

Appendix

(See CONSORT checklist starting p. 8 of this appendix).

Supplementary Material

1. Trial registration

This cluster randomized control trial, PACTR201811609257043, is registered at:

- i. WHO
Website: <http://apps.who.int/trialsearch/Trial2.aspx?TrialID=PACTR201811609257043>
- ii. Pan African Clinical Trials Registry
Website: <https://pactr.samrc.ac.za/TrialDisplay.aspx?TrialID=4685Protocol>

2. Protocol

The study protocol was initially approved by the Western Institutional Review Board (WIRB), IRB Tracking Number: 20141630, effective December 18, 2014; and Swaziland National Health Research Review Board (NHRRB), Board registration number: FWA00026661/IRB00011253, effective August 15, 2015. The protocol amendment approval has been granted by both reviews boards a number of times over the implementation period, with the latest approval by NHRRB effective 12 August 2019, and WIRB effective 26 September 2019.

3. Supplementary appendix

Risk ratios and Incidence Rate Ratios

To facilitate comparisons across studies, we are including in Table S1 a comparison of the main intervention results expressed as unadjusted and adjusted odds ratios (ORs), risk ratios (RRs) and incidence rate ratios (IRRs). The results are similar across all 3 specifications and lead to the same conclusions.

Table S1: HIV incidence and bivariate and multivariable association with baseline characteristics. Odds Ratios, Risk Ratios and Incidence Rate Ratios.

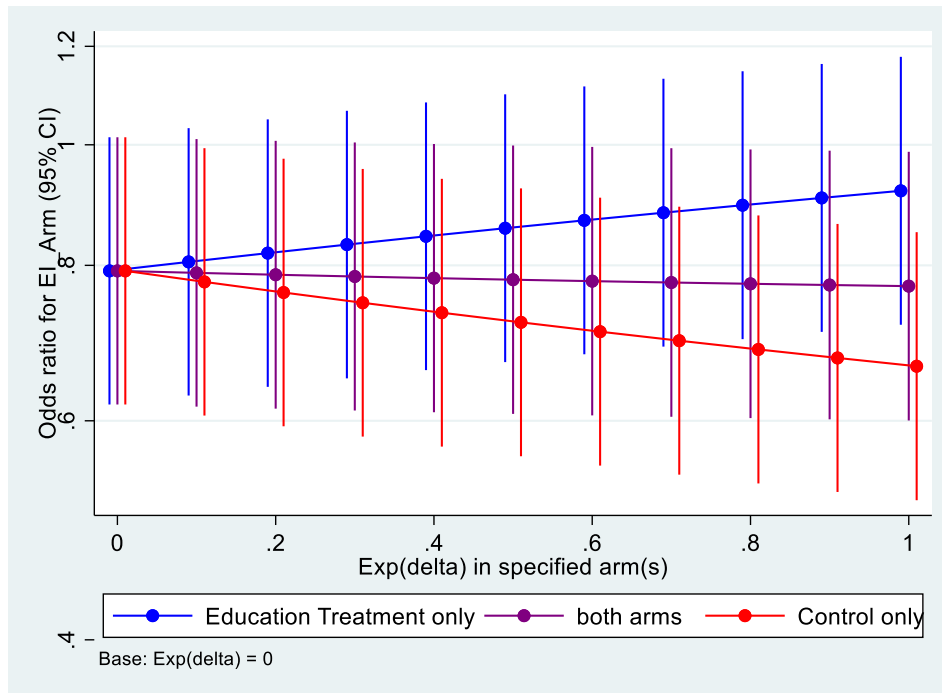
	(1)	(2)	(3)	(4)
Variables	OR [95% CI]	P-Value	aOR*[95% CI]	P-Value
Education Incentive Arm				
Education Incentive Control	1		1	
Education Incentive	0.766 [0.598, 0.981]	0.035	0.754 [0.585, 0.972]	0.029
Raffle incentive				
Raffle treatment arm	0.827 [0.645, 1.060]	0.133	0.826 [0.645, 1.060]	0.133
Raffle control	1		1	
Randomization sub-arm				
Control	1		1	
Raffle	0.822 [0.585, 1.154]	0.257	0.839 [0.598, 1.177]	0.310
Education	0.761 [0.542, 1.069]	0.115	0.766 [0.537, 1.093]	0.142
Education + Raffle	0.634 [0.443, 0.907]	0.013	0.622 [0.433, 0.893]	0.010
Variables	Risk Ratio [95% CI]	P-Value	aRisk Ratio *[95% CI]	P-Value
Education Incentive Arm				
Education Incentive Control	1		1	
Education Incentive	0.781 [0.620, 0.983]	0.035	0.773 [0.613, 0.975]	0.030
Raffle incentive				
Raffle treatment arm	0.839 [0.666, 1.055]	0.133	0.851 [0.678, 1.068]	0.164
Raffle control	1		1	
Randomization sub-arm				
Control	1		1	
Raffle	0.835 [0.611, 1.141]	0.257	0.867 [0.639, 1.178]	0.363
Education	0.777 [0.568, 1.064]	0.115	0.789 [0.572, 1.089]	0.149
Education + Raffle	0.655 [0.470, 0.914]	0.013	0.655 [0.470, 0.913]	0.013
Variables	IRR [95% CI]	P-Value	aIRR*[95% CI]	P-Value
Education Incentive Arm				
Education Incentive Control	1		1	
Education Incentive	0.781 [0.620, 0.983]	0.035	0.774 [0.615, 0.975]	0.030
Raffle incentive				
Raffle treatment arm	0.839 [0.666, 1.055]	0.133	0.841 [0.671, 1.055]	0.135
Raffle control	1		1	
Randomization sub-arm				
Control	1		1	
Raffle	0.835 [0.611, 1.141]	0.257	0.854 [0.630, 1.158]	0.311
Education	0.777 [0.568, 1.064]	0.115	0.787 [0.571, 1.084]	0.143
Education + Raffle	0.655 [0.470, 0.914]	0.013	0.649 [0.466, 0.904]	0.010

Notes: CI: Confidence Interval. OR (Odds Ratio), RR (Risk Ratio), IRR (Incidence Rate Ratio) and aOR (adjusted Odds Ratio), aRR (adjusted risk ratio), aIRR (adjusted Incidence Rate Ratio)– Adjusted for being in the raffle arm; aOR, aRR and aIRR– Adjusted odds ratios for the randomization arms, raffle randomization arms and randomization sub-arm are from separate logistic regression models with the same covariates. Standard errors adjusted for clustering.

Sensitivity Analysis Results

Figure S1, and Table S2 show results from the sensitivity analysis undertaken to assess the MAR assumption in the ITT complete case analysis. Figure S1 shows analysis graph with sensitivity parameter delta varying from 0 to 1. Table S2 presents un-adjusted and adjusted ITT results from pattern-mixture multiple imputation model. Adjusted odds ratios for were adjusted for schooling status at baseline; rural/urban locality; region of residence; highest schooling level attained; participant age; assets based social economic status; and risk behaviour preference. Both un-adjusted and adjusted odds ratio show nearly identical results with no change in interpretation of the MAR analytical results.

Figure S1: The sensitivity analysis graph



Note: CI: Confidence Interval, EI: education incentive

Table S2: Un-adjusted and adjusted OR from pattern-mixture multiple imputation model

Variable	OR	[95%CI]	aOR	[95%CI]
Education Incentive Arm				
Education Incentive Control	1		1	
Education Incentive Treatment	0.792	[0.619,1.014]	0.767	[0.595,0.989]

Notes: CI: Confidence Interval; OR: Odds Ratios, aOR: adjusted Odds ratios, n= number of observations. Analysis sample, n=4,389, aOR– Adjusted for schooling status at baseline; rural/urban locality; region of residence; highest schooling level attained; participant age; assets based social economic status; and risk behavior preference, coefficient estimates not shown.

Incentive payments

There were four annual rounds of payments for those in the education incentive treatment arm who were enrolled in formal education. These were enrolment payment at the beginning of the year, and three payment rounds based on school attendance upon a verified 80% of higher school attendance.

Table S3 shows that the number verified for enrolment and attendance incentive decreased over time from about 80% at baseline (Enrolment: January 2016) to about 45% (Term 2: September 2018) among those who were in school at baseline (ISAB). The decrease was as expected due to AGW graduating from formal education or dropping out of education due to pregnancy. Enrolment and attendance among those who were out of school at baseline was 7%-8% throughout the impact evaluation period.

The incentive payment to participants who were verified to be enrolled or achieved 80% or higher school attendance in 2016 was lower (under 80%) among those who were out of school at baseline compared to those in school at baseline (above 90%), see Table S2. Proportion of participants paid among those out of school at baseline significantly increased in 2017 and 2018 to over 90% following implementation improvements following 2016 observations of low proportion of payments for those who qualified to be paid. Implementation changes which led to this improvement are detailed in the Implementation Report.

Table S3: Education Incentive payments

Period		Eligible Participants this Round				Verified in School in Eswatini				Verified registered in STU				Basic education payments			STU Registration Payments		
Year	Term	Round	Control		Education Incentive		Control		Education Incentive		Control		Education Incentive		Did not receive incentive for round	Received incentive for round	% paid	Did not receive incentive for registration	Received incentive for registration
			ISAB	OSA B	ISAB	OSA B	ISA B	OSA B	ISA B	OSA B	ISA B	OSA B	ISA B	OSA B					
2016	Term 1 Enrolment	2	1146	1084	1068	1001	869	74	858	94	28	28	52	62	7	945	99%	7	107
	Term 1 Attendance	3	1146	1084	1068	1001	866	72	844	86					39	891	96%		
	Term 2 Attendance	4	1146	1084	1068	1001	846	71	824	78					96	806	89%		
	Term 3 Attendance	5A	1146	1084	1068	1001	824	67	805	76					96	785	89%		
2017	Term 1 Enrolment	5B	1146	1084	1068	1001	684	93	671	77	34	54	57	65	43	705	94%	31	91
	Term 1 Attendance	6	1144	1083	1067	1001	678	92	660	76					79	657	89%		
	Term 2 Attendance	7	1132	1073	1058	1071	658	88	651	72					87	636	88%		
	Term 3 Attendance	8	1027	946	983	942	637	82	623	70					71	622	90%		
2018	Term 1 Enrolment	9	1027	946	983	942	492	80	473	86	28	35	85	148	0	559	100%	8	225
	Term 1 Attendance	10	1027	946	983	942	486	79	470	81					13	538	98%		
	Term 2 Attendance	11	1027	946	983	942	474	77	460	80					7	533	99%		

Table S4 shows participation in the raffle incentive by raffle randomization sub-arms, raffle round and by schooling status at baseline. Raffle payments for participants who were randomly sampled and tested negative for *Trichomonas vaginalis* and syphilis was between 94% and 100%. There was no significant variation by schooling status at baseline. The less than 100% payment to the raffle “winners” was mainly due to non-contact of raffle “winners” post STI testing. Note: STU: Short Course, Tertiary/Technical/Vocational Training and Upgrading classes; ISAB: in-school at baseline; OSAB: Out-of-school at baseline, STI: sexually transmitted infection.

Table S4: Raffle payments

Raffle	Sub-Arm	School status at Baseline	Number eligible for round	Number selected for round (%)	Number screened for GBV (%)	Number tested for STI's (%)	Number of winners (%)	Number paid (%)
1 st Raffle [May-Jun 16]	Raffle	ISAB	611	101 (16.5)	93 (92)	94 (93)	18 (19.1)	18 (100)
		OSAB	551	99 (17.9)	92 (92.9)	92 (92.9)	22 (23.9)	22 (100)
	EI & Raffle	ISAB	523	91 (17.3)	89 (97.8)	87 (95.6)	13 (14.9)	13 (100)
		OSAB	548	109 (19.8)	102 (93.5)	101 (92.6)	27 (26.7)	26 (96.2)
	SUB-TOTAL			400 (17.9)	376 (94)	374 (93.5)	80 (21.3)	79 (98.7)
2 nd Raffle [Jul-Aug 16]	Raffle	ISAB	611	107 (17.5)	100 (93.4)	100 (93.4)	23 (23)	22 (95.6)
		OSAB	551	93 (16.8)	84 (90.3)	84 (90.3)	17 (20.2)	16 (94.1)
	EI & Raffle	ISAB	523	97 (18.5)	90 (92.7)	90 (92.7)	19 (21.1)	19 (100)
		OSAB	548	103 (18.7)	93 (90.2)	93 (90.2)	21 (22.5)	21 (100)
	SUB-TOTAL			400 (17.9)	367 (91.7)	367 (91.7)	80 (21.7)	78 (97.5)
3 rd Raffle [Oct-Nov 16]	Raffle	ISAB	611	108 (17.6)	94 (87)	94 (87)	24 (25.5)	23 (95.8)
		OSAB	551	92 (16.6)	78 (84.7)	78 (84.7)	16 (20.5)	16 (100)
	EI & Raffle	ISAB	523	103 (19.6)	93 (90.2)	93 (90.2)	22 (23.6)	22 (100)
		OSAB	548	97 (17.7)	75 (77.3)	76 (78.3)	18 (23.6)	18 (100)
	SUB-TOTAL			400 (17.9)	340 (85)	341 (85.2)	80 (23.4)	79 (98.7)
4 th Raffle [Nov 16-Apr 17]	Raffle	ISAB	611	115 (18.8)	105 (91.3)	105 (91.3)	21 (20)	21 (100)
		OSAB	551	85 (15.4)	75 (88.2)	75 (88.2)	20 (26.6)	18 (90)
	EI & Raffle	ISAB	523	103 (19.6)	99 (96.1)	99 (96.1)	20 (20.2)	20 (100)
		OSAB	548	97 (17.7)	86 (88.6)	86 (88.6)	20 (23.2)	18 (90)
	SUB-TOTAL			400 (17.9)	365 (91.2)	365 (91.2)	81 (22.1)	77 (95)
5 th Raffle [Jul-Aug 17]	Raffle	ISAB	607	104 (17.1)	95 (91.3)	95 (91.3)	22 (23.1)	22 (100)
		OSAB	546	96 (17.5)	88 (91.6)	88 (91.6)	18 (20.4)	18 (100)
	EI & Raffle	ISAB	523	106 (20.2)	101 (95.2)	101 (95.2)	24 (23.7)	23 (95.8)
		OSAB	540	94 (17.4)	90 (95.7)	90 (95.7)	16 (17.7)	16 (100)
	SUB-TOTAL			400 (18)	374 (93.5)	374 (93.5)	80 (21.3)	79 (98.7)
6 th Raffle [Feb-Mar 18]	Raffle	ISAB	548	108 (19.7)	104 (96.2)	104 (96.2)	25 (24)	24 (96)
		OSAB	485	92 (18.9)	90 (97.8)	90 (97.8)	15 (16.6)	15 (100)
	EI & Raffle	ISAB	481	106 (22)	103 (97.1)	103 (97.1)	24 (23.3)	24 (100)
		OSAB	468	94 (20)	92 (97.8)	92 (97.8)	16 (17.3)	16 (100)
	SUB-TOTAL			400 (20.1)	389 (97.2)	389 (97.2)	80 (20.5)	79 (98.7)
7 th Raffle [Jul-Aug 18]	Raffle	ISAB	548	103 (18.7)	100 (97)	100 (97)	18 (18)	18 (100)
		OSAB	484	97 (20)	93 (95.8)	93 (95.8)	22 (23.6)	21 (95.4)
	EI & Raffle	ISAB	481	97 (20.1)	93 (95.8)	93 (95.8)	18 (19.3)	18 (100)
		OSAB	468	103 (22)	97 (94.1)	97 (94.1)	22 (22.6)	21 (95.4)
	SUB-TOTAL			400 (20.1)	383 (95.7)	383 (95.7)	80 (20.8)	78 (97.5)

Note: Note: GBV: Gender-based violence ; ISAB: in-school at baseline; OSAB: Out-of-school at baseline, STI: sexually transmitted infection.

Table 1: CONSORT 2010 checklist of information to include when reporting a cluster randomised trial

Section/Topic	Item No	Standard Checklist item	Extension for cluster designs	Page No *
Title and abstract				
	1a	Identification as a randomised trial in the title	Identification as a cluster randomised trial in the title	p.1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts) ^{i,ii}	See table 2	p.4 see detail in CONSORT for abstract)
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Rationale for using a cluster design	p.6
	2b	Specific objectives or hypotheses	Whether objectives pertain to the cluster level, the individual participant level or both	p.6/7
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Definition of cluster and description of how the design features apply to the clusters	p.6/7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons		p.8 and p.10
Participants	4a	Eligibility criteria for participants	Eligibility criteria for clusters	p.7 Table 1
	4b	Settings and locations where the data were collected		p. 6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Whether interventions pertain to the cluster level, the individual participant level or both	p.7-8 Tables 1, 2
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Whether outcome measures pertain to the cluster level, the individual participant level or both	p.8 p.10
	6b	Any changes to trial outcomes after the trial commenced, with reasons		N/A
Sample size	7a	How sample size was determined	Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or <i>k</i>), and an indication of its uncertainty	p.8-9

	7b	When applicable, explanation of any interim analyses and stopping guidelines		N/A
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence		p.9 (clusters) p.10 (individuals)
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Details of stratification or matching if used	p.9-10
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both	p.10
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Replace by 10a, 10b and 10c	p.9-10
	10a		Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions	p.9-10
	10b		Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling)	p.9 Table 1, Figure 1
	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	p.10-11
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		p.10
	11b	If relevant, description of the similarity of interventions		N/A
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	How clustering was taken into account	p.10-11
	12b	Methods for additional analyses, such as subgroup		p.10-11

		analyses and adjusted analyses		
Results				
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome	p.12 Figures 1 & 2
	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	p.12 Figures 1 & 2
Recruitment	14a	Dates defining the periods of recruitment and follow-up		p.10
	14b	Why the trial ended or was stopped		N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Baseline characteristics for the individual and cluster levels as applicable for each group	p.12-13 Table 3
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each group, number of clusters included in each analysis	p.13
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome	p.13 Table 4
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended		p.13
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory		p.13
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms ⁱⁱⁱ)		(p.12, unintended effect (i.e. non-contact) but no harm, see intervention exposure)
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses		p.15

Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Generalisability to clusters and/or individual participants (as relevant)	p.14-15
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence		p.15-16
Other information				
Registration	23	Registration number and name of trial registry		p.4
Protocol	24	Where the full trial protocol can be accessed, if available		p.7 (reference 18)
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders		p.3

* Note: page numbers optional depending on journal requirements

REFERENCES

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- i Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG, et al. CONSORT for reporting randomised trials in journal and conference abstracts. *Lancet* 2008, 371:281-283
 - ii Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG at al (2008) CONSORT for reporting randomized controlled trials in journal and conference abstracts: explanation and elaboration. *PLoS Med* 5(1): e20
 - iii Ioannidis JP, Evans SJ, Gotzsche PC, O'Neill RT, Altman DG, Schulz K, Moher D. Better reporting of harms in randomized trials: an extension of the CONSORT statement. *Ann Intern Med* 2004; 141(10):781-788.