

MTN-036 Behavioral Assessments

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Overview

- Behavioral protocol objectives and endpoints
- Computer-assisted self-interview (CASI) assessments
- In-depth interview (IDIs)
- Ring Adherence CRF

The big picture - objectives

□ Secondary Objectives

■ Adherence

- To evaluate participant adherence to the three DPV VRs when used for 13 weeks

■ Acceptability

- To compare overall acceptability of the two extended duration DPV VRs (100 mg and 200 mg) to the current 25 mg DPV VR

□ Exploratory Objectives

■ Acceptability

- To evaluate components of acceptability of ring use for the three DPV VRs

The big picture - endpoints

□ Secondary Endpoints

■ Adherence

- Frequency of study VR removal/expulsions (voluntary and involuntary) and duration without VR in vagina (by self-report)
- VR use initiation and persistence (whether the VR is in place when participants come to the clinic for their study visits)

■ Acceptability

- Degree to which study participants liked or disliked using the three DPV VRs (by self-report)

□ Exploratory Endpoints

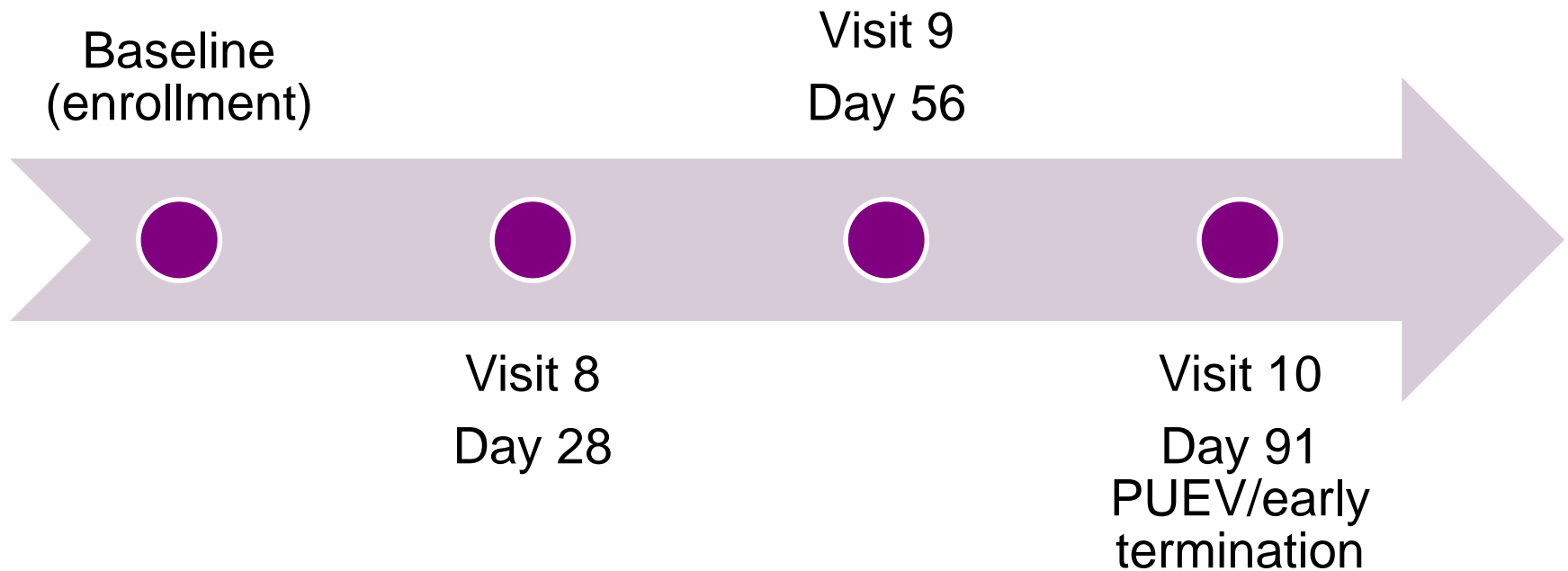
■ Acceptability

- Self-reported attitudes about VR attributes, including dosing regimen, and willingness to use the VR in the future
- Interest/preference in a single vs. dual-purpose indication
- Proportion of participants who find the study VRs to be at least as acceptable as other HIV prevention methods

CASI questionnaires



CASI assessments





Domains

- Demographic
- Drug/alcohol use
- Vaginal practices
- Sexual history
- Recent sexual behavior
- Condom and other HIV prevention method use
- Adherence
- Acceptability
- Preference



Acceptability details

- Acceptability questions include:
 - Rating scale of 1-10 (dislike very much – like very much)
 - Whether the ring was felt during sex by woman and her partner and if so, whether this was bothersome
 - Vaginal changes experienced and whether these were bothersome
 - Worries about the ring such as being dirty/unhygienic or causing infection/infertility/other health problems
 - Experiences with the ring during menses
 - Perceived comfort of the ring
 - Likelihood of future use of an active product
- Will examine changes over time



Preference details

- Preference questions include:
 - Preference for 1 month vs 3 month ring
 - Preference for event-driven dosing (with sex) vs a continually worn ring
 - Preference for dual purpose (combined HIV and pregnancy prevention) ring
 - Preference for ring vs condom vs oral PrEP
- Assessed at the end of the study



Adherence details

- Adherence questions include:
 - How often was the ring in the vagina during sex
 - Removals
 - Expulsions
 - Partial expulsions
 - Self-reported adherence (“how good of a job did you do?”)
- Note reasons for removals/expulsions are collected on adherence CRF

CASI assessment time points

Domain	ENR	Day 28	Day 56	PUEV
Demographics	X			
Drug/alcohol use	X			
Vaginal practices				
Sexual behavior	X	X	X	X
Condom, other HIV prevention method use	X			
Adherence		X	X	X
Acceptability	X	X		X
Preference				X



In-depth Interviews (IDIs)

- Goal: to assess acceptability and use experiences in greater depth using a semi-structured interview guide
- Interviews will be recorded, transcribed, and analyzed for themes
- Topics:
 - Challenges of use
 - Effect of ring use on sex
 - Perceived benefits and barriers to ring use
 - Perceived method preferences for HIV prevention and multipurpose prevention technologies

IDI selection and randomization

- Subset of 24 randomly selected participants across both sites
- Only include women who have had penile-vaginal sex in past year
- Will oversample in SF to account for higher likelihood of lesbian participants

IDI implementation

- Interviewer will be based in SF and will conduct IDIs over video (webcam)
- Site staff will email interviewer to notify her of scheduled interviews in advance
 - Confirmed IDIs will be entered on a Google calendar
- Responses will be audio recorded but not video recorded

CRFs – Adherence and Insertion/Removal

- Two CRFs with behavioral components
 - Ring Adherence CRF
 - Reasons for removal/expulsion
 - Insertion and Removal CRF
 - After inserting the ring, how easy or difficult was it to insert
 - Reasons for difficulty
 - Did the participant require help inserting
 - Was the ring correctly inserted by the participant

Questions?

Note additional, in-depth behavioral assessment training sessions will be scheduled with both sites to:

- Walk through CASI (tablet computer) system (prior to activation)
- Conduct practice video IDI (prior to IDIs)