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The Regai Dzive Shiri Project: results of a randomised trial of an HIV prevention intervention for Zimbabwean youth

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Abstract

Background—HIV prevention among young people in southern Africa is a public health priority. There is little rigorous evidence of the effectiveness of different intervention approaches. We describe findings of a cluster randomised trial of a community-based, multi-component HIV

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Dr Frances M Cowan, Project Director and Principal Investigator - based in Zimbabwe, designed the study and oversaw all aspects of the project implementation and evaluation.

Ms Sophie Pascoe, project statistician oversaw data management and collection, drafted the statistical analysis plan and undertook the statistical analysis for the paper.

Dr Lisa F Langhaug, evaluation manager ran the baseline, interim and final surveys, and oversaw the day to day running of all research activities

Webster Mavhu was the senior social scientist on the project. He ran the process evaluation and qualitative data collection.

Mr Samson Chidiya was intervention director who helped design and oversaw implementation of the intervention being evaluated in this trial

Dr Shabbar Jaffar, London-based statistician and epidemiologist assisted with study design, drafting of the analysis plan and supervised the statistical analysis

Professor Michael Mbizvo is a co-investigator who helped with study design and implementation.

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Dr Godfrey Woelk is the Zimbabwean principal investigator who helped with implementation of both intervention and evaluation surveys

Professor Richard J Hayes, is a co-investigator who had a key role in study design, finalizing the analysis plan and oversaw the statistical analysis.

In addition to the authors previously listed the Regai Dzive Shiri Trial team included Jeffrey Dirawo, Data manager in the Department of Community Medicine University of Zimbabwe Mr Martin Worster, Director SPW Zimbabwe, Professor Anne M Johnson (co-investigator) Professor Judith M Stephenson. (co-investigator) of the Research Department of Infection and Population Health at University College London

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and reproductive health intervention aimed at changing social norms for adolescents in rural Zimbabwe.

Methods—Thirty rural communities were randomised to early or deferred implementation of the intervention in 2003. Impact was assessed in a representative survey of 18–22 year olds after 4 years. Participants self-completed a questionnaire and gave a dried blood spot sample for HIV and HSV-2 antibody testing. Young women had a urinary pregnancy test. Analyses were by intention-to-treat and were adjusted for clustering.

Findings—4,684 18–22 year olds participated in the survey (97.1% of eligibles, 55.5% female). Just over 40% had been exposed to ≥ 10 intervention sessions. There were modest improvements in knowledge and attitudes among young men and women in intervention communities, but no impact on self-reported sexual behaviour. There was no impact of the intervention on prevalence of HIV or HSV-2 or current pregnancy. Women in intervention communities were less likely to report ever having been pregnancy.

Interpretation—Despite an impact on knowledge, some attitudes and on reported pregnancy, there was no impact of this intervention on HIV or HSV-2 prevalence, further evidence that behavioural interventions alone are unlikely to be sufficient to reverse the HIV epidemic. The challenge remains to find effective HIV prevention approaches for young people in the face of continued and unacceptably high HIV incidence, particularly among young women.

Keywords

Randomised trial; adolescents; prevention; HIV infection; sexually transmitted infections; pregnancy; Zimbabwe

Background

Recent surveillance suggests that 2.5 million people become infected with HIV annually. Forty percent are aged 15–24 years.[1,2] Of the six million HIV positive young people in Sub-Saharan Africa, 76% are female.[3] The United Nations General Assembly Special Session on HIV/AIDS declared[4] that by 2005 90% of youth aged 15–24 should have the information, education, and life-skills needed to reduce their chances of HIV infection (no country achieved this)[5] and that there should be a 25% reduction in new HIV infections in the worst affected countries (six countries achieved this). Encouragingly the proportion of young people who first have sex aged <15 years appears to be declining.[5]

In 2004 the Joint United Nations Programme on HIV/AIDS (UNAIDS) commissioned systematic reviews on the effectiveness of HIV prevention interventions for young people.[6] They found good evidence that school-based interventions can reduce reported sexual risk taking.[7] There was also evidence that providing training to make health clinics more ‘youth friendly’ increases clinic usage.[8] However, there remains sparse data to support the implementation of community-based approaches, which aim to change societal norms to support individual behaviour change.[9] Overall few trials of adolescent HIV prevention interventions with objective biomedical endpoints were identified and one of the key recommendations of the review was that more rigorous research should be funded and conducted.

We report the results of a cluster randomised trial to determine the effectiveness of a community-based multi-component HIV prevention intervention for young people, conducted in rural Zimbabwe between 2003 and 2007. The trial had two primary endpoints: prevalence of HIV and of HSV-2 was compared between clusters in early and deferred

intervention arms. Secondary endpoints included pregnancy prevalence, and reported knowledge, behaviour and attitudes.

Methods

Study population

The trial was conducted in 30 communities in seven districts in South-Eastern Zimbabwe (map shown figure 1 suppl data). Communities were randomised to early intervention implementation (2003) or delayed implementation (2007) using restricted randomisation.[10] A community comprised a rural clinic, its catchment population and its secondary schools.

The Regai Dzive Shiri intervention

The intervention has been described in detail elsewhere.[11] It was delivered to young people, parents and clinic staff and was theoretically based in social learning theory[12] and the stages of change model[13]. It aimed to achieve change in societal norms within communities. The intervention had three integrated components:

- *The **youth programme*** for in- and out-of-school youth, was delivered by carefully selected, trained and supervised Zimbabwean school leavers in the year between leaving school and starting university. These professional peer educators (PPEs) lived and worked in the intervention communities for 8–10 months of the year. They used theoretically-based materials delivered using participatory methods which aimed to enhance knowledge and develop skills. During the trial, secondary school attendance in Zimbabwe dropped as a result of the political and economic challenges facing the country and so intervention activities shifted from schools to communities. Both in and out-of-school youth attended activities throughout. The peer educator model was developed by Students Partnership Worldwide (www.SPW.org).
- The ***programme for parents and community stakeholders***, a 22 session community-based programme, which aimed to improve knowledge about reproductive health, to improve communication between parents and their children and to improve community support for adolescent reproductive health.
- A ***training programme for nurses and other staff working in rural clinics,*** which aimed to improve accessibility of clinics for young people.

Standard HIV prevention activities were implemented through the District AIDS Action Committees across all communities. No other HIV prevention activities aimed specifically at youth were conducted in either arm of the trial during the period of implementation.

Impact evaluation

The original intention was to determine the impact of the intervention within a cohort of Form 2 pupils (9^{th} school year) attending trial secondary schools (n=82). All Form 2 pupils were invited to join the cohort and to participate in the baseline survey (in 2003); 6791 pupils, median age 15 years, participated (87% of eligibles); crude HIV prevalence was 0.8% (95%CI:0.6–1.0) and HSV-2 prevalence was 0.2% (95%CI:0.1–0.3)[11]. It was intended to follow this cohort for four years till 2007. However during our interim survey in 2006, we found that there had been considerable out-migration (46%)[14]. Those who remained were of lower risk than those who had left (HIV prevalence among remaining cohort was 1.2% (95%CI:0.7–1.9%)).

We also conducted a representative population-based survey of 3,960 18–21 year olds (91% of eligibles) in 2006 to see if the well publicised decline in HIV incidence in Zimbabwe[15] was likely to reduce the power of the trial. Community HIV prevalence in females was 8.3% (95%CI:7.0–9.8%) and in males was 3.3% (95%CI:2.6–4.1). Revised sample size calculations suggested that the trial would have considerably reduced power if we followed the original cohort, but that a cross-sectional population-based survey of 18–22 year olds would provide >95% power to detect a 40% reduction in HIV prevalence and 80% power to detect a 30% reduction. As the intervention had become increasingly community-based, assessing intervention impact using a population-based survey rather than among the original school-going cohort seemed logical. As a result it was decided at a meeting of investigators and the data and safety monitoring board chair to change the design accordingly.

For the final survey, we selected six enumeration areas (EAs) (Census Bureau geographical areas ≈100 households) in each trial community. The EAs were purposively selected to ensure that sites where intervention activities took place in that community were included (clinics, schools, community centres). Each trial community comprised approximately 50 EAs suggesting that around 12% (i.e. those from 6/50 EAs) of 18–22 year olds living in trial communities as originally defined were eligible for inclusion in the final survey. Of note while the age of the cohort spanned 11 years, the age of participants surveyed at the end of the trial spanned 5 years. Without outmigration from communities, the proportion of original cohort members being included in the final survey was unlikely to be more than 7%. All 18–22 year olds who lived in the 180 EAs selected were eligible for inclusion.

Survey procedures—Participants provided written consent, and completed a questionnaire in two stages; (i) using audio-self administered questionnaire (audio-SAQ), (ii) using audio-computer-assisted-survey-instrument (ACASI)).[14] ACASI was used for collection of particularly sensitive data and for all questions that required use of complex skip patterns.[14] Data collected using audio-SAQ were double-entered onto a Microsoft Access password-protected database. All participants were asked to provide a finger-prick blood sample. Women gave a urine sample for pregnancy testing.

Laboratory procedures—Blood samples were collected onto filter paper and tested for HIV-1 antibody in Harare using a validated testing algorithm[11]. All specimens were tested using two ELISA tests (Vironostika® HIV Microelisa System BioMerieux, Inc., NC and AniLabsytems EIA kit (AniLabsystems Ltd, Finland), with additional western blot for discrepant results. Dried blood spot samples were tested for antibodies to HSV-2 using a type-specific HSV-2 assay (Focus HerpeSelect EIA, Focus Technologies, CA) with the index for diagnosing positive samples raised to >3.4 to improve specificity.[16] Urine samples were tested on site for pregnancy using Cortez OneStep hCG Rapidip InstaTest®.

Statistical analyses—Statistical analyses were conducted using Stata 10 (Stata Corp., TX), and were stratified by sex. The primary analysis was intention-to-treat. Continuous variables were categorized using recognized cut-off values or dichotomized at the median value. Attitudinal and knowledge outcomes were based on questions in 11 domains (suppl data Table 1). Binary variables were created, for those participants who answered all questions ‘correctly’ in each domain.

Univariate and multivariate analyses were performed using generalized estimating equations (GEE) with exchangeable correlation matrix and robust standard errors to account for cluster randomisation. Impact of the intervention programme on primary and secondary endpoints was assessed by performing an unadjusted GEE analysis comparing the outcomes between study arms. Crude odds ratios were adjusted *a priori* for age, marital status, education and

the strata used for randomisation[10], and further adjusted for any other potential confounding variables showing an imbalance between study arms. Cox regression, with robust standard errors to allow for clustered design, was used to explore the association between intervention status and age of sexual debut.

A sub-group analysis was undertaken to assess whether impact varied with intensity of intervention exposure, which compared the impact of the intervention among those participants who had attended Regai Dzive Shiri trial schools *and* had lived in trial communities over the period of intervention delivery.

Analyses were pre-planned and the analytical plan submitted to the data and safety monitoring board before analysis was undertaken.

Ethical approval—The trial was approved by the Medical Research Council of Zimbabwe and the ethics committees of University College London Hospitals and the London School of Hygiene & Tropical Medicine.

Results

Overall 4,684 of 4,822 (97.1%) eligible individuals identified, participated in the final survey (Figure 1); 2593 (56%) were female.

The two trial arms were well balanced (Table 1). Women were more likely than men to report having been married (45.6% vs. 7.6%), and to having married younger. Men had lived in communities longer than women and were better educated. Women were more likely to have left school due to pregnancy or marriage. Orphaning and poverty were widespread.

Intervention exposure

Around 54% of participants (61% of males and 46% of females) had attended a trial school. Few participants in intervention communities went to comparison schools or vice versa (<3%) (Table 1).

Overall 30% (n=695) of survey participants in the intervention arm (48% of males and 15% of females) reported attending an intervention school when a PPE was present and so are likely to have received the in-school intervention (supplementary data Figure 2). Overall 20% (n=478) of the intervention arm reported attending ≥ 10 out-of-school youth sessions; 9% (n=212) had attended both the in- and out-of-school intervention, 41% (n=961) had attended either the in-school and/or out-of-school youth programme. One third of males and 61% of females surveyed did not report receiving any intervention (ie had not attended a trial school or the out-of school intervention).

Impact of the intervention on knowledge and condom self-efficacy

In males there was an increase in knowledge related to sexually transmitted disease (STD) acquisition (AOR=1.32;95%CI:1.08–1.61) and pregnancy prevention (AOR=1.59;95%CI: 1.27–1.99) in the intervention arm but not for HIV acquisition (Table 2a). There was no effect on reported self-efficacy. In women there was an increase in knowledge related to STD acquisition (AOR=1.45;95%CI:1.17–1.79) and pregnancy prevention (AOR=1.32;95%CI:1.14–1.55) in the intervention arm but again not for HIV acquisition (Table 2b). There was a modest impact on reported self-efficacy.

Impact of the intervention on reported attitudes and behaviours

Among men there was no impact on attitudes relating to relationship control overall, although there was an impact on certain items within the scale. There was also no overall impact of the intervention on gender empowerment among men, but again there was on certain items. The intervention did have an impact on women's attitudes to both relationship control (AOR=1.34;95%CI:1.11–1.63) and to gender empowerment (AOR=1.32 95%CI: 1.05–1.66).

Sexual behaviour—Females were more likely to report having had sex than males (53% vs. 42%). Median age of partner at first sex was 24 for females and 17 for males. Sexually active males reported more lifetime partners (median=2 vs. 1) and more partners in the last 12 months (median 2 vs. 1) than females. Males were more likely to report condom use at last sex (81% vs. 59%). There was no effect of the intervention on any of these behavioural outcomes in men or women (Table 2). Age at sexual debut was the same across trial arms (adjusted Hazard ratio for males 1.02[95%CI:0.90–1.15] and females 0.94[95%CI:0.86–1.04]. There was also no effect on reported use of pregnancy prevention.

Impact of the intervention on clinic attendance

There was no effect of the intervention on any aspect of clinic attendance (Table 2a and 2b). Women in the intervention arm were more likely to report that they would go to a clinic if they needed to access contraception (AOR=1.33;95%CI:1.05–1.69).

Impact of the intervention on the prevalence of biological outcomes

Eighteen HIV and 119 HSV-2 results were indeterminate (similarly distributed between trial arms). Indeterminate results were assumed negative. HIV prevalence was 1.5% in males and 7.7% in females, HSV-2 prevalence was 1.6% in males and 10.8% in females; both HIV and HSV-2 prevalence increased steeply with age (supplementary data Figure 3).

There was no effect of the intervention on the primary endpoints of HIV or HSV-2 prevalence in either males (Table 3a) or females (Table 3b).

The proportion of women with a positive pregnancy test did not differ significantly between arms. There was a reduction in reported current or past pregnancies in the intervention arm among all women (AOR=0.64;95%CI:0.49–0.83) and among married women (AOR=0.65; 95%CI:0.49–0.87). Among unmarried women, there were non-significant reductions in the number of current pregnancies, and the number of reported past, current and unwanted pregnancies. Unmarried women in intervention communities were at significantly lower risk of any pregnancy[1] (AOR=0.55;95%CI:0.32–0.95) than those in comparison communities. There was no effect of the intervention on reporting of symptoms of STDs in either men or women.

Impact of the intervention by intensity of intervention exposure

A subgroup analysis was carried out among participants who attended an RDS trial school and lived in the trial community throughout the duration of the intervention (Table 4). Effects of the intervention on knowledge and attitudinal outcomes in this subgroup tended to be somewhat larger than in the full study population, but there was no evidence of an increased impact on the primary outcomes of HIV or HSV-2 in either males or females.

[1]Defined as positive on pregnancy test and or reported current or past pregnancy

Discussion

This is one of the first reported trials of a community-based multi-component behavioral intervention aimed at changing social norms for young people in Africa, that had biological endpoints as its primary outcomes. There was no effect of the intervention on any of these including HIV prevalence, HSV-2 prevalence or current pregnancy as measured by pregnancy test. There was an effect on some secondary endpoints including an increase in knowledge related to STD acquisition and pregnancy prevention in intervention communities and a positive effect on some attitudes relating to relationship control and to gender empowerment. Among young women, there was also an increase in reported self-efficacy.

There was no effect of the intervention on reported sexual behaviour, reported clinic use or reported use of pregnancy prevention in males or females in intervention communities. Importantly there was also no evidence to suggest that young people taking part in the intervention were more sexually 'promiscuous' a concern raised by adult community members and policy makers within Zimbabwe (and elsewhere). Despite the change in knowledge and reported attitudes, there was no difference in effect on HIV or HSV-2 prevalence in males or females, nor was there a difference in prevalence of positive pregnancy test between arms of the trial. There was a significant reduction in reported pregnancies among women. Despite the widely reported fall in HIV incidence in Zimbabwe, [15,17] these trial data clearly illustrate that HIV acquisition continues to be a serious public health problem with annual incidence of 4% in young women and 0.8% in young men, the higher rates of infection in women likely reflecting the greater age disparity between themselves and their partners.

This trial was carefully designed and implemented. The intervention was theoretically-based and fulfilled all the criteria for likely effectiveness identified by the systematic review of community-based interventions for young people in developing countries.[9] Qualitative and process evaluation data (not shown) suggested that the intervention model was popular with both adults and young people and that the highly skilled and motivated PPEs were an inspiration to young people within the communities where they worked. Although such careful selection, training and supporting of PPE is expensive (total cost US$ 400/peer/annum), each peer reaches hundreds of young people and adults within the community in which they work and is able to provide ongoing motivation to key people within the community to become actively involved in HIV prevention. Had it been shown to be effective this intervention model had the potential to go to scale, as part of a system of national service for young people.

The effect of the intervention was assessed in the wider community rather than just among intervention recipients so the modest intervention effects that we detected are likely to have been diluted. Of note the effects on knowledge and attitudes were of similar magnitude to those found with the MEMA kwa Vijana trial[18] which assessed impact in a cohort of intervention recipients. While we found no evidence of dose-response, however our data on intervention exposure showed considerable inconsistency, which limits our ability to detect this. Exposure misclassification also reduced our ability to discern the extent to which the intervention impact diffused beyond intervention recipients into the wider population, although a feature of both the out-of-school youth and parents' intervention was to encourage participants to engage friends and relatives in discussions around HIV prevention.

Clearly improving knowledge and changing attitudes of young people are important endpoints in their own right. While the rates of comprehensive knowledge (participants responding to all items correctly) were low, when responses to individual items were

examined separately (data not shown) levels were somewhat better at 50–60%. Changing attitudes relating to gender issues is thought to be a particularly important prerequisite to changing the HIV risk environment[19] and it is encouraging that the intervention was able to make modest gains in this regard, particularly among young women. However, beliefs relating to the rights of women are deeply entrenched, and will consequently be difficult to change.

Encouragingly there was some evidence of an effect on reported past pregnancy in married women and all pregnancies in unmarried women. While self-reported data on pregnancy need to be interpreted with caution, there was no evidence of reporting bias for current pregnancy (actual and reported pregnancy were highly correlated). We also demonstrated that pregnancy prevention knowledge was increased in both men and women and that young women in the intervention arm were more likely to report that they would be able to go to the clinic to access contraception. Unlike antibiotic treatment for STIs, contraception was consistently available at clinics throughout the trial. Several studies in Africa, including this one, have found that pregnancy is of more immediate concern to young women than HIV.[20,21]

To date there have been relatively few published trials of HIV prevention interventions among young people in Africa that have used objective endpoints. MEMA kwa Vijana, a trial of a school-based intervention supported by a youth-friendly clinic intervention in Tanzania found that intervention recipients had increased knowledge as well as reductions in reported unsafe sexual behaviour.[18] There was however no effect on biological outcomes. A follow-up survey conducted 5 years after the trial found that while some knowledge, attitude and behavioural change persisted, again there was no evidence of long-term impact on biological endpoints.[22] Jewkes et al conducted a cluster randomised trial of the “Stepping Stones” community-based intervention in rural South Africa and were able to show an effect on knowledge, attitudes and behaviour as well as a reduction in incidence of HSV-2 that was of borderline significance.[23]

There were some limitations to intervention implementation which may have undermined its potential effectiveness. Firstly, in Zimbabwe as in many other countries there is ambivalence about promoting condoms to young people and mention of condoms was not permitted in schools. Many churches continue to denigrate their effectiveness.[24] While our intervention was able to tackle this issue to some extent by educating young people and adults within communities, young people were aware of these conflicting opinions and this may have undermined intervention impact. The recent HIV prevention series in the Lancet[25] called for better scaling up of interventions that are known to be effective.[19] Finding ways to convince and educate policy makers and other stakeholders that adolescent interventions in general and condom promotion in particular do no harm is clearly going to be key to successful scale-up.

A further limitation to intervention implementation was the high level of mobility of young people. Relatively few survey participants were exposed to both in and out-of-school programmes. Only 55% of young women and 68% of young men had lived in trial communities throughout the four years of the trial; women were more likely to leave or enter the community around the time of marriage than men. While this sub-optimal exposure of survey participants (as opposed to those living in communities during the course of the trial) reduces the likelihood of demonstrating intervention effectiveness, it also likely reduces the possibility that a critical mass of young people were reached, sufficient to bring about change in community norms to reduce sexual risk taking. Quantifying the extent to which the high mobility could have affected intervention effectiveness or our measurement of it is not possible with the data collected. This high mobility emphasises the need to bring

interventions to scale to ensure that people who move from one community to another continue to be able to access HIV prevention programmes and are not disadvantaged by their mobility. Orphans and women who are married (two groups with high rates of HIV) are those most likely to have moved and are also those most in need or HIV prevention education.[26,27]

In addition, the political and economic climate in Zimbabwe during the trial made many aspects of intervention implementation and evaluation challenging. For example, it became difficult to implement the intervention within secondary schools for political reasons. This coincided with a fall in school attendance for economic reasons. We therefore shifted delivery of the intervention into the community from 2005. In addition the clinics suffered from high rates of staff attrition; trained staff were frequently lost and those remaining were increasingly overstretched. The STD drugs supply at clinics was poor. In focus group discussions, young people cited lack of drug availability as a reason for non-attendance.

Population mobility also affected intervention evaluation and resulted in a change in the design of the trial from a cohort to serial cross-sectional evaluation which diluted intervention effects. The rationale for altering the design was not only based on the high rate of out-migration from communities but also on the fact that the intervention had become increasingly community-based. While this clearly affected our ability to detect intervention effectiveness it is not possible to say whether the trial outcomes would have been different if it had been implemented under different circumstances.

This trial is one of several that contributed to a recently published systematic review of behavioural interventions for HIV prevention. Disappointingly none of the behavioural interventions included in that review had an impact on HIV endpoints either because the interventions were ineffective or because of trial design/implementation issues.[28] A consensus seems to be emerging however, that behavioural interventions alone are unlikely to be sufficient to reverse the HIV epidemic and that it is likely that combination approaches which integrate behavioural, biomedical and structural components will be more effective at a population level.[25] Finding ways to implement those HIV prevention interventions that are known to be effective (such as male circumcision, HIV testing and counselling, condom promotion) while looking for innovative ways to combine or layer them, in addition to searching for novel intervention approaches, is the challenge for the next generation of HIV prevention research. The urgency of meeting this challenge could not be more clearly exemplified than by the unacceptably high HIV incidence among the young Zimbabweans in this trial, particularly the young women.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1.
Trial design

Table 1

Characteristics of final evaluation survey participants

Characteristic	Male n (%)		Female n (%)	
	Control (n=1001)	Intervention (n=1078)	Control (n=1352)	Intervention (n=1241)
Age:				
18 years	364 (36.4)	388 (36.0)	515 (38.1)	441 (35.5)
19–20 yrs	356 (35.6)	355 (32.9)	422 (31.2)	373 (30.1)
21–22 yrs	281 (28.1)	335 (31.1)	415 (30.7)	427 (34.4)
Religion:				
Catholic	192 (19.2)	208 (19.3)	240 (17.8)	230 (18.5)
Anglican	281 (28.1)	279 (25.9)	345 (25.5)	322 (26.0)
Apostolic	203 (20.3)	212 (19.7)	315 (23.3)	266 (21.4)
Pentecostal	91 (9.1)	92 (8.5)	173 (12.8)	149 (12.0)
Other/none	219 (21.9)	278 (25.8)	263 (19.4)	265 (21.4)
Missing	15 (1.5)	9 (0.8)	16 (1.2)	9 (0.7)
Ever married	72 (7.2)	84 (7.8)	599 (44.3)	579 (46.7)
Missing	9 (0.9)	8 (0.7)	6 (0.4)	3 (0.2)
Married aged ≤ 16 years	10 (1.0)	14 (1.3)	228 (16.7)	239 (19.3)
Missing	29 (40.3)	30 (35.7)	138 (23.0)	104 (18.0)
Lived in community ≥ 5 years	692 (69.1)	738 (68.5)	760 (56.2)	672 (54.2)
Missing	94 (9.4)	81 (7.5)	156 (11.5)	141 (11.4)
Level of education:				
None/primary only	106 (10.6)	118 (10.9)	201 (14.9)	180 (14.5)
F1–2	118 (11.8)	142 (13.2)	181 (13.4)	187 (15.1)
F3–4	635 (63.4)	661 (61.3)	825 (61.0)	752 (60.6)
F5 or higher	137 (13.7)	149 (13.8)	135 (10.0)	118 (9.5)
Missing	5 (0.5)	8 (0.7)	10 (0.7)	4 (0.3)
Orphan status:				
Non-orphan	498 (49.7)	566 (52.6)	718 (53.1)	666 (53.7)
Lost one/both parents	494 (49.4)	493 (45.7)	622 (46.0)	565 (45.5)
Missing	9 (0.9)	19 (1.8)	12 (0.9)	10 (0.8)
Socio-economic status:				
Cannot afford soap to wash clothes	209 (20.9)	244 (22.6)	278 (20.6)	268 (21.6)
Missing	47 (4.7)	67 (6.2)	54 (4.0)	55 (4.4)
Child/children in house receiving external assistance[1]	181 (18.1)	236 (21.9)	225 (16.6)	197 (15.9)
Missing	6 (0.6)	12 (1.1)	5 (0.4)	4 (0.3)
Adult in house skipped meal in last week	162 (16.2)	203–18.8	254 (18.8)	222 (17.9)

Characteristic	Male n (%)		Female n (%)	
	Control (n=1001)	Intervention (n=1078)	Control (n=1352)	Intervention (n=1241)
Missing	8 (0.8)	7 (0.7)	8 (0.6)	3 (0.2)
Participant gone day without food in last week	148 (14.8)	176 (16.3)	204 (15.1)	174 (14.0)
Missing	8 (0.8)	7 (0.7)	3 (0.2)	4 (0.3)
Attended RDS study school:				
Control school	623 (62.2)	22 (2.0)	693 51.3)	35 (2.8)
Intervention school	22 (2.2)	661 (61.3)	45 (3.3)	569 (45.8)
Non-RDS School	210 (21.0)	234 (21.7)	348 (25.7)	409 (33.0)
No secondary education	119 (11.9)	138 (12.8)	238 (17.6)	206 (16.6)
Missing	27 (2.7)	23 (2.1)	28 (2.1)	22 (1.8)

[1]External assistance includes financial, food, education assistance provided by government or aid.

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Table 2a

Impact of the intervention on population prevalence of knowledge, attitudinal and behavioural outcomes – males

Endpoint	Prevalence[1]				Crude	Adjusted[2]	
	Control (N=1001)		Intervention (N=1078)				
	n/N	(%)	n/N	%	OR	OR	[95% CI]
Knowledge and self-efficacy (% responding "correctly" to questions)							
HIV acquisition (3 questions)	229/1000	(22.9)	264/1074	(24.6)	1.10	1.09	[0.88–1.35]
STD acquisition (2 questions)	407/1000	(40.7)	502/1074	(46.7)	1.29	1.32	[1.08–1.61]
Pregnancy prevention (2 questions)	261/995	(26.2)	380/1073	(35.4)	1.54	1.59	[1.27–1.99]
Condom self-efficacy (3 questions)	448/989	(45.3)	524/1067	(49.1)	1.12	1.18	[0.94–1.48]
Sexual refusal self-efficacy (2 questions)	638/964	(66.2)	661/1031	(64.1)	0.91	0.92	[0.74–1.14]
HIV-testing self-efficacy (3 questions)	616/990	(62.2)	685/1065	(64.3)	1.09	1.08	[0.89–1.30]
Attitudes - Control over sex (% responding "correctly" to questions)							
All responses "correct" (10 questions)	38/912	(4.2)	54/977	(5.5)	1.36	1.44	[0.90–2.32]
≥ 7/10 questions responded to "correctly" [3]	525/912	(57.6)	598/977	(61.2)	1.16	1.18	[0.94–1.48]
Control around sexual refusal (3 questions)	229/954	(24.0)	277/1023	(27.1)	1.17	1.22	[1.02–1.47]
Control around sexual partners (4 questions)	323/934	(34.6)	363/997	(36.4)	1.08	1.08	[0.87–1.32]
Safe sex and condoms (2 questions)	342/956	(35.8)	411/1024	(40.1)	1.20	1.20	[0.95–1.52]
Attitudes - Jewkes scale: Gender empowerment (% responding "correctly" to questions)							
≥ 4/8 responses "correct"[3]	490/946	(51.8)	546/1010	(54.1)	1.09	1.12	[0.93–1.35]
Right to refuse sex (2 questions)	465/968	(48.0)	542/1038	(52.2)	1.18	1.20	[0.98–1.46]
Rights within marriage (2 questions)	14/966	(1.4)	27/1041	(2.6)	1.81	1.79	[1.05–3.04]
Control over life & future							
Have long range goals	845/991	(85.3)	931/1070	(87.0)	1.16	1.19	[0.94–1.51]
Reported Sexual Behaviour (reported on ACASI)							
Ever had sex	402/974	(41.3)	442/1038	(42.6)	1.07	1.04	[0.87–1.24]
Sexual debut 17 or younger[4]	189/974	(19.4)	201/1038	(19.4)	1.01	1.01	[0.78–1.31]
Two or more lifetime partners[4]	278/974	(28.5)	303/1038	(29.2)	1.04	1.03	[0.80–1.31]

Endpoint	Prevalence[1]				Crude	Adjusted[2]	
	Control (N=1001)		Intervention (N=1078)				
	n/N	(%)	n/N	%	OR	OR	[95% CI]
Two or more partners in last 12m[4]	117/789	(14.8)	109/818	(13.3)	0.89	0.86	[0.59–1.26]
Did not use condom at last sex [4]	179/971	(18.4)	202/1035	(19.5)	1.08	1.03	[0.83–1.29]
Reported Pregnancy prevention							
No pregnancy prevention used with first partner [5]	172/420	(41.0)	179/459	(39.0)	0.92	0.90	[0.69–1.17]
No pregnancy prevention used with last partner [5]	175/420	(41.7)	179/459	(39.0)	0.89	0.87	[0.64–1.17]
No pregnancy prevention used with any partner [5]	130/420	(31.0)	133/459	(29.0)	0.91	0.87	[0.63–1.21]
Clinic attendance and perceptions of staff							
Been to the clinic in the last 12 months	447/999	(44.7)	482/1075	(44.8)	0.99	0.99	[0.76–1.29]
Never worry that clinic staff will tell others purpose of my visit[6]	252/399	(63.2)	281/426	(66.0)	1.13	1.10	[0.81–1.51]
Always seen in private, never worry that other patients will know purpose of my visit [6]	300/399	(75.2)	314/426	(73.7)	0.89	0.87	[0.66–1.14]
Would go to clinic for treatment if had discharge from penis	756/986	(76.7)	845/1062	(79.6)	1.18	1.19	[0.90–1.57]

[1] Denominators vary depending on missing values

[2] Adjusted for *a priori* confounders (age, strata, marital status & education)

[3] Cut-off set at median number of “correct” responses

[4] Reference category includes not reporting the characteristic and does not exclude those who have never had sex

[5] Restricted to those who reported ever having had sex (includes those who reported non-consensual sex, anal sex, or sex when too drunk to say no)

[6] Restricted to those who visited the clinic in the last 12 months

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Table 2b

Impact of the intervention on population prevalence of knowledge, attitudinal and behavioural outcomes – females

Endpoint	Prevalence[1]				Crude	Adjusted[2]	
	Control (N=1352)		Interventio (N=1241)				
	n/N	%	n/N	%	OR	OR	[95% CI]
Knowledge and self-efficacy (% responding "correctly" to questions)							
HIV acquisition (3 questions)	233/1351	(17.2)	246/1241	(19.8)	1.19	1.16	[0.92–1.45]
STD acquisition (2 questions)	464/1350	(34.4)	524/1239	(42.3)	1.45	1.45	[1.17–1.79]
Pregnancy prevention (2 questions)	355/1351	(26.3)	404/1239	(32.6)	1.36	1.32	[1.14–1.55]
Condom self-efficacy (3 questions)	311/1335	(23.3)	339/1223	(27.7)	1.27	1.22	[1.01–1.48]
Sexual refusal self-efficacy (2 questions)	887/1329	(66.7)	847/1215	(69.7)	1.16	1.17	[0.95–1.43]
HIV-testing self-efficacy (3 questions)	897/1335	(67.2)	872/1222	(71.4)	1.22	1.22	[1.03–1.44]
Attitudes - Control over sex (% responding "correctly" to questions)							
All responses "correct" (10 questions)	47/1181	(4.0)	60/1091	(5.5)	1.42	1.36	[0.87–2.14]
≥ 7/10 questions responded to "correctly" [3]	586/1181	(49.6)	616/1091	(56.5)	1.34	1.34	[1.11–1.63]
Control around sexual refusal (3 questions)	304/1274	(23.9)	301/1162	(25.9)	1.12	1.16	[0.95–1.43]
Control around sexual partners (4 questions)	373/1231	(30.3)	378/1137	(33.2)	1.15	1.14	[0.91–1.43]
Safe sex and condoms (2 questions)	406/1272	(31.9)	430/1162	(37.0)	1.25	1.24	[1.03–1.48]
Attitudes - Jewkes scale: Gender empowerment (% responding "correctly" to questions)							
≥ 4/8 responses "correct" [3]	569/1268	(44.9)	596/1157	(51.5)	1.31	1.32	[1.05–1.66]
Right to refuse sex (2 questions)	585/1309	(44.7)	576/1192	(48.3)	1.18	1.17	[0.95–1.44]
Rights within marriage (2 questions)	33/1315	(2.5)	31/1201	(2.6)	1.04	1.19	[0.74–1.91]
Control over life & future							
Have long range goals	1126/1334	(84.4)	1054/1232	(85.6)	1.10	1.10	[0.88–1.38]
Reported Sexual Behaviour (reported on ACASI)							
Ever had sex	681/1289	(52.8)	648/1217	(53.2)	1.01	0.83	[0.61–1.13]
Sexual debut 17 or younger [4]	298/1289	(23.1)	295/1217	(24.2)	1.01	1.02	[0.80–1.28]
Two or more lifetime partners [4]	138/1289	(10.7)	142/1217	(11.7)	1.12	1.11	[0.79–1.56]

Endpoint	Prevalence[1]				Crude	Adjusted[2]	
	Control (N=1352)		Interventio (N=1241)				
	n/N	%	n/N	%	OR	OR	[95% CI]
Two or more partners in last 12m [4]	35/1102	(3.2)	27/957	(2.8)	0.89	0.91	[0.56–1.47]
Did not use condom at last sex [4]	514/1282	(40.1)	498/1209	(41.2)	1.04	0.93	[0.72–1.20]
Reported Pregnancy prevention							
No pregnancy prevention used with first partner [5]	372/696	(53.4)	352/667	(52.8)	0.97	0.97	[0.76–1.25]
No pregnancy prevention used with last partner [5]	369/696	(53.0)	361/667	(54.1)	1.04	1.04	[0.77–1.40]
No pregnancy prevention used with any partner [5]	345/696	(49.6)	329/667	(49.3)	0.98	0.99	[0.74–1.30]
Clinic attendance and perceptions of staff							
Been to the clinic in the last 12 months	782/1340	(58.4)	729/1238	(58.9)	1.01	0.98	[0.76–1.28]
Never worry that clinic staff will tell others purpose of my visit[6]	472/706	(66.9)	447/661	(67.6)	1.03	1.04	0.80–1.36]
Always seen in private, never worry that other patients will know purpose of my visit [6]	556/706	(78.8)	517/661	(78.2)	0.96	0.96	[0.72–1.28]
Able to go to the clinic if I needed to get contraception	933/1294	(72.1)	928/1195	(77.7)	1.36	1.33	[1.05–1.69]

[1] Denominators vary depending on missing values

[2] Adjusted for *a priori* confounders (age, strata, marital status & education)

[3] Cut-off set at median number of “correct” responses

[4] Reference category includes not reporting the characteristic and does not exclude those who have never had sex

[5] Restricted to those who reported ever having had sex (includes those who reported non-consensual sex, anal sex, or sex when too drunk to say no)

[6] Restricted to those who visited the clinic in the last 12 months

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Table 3a

Impact of the intervention on population prevalence of biological outcomes males

Endpoint	Prevalence[1]				Crude		Adjusted[2]	
	Control (N=1001)		Intervention (N=1078)					
	n	%	n	%	OR	[95% CI]	OR	[95% CI]
Reported symptoms of STDs								
Ever had symptoms of STD [3]	145/974	14.9	157/1038	15.1	1.02	[0.79–1.32]	0.98	[0.76–1.25]
Sought treatment for STD symptoms [3,4]	72/145	49.7	74/157	47.1	0.89	[0.49–1.62]	0.82	[0.44–1.53]
Genital discharge prevalence	83/950	8.7	95/1023	9.3	1.08	[0.77–1.51]	1.09	[0.81–1.46]
Genital warts or sores prevalence	84/950	8.8	84/1013	8.3	0.95	[0.65–1.40]	0.92	[0.67–1.27]
Prevalence of any symptom of STD	367/991	37.0	407/1060	38.4	1.06	[0.88–1.27]	1.06	[0.90–1.24]
Primary biological outcomes								
HIV infection	13/1001	1.3	18/1078	1.7	1.28	[0.68–2.41]	1.20	[0.66–2.18]
HSV-2 infection	15/1001	1.5	19/1078	1.8	1.13	[0.65–1.96]	1.23	[0.69–2.18]

[1] Denominators vary depending on missing values

[2] Adjusted for *a priori* confounders (age, strata, marital status & education)

[3] Reported on ACASI

[4] Among those who reported symptoms of STDs on ACASI

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Table 3b

Impact of the intervention on population prevalence of biological outcomes females

Endpoint	Prevalence[1]				Crude		Adjusted[2]	
	Control (N=1352)		Intervention (N=1241)					
	n	%	n	%	OR	[95% CI]	OR	[95% CI]
Pregnancy and reported pregnancy								
All women (n=2593)								
Currently pregnant[5]	109/1349	8.1	95/1237	7.7	0.94	[0.69–1.28]	0.92	[0.70–1.19]
Reported unwanted pregnancy	183/1324	13.8	159/1218	13.0	0.93	[0.70–1.23]	0.88	[0.69–1.12]
Reported past or current pregnancy	572/1346	42.5	517/1235	41.9	0.97	[0.75–1.27]	0.64	[0.49–0.83]
Reported aborted pregnancy	31/1332	2.3	36/1224	2.9	1.30	[0.85–2.00]	1.26	[0.82–1.94]
Any evidence of pregnancy (incl.currently pregnant[5])	600/1352	44.4	541/1241	43.6	0.97	[0.74–1.27]	0.64	[0.49–0.83]
Unmarried women (n=1406)								
Currently pregnant[5]	20/745	2.7	11/656	1.7	0.63	[0.30–1.31]	0.66	[0.32–1.36]
Reported unwanted pregnancy	24/731	3.3	13/648	2.0	0.61	[0.24–1.53]	0.54	[0.19–1.54]
Reported past or current pregnancy	37/743	5.0	21/655	3.2	0.64	[0.32–1.28]	0.60	[0.27–1.31]
Reported aborted pregnancy	8/737	1.1	8/648	1.2	1.07	[0.46–2.52]	0.98	[0.42–2.25]
Any evidence of pregnancy (incl.currently pregnant[5])	58/747	7.8	31/659	4.7	0.59	[0.36–0.95]	0.55	[0.32–0.95]
Married women (n=1178)								
Currently pregnant[5]	89/598	14.9	84/578	14.5	0.99	[0.74–1.33]	1.02	[0.78–1.35]
Reported unwanted pregnancy	158/587	26.9	145/567	25.6	0.93	[0.68–1.26]	0.93	[0.72–1.19]
Reported past or current pregnancy	533/597	89.3	495/577	85.8	0.72	[0.54–0.95]	0.65	[0.49–0.87]
Reported aborted pregnancy	22/589	3.7	27/573	4.7	1.30	[0.77–2.20]	1.20	[0.63–2.26]
Any evidence of pregnancy (incl.currently pregnant[5])	540/599	90.2	509/579	87.9	0.79	[0.60–1.06]	0.70	[0.53–0.93]
Reported symptoms of STDs								
Ever had symptoms of STD[3]	222/1289	17.2	209/1217	17.2	1.00	[0.80–1.25]	0.97	[0.79–1.19]
Sought treatment for STD symptoms[3,4]	100/222	45.0	93/209	44.5	0.98	[0.67–1.43]	0.91	[0.62–1.35]
Genital discharge prevalence	160/1297	12.3	139/1191	11.7	0.94	[0.71–1.23]	0.91	[0.70–1.19]

Endpoint	Prevalence[1]				Crude		Adjusted[2]	
	Control (N=1352)		Intervention (N=1241)					
	n	%	n	%	OR	[95% CI]	OR	[95% CI]
Genital warts or sores prevalence	112/1280	8.8	83/1164	7.1	0.80	[0.59–1.09]	0.78	[0.57–1.05]
Prevalence of any symptom of STD	482/1336	36.1	411/1231	33.4	0.89	[0.73–1.08]	0.86	[0.72–1.02]
Primary biological outcomes								
HIV infection	98/1352	7.2	101/1241	8.1	1.15	[0.78–1.69]	1.15	[0.81–1.64]
HSV-2 infection	132/1352	9.8	148/1241	11.9	1.26	[0.91–1.74]	1.24	[0.93–1.65]

[1] Denominators vary depending on missing values

[2] Adjusted for *a priori* confounders (age, strata, marital status & education)

[3] Reported on ACASI

[4] Among those who reported symptoms of STDs on ACASI

[5] Based on result of pregnancy test

Table 4

Sub-analysis restricted to survey participants who attended a Regai Dzive Shiri trial school and had lived in the community for the duration of the intervention (i.e. 5 years or more)

Endpoint	Male					Female				
	Control	Intervention	Crude	Adjusted[1]		Control	Intervention	Crude	Adjusted[1]	
	%	%	OR	OR	[95% CI]	%	%	OR	OR	[95% CI]
Participants who had lived in trial community 5 years or more and attended an RDS trial school										
n	485	519				493	399			
HIV	1.4	1.5	1.07	0.91	[0.35–2.34]	3.8	6.5	1.77	1.65	[0.90–3.03]
HSV-2[2]	0.8	1.4	1.40	1.34	[0.51–3.53]	5.9	7.5	1.30	1.21	[0.71–2.05]
Pregnancy						5.9	5.3	0.90	0.83	[0.50–1.35]
Any evidence of pregnancy (incl.currently pregnant[3])						33.5	31.1	0.87	0.49	[0.29–0.84]
Knowledge and self-efficacy (% responding "correctly" to questions)										
HIV acquisition (3 questions)	25.0	25.5	1.03	1.01	[0.73–1.41]	15.8	22.3	1.56	1.52	[0.98–2.37]
STD acquisition (2 questions)	43.6	50.4	1.31	1.30	[1.00–1.68]	35.9	41.6	1.29	1.23	[0.91–1.66]
Pregnancy prevention (2 questions)	26.0	41.9	2.05	2.05	[1.51–2.77]	26.8	36.6	1.59	1.56	[1.18–2.07]
Attitudes - Control over sex (% responding "correctly" to questions)										
≥ 7/10 questions responded to "correctly"[4]	61.2	63.3	1.08	1.07	[0.76–1.50]	53.0	60.8	1.38	1.37	[1.04–1.80]
Control around sexual refusal (3 questions)	26.9	30.2	1.17	1.19	[0.93–1.52]	26.9	33.2	1.35	1.48	[1.17–1.87]
Control around sexual partners (4 questions)	36.7	37.6	1.06	1.02	[0.82–1.26]	34.9	36.9	1.09	1.06	[0.79–1.44]
Safe sex and condoms (2 questions)	37.5	40.2	1.11	1.11	[0.82–1.50]	31.8	39.5	1.38	1.35	[0.98–1.85]
Attitudes - Jewkes scale: Gender empowerment (% responding "correctly" to questions)										
≥ 4/8 responses "correct"[4]	49.4	56.9	1.34	1.40	[1.05–1.87]	44.1	56.1	1.62	1.58	[1.20–2.10]
Right to refuse sex (2 questions)	48.5	53.8	1.24	1.24	[0.97–1.59]	44.0	49.5	1.25	1.20	[0.91–1.59]

[1] Adjusted for *a priori* confounders (age, strata, marital status & education)

[2] Adjusted OR obtained using logistic regression with robust standard errors to allow for clustering

[3] Based on result of pregnancy test

[4]Cut-off set at median number of "correct" responses