RESULTS

Trial participants' baseline characteristic

The intervention and control arm participants were 119 and 127, respectively (Figure 1). Participants were followed up for one year (i.e. until February 28, 2020, for the last recruited participant). The mean age and the gender of participants in both arms were not statistically different (13.7 ± 2.4 versus 14.0 ± 2.7, p = 0.35 for intervention versus control respectively). More participants in the intervention arm received more Zidovudine/Lamivudine/Nevirapine regimen than those in the control arm. Conversely, more participants in the control arm received Tenofovir/Lamivudine/Efavirenz and Tenofovir/Lamivudine/Dolutegravir combinations compared to those in the intervention arm. More participants in the control arm had an undetectable viral load (≤20 copies/ml) compared to those in the intervention arm at baseline (42.5% versus 2.18%, p < 0.001 respectively). There was no statistically significant difference in the CD4+ count of the participants in the two arms at baseline (665 ± 685 versus 665 ± 437, p = 0.99 for intervention versus control respectively). More participants in the intervention arm had ≥95% adherence to antiretroviral therapy compared to those in the control arm (51.3% versus 27.6%, p < 0.01 for intervention versus control respectively). The details of the baseline characteristics of participants are shown in Table 2.

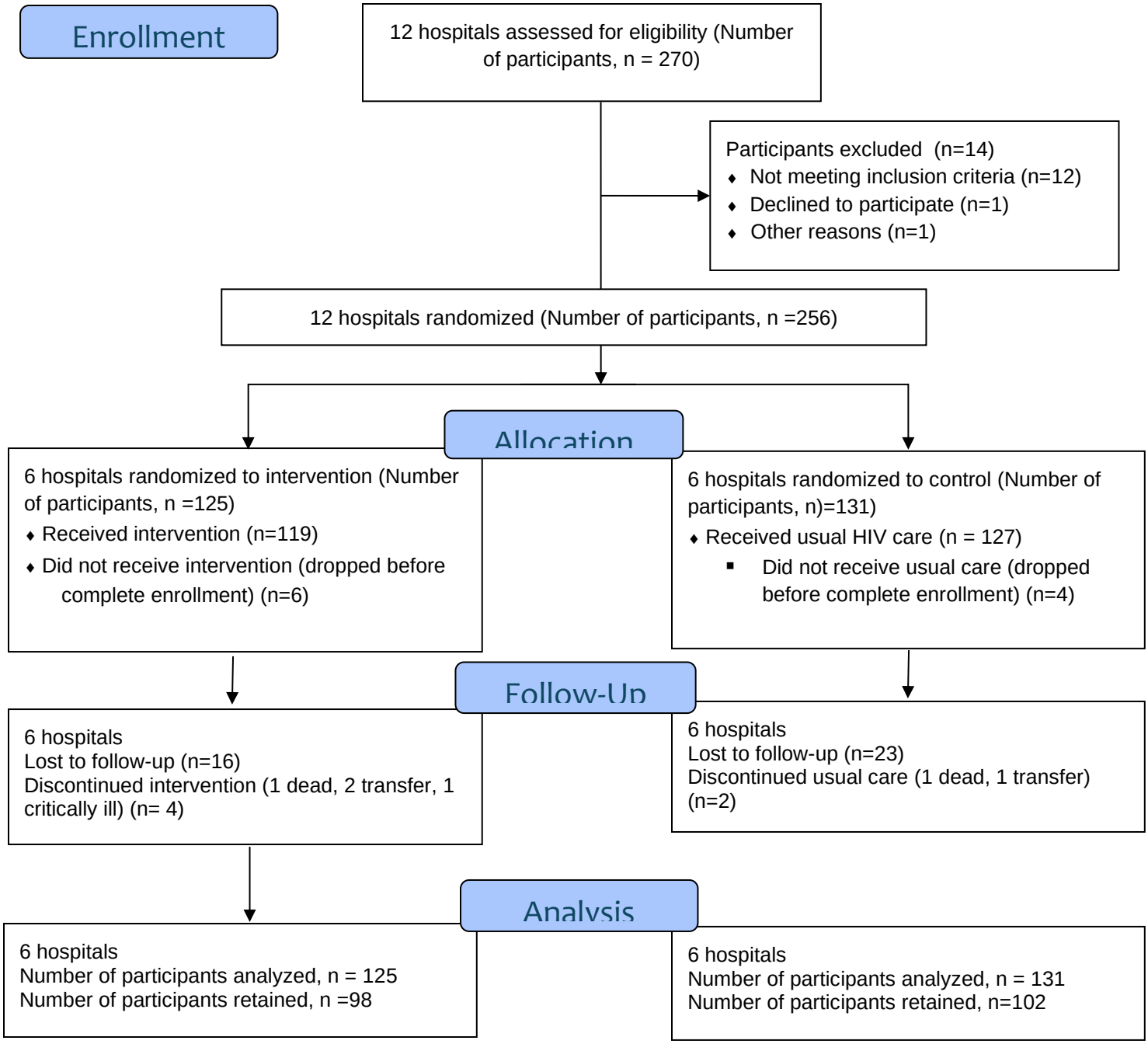

Figure 1: Trial flow diagram

Table 2: Baseline characteristics of trial participants (N=246)

	Intervention	**Control**	***P*-value**
Number of participants	119 (48.4%)	127 (51.6%)	0.61
Mean age of participants ± Std. deviation	13.67 ± 2.43	13.98 ± 2.72	0.35
Gender of participants			
Male	63 (52.9%)	60 (47.2%)	0.44
Female	56 (47.1%)	67 (52.8%)	
ART Regimen at baseline			
Zidovudine/ Lamivudine/Nevirapine	67 (56.3%)	45 (35.4%)	-
Tenofovir /Lamivudine/Efavirenz	32 (26.9%)	43 (33.9%)	
Tenofovir/Lamivudine/Dolutegravir	5 (4.2%)	16 (12.6%)	
Abacavir/Lamivudine/Lopinavir/ritonavir	2 (1.7%)	8 (6.3%)	
Zidovudine /Lamivudine/ Lopinavir/ritonavir	2 (1.7%)	7 (5.5%)	
Tenofovir /Lamivudine Lopinavir/ ritonavir	5 (4.2%)	4 (3.1%)	
Abacavir /Lamivudine/Efavirenz	5 (4.2%)	3 (2.4%)	
Zidovudine/ Lamivudine/Efavirenz	1 (0.8%)	1 (0.8%)	
Number of participants with undetectable viral load (≤20 copies/ml)	26/119 (21.8%)	54/127 (42.5%)	<0.001
Mean CD4+ count ± Std. deviation	665 ± 685	665 ± 437	0.99
Number of participants with ≥95% adherence	61/119 (51.3%)	35/127 (27.6%)	<0.001

Abbreviations:

Zidovudine /Lamivudine/ Lopinavir/ritonavir
Tenofovir /Lamivudine Lopinavir/ ritonavir ART *Antiretroviral therapy*

Impact of incentive scheme after 12 months

The unadjusted impact of the incentive scheme on health outcomes after 12 months is shown in Table 3. There was a 10.1 percentage point increase in the number of participants with undetectable viral load (≤20 copies/ml) in the intervention arm, while a 1.6 percentage point decrease was observed in the control arm. The mean CD4+ count decreased more in the intervention arm than in the control arm. Also, the control arm had a greater number of participants achieving ≥95% adherence than the intervention arm. Lastly, participants in the intervention arm achieved higher retention in care than those in the control arm (Table 3).

Table 3: Unadjusted primary and secondary outcomes at 12 months (N = 246)

	Intervention			**Control**		
	Baseline	*At 12 months*	*Change over 12 months*	*Baseline*	*At 12 months*	*Change over 12 months*
Number of participants with undetectable viral load (≤20 copies/ml)	26/119 (21.8%)	38/119 (31.9%)	10.1%	54/127 (42.5%)	52/127 (40.9%)	-1.6%
Mean CD4+ count ± Std. deviation	665 ± 685	587 ± 379	-78	665 ± 437	611 ± 387	-54
Number of participants with ≥95% adherence	61/119 (51.3%)	59/119 (49.6%)	-1.7%	35/127 (27.6%)	40/127 (31.5%)	3.9%
Number of participants retained in care	-	98/119 (82.4%)	-		102/127 (80.3%)	-

Adjustment of study outcomes for baseline differences

Table 4 shows the incidence risk ratio (IRR) or mean difference for the primary and secondary outcomes at 12 months adjusted for baseline viral load, gender and age of participants in the two arms. There was no significant difference after 12-month on number of participants with undetectable viral load (Incidence risk ratio, IRR = 1.01, p-value = 0.96), number of participants with ≥95% adherence (IRR = 0.69, p = 0.10), number of participants retained in care (IRR = 1.03, p = 0.79) and mean CD4+ count (IRR = 0.79, p = 0.92) between the intervention and treatment arm.

Table 4: Adjusted primary and secondary outcomes at 12 months using Poisson multilevel regression analysis

Variables	**IRR**	**P-value**	**95% Conf. Interval**
Number of participants with undetectable viral load (≤20 copies/ml)	1.01	0.96	0.72 – 1.41

Number of participants with ≥95% adherence	0.69	0.10	0.45 – 1.07
Number of participants retained in care	1.03	0.79	0.78 – 1.38
	MD	**P-value**	**95% Conf. Interval**
Mean CD4+ count	0.79	0.92	-14.53 – 16.12

IRR – Incidence risk ratio. MD – Mean difference. Usual care was the reference category. The final multilevel analysis was adjusted for baseline viral load, gender (females versus males), and age (10 – 14 yrs versus 15 – 19 yrs).

Management of incidental findings

All anticipatable incidental findings due to the increased number of laboratory testing, which included clinical failure, immunological failure, and virologic failure, were disclosed to the participants and their parents/legal guardians (for those less than 18 years) and managed following the National Guidelines for HIV Prevention, Treatment, and Care (18).