LBPED36

Twelve-month retention and viral load outcomes from a non-inferiority cluster randomized trial extending adherence club ART refill dispensing intervals to 6-monthly

Keitu Lebelo[1], Tali Cassidy[1,2], Anna Grimsrud[3], Claire Keene[1], Sibusiso Ndlovu[1], Helen Hayes[4], Catherine Orrell[5,6], Nompumelelo Zokufa[1], Tabitha Mutseyekwa[1], Jacqueline Voget[4], Rodd Gerstenhaber[1], Lynne Wilkinson[7]

1 Medécins Sans Frontières, Khayelitsha, South Africa; 2 Department of Public Health Medicine, School of Public Health and Family Medicine, University of Cape Town, Cape Town, South Africa; 3 International AIDS Society, Cape Town, South Africa; 4 Western Cape Government Department of Health, Cape Town, South Africa; 5 Department of Medicine, Faculty of Health Sciences, Cape Town, South Africa; 6 The Desmond Tutu HIV Centre, Institute for Infectious Disease and Molecular Medicine, University of Cape Town, Cape Town, South Africa; 7 Center for Infectious Disease and Epidemiological Research, School of Public Health and Family Medicine, University of Cape Town

Corresponding author: Dr Claire Keene; msfocb-khayelitsha-hivmam@brussels.msf.org

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 increased ART refill intervals and fewer visits.
- We conducted a non-inferiority cluster randomized trial comparing standard of care (SoC) ACs and 6-month refill intervention ACs in a primary care facility in Khayelitsha, South Africa.

Methods

Table 1: Description of intervention

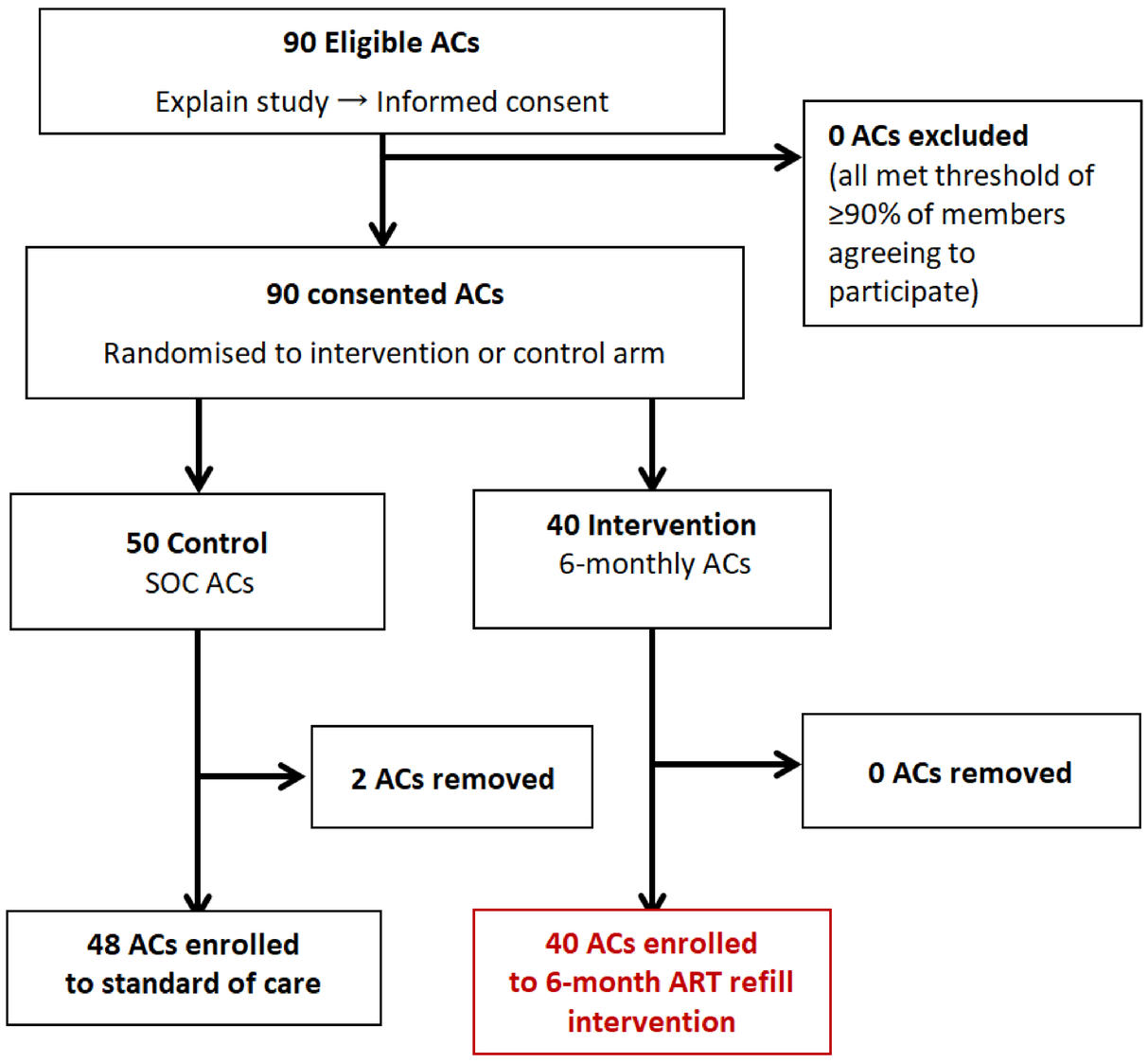
Standard of care AC	Intervention AC (Six-months refills)
2-monthly club visits (5 per year including blood draw and clinical visit)	6-monthly club visits + one blood draw (3 per year including blood draw and clinical visit)
Annual clinical visit	Annual clinical visit
5 day grace period	5 day grace period
Can send treatment buddy at alternate club visits	Cannot send a treatment buddy to any club visit

Data analysis

- Study enrolment was in 2017 with the first study visits happening between October-November 2017.
- The database closed on 15/2/2019.
- Retention was defined as any visit within 3-months of the 12-month scheduled appointment and was described using Kaplan-Meier methods and Cox proportional hazards regression using robust standard errors to account for clustering.
- 12-month viral load (VL) completion and suppression (<400copies/mL) proportions are compared with cluster-weighted chi-square tests
- Death outcomes were ascertained using data from the provincial health data center which uses probabilistic matching algorithms to link patient data from different Western Cape facilities, laboratory systems and pharmacy data.

Results

Figure 1: Patient flow



Results (continued)

- Over 2,000 patients (22.3% male, median age 41.1 years) with a median of 7.3 years on ART from 98 ACs were enrolled in the trial (Table 2).
- After 12-months of the study, there were high rates of retention in care (Figure 2), retention in club care, viral load completion and viral load suppression in both arms (Table 3). Mortality was low (n=4 in SoC and n=2 in the intervention arm, results not shown).
- There were no differences in outcomes between the SoC and intervention arm, with an adjusted hazard ratio for retention in care of 1.47 (95% CI 0.79-2.7) in the intervention compared to the SoC.
- There were 9 cases of lost antiretroviral drugs in the intervention arm (<0.5% of drugs distributed)

Table 2: Baseline characteristics

	Standard of care AC	Intervention AC (Six-month refills)	TOTAL
# of ACs	48	40	98
# of patients	1,173	977	2,150
% in community ACs (vs facility ACs)	48.3%	44.4%	46.6%
% male (n)	23.6% (274)	21.8% (212)	22.8% (486)
Median time on ART at study start, years (IQR)	7.2 (4.5-10.5)	7.5 (5.1-10.0)	7.3 (4.7-10.2)
Median age at study start in years (IQR)	41.4 (36.2-47.1)	41.5 (36.6-47.4)	41.4 (36.5-47.2)
% on fixed dose regimen at study start (TDF/3TC/EFV)	87.9%	85.2%	86.6%

Figure 2: Kaplan-Meier survival estimates of retention in care by study arm

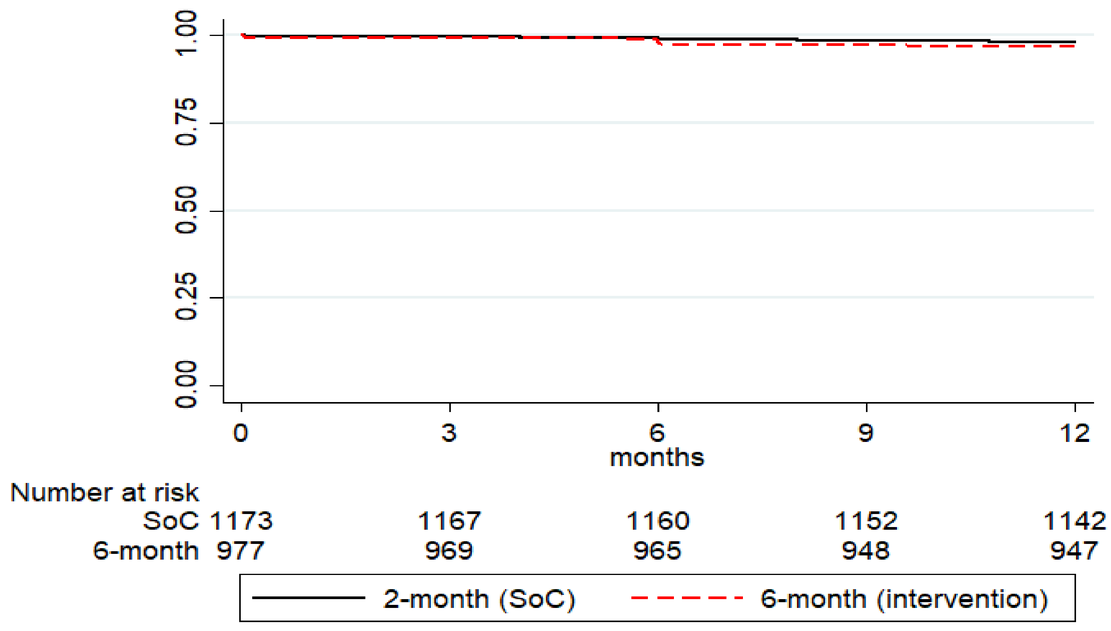


Table 3: 12-month outcomes

	Standard of care AC	Intervention AC (Six-month refills)	p-value
Retention in care	98% (97.2-98.8)	97% (96.1-98.2)	0.252
Retention in club care	83% (80.4-84.9)	86% (83.5-87.9)	0.186
Viral Load completion	94.4% (92.9-95.7)	98.0% (96.9-98.8)	0.06
Viral Load suppression	96.5% (95.2-97.4)	97.8% (96.7-98.8)	0.11

Conclusions

- Comparable 12-month outcomes were achieved in intervention (6-month ART refills) compared to SoC ACs.
- Clinically stable patients can sustain good outcomes with fewer visits in the Adherence Club model
- Longer outcomes (24 months) and qualitative findings of the full cohort will be released at the end of the study.