METHODS

HIV pre-exposure chemoprophylaxis (PrEP) is becoming a standard of prevention care in many countries; however concerns about costs and side effects can limit uptake. The HPTN 067/ADAPT trial, a Phase II, randomized, open-label clinical trial of oral emtricitabine/tenofovir disoproxil fumarate (FTC/TDF) PrEP, included a cohort of South African women in Cape Town. The study investigated whether a nondaily versus daily regimen of FTC/TDF, resulted in equivalent prophylactic coverage of sex events, less tablets required and fewer side effects.

RESULTS

Of 191 women enrolled in the DOT phase, 179 were randomized to the self-administered phase (Fig 3). Median age was 26 years (range 18-52), 80% were unmarried and 83% unemployed. PrEP coverage differed by arm as shown in Table 1. Fewer pills were required in T and E compared with D. Side effects were uncommon in D, and less frequent in T and E. Adherence to the assigned regimen was greater in D compared with T and E (P<0.001); adherence to post-intercourse dosing in the nondaily arm was low. When sex was reported in the prior week, both plasma TFV (consistent with ≥1 pill in prior week) and PBMC TFV dihydrogen phosphate (consistent with ≥2 pills in prior week) were detected in more women in D at weeks 10 and 30, compared with T and E (p < 0.05).

HIV seroconversions were not significantly different by arm.

CONCLUSION

- The majority of women in this study took oral PrEP when made available in an open-label study.
- Daily dosing resulted in better coverage of sex acts and adherence, and higher drug levels.
- Daily dosing may foster better habit formation and provide the most forgiveness for missed doses at observed adherence levels.
- These findings support current recommendations for daily use of oral FTC/TDF PrEP in women.