

**Point-of-care HIV viral load testing in a community antiretroviral therapy delivery programme: a randomised trial (PHILA)**

**Results summary reporting for Pan-African Clinical Trials Registry:  
PACTR202002785960123**

**Date: 19<sup>th</sup> December 2024**

**1. Baseline characteristics**

**Table 1: Baseline characteristics of PHILA participants at enrolment**

Variable	Levels	Intervention arm	Standard of care arm	Total
Age, years	Median (IQR)	44.0 (37.8 to 49.0)	44.0 (36.8 to 49.0)	44.0 (37.0 to 49.0)
Gender	Female	70 (70.0)	61 (61.0)	131 (65.5)
	Male	30 (30.0)	39 (39.0)	69 (34.5)
Time since HIV diagnosis, years	Median (IQR)	9.3 (7.0 to 12.0)	8.9 (6.5 to 12.1)	9.1 (6.7 to 12.0)
Time since ART initiation, years	Median (IQR)	8.9 (6.7 to 10.9)	7.9 (6.0 to 10.2)	8.0 (6.0 to 10.9)
Initiation CD4 count, cells/ $\mu$ L	Median (IQR)	225.5 (140.0 to 339.0)	308.0 (196.5 to 456.5)	251.0 (158.5 to 387.5)
Initiation CD4 count category, cells/ $\mu$ L	<200	40 (40.0)	23 (23.0)	63 (31.5)
	200-349	29 (29.0)	27 (27.0)	56 (28.0)
	350-499	11 (11.0)	21 (21.0)	32 (16.0)
	$\geq$ 500	8 (8.0)	16 (16.0)	24 (12.0)
	(Missing)	12 (12.0)	13 (13.0)	25 (12.5)
Current ART regimen at enrolment	TDF / 3TC / DTG	86 (86.0)	80 (80.0)	166 (83.0)
	TDF / FTC / EFV	14 (14.0)	15 (15.0)	29 (14.5)
	Other		5 (5.0)	5 (2.5)
Time on current regimen, years	Median (IQR)	2.7 (1.8 to 2.9)	2.7 (1.9 to 3.0)	2.7 (1.8 to 2.9)
ART side effects	No	100 (100.0)	98 (98.0)	198 (99.0)
	Yes		2 (2.0)	2 (1.0)
Number of ART doses missed in past 4 days	0	87 (87.0)	91 (91.0)	178 (89.0)
	1	8 (8.0)	8 (8.0)	16 (8.0)
	2	3 (3.0)	1 (1.0)	4 (2.0)
	3	1 (1.0)	0 (0.0)	1 (0.5)
	4	1 (1.0)	0 (0.0)	1 (0.5)
Last time participant missed a dose of ART	Within past the week	11 (11.0)	8 (8.0)	19 (9.5)
	1-2 weeks ago	6 (6.0)	4 (4.0)	10 (5.0)
	2-4 weeks ago	1 (1.0)	2 (2.0)	3 (1.5)
	1-3 months ago	2 (2.0)	1 (1.0)	3 (1.5)
	>3 months ago	1 (1.0)	0 (0.0)	1 (0.5)
	Never	79 (79.0)	85 (85.0)	164 (82.0)
Time since first CCMDD referral, years	Median (IQR)	4.0 (1.8 to 6.3)	3.7 (1.8 to 5.9)	3.8 (1.8 to 6.0)
Time since latest CCMDD referral, days	Median (IQR)	168.0 (164.0 to 168.2)	168.0 (161.0 to 174.2)	168.0 (161.0 to 172.2)
Time between CCMDD due and enrolment, days	Median (IQR)	0.0 (-1.0 to 0.0)	0.0 (-4.5 to 0.0)	0.0 (-3.0 to 0.0)
Hazardous drinking (AUDIT-C)	No	76 (76.0)	66 (66.0)	142 (71.0)
	Yes	24 (24.0)	34 (34.0)	58 (29.0)

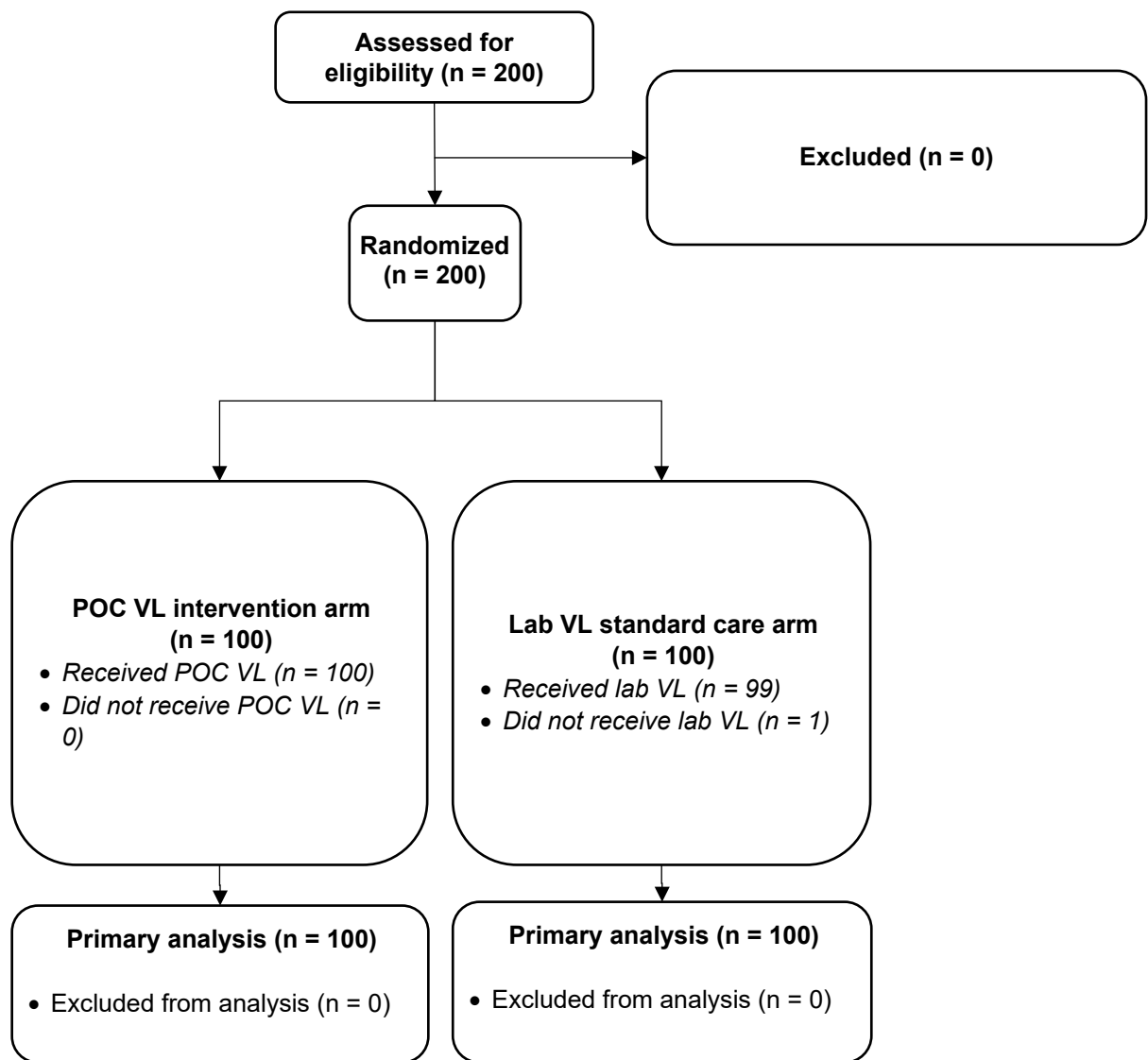
Variable	Levels	Intervention arm	Standard of care arm	Total
Ethnicity	Black African	99 (99.0)	100 (100.0)	199 (99.5)
	Other	1 (1.0)		1 (0.5)
Highest level of education completed	None	2 (2.0)	3 (3.0)	5 (2.5)
	Primary school only	13 (13.0)	5 (5.0)	18 (9.0)
	Secondary school but not matric	32 (32.0)	43 (43.0)	75 (37.5)
	Matriculation	46 (46.0)	39 (39.0)	85 (42.5)
	Tertiary	7 (7.0)	10 (10.0)	17 (8.5)
Employment status	Unemployed	29 (29.0)	20 (20.0)	49 (24.5)
	Informal employment	4 (4.0)	2 (2.0)	6 (3.0)
	Part time employment	18 (18.0)	24 (24.0)	42 (21.0)
	Full-time employment	41 (41.0)	44 (44.0)	85 (42.5)
	Student	1 (1.0)	1 (1.0)	2 (1.0)
	Self-employed	7 (7.0)	9 (9.0)	16 (8.0)
Monthly personal income, ZAR	Median (IQR)	3000.0 (0.0 to 5000.0)	4000.0 (1200.0 to 6000.0)	3500.0 (350.0 to 5000.0)
Mode of transport to clinic	Private transport	5 (5.0)	5 (5.0)	10 (5.0)
	Public transport	89 (89.0)	92 (92.0)	181 (90.5)
	Walking	6 (6.0)	3 (3.0)	9 (4.5)
Travel time to clinic, minutes	Median (IQR)	30.0 (23.8 to 45.0)	30.0 (25.0 to 41.2)	30.0 (25.0 to 45.0)
Cost of travel to clinic and back, ZAR	Median (IQR)	40.0 (26.0 to 50.0)	45.0 (30.0 to 50.0)	44.0 (28.0 to 50.0)
Mode of transport to PuP	Private transport	6 (6.0)	4 (4.0)	10 (5.0)
	Public transport	82 (82.0)	83 (83.0)	165 (82.5)
	Walking	12 (12.0)	13 (13.0)	25 (12.5)
Travel time to PuP, minutes	Median (IQR)	25.0 (15.0 to 30.0)	25.0 (15.0 to 31.2)	25.0 (15.0 to 30.0)
Cost of travel to PuP and back, ZAR	Median (IQR)	30.0 (20.0 to 50.0)	30.0 (20.0 to 50.0)	30.0 (20.0 to 50.0)
Time since pre-enrolment viral load, days	Median (IQR)	358.5 (342.5 to 371.0)	356.5 (349.0 to 371.0)	357.0 (344.0 to 371.0)
Pre-enrolment viral load category, copies/mL	< 50	98 (98.0)	100 (100.0)	198 (99.0)
	50 - 999	0 (0.0)	0 (0.0)	0 (0.0)
	>= 1000	1 (1.0)	0 (0.0)	1 (0.5)
	(Missing)	1 (1.0)	0 (0.0)	1 (0.5)
Most recent CD4 count, cells/ $\mu$ L	Median (IQR)	482.0 (369.0 to 613.5)	556.5 (398.0 to 738.8)	522.5 (387.2 to 664.5)
Most recent CD4 count category, cells/ $\mu$ L	<200	1 (1.0)	1 (1.0)	2 (1.0)
	200-349	18 (18.0)	14 (14.0)	32 (16.0)
	350-499	28 (28.0)	15 (15.0)	43 (21.5)
	>=500	39 (39.0)	54 (54.0)	93 (46.5)
	(Missing)	14 (14.0)	16 (16.0)	30 (15.0)
Time since recent CD4 count, days	Median (IQR)	2195.5 (1055.5 to 2574.0)	2186.5 (771.0 to 2576.0)	2194.5 (950.5 to 2575.5)
Enrolment creatinine, $\mu$ mol/L	Median (IQR)	82.5 (75.0 to 97.0)	85.0 (72.0 to 91.5)	83.0 (73.0 to 93.5)
Enrolment viral load, cps/mL	< 50	94 (94.0)	92 (92.0)	186 (93.0)
	50 - 999	2 (2.0)	3 (3.0)	5 (2.5)
	>= 1000	0 (0.0)	2 (2.0)	2 (1.0)
	Invalid	4* (0.0)	3** (3.0)	7 (3.5)

\* 4 invalid point-of-care enrolment viral load results repeated on the same day and <50 copies/mL

\*\* 3 invalid laboratory enrolment viral load results repeated at next visit and <50 copies/mL

## 2. Participant flow

Figure 1: PHILA study CONSORT diagram



## 3. Adverse events

As per the study protocol, because this study does not involve an investigational medicinal product or intervention that affects physiology, only adverse events of hospitalisations and deaths were recorded.

During follow-up, there was one death due to pneumonia in the intervention arm. This was not deemed to be related to the intervention.

## 4. Outcomes

**Table 2: Primary and secondary outcomes for the PHILA study**

	Intervention n/N (%)	Standard care n/N (%)	Risk difference (95% CI)	p value
<b>Primary outcome</b>				
CCMDD prescription renewal within 3 weeks	94/100 (94.0%)	81/100 (81.0%)	13.0% (3.0 to 23.0)	0.010
<b>Secondary outcomes</b>				
CCMDD prescription renewal within:				
2 weeks	94/100 (94.0%)	76/100 (76.0%)	18.0% (7.42 - 28.58)	0.001
4 weeks	94/100 (94.0%)	88/100 (88.0%)	6.0% (-2.89 - 14.89)	0.217
8 weeks	96/100 (96.0%)	92/100 (92.0%)	4.0% (-3.56 - 11.56)	0.372
12 weeks	96/100 (96.0%)	92/100 (92.0%)	4.0% (-3.56 - 11.56)	0.372
16 weeks	97/100 (97.0%)	94/100 (94.0%)	3.0% (-3.73 - 9.73)	0.495
First CCMDD ART collection within:				
2 weeks	0/100 (0.0%)	1/100 (1.0%)	-1.0% [-3.95 - 1.95]	1.000
4 weeks	0/100 (0.0%)	1/100 (1.0%)	-1.0% [-3.95 - 1.95]	1.000
8 weeks	3/100 (3.0%)	3/100 (3.0%)	0.0% [-4.73 - 4.73]	1.000
12 weeks	29/100 (29.0%)	16/100 (16.0%)	13.0% [0.57 - 25.43]	0.042
16 weeks	80/100 (80.0%)	78/100 (78.0%)	2.0% [-10.29 - 14.29]	0.862
Proportion of participants retained in care	89/100 (89.0%)	86/100 (86.0%)	3.0% (-7.1 to 13.2)	0.669
Participants who received viral load results within:				
2 weeks	97/100 (97.0%)	35/100 (35.0%)	62.0% [51.1 - 72.93]	<0.001
4 weeks	97/100 (97.0%)	49/100 (49.0%)	48.0% [36.7 - 59.4]	<0.001
8 weeks	97/100 (97.0%)	54/100 (54.0%)	43.0% [31.7 - 54.3]	<0.001
12 weeks	97/100 (97.0%)	56/100 (56.0%)	41.0% [29.7 - 52.3]	<0.001
16 weeks	97/100 (97.0%)	56/100 (56.0%)	41.0% [29.7 - 52.3]	<0.001
	<b>Mean (95% CI)</b>	<b>Mean (95% CI)</b>	<b>Mean difference (95% CI)</b>	
Number of clinic visits required for CCMDD renewal	1.05 (0.99 - 1.11)	1.50 (1.37 - 1.63)	-0.45 (-0.31 to -0.59)	<0.001
Travel costs from the patient perspective to have CCMDD prescription renewed (ZAR)	47.5 (39.3 - 55.6)	69.2 (55.2 - 83.1)	-21.7 (-5.7 to -37.7)	<0.001