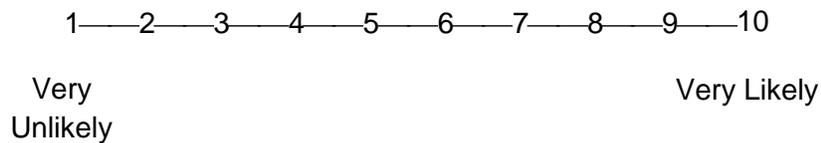
C1f. How much did you like how the rectal insert felt inside your rectum 30 minutes after using it?



C2. If it were available, how likely would you be to continue using the rectal insert provided as part of this study?



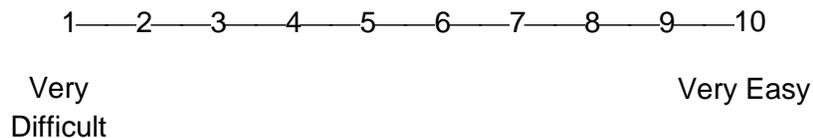
C3. How likely would you be to recommend the rectal insert to your friends?



C4. Compared to other rectal inserts that you may have used in the past, how satisfied were you with the rectal insert used in this study?

1. Very satisfied
2. Satisfied
3. Neutral
4. Dissatisfied
5. Very dissatisfied
6. I had never used a rectal insert in the past

C5. [IF B2 > 0] **Overall**, how easy or difficult was it to use the rectal insert BEFORE having receptive anal sex?



C6. **Overall**, how easy or difficult was it to use the rectal insert?



Very
Difficult

Very Easy

C7. The **last time** you used the rectal insert in your rectum, how difficult or easy was it to apply?

1—2—3—4—5—6—7—8—9—10

Very
Difficult

Very Easy

The following questions are about any changes that you may have experienced while using the rectal insert over the past 4 weeks.

C8. Did your douching practices change over the past 4 weeks?

1. No, I douched as frequently as I typically do
2. Yes, I douched less frequently than I typically do
3. Yes, I douched more frequently than I typically do
4. Not applicable, I don't douche

C9. **Overall**, how did it feel to use the rectal insert over the past 4 weeks?

1— 2— 3— 4—5—6—7—8—9—10

Very
Uncomfortable

Very Comfortable

C10. Please indicate how hard or easy it would be for you to do each of the following things.

| [1] Very Easy to Do | [2] Fairly Easy | [3] Fairly Hard | [4] Very Hard to Do |
|------------------------|--------------------|--------------------|------------------------|
|------------------------|--------------------|--------------------|------------------------|

- a. To use the **rectal insert** every time BEFORE having sex?
- b. To discuss your use of the **rectal insert** with a sexual partner BEFORE having sex?
- c. To discuss your use of the **rectal insert** with a sexual partner AFTER having sex?
- d. To use the **rectal insert** while under the influence of alcohol or drugs?
- e. To keep the **rectal insert** stored in a private location?
- f. To discretely dispose of the **rectal insert** after use?

C11. How much did you like the packaging of the rectal insert?

1—2—3—4—5—6—7—8—9—10

Disliked
very much

Liked
very much

D3. After using the rectal insert, did you experience any other unexpected stomach or abdominal problems (such as cramps, bloating, gassiness or passing wind or urge to have a bowel movement)?

1. None [GO TO D4]
2. Some
3. A lot

D3b. How much were you bothered by these stomach or abdominal problems?

1. Not at all
2. A little
3. Somewhat
4. Very much

D4. Over the past 28 days, on how many days did you experience any pain because of the rectal insert?

_____ day(s) [IF D4=0, SKIP TO D5]

D4b. Overall, how much did the pain bother you?

1. Not at all
2. A little
3. Somewhat
4. Very much

D5. Did the rectal insert cause you any emotional discomfort such as feeling worried, guilty or any other unpleasant feelings?

0. No [GO TO D6]
1. Yes

D5b. Overall, how much did this emotional discomfort bother you?

1. Not at all
2. A little
3. Somewhat
4. Very much

D6. During the four weeks in which you were asked to use the rectal insert, how did it affect your sexual enjoyment?

1. My sexual enjoyment was not affected at all
2. I had less sexual enjoyment than usual
3. I had more sexual enjoyment than usual

D7. [IF B2 > 0] Compared to prior times when you have had receptive anal sex, how different did you feel while having anal sex after using the **rectal insert** before sex?

1. Not at all
2. A little

3. Somewhat
4. Very different

D8. [IF B2 > 0] How did the rectal insert affect your sexual pleasure?

1. Increased my sexual pleasure
2. Did not change my sexual pleasure
3. Decreased my sexual pleasure

D8b. How much were you bothered by having to wait a while to have sex after using the rectal insert?

1—2—3—4—5—6—7—8—9—10
 Not at all Very much

D9. [IF B2 > 0] How did the rectal insert affect **your sex partner's** sexual pleasure?

1. Increased my partner's sexual pleasure
2. Did not change my partner's sexual pleasure
3. Decreased my partner's sexual pleasure
4. Don't know

D10. Over the past 4 weeks, did any of your partners have a negative reaction regarding your use of the rectal insert?

1. No
2. Yes, (please specify: _____)

D11. Over the past 4 weeks, did any of your partners have a positive reaction regarding your use of the rectal insert?

1. No
2. Yes, (please specify: _____)

D12. Over the past 4 weeks, did you have an injury as a result of using the rectal insert?

1. Yes **[IF NO, SKIP TO NEXT SECTION]**
2. No

D13. How many times have you had an injury to the anus or rectum due to using the rectal insert in the past 28 days?

_____ **[If "0," SKIP to NEXT SECTION]**

D14. When injuries have occurred, what was the cause? *Indicate all that apply*

1. Problems with the Insert
2. Position played a role
4. Insufficient lubrication

5. Other, *please specify*: _____

SECTION E. SEXUAL BEHAVIOR

First, we will ask you questions about your body.

E1. Do you currently have a penis?

_____ 1 Yes [SKIP TO E3]

_____ 2 No

[IF REFUSE TO ANSWER, ask:]

You selected "Refuse to answer." If you do not answer this question, you may be asked questions about your sexual behavior that do not apply to you. Please confirm your answer.

1. Yes, I refuse to answer

2. No, I want to change my answer

E2. Do you currently have a vagina?

_____ 1 Yes

_____ 2 No

[IF REFUSE TO ANSWER, ask:]

You selected "Refuse to answer." If you do not answer this question, you may be asked questions about your sexual behavior that do not apply to you. Please confirm your answer.

1. Yes, I refuse to answer

2. No, I want to change my answer

RECENT SEXUAL BEHAVIOR

E3. In the past 30 days, how many people have you had **sex** with? (Sex can include anal sex, vaginal sex, oral sex, or analingus).

[IF REFUSE TO ANSWER, ask:]

You selected "Refuse to answer." If you do not answer this question, you may be asked questions about your sexual behavior that do not apply to you. Please confirm your answer.

1. Yes, I refuse to answer

2. No, I want to change my answer

[If E3=1, ask 4.1. If E3> 1, ask 4.2.]

E4.1. You said you had **sex** with *one* person in the past 30 days. Please indicate whether this person was a....

- 1 Man
- 2 Woman
- 3 Transgender man
- 4 Transgender woman

[IF REFUSE TO ANSWER, ask:]

You selected "Refuse to answer." If you do not answer this question, you may be asked questions about your sexual behavior that do not apply to you. Please confirm your answer.

- 1. Yes, I refuse to answer
- 2. No, I want to change my answer

E4.2. You said you had **sex** with [E4] people in the past 30 days. Please indicate how many of these people were men, women, or transgender. Note that your answers must add up to [E4].

- 1 Men
- 2 Women
- 3 Transgender man
- 4 Transgender woman

[IF REFUSE TO ANSWER, ask:]

You selected "Refuse to answer." If you do not answer this question, you may be asked questions about your sexual behavior that do not apply to you. Please confirm your answer.

- 1. Yes, I refuse to answer
- 2. No, I want to change my answer

[SKIP PATTERNS WILL BE BASED ON ANSWERS TO ANATOMY AND PARTNER' S GENDER]

E5. During the past 30 days, how many times did you have **vaginal sex**, when you put your **penis** into a partner's **vagina**? _____ [RANGE 0-900]

E6. Of the [E5] times you had **vaginal sex**, how many times did you put your **penis** into a partner's **vagina** without a condom, even for a little while? _____

E7. During the past 30 days, how many times did you have **insertive anal sex**, when you put your **penis** into a partner's **rectum**? _____

E8. Of the [E7] times you had **insertive anal sex**, how many times did you put your **penis** into a partner's rectum without a condom, even for a little while? _____

E9 During the past 30 days, how many times did you have **receptive anal sex**, when a partner's penis was in your rectum? _____

E10. Of the [E9] times you had **receptive anal sex**, how many times was a partner's penis in your **rectum** without a condom, even for a little while? _____

Now we would like to ask you about oral sex:

E11. During the past 30 days, how many times did you put your mouth on a partner's **penis**? _____

E12. During the past 30 days, how many times did a partner put their mouth on your **penis**? _____

E13. During the past 30 days, how many times did you put your mouth on a partner's **anus**? _____

E14. During the past 30 days, how many times did a partner put their mouth on your **anus**?

E15. During the past 30 days, how many times did you put your mouth on a partner's **vagina**?

E16. During the past 30 days, how many times did a partner put their mouth on your **vagina**?

E17. During the past 30 days, how many times did you have **vaginal sex**, when a partner's penis was in your vagina? _____

E18. Of the [E17] times you had **vaginal sex**, how many times was a partner's penis in your **vagina** without a condom, even for a little while? _____

The next two questions refer to exchanging sex for money or other goods or services. Remember, your answers are confidential and will not be viewed by clinic staff.

E19. During the past 30 days, how many times did you receive money or other goods or services in exchange for sex? _____

E20. During the past 30 days, how many times did you pay money or provide other goods or services in exchange for sex? _____

E21. Please leave us any comments you have about this sexual behavior questionnaire, especially if you thought these questions did not apply to you:

SECTION F. SUBSTANCE USE

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

F1. Now you will see a list of different drugs. During the last 30 days, 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.

| | [A] Number of times used in past 30 days | [B] Number of times used before or during sex in past 30 days [Only ask if A > 0] |
|---|--|--|
| a. Tobacco (cigarettes, cigars, chew, snuff, e-cigs) | ___ ___ times | ___ ___ times |
| b. Alcohol (beer, wine, liquor) | ___ ___ times | ___ ___ times |
| c. Marijuana/hashish/pot/weed/chamba | ___ ___ times | ___ ___ times |
| d. Synthetic Marijuana/K2/Spice | ___ ___ times | ___ ___ times |
| e. Ecstasy/MDMA | ___ ___ times | ___ ___ times |
| f. Crystal Meth/amphetamines/ methamphetamines/speed/crank/ice/yaba | ___ ___ times | ___ ___ times |
| G. Ketamine/special K | ___ ___ times | ___ ___ times |
| H. GHB (Gamma hydroxybutyrate) | ___ ___ times | ___ ___ times |
| I. Other hallucinogens/LSD/ mushrooms | ___ ___ times | ___ ___ times |
| J. Poppers/amyl nitrate/butyl nitrate | ___ ___ times | ___ ___ times |
| K. Crack | ___ ___ times | ___ ___ times |
| L. Cocaine (not crack) | ___ ___ times | ___ ___ times |
| M. Opium/Opioids (Heroin, Codeine, Vicodin, OxyContin) | ___ ___ times | ___ ___ times |
| N. Mandrax/Quaalude | ___ ___ times | ___ ___ times |
| O. Kratom | ___ ___ times | ___ ___ times |
| P. Khat | ___ ___ times | ___ ___ times |
| Q. Any other pharmaceutical drugs not prescribed to you by a physician | ___ ___ times | ___ ___ times |
| R. Other, <i>please specify</i> : _____ | ___ ___ times | ___ ___ times |

F2. [IF F1A_b>0] Thinking about the times you used alcohol during the last 30 days, 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
6. Enough to pass out

SECTION G. Discussion with Social Network

G1. Have you talked about this study with anyone in your social network?

1. No
2. Yes (GO TO G1b)

G1a. {IF G1=1, ASK QUESTION THEN JUMP TO NEXT SECTION} Different circumstances may prevent people from discussing participation in the study with social networks. Thinking about your experience since you last completed the survey, please choose all the reasons that have made it difficult to talk about the study?

- Embarrassment
- Fear of Violence
- Potential Misunderstanding
- Don't think it's important
- Lack of Trust
- Stigmatization
- Shyness
- Awkwardness
- Fear of job loss
- Fear of losing housing
- Fear of criminalization

G1b. Who did you talk about it with? (Check all that apply)

- Friends
- Family
- Sex partners
- Coworkers
- Roommates
- Other _____

G2a. Have you talked about the rectal insert used in this study with anyone in your social network?

- Yes
- No (GO TO NEXT SECTION)

G2b. Who did you talk about it with? (Check all that apply)

- Friends
- Family
- Sex partners
- Coworkers
- Roommates
- Other _____

G2c. How comfortable did you feel talking about the rectal Insert?

| {NOTE: LIST FILLS BASED ON G2A answers} | Very Uncomfortable | Uncomfortable | Neutral | Comfortable | Very Comfortable |
|---|--------------------|---------------|---------|-------------|------------------|
| Friends | | | | | |
| Family | | | | | |
| Sex Partner | | | | | |
| Co-Workers | | | | | |
| Roommates | | | | | |
| Fill-in from #2 | | | | | |

G2d. How did they respond when you talked about the rectal Insert?

| {NOTE: LIST FILLS BASED ON G2A answers} | Negatively | Somewhat Negatively | Neutral | Somewhat Positively | Positively | N/A |
|---|------------|---------------------|---------|---------------------|------------|-----|
| Friends | | | | | | |
| Family | | | | | | |
| Sex Partner | | | | | | |
| Co-Workers | | | | | | |
| Roommates | | | | | | |
| Fill-in from #2 | | | | | | |

SECTION H. RECOMMENDATIONS

H1. Think about the positive and negative experiences you have had using the rectal Insert during the past 4 week period. If this rectal insert was available and it provided some protection against HIV, how likely would you be to use it before receptive anal sex?

1—2—3—4—5—6—7—8—9—10

Very
Unlikely

Very Likely

H2. Thinking about the size of the Insert you used, would you be willing to use the product if it were... (Check the greatest possible size.)

1. Half the size of the Insert you used
2. Same size as the Insert you used
3. Twice as big as the Insert you used
4. 3 times as big as the Insert you used
5. 4 times as big as the Insert you used
6. Other: _____

H3. What were the things you liked the most?

1. _____
2. _____
3. _____

H4. What were the things you liked the least?

1. _____
2. _____
3. _____

Thank you for completing this questionnaire! Please notify the study staff that you are finished.

END OF QUESTIONNAIRE