Supplementary File 1: CONSORT checklist for cluster-randomised trials

PAPER SECTION and topic	Item	Descriptor	Reported on Page No.		
TITLE & ABSTRACT	,				
	1a*	Identification as a randomised trial in the title	Title		
	1b	How participants were allocated to interventions (e.g., "random allocation", "randomised", or "randomly assigned"), specifying that allocation was based on clusters	Abstract		
INTRODUCTION					
Background & Objectives	2a	Scientific background and explanation of rationale, including the rationale for using a cluster design.	Introduction, Study design, Naikoba et al. [9]		
	2b	Specific objectives or hypotheses, whether objectives pertain to the cluster level, the individual participant level or both	Introduction		
METHODS					
Trial Design	За	Description of trial design (such as parallel, factorial) including allocation ratio	Study design		
	3b Important changes to methods after trial commencement (such as eligibility criteria), with reasons				
Participants	4a	Eligibility criteria for participants <i>and clusters</i> and the settings and locations where the data were collected.	Participants and eligibility, Miceli et al.[16], Naikoba et al.[9]		
	4b	Settings and locations where the data were collected	Participants and eligibility, Naikoba et al.[9]		
Interventions	5	Precise details of the interventions intended for each group, whether they pertain to the individual level, the cluster level or both, and how and when they were actually administered.	Interventions, Micel et al.[16], Naikoba et al.[9]		
Outcomes	6a	Report clearly defined primary and secondary outcome measures, whether they pertain to the individual level, the cluster level or both, and, when applicable, any methods used to enhance the quality of measurements (e.g., multiple observations, training of assessors).	Outcome definitions, Data collection		
	6b	Any changes to trial outcomes after the trial commenced, with reasons	Outcome definitions		
Sample size	7a	How total sample size was determined (including method of calculation, number of clusters, cluster size, a coefficient of intracluster correlation (ICC or k), and an indication of its uncertainty) and, when applicable, explanation of any interim analyses and stopping rules.Sample si			

PAPER SECTION and topic	ltem	Descriptor	Reported on Page No.	
	7b	When applicable, explanation of any interim analyses and stopping guidelines	Not applicable	
RANDOMIZATION				
Sequence generation			Randomization, Naikoba et al. [9], Weaver et. al.[12]	
	8b	Type of randomisation; details of any restriction (such as blocking and block size) Details of stratification or matching if used	Randomization, Naikoba et al. [9], Weaver et. al. [12]	
Allocation concealment	9*	Method used to implement the random allocation sequence, <i>specifying that allocation was based on</i> <i>clusters rather than individuals and</i> clarifying whether the sequence was concealed until interventions were assigned.	Randomization, Naikoba et al. [9]	
Implemen- tation	10a	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.	Randomization, Naikoba et al. [9]	
	10b	Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling)	Participants and eligibility	
	10c	From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomisation	Ethical considerations	
Blinding 11a Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment.			Randomization	
	Not applicable			
Statistical methods				
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Data Management and Statistical Methods	
RESULTS	1		1	
Participant flow	13a	Flow of <i>clusters and</i> individual participants through each stage (a diagram is strongly recommended). Specifically, for each group report the numbers of <i>clusters and</i> participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome. Describe protocol deviations from study as planned, together with reasons.	Recruitment and Enrollment, Figure 1	

PAPER SECTION and topic	Item	Descriptor	Reported on Page No.		
	13b	For each group, losses and exclusions after randomisation, together with reasons. For each group, losses and exclusions for both clusters and individual cluster members	Recruitment and Enrollment, Figure 1		
Recruitment	14a	Dates defining the periods of recruitment and follow- up.	Study Design		
	14b	Why the trial ended or was stopped	Not applicable		
Baseline data	15	Baseline information for each group for the individual and cluster levels as applicable	Results, Figure 2, Tables 2-3		
Numbers analyzed	16	Number of <i>clusters and</i> participants (denominator) in each group included in each analysis and whether the analysis was by "intention-to-treat". State the results in absolute numbers when feasible (e.g., 10/20, not 50%).	Outcomes, Figure 1		
Outcomes and Estimation	17a	For each primary and secondary outcome, a summary of results for each group measures <i>for the individual or</i> <i>cluster level as applicable</i> , and the estimated effect size and its precision (e.g., 95% confidence interval)	Outcomes, Tables 2 3		
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Outcomes, Tables 2 3		
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Outomes, Table 3		
Adverse events	19	All important adverse events or side effects in each Not appli intervention group.			
DISCUSSION					
Interpretation	20	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Discussion		
Limitations	21	Trial limitations, addressing sources of potential bias, Lim imprecision, and, if relevant, multiplicity of analyses			
Generalizability	22	Generalizability (external validity) to individuals and/or Discussers (as relevant) of the trial findings			
Overall evidence	23	General interpretation of the results in the context of Conclusion current evidence.			
OTHER INFORMATIO	ON				
Registration	24	Registration number and name of trial registry	Not applicable		
Protocol	25	Where the full trial protocol can be accessed, if available	Study Design, Weaver et. al. [12]		
Funding	26	Sources of funding and other support (such as supply Acknowledgerr of drugs), role of funders			

Supplementary File 2:

IDCAP HIV Clinical Observation Form	^A Observation #:					
^B Site #: ^{C.} Trainee #:	^{D.} Date of visit (d/m/y):					
^{E.} Observer #:	^{F.} Quality Control #:					
G. Triage status: H. Emergency (A B C D O) . Priority (Specify) Not Emerge						
If emergency, support trainee to manage pat	ient. Emergency treatment is higher priority than clinical assessment.					
^{J.} Language of patient during visit: ^{K.} T	ranslation? Yes No					
^L Gender of patient: F M Age of patient	nt: ^{M.} months (LT 5 years) ^{N.} years (GE 5 years)					
I.Vital signs: ¹ .Reported by other health profe	ssional or volunteer before consultations? Yes No					
^{2.} TemperatureC ^{3.} If no thermometer, fe ^{4.} Current weight kg ^{5.} Weight last visit _ ^{8.} BP	ebrile to touch Y N kg ⁶ ·Peak weight kg ⁷ ·Height cm					
II. History						
¹ New enrollee at site? Y N ² If yes, ne	ew dx ortransfer? 3. Date of HIV diagnosis (m/d/y)//					
Medication: ⁴ .Current ART? Yes No ^{5.} If Yes, regimen:						
^{6.} If yes, ART start date (d/m/y)//						
	es, regimen:					
	Other ¹⁰ If yes, ART stop date(d/m/y)//					
¹⁴ ·CTX preventive? Yes No NR ¹⁵ ·Otl	ensive continuation) Previous; (^{13.} d/m/y)last dose_/_/_					
¹⁶ -Allergy to Medication: None CTX SP Other NR ¹⁷ - Additional history: None Previous OI (specify) NR Incompared						
¹⁸ If female, now pregnant: Yes No NR Suspected, not confirmed ²⁰ LNMP:/						
	Code Patient Code					
III. Symptoms Patient	ART adherence:					
¹ .Fever: ² .Duration days Y N NR	^{9.} How many taken?pillsNRNA ^{10.} How many prescribed?pillsNRNA ^{11.} Prescription date? (m/d/y)// NRNA					
^{3.} Coughing: ^{4.} Durationdays Y N NR	^{13.} Side effects of ART					
^{5.} Night sweats:	^{14.} Specify					
^{6.} Weight loss: ^{7.} Specify % Y \N \NR	^{15.} Functional status Able to work ^{16.} If bedridden, % of Ambulatory					
^{8.} Recent contact with someone who has TB:	time: Bedridden					
¹⁷ Does patient have specific complaints or co	ncerns? Y N NR (If yes, specify below with Y, N or V.)					
¹⁸ .Abdominal pain 2 ^{3.} Convulsions	^{30.} Headache ^{B6.} Skin lesions					
^{19.} Anxiety 24. Depression	31. Loss of appetite 37. Skin Rash					
^{20.} Breathing –	32. Mouth 38. Swallowing					
shortness of breath ^{26.} Duration_da ^{21.} Burning, tingling, ^{27.} Blood? Y	ays problems difficulty] N ^{33.} Myalgias I ^{39.} Vomiting I					
loss or change in	^{34.} Nausea ^{40.} Other					
sensation 22. Chest pain 29. Genital problem						
Specify						

IV. Physica	al Ex	am					
^{1.} General			A. normal B. wasting C. palor D. jaundice E. oedema F. lymphadenopathy G. agitation H. fat change(lipodystrophy) L temperature C J. other				
^{2.} Mouth			normal ^{B.} abscess ^{C.} oral thrush ^{D.} caries ^{E.} gingivitis ^{F.} Kaposi ^{G.} ulcers other				
^{3.} Skin			A. normal ^{B.} abscess ^{C.} ecchymosis ^{D.} erythema ^{E.} herpes zoster scar ^{F.} Kaposi ^{G.} nodules ^{H.} papules ^{I.} pus ^{J.} pustules ^{K.} scaling ^{L.} vesicles ^{M.} wound ^{N.} other				
		1.	A. normal ^{B.} breathing difficulty ^{C.} chest in-drawing ^{D.} stridor				
^{4.} Lungs		2.	If cough, ^{E.} RR–traineebpm ^{F.} RR–observerbpm Listen to lung: ^{G.} Clear ^{H.} abnormal sound on percussion ^{I.} tenderness				
		3.	^{J.} Crepitations ^{K.} Irhonchi ^{L.} wheezing ^{M.} decreased breath sounds ^{N.} other				
^{5.} Cardio- vascular			^{A.} pulse ^{B.} gallop ^{C.} murmur ^{D.} rub ^{E.} other				
^{6.} Abdo- men			 A. normal B. distended C. tenderness D. abnormal sound on percussion E. hepatomegaly F. splenomegaly G. abnormal mass H. pregnancy I. ascites J. other 				
^{7.} Genita- lia			^{A.} normal ^{B.} discharge ^{C.} tenderness ^{D.} ulcers ^{E.} other				
^{8.} Muculo skeletal			^{A.} normal ^{B.} other				
^{9.} Neuro			A. normal B. coma C. confusion, disorientation D. focal deficit E. meningismus F. paresthesia G. seizure H. other				
¹⁰ Other- Specify:			Specify ^{A.} exam and ^{B.} findings				

^{11.}Did equipment or resource gaps affect trainee's physical exam for this patient? Yes No ^{12.}If yes, please

explain__

^{IX1.}Did trainee conduct a focused and thorough history that is relevant to evolution of current symptom/complaint? \cdot Yes \Box No ^{IX2.}If no, summarize reason.

Omission (Specify if not obvious on checklist)

Misinterpretation (Must specify)

Unnecessary (Must specify)

^{IX3.}Did trainee conduct a complete physical exam? Yes No ^{IX4.}If no, summarize reason.

Omission (Specify if not obvious on checklist)

Misinterpretation (Must specify)

Unnecessary (Must specify)

				Site/trainee/Observation	on #://		
V. Ple	V. Please tell me the relevant information from the patient's file. ^{1.} Not available						
Code		Results	Code		Results		
	^{2.} Ab (HIV antibody)			^{3.} Ag/PCR (child<			
				18mo)			
	^{4.} CBC (hemogram)			^{5.} HB (haemoglobin)			
	^{6.} CXR			^{7.} Creatinine			
	^{8.} Glucose			^{9.} HepB			
	^{10.} LFT			^{11.} Malaria BS			
	transaminases						
	^{12.} Malaria RDT			^{13.} Pregnancy (HCG)			
	^{14.} RPR			^{15.} TB Sputum			
	^{16.} Viral Load						
	^{17.} Other1- Specify			^{18.} Other2- Specify			
	^{19.} CD4 cells/mm ³	1.		^{20.} Date (m/d/y) of CD4	1.		
	^{21.} CD4 cells/mm ³	2.		^{22.} Date (m/d/y) of CD4	2.		
	^{23.} CD4 cells/mm ³	3		^{24.} Date (m/d/y) of CD4	3.		
	-	ed WHO clinical disease st	tage for	this patient: 🗌 I 📃 II 🗌			
^{26.} Wha	it is the basis for this sta	ging decision? (specify)					
^{27.} Date	e (d/m/y) of staging diag	nosis//					

^{IX5.}Did the trainee demonstrate accurate interpretation of laboratory values and schedule for routine laboratory surveillance of HIV/AIDS? Yes No ^{IX6} If no, summarize reason.

Omission (Specify if not obvious on checklist)

Misinterpretation (Must specify)

Unnecessary (Must specify)

VI. Differential Diagnosis

¹ Does this patient have any clinical staging conditions today?		Yes		No	If yes	, what	were th	ey?
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^{A.} Trainee 1	^{B.} Observer Agree? Yes No ^{C.} Observer 1
^{D.} Trainee 2	^{E.} Observer Agree? Yes No ^{F.} Observer 2
^{G.} Trainee 3	_ ^{H.} Observer Agree? []Yes []No ^{I.} Observer 3
^{IX5.} Did the trainee accurately diagnose of	clinical staging conditions? Yes No ^{IX6.} If no, summarize reason.
Omission (Specify if not obvious on c	checklist)
Misinterpretation (Must specify)	
Unnecessary (Must specify)	
^{2.} Does this patient have other diagnoses	s today? Yes No NA If yes, what were they?
^{A.} Trainee 1	_ ^{B.} Observer Agree?
^{D.} Trainee 2	_ ^{E.} Observer Agree? Yes No ^{F.} Observer 2
^{G.} Trainee 3	_ ^{H.} Observer Agree? [Yes]No ^{I.} Observer 3
^{J.} Trainee 4	^{K.} Observer Agree? Yes No ^{L.} Observer 4
^{IX7.} Did the trainee accurately diagnose of	other problems? Yes No ^{1X8.} If no, summarize reason.
Omission (Specify if not obvious on c	checklist)
Misinterpretation (Must specify)	
Unnecessary (Must specify)	

^{3.} What is the patient's clinical stage today What was the supporting evidence?	?IIIIIIIIVI-ТIII-ТIII-ТIV-Т
^{A.} Trainee 1 ^B	Observer Agree? Yes No ^{C.} Observer 1
	Observer Agree? Yes No ^F Observer 2
^{G.} Trainee 3	¹ Observer Agree? Yes No ¹ Observer 3
^{IX9.} Did the trainee accurately assess WHO	clinical stage? Yes No ^{IX10.} If no, summarize reason.
 Omission (Specify if not obvious on che Misinterpretation (Must specify) Unnecessary (Must specify) 	ecklist)
^{4.} Is the patient eligible for ART? Yes	No NA If yes, what was the supporting evidence?
^{A.} Trainee 1 ^B	Observer Agree? Yes No ^{c.} Observer 1
^{D.} Trainee 2 ^E	Observer Agree? Yes No ^C Observer 1 Observer Agree? Yes No ^F Observer 2
^{IX11} Did the trainee accurately identify elig	ibility for ART? Yes No NA ^{IX12.} If no, summarize reason.
 Omission (Specify if not obvious on che Misinterpretation (Must specify) Unnecessary (Must specify) 	ecklist)
 ⁵ If on ART, what % of drugs were taken? % =_No. of drugs taken x 100/Total no. of p 	⊇≥95% 285-94% 2<85% NR NA
^{IX13.} Did the trainee address ART adherence	ce? Yes No NA ^{IX14.} If no, summarize reason.
 Omission (Specify if not obvious on che Misinterpretation (Must specify) Unnecessary (Must specify) 	ecklist)
^{6.} If on ART, do you suspect side effects?	Yes No NA If yes, what were they?
^{A.} Trainee 1	Observer Agree? Yes No ^C Observer 1
D.Trainee 2E	Observer Agree? Yes No ^C Observer 1 Observer Agree? Yes No ^F Observer 2
^{IX15.} Did the trainee accurately diagnose sig	de effects? Yes No NA ^{IX16.} If no, summarize reason.
Omission (Specify if not obvious on che Misinterpretation (Must specify)	ecklist)
Unnecessary (Must specify)	
^{7.} If on ART, does the patient have signs of	treatment failure? Yes No NA If yes, what were they?
^{A.} Trainee 1 ^B	Observer Agree? Yes No ^{c.} Observer 1 Observer Agree? Yes No ^{F.} Observer 2
^{D.} Trainee 2 ^E	Observer Agree? Yes No ^F Observer 2
^{IX17.} Did the trainee accurately assess for tr	reatment failure? Yes No NA ^{IX18.} If no, summarize reason.
Omission (Specify if not obvious on che Misinterpretation (Must specify)	ecklist)
Unnecessary (Must specify)	

Site/trainee/Observation#____/____/_____/

VII. W	VII. What laboratory investigations would you order today? ^{1.} None					
Code		Results	Code		Results	
	^{2.} Ab (HIV antibody)			^{3.} Ag/PCR (child<		
				18mo)		
	^{4.} CBC (hemogram)			^{5.} HB (haemoglobin)		
	^{6.} CD 4			^{7.} Creatinine		
	^{8.} Glucose			^{9.} Hep B		
	^{10.} LFT			^{11.} Malaria BS		
	Transaminases					
	^{12.} Malaria RDT			^{13.} Pregnancy		
	^{14.} RPR			^{15.} TB Sputum		
	^{16.} Viral Load					
	^{17.} Other1- Specify			^{18.} Other2- Specify		
^{19.} Did e	quipment or resource ga	ps affect trainee's invest	igations	for this patient? Yes	No	
	, please explain					

^{21.} Wou	^{21.} Would you order other investigations or procedures today? Yes No If yes, specify below.					
Code		Results	Code		Results	
	^{22.} Chest x-ray			^{23.} Ultrasound scan Specify		
	^{24.} Other x-ray - Specify			^{25.} Other3-Specify		

^{IX19.} Did the trainee recommend appropriate investigations? Yes No NA ^{IX20.} If no, summarize reason.
 Omission (Specify if not obvious on checklist) Misinterpretation (Must specify) Unnecessary (Must specify)

Please use this space to document additional relevant information about this case.

VIII. What treatment would you recommend?		
¹ .Prevention?	^{2.} Observer agree w/ CTXI? Yes No, Specify	
CTX: Start Stop Continue	³ CTX: Start Stop Continue	
^{4.} Tx for OI?: Yes No If yes, specify	^{5.} Observer agree w/Tx for OI Yes No Specify	
^{6.} Treatment 1?	^{7.} Treatment 1?	
⁸ Route: oral parenteral Specify	^{9.} Route: oral parenteral Specify	
^{10.} Treatment 2	^{11.} Treatment 2	
^{12.} Route:oralparenteralSpecify	^{13.} Route: oral parenteral Specify	
^{14.} Tx for other dx? Yes No If yes, specify	^{15.} Observer agree w/Tx for other dx?OI Yes NoSpecify	
^{16.} Treatment 1?	^{17.} Treatment 1?	
^{18.} Route: oral parenteral Specify	^{19.} Route: oral parenteral Specify	
^{20.} Treatment2	^{21.} Treatment 2	
^{22.} Route: oral parenteral Specify	^{23.} Route: oral parenteral Specify	
	^{25.} Observer agree w/ART: Yes No, Specify	
^{24.} ART: Continue Start Stop Modify	^{27.} Continue Start Stop Modify	
^{26.} If change, new regimen: 3TC AZT d4T	²⁹ If change, new regimen: 3TC AZT d4T	
□TDF □FTC □NVP □EFV □Other	TDF FTC NVP EFV Other	
^{28.} Reason:		
	^{30.} Reason:	
^{31.} Tx for side effects? Yes No If yes, specify	^{32.} Observer agree w/Tx for side effects? Yes No, Specify	
^{33.} Treatment 1?	^{34.} Treatment 1?	
^{35.} Route: oral parenteral Specify	^{36.} Route: oral parenteral Specify	
^{37.} Treatment 2	^{38.} Treatment 2	
^{39.} Route: Oral parenteral Specify	^{40.} Route: Oral Darenteral Specify	
^{41.} Internal referral or consult?: Yes No	^{42.} Observer agree w/ internal referral or consult:	
^{43.} Who?	Yes No, Specify. ^{44.} Who?	
^{45.} Reason?	⁴⁶ ·Reason?	
^{47.} External referral or consult?: Yes No	^{48.} Observer agree w/ external referral or consult:	
^{49.} Where?	Yes No, Specify. ^{50.} Who?	
^{51.} Reason?	^{52.} Reason?	
^{53.} Admitted this site: Yes No	^{54.} Observer agree w/admission?: Yes No	
^{55.} Date of next visit://	^{56.} Observer agree w/Date of next visit?: Yes No	
Prevention provided?		
	Io 🔲 NA	
	lo	
^{59.} If female, recommend family planning Yes		
^{60.} Did equipment or resource gaps affect trainee's treatment plan for this patient? Yes No		
⁶¹ If yes, please explain		
^{IX21.} Did the trainee recommend appropriate drug treatment? Yes No NA ^{IX22.} If no, summarize reason.		
Omission (Specify if not obvious on checklist)		
Misinterpretation (Must specify)		
Unnecessary (Must specify)		

Brief Tool Marking & Scoring Protocol

During Observation:

- 1. Mark all questions asked by the trainee and patient findings in blue or black ink.
- 2. Mark all questions asked by the clinical faculty and patient findings in red ink.

Scoring Observation:

- 1. If the trainee asks the appropriate questions or performs task correctly, as determined by the clinical faculty, the score of the item is 1.
- 2. If the trainee did not ask the appropriate questions or performs task incorrectly including errors of omission and commission, as determined by clinical faculty, the score of the item is 0.

Outcome (Total Score Possible)	Scored Items (Item number on HIV/ART Clinical Observation – Patient
	Form)
History Taking (7-11)	Required for all patients
	1. Current weight (I.4)
	2. Current ART Status (II.4)
	3. Cotrimoxazole history (II.14)
	4. Fever (III.1)
	5. Cough (III.3)
	6. Functional status (III.15 and III.16)
	7. Asked for any other symptoms (III.17)
	Only appropriate if indicated by patient status or symptoms
	8. (if female 13-49) Pregnancy status (II.18)
	9. (if fever) fever duration (III.2)
	10. (if cough) cough duration (III.4)
	11. (if on ART) ART status (III.13)
Physical Examination (5-6)	Required for all patients
	1. General (IV.1)
	2. Skin (IV.2)
	3. Mouth (IV.3)
	4. Lungs (IV.4)
	5. Abdomen (IV.6)
	Only appropriate if indicated by patient history or initial findings of physical
	examination
	6. Any other examination based on signs/symptoms (IV.10)
Laboratory Test (1)	Summary score that all appropriate laboratory and other investigations
,	were ordered correctly based on differential diagnosis. (VII1-VII18, VII22-
	VII25)
Diagnoses (2)	Required for all patients
0 ()	1. Summary score for Clinical staging conditions (IV.1 B/E/H) Other
	diagnoses (IV.2 B/E/H), and Treatment side effects (IV.6 B/E/H)
	Required only for patients not on ART
	2. ART eligibility (IV.4 B/E)
	Required only for patients on ART
	2. Treatment failure (IV.7B/E)
Treatment (2-3)	Required for all patients
	1. Prescribes cotrimoxazole correctly (VIII.1 and VIII2)
	2. All other treatments are correct (VIII4 and VIII5, VIII14 and VIII15,
	VIII31 and VIII32)
	Required only for patients on ART
	3. Prescribes ART correctly (VIII.24 and VIII.25)
Patient/caregiver	
Patient/caregiver Education (2)	Required for all patients 1. Positive prevention (VIII.57)
	2. Recommend Mosquito Net (VIII.58)