Abstract: Retention and viral load outcomes from a cluster randomized trial comparing extending adherence club ART refill dispensing intervals from 2 to 6 monthly

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Background
The antiretroviral therapy (ART) adherence club (AC) model has supported clinically stable patients’ retention with group ART refills and psychosocial support. Patients and health systems could benefit from reduced visit frequency by increasing ART refills. We conducted a cluster randomized controlled trial comparing standard of care (SoC) ACs and six month refill intervention ACs in a primary care facility in Khayelitsha, South Africa.

Methods
Existing ACs were randomized to either SoC or intervention. SoC ACs meet five times annually, receiving two month refills with a four month refill over year-end. Blood is drawn at one AC visit with a clinical consultation at the next. Intervention ACs meet twice annually receiving six month refills, with a third blood collection clinic visit anytime two-four weeks before the annual clinical consultation AC visit. Participants were included in this analysis if their first study visit was before 13/11/2017; analysis closed 12 months later. Retention was defined as AC or clinic attendance on or within three months of a scheduled appointment. Twelve-month retention was calculated using Kaplan-Meier methods, comparing groups using the log-rank test for equality of survivor functions. Viral load (VL) completion and suppression (<400 copies/mL) at analysis closure are presented by group.

Results
A total of 1,280 patients were included in the analysis; 602 in 26 SoC ACs (26% male) and 678 in 27 intervention ACs (24% male). Twelve-month retention was high in both arms; 97.8% (95% confidence interval [CI]: 96.3-98.7%) in SoC and 96.5% (95%CI:94.8-97.7%) in intervention ACs, with no significant difference between groups (p = 0.2928) (Figure 1). VL completion (592/629; 94.1% [CI:92-95.8%] vs. 504/562; 89.7% [CI:86.8-92.1%]) and suppression (579/592; 97.8% [95%CI:96.3-98.8%] vs. 480/504; 95.2% [95%CI:93-96.9%]) was higher in the intervention ACs.

Conclusions
Comparable 12-month retention and favourable VL outcomes in the intervention ACs compared to SoC ACs suggest clinically stable patients can achieve good outcomes with fewer visits and 6-monthly refills. These are interim findings from an ongoing trial.