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RCT of early referral of HIV-infected adults starting ART to community-based adherence clubs

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BACKGROUND

- Numerous differentiated models of service delivery (DSD) have been developed to facilitate engagement in HIV care and accommodate ART expansion.
- In South Africa, the "Adherence Club" (AC) model is most widely implemented; ART services for stable adults are decentralized into the community and run by community health workers (CHWs).
- However, data on how soon after ART initiation patients may be referred to DSD are few.

METHODS

- The study site was a large primary health care clinic in Gugulethu, Cape Town.
- We randomized adults 4 months after starting TDF+FTC+EFV at the clinic to either (a) referral to ACs, or (b) continued clinic-based care (NCT03199027).
- Study eligibility criteria were based on eligibility for referral to ACs: viral load (VL) <400 copies/mL and no comorbidities requiring regular clinical follow-up.
- ACs consist of 20-30 patients who meet at a community venue 2-4 monthly for group counselling and ART refills, with nurse checks done annually; clinic-based services are clinician-driven with 1-3 monthly ART refills.
- Trial measurement visits were done separately from routine care in either arm, and included phlebotomy for batched HIV RNA VL testing by the South African National Health Laboratory Services using the Abbott RealTime HIV-1 Assay (Abbott Laboratories, Abbott Park, Illinois, US).
- The primary outcome was VL <400 copies/mL at 8 months post-randomization; primary analyses were by intention-to-treat.

RESULTS

Table 1: Comparison of arms at randomization

	All (n=220), n (%) or median (IQR)	Control: clinic (n=109), n (%) or median (IQR)	Intervention: AC (n=111), n (%) or median (IQR)	*p**
Age, years	34.7 (29.1-42.1)	34.4 (28.6-44.0)	34.9 (29.2-42.1)	0.92
Sex: Female	147 (66.8)	72 (66.1)	75 (67.6)	0.81
Completed high school	205 (93.2)	102 (93.6)	103 (92.8)	0.82
Employed	132 (60.0)	68 (62.4)	64 (57.7)	0.47
Any previous ARV use	52 (23.6)	26 (21.9)	26 (23.4)	0.94
Duration on ART, weeks	18 (17-20)	18 (17-20)	19 (17-20)	0.65
ART regimen: TDF+FTC+EFV	220 (100)	109 (100)	111 (100)	
Nadir CD4 count, cells/µl *5 missing*	366 (225-496)	320.5 (219-495)	385 (264-496)	0.38
Viral load, copies/mL				
• <100	196 (89.1)	96 (88.1)	100 (90.1)	0.83
• 100-1000	22 (10.0)	12 (11.0)	10 (9.0)	
• >1000	2 (0.9)	1 (0.9)	1 (0.9)	
Viral load, copies/mL				
• <400	218 (99.1)	108 (99.1)	110 (99.1)	1.00
• ≥400	2 (0.9)	1 (0.9)	1 (0.9)	

*Chi-square or Fischer's exact test. AC: adherence club; ART: antiretroviral therapy; ARV: antiretroviral; IQR: interquartile range; VL: viral load.

Stable patients referred to adherence clubs at 4 months on ART did not have different outcomes to those managed in routine clinics through 12 months on ART.

RESULTS (continued)

- Between Jan 2017 and Apr 2018, 220 adults were enrolled and randomized
- Table 1 shows characteristics at randomization (mean age 34.7 years; 66.8% female; 23.6% previous ART; median nadir CD4 count 366 cells/µl; median time on ART 18 weeks); there were no significant differences by arm.
- 103/109 (94.5%) of those referred to the clinic and 95/111 (85.6%) of those referred to ACs attended the allocated service within three months of referral.
- VL measures for the primary outcome were available on 205 participants (93.2%) with no differences in those retained vs lost to follow-up, overall and by arm.
- By 12 months on ART, VL<400 copies/mL was observed in 89% of participants retained in the AC arm versus 93% of participants retained in the clinic arm (risk difference, -1.9%; 95% CI, -9.2% to 5.5%).

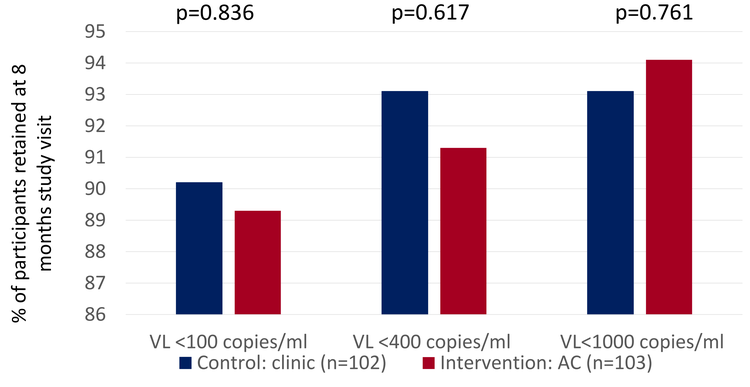


Figure 1: Viral load outcomes by arm at 8 months post-randomization

RESULTS (continued)

- The finding for no difference in outcomes between AC and clinic-based care was consistent across subgroups of age, sex, previous ART use and nadir CD4 cell count (table 2); in a binomial model adjusted for the same factors (table 3); and when the outcome was examined at alternate VL cutpoints (figure 1).

Table 2: Results of binomial models examining the association between trial arm and primary outcome (unadjusted)

	Risk difference (intervention – control)	95% CI
Sex		
• Male	-0.0164	-0.0989 to 0.0661
• Female	-0.0205	-0.1665 to 0.1254
Previous ART use		
• Yes	-0.0120	-0.0847 to 0.0606
• No	-0.0417	-0.2410 to 0.1577
Nadir CD4 category		
• <200	0.0565	-0.0991 to 0.2122
• ≥200	-0.0390	-0.1227 to 0.0447
Age category		
• <25 years	-0.125	-0.3542 to 0.1042
• 25-35 years	-0.0667	-0.1765 to 0.0431
• 35-45years	0.0906	-0.0489 to 0.2301
• >45 years	-0.0341	-0.2358 to 0.1676

ART: antiretroviral therapy; CI: confidence interval.

Table 3: Results of additive binomial model examining the association between trial arm and primary outcome (VL<400 copies/mL) adjusted for demographic and clinical characteristics

	Risk difference (intervention-control)	95% CI
Trial arm (intervention-control)	-0.0130	-0.0796 to 0.0535
Sex (male vs female)	-0.0265	-0.1063 to 0.0534
Previous ART use vs no previous ART use	-0.0833	-0.1890 to 0.0224
CD4 category (≥200 vs <200)	0.0008	-0.0830 to 0.0846
Age (years)	-0.0009	-0.1765 to 0.0431

ART: antiretroviral therapy; CI: confidence interval; VL: viral load.

CONCLUSIONS

- These novel data suggest that referral of stable ART patients to community-based DSD may take place as early as 4 months after ART initiation in this setting, with no difference in virologic outcomes versus clinic-based services.

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