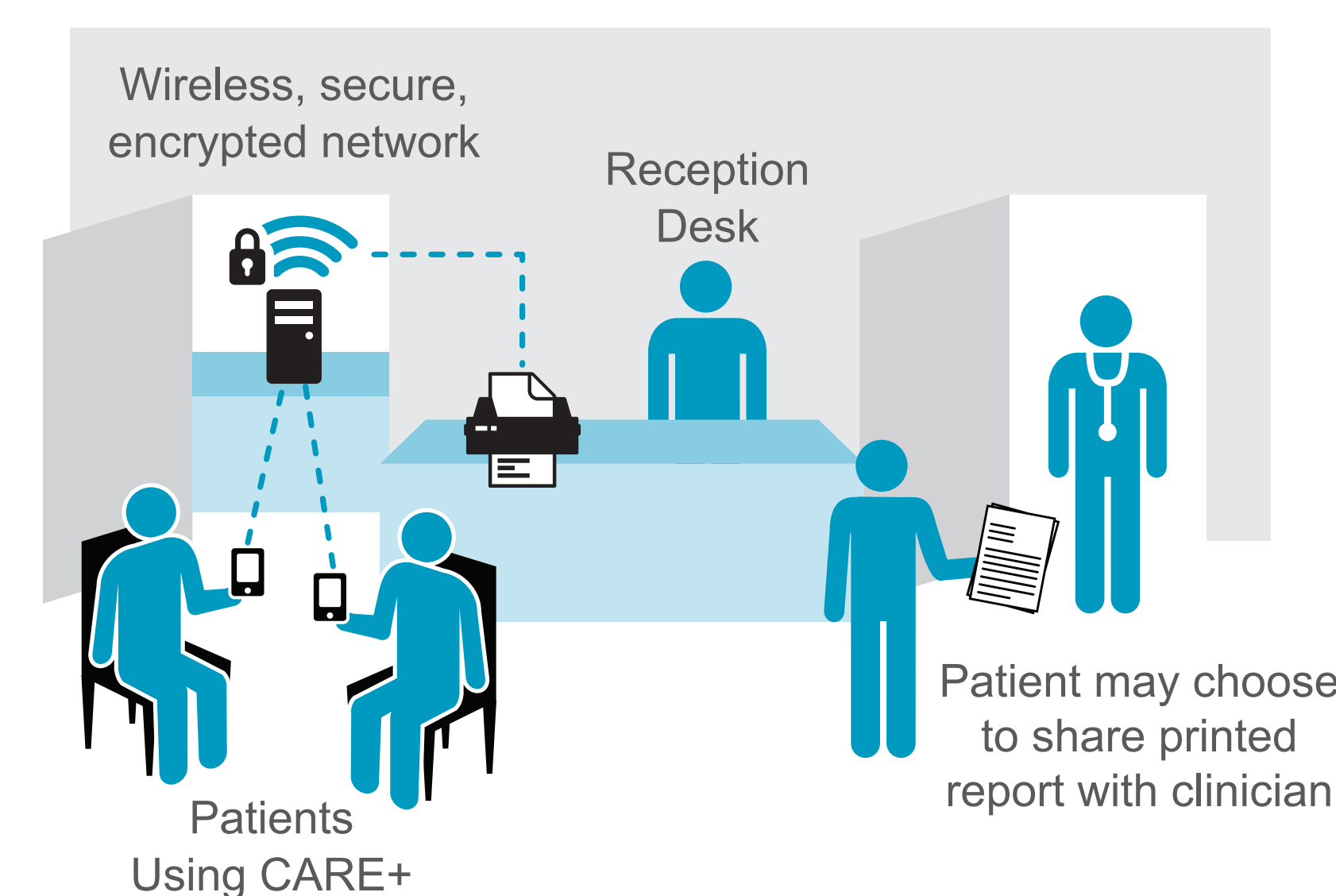


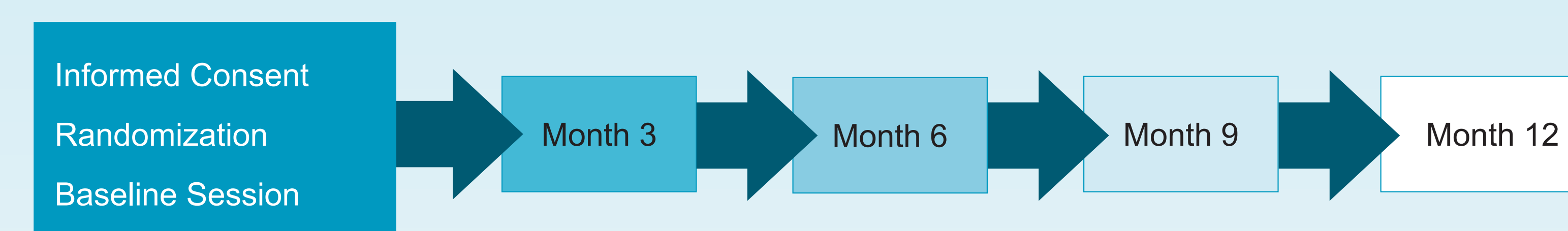
BACKGROUND

- HPTN 065, a large study funded by NIAID, NIH and conducted by the HIV Prevention Trials Network (HPTN), examined the feasibility of a test, link-to-care, plus treat strategy for HIV prevention in the Bronx, NY and Washington, DC. One component of the study evaluated a computer-based prevention counseling intervention (CARE+) for HIV-infected persons in care, to determine its effect on reducing unprotected sex.
- CARE+, an intervention designed and evaluated in prior HIV prevention and adherence studies, was adapted for HPTN 065. The software:
 - is delivered on computer tablets and headphones
 - is available in English and Spanish with audio-narration for all text (see screens below where avatars may be chosen in English or Spanish)
 - provides tailored feedback based on participant input to those randomized to the intervention arm
 - participants randomized to the intervention arm may print out a care plan (see below).



METHODS

- HIV patients at 10 study clinics (6 in DC, 4 in NY) were randomized 1:1 to either the intervention arm of CARE + ACASI risk assessment and intervention plus standard of care (SOC) prevention counseling or to the control arm of CARE + ACASI risk assessment only plus SOC prevention counseling.
- Participants completed the assigned computer-based session at baseline and months 3, 6, 9, and 12.
- Generalized estimating equation models were used to analyze the proportion of participants reporting condomless vaginal or anal sex the last time they had sex. Of 948 enrolled participants, 894 (94%) completed at least one follow-up visit and were included in the longitudinal statistical modeling.



RESULTS

Participant Characteristics

- Participant characteristics are described in Table 1 and Figure 1.
- Retention at month 12 was 75% (n=354) in the CARE+ arm and 78% (n=370) in the control arm.

Self-Reported Condomless Sex Acts

- At baseline, 499 (53%) participants reported having any sex in the last 3 months (236 [50%] CARE+ intervention arm participants and 263 [55%] control arm participants).
- Nearly half of participants reported no sex in the prior 3 months (Figure 2) (43% and 39%) at baseline and (45% and 38%) at month 12 in the CARE+ and control arms, respectively.
- 33% and 27% of CARE+ and control participants, respectively, reported not having any sex throughout the study duration (Figure 3).
- The proportion of reported condomless sex with any partner did not change over time in CARE+ participants (13% at baseline, 12% at 12 months, odds ratio (OR): 0.995 (95% CI: 0.91, 1.1), p=0.91) (Figure 4).
- There was no significant difference between CARE+ and control participants in rates of condomless sex with any partner over time (OR comparing time trends, control versus CARE+: 1.03 (95% CI: 0.91, 1.2), p=0.67). (Figure 4).
- At baseline, 33/471 (7%) of CARE+ participants reported condomless sex with an HIV-negative or unknown status partner compared to 35/477 (7%) among control participants. At 12 months, the numbers were 26/354 (7%) among CARE+ and 34/370 (9%) among controls (difference not significant) (Figure 4).

TABLE 1. Participant Characteristics.

Characteristics N=894	Intervention Arm N=417	Control Arm N=477
Median Age (range)	51 years (19–76)	52 years (18–77)
Gender	317 (67%) male	326 (68%) male
Race	282 (60%) black	299 (63%) black
Hispanic/Latino	102 (22%)	88 (18%)
Household Income below \$10,000	129 (27%)	137 (29%)
Taking ART at baseline	409 (87%)	425 (89%)

FIGURE 1. Self-Reported HIV Transmission Risk Factors.

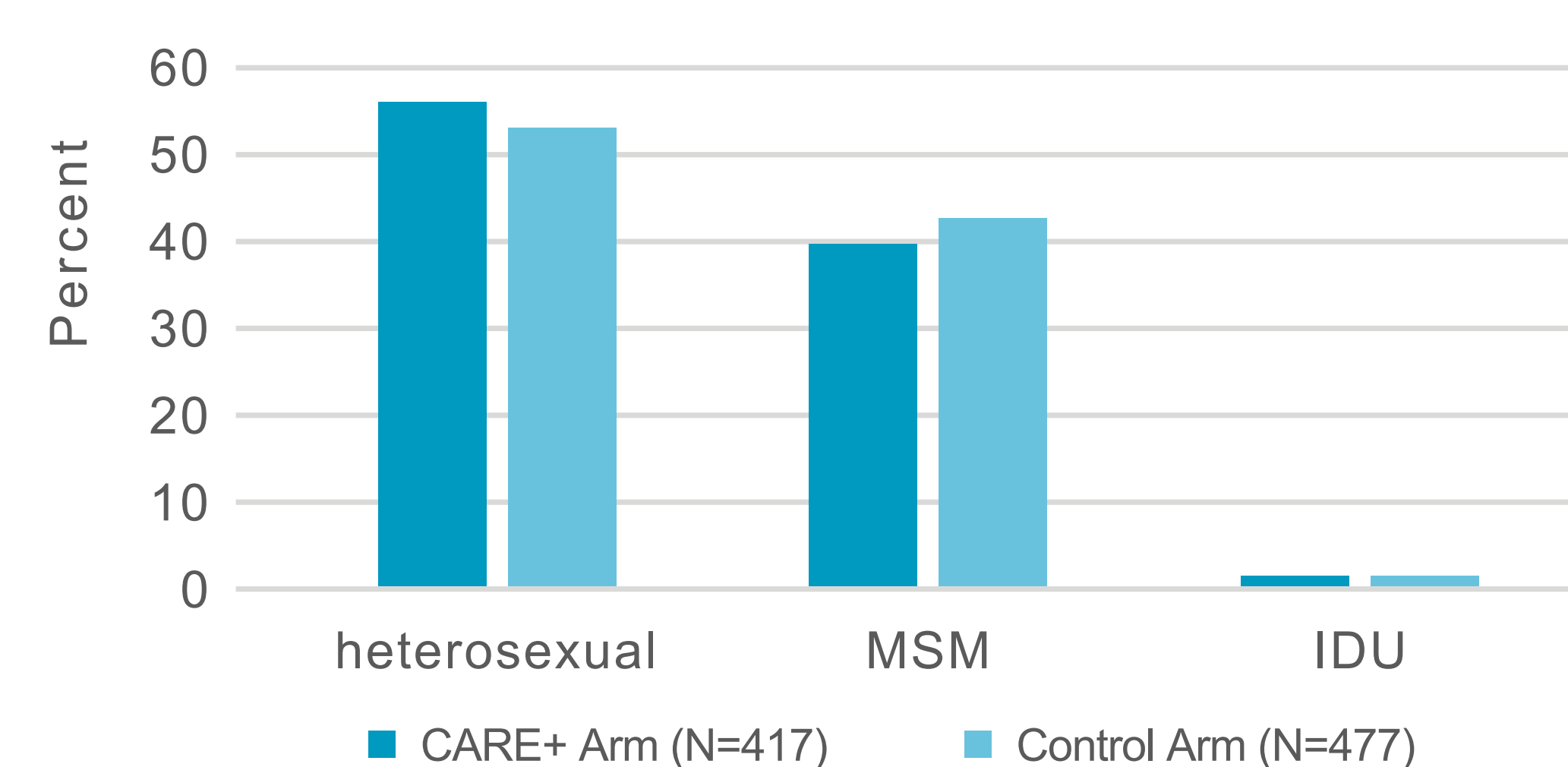


FIGURE 2. Frequency of Participants Reporting Having No Sex in the Past Three Months.

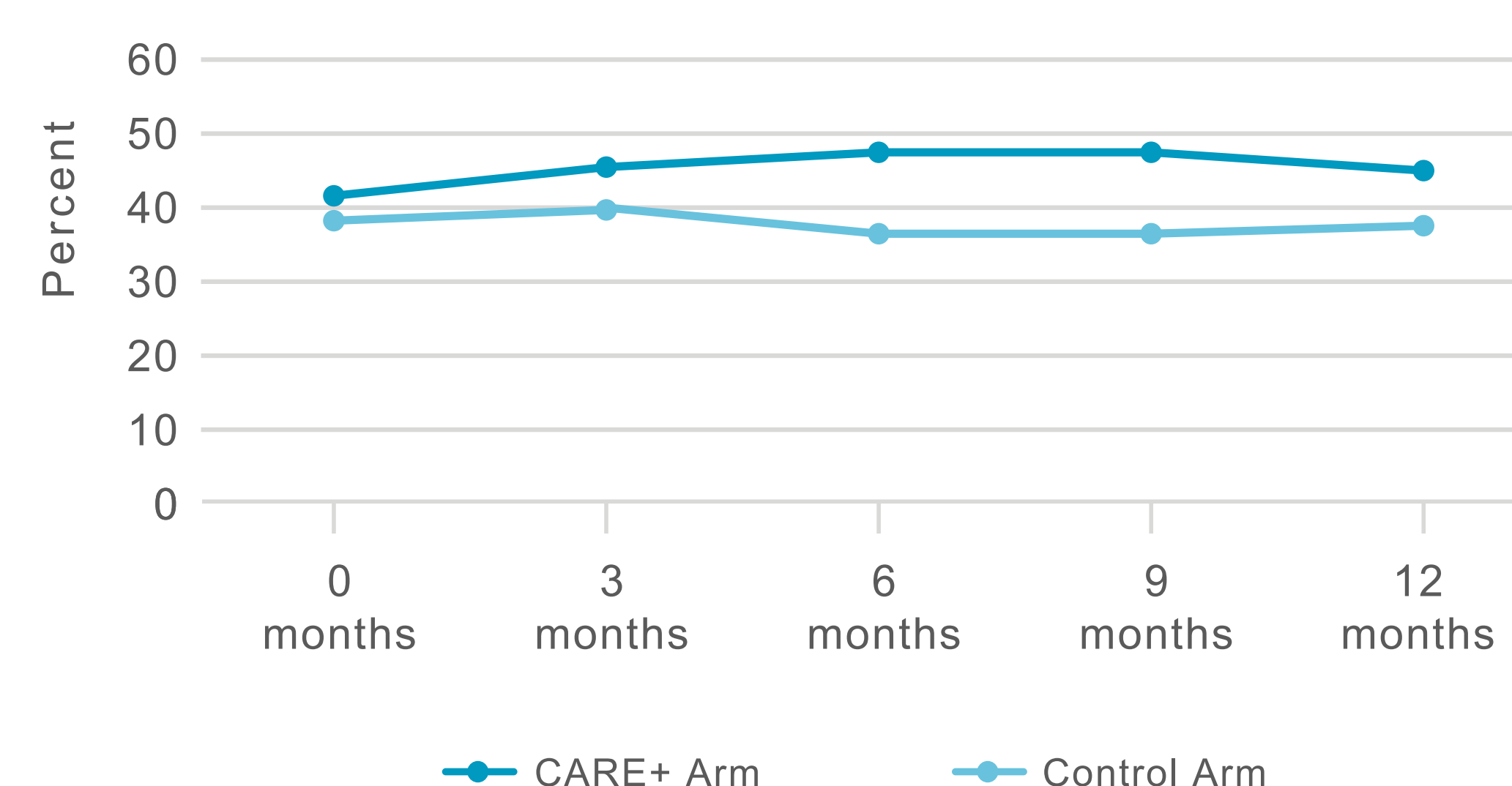


FIGURE 3. Participants Reporting No Sex Throughout the Study Duration.

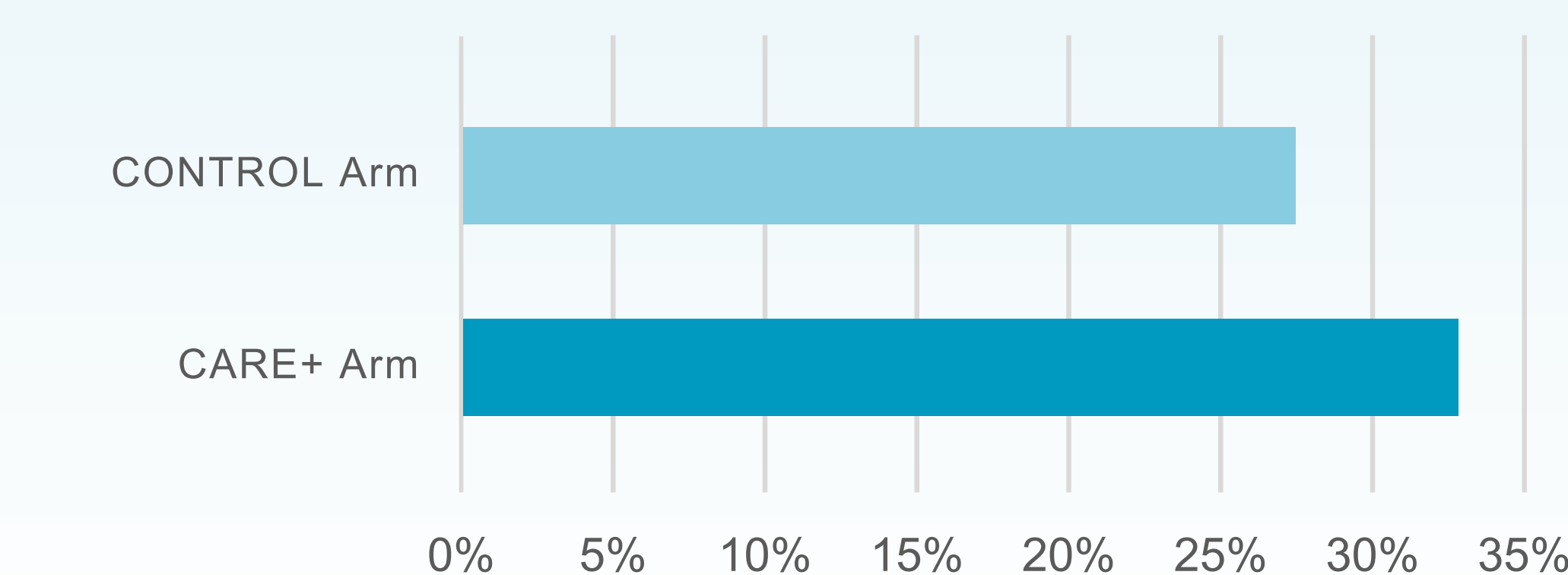
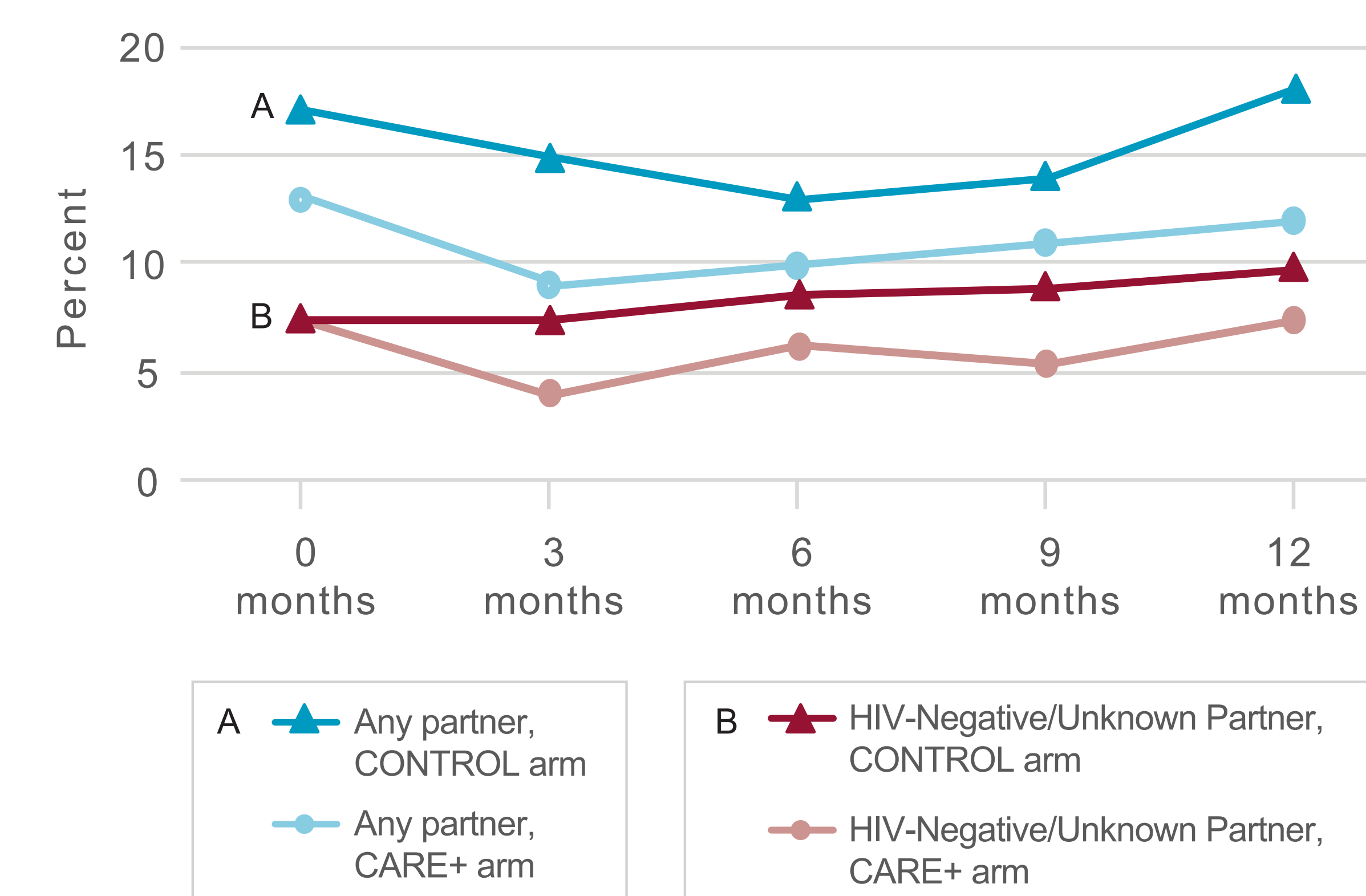


FIGURE 4. Proportion of participants reporting condomless sex during last sex act with (A) any partner and with (B) a partner who is either HIV-negative or of unknown status.



CONCLUSIONS

- We successfully recruited HIV infected persons in care, largely Black and Hispanic men, with about 40% reporting as MSM.
- The CARE+ computer-based intervention did not reduce the proportion of HIV-infected patients in care who reported condomless sex.
- Reported sexual activity was relatively low in this study population, with 41% reporting no sex during the last three months before baseline. High transmission-risk-sexual activity (i.e., condomless sex with HIV-negative or unknown status partner) also was low throughout study duration. A substantial proportion of participants in both arms did not report having sex throughout the study.
- This intervention was not found to have an effect on reported sexual transmission risk behaviors. The study included a diverse group of HIV-infected individuals, largely consistent with HIV-infected population in the US.

ACKNOWLEDGEMENTS

- We sincerely thank the participating sites and the following investigators for their support: Dr. Theo Hodge (Capital Medical Associates), Angela Wood (Family Medical and Counseling Service), Dr. Princy Kumar (Georgetown University), Dr. Gary Simon (George Washington University), Dr. Fred Gordin (Washington DC VA Medical Center), Dr. Rick Elion (Whitman-Walker Health), Dr. Jason Leider (Jacobi Medical Center), Dr. Barry Zingman (Montefiore Adult AIDS Clinic), Dr. Viraj Patel (Montefiore Medical Center), and Dr. Sheldon Brown (JJP VA Medical Center).
- The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute of Allergy and Infectious Diseases, the National Institutes of Health, or the Centers for Disease Control and Prevention.
- HPTN 065 (TLC-Plus) Study is supported by NIAID, NIDA, and NIMH (Cooperative Agreement #UM1 AI068619; #UM1 AI068617) and the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, US Centers for Disease Control and Prevention.