

# The Regai Dzive Shiri Project: a cluster randomised controlled trial to determine the effectiveness of a multi-component community-based HIV prevention intervention for rural youth in Zimbabwe – study design and baseline results

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## Summary

**OBJECTIVE** To assess the effectiveness of a community-based HIV prevention intervention for adolescents in terms of its impact on (1) HIV and *Herpes simplex virus* type 2 (HSV-2) incidence and on rates of unintended pregnancy and (2) reported sexual behaviour, knowledge and attitudes.

**METHODS** Cluster randomised trial of a multi-component HIV prevention intervention for adolescents based in rural Zimbabwe. Thirty communities were selected and randomised in 2003 to early or deferred intervention implementation. A baseline bio-behavioural survey was conducted among 6791 secondary school pupils (86% of eligibles) prior to intervention implementation.

**RESULTS** Baseline prevalences were 0.8% (95% CI: 0.6–1.0) for HIV and 0.2% (95% CI: 0.1–0.3%) for HSV-2. Four girls (0.12%) were pregnant. There was excellent balance between study arms. Orphans who made up 35% of the cohort were at increased risk of HIV [age–sex adjusted odds ratio 3.4 (95% CI: 1.7–6.5)]. 11.9% of young men and 2.9% of young women reported that they were sexually active ( $P < 0.001$ ); however, there were inconsistencies in the sexual behaviour data. Girls were less likely to know about reproductive health issues than boys ( $P < 0.001$ ) and were less likely to have used and to be able to access condoms ( $P < 0.001$ ).

**CONCLUSION** This is one of the first rigorous evaluations of a community-based HIV prevention intervention for young people in southern Africa. The low rates of HIV suggest that the intervention was started before this population became sexually active. Inconsistency and under-reporting of sexual behaviour re-emphasise the importance of using externally validated measures of sexual risk reduction in behavioural intervention studies.

**keywords** randomised controlled trial, HIV infection, prevention and control, adolescent, behaviour, Zimbabwe

## Introduction

Of the four million people infected with HIV in 2006, 40% were aged 15–24 (UNAIDS 2006). Young women are disproportionately affected. Of the six million HIV-positive young people in sub-Saharan Africa, 76% are female (Regional Office for Africa 2003). In a review of 11 national surveys, young women have 1.3–12 times higher infection rates than young men (Regional Office for Africa 2003). The United Nations General Assembly Special Session on HIV/AIDS declaration (2001) resolved to

achieve a 25% reduction in the rate of new HIV infections in young people by 2005 in the worst affected countries (United Nations General Assembly Special Session on HIV/AIDS 2001). Despite this, many young people continue to lack basic information and skills to protect themselves. However, in countries where trends in HIV are reversing, it is among the young people where the greatest changes have been observed (UNAIDS Interagency Task Team on Young People 2004). While young people are at the centre of the epidemic, they also represent the greatest hope in the fight against HIV/AIDS.

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In 2004, the Joint United Nations Programme on HIV/AIDS (UNAIDS) commissioned a series of systematic reviews to provide policy makers with evidence on the effectiveness of HIV prevention for young people (UNAIDS Interagency Task Team on Young People 2006). Evidence was assembled for interventions in schools (Kirby *et al.* 2006), in communities (Maticka-Tyndale & Brouillard-Coyle 2006) and to improve young people's access to health services (Dick *et al.* 2006). While there was good evidence that school-based interventions can reduce reported sexual risk taking and that providing training to make health clinics more 'youth friendly' increases clinic usage by young people, data to support or argue against the implementation of broader, more community-based approaches, which aim to change societal norms in order to support individual behaviour change, were relatively sparse.

In this paper, we report the design and baseline results of a community randomised trial of a multi-component community-based HIV prevention intervention for young people underway in rural Zimbabwe. The main aim of the trial is to measure the effectiveness of the intervention delivered to secondary school students, out-of-school youth and the wider community in reducing the rates of HIV-1, *Herpes simplex virus* type 2 (HSV-2) and of unintended pregnancy among young Zimbabweans after 4 years of intervention delivery. The project is called the Regai Dzive Shiri Project (taken from the Shona proverb 'Regai dzive shiri mazai haana muto' – which literally translates as 'Give the eggs a chance to hatch, because birds are better to eat than eggs which have no sauce'. The proverb is used to support the notion of giving young people time to grow up. In rural Zimbabwe, in 2003, a majority (>90%) of young people attended secondary school, transitioning from primary to secondary school at around 11–13 years, and secondary school students were therefore representative of Zimbabwean youth more generally.

## Methods

### Study area and population

The study is being conducted in seven districts in three provinces in south-eastern Zimbabwe (Figure 1). Thirty rural communities were selected for inclusion. A community is defined as the rural health clinic, its catchment population and the secondary schools; in nine communities, there are two clinics rather than one. Communities were selected if there were at least 250 Form 2 (ninth year of schooling) students attending local secondary schools and there was an



**Figure 1** Location of the Regai Dzive Shiri Project within Zimbabwe – map shows district boundaries across Zimbabwe.

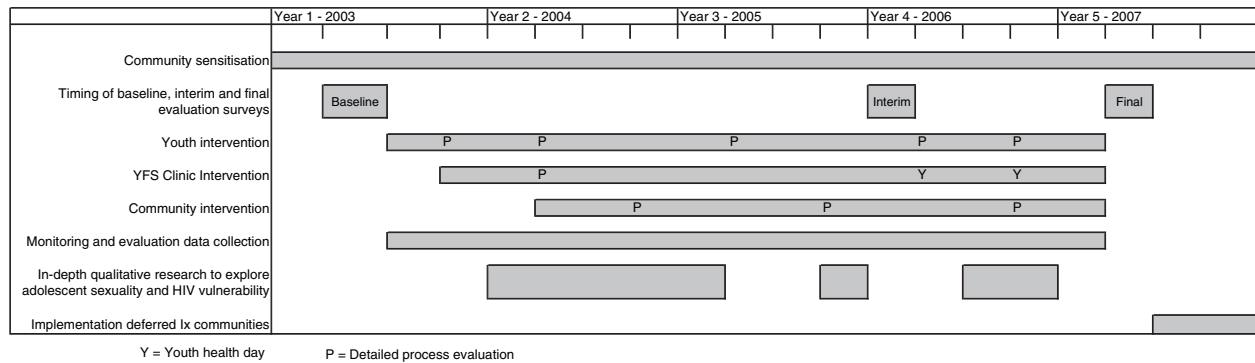
absence of HIV prevention specifically targeting young people.

The intervention is being delivered to in- and out-of-school youth, parents and rural clinic health staff. The impact is being measured in a cohort of 6791 young people who were attending Form 2 in study secondary schools between March 2003 and June 2003, when school-going youth were broadly representatives of young people living in rural Zimbabwe. School attendance has fallen since then as a consequence of the deteriorating economic situation.

The overall design of this trial is illustrated in Figure 2. In brief, a cohort of young people enrolled in Form 2 at study schools, was recruited in 2003. The baseline survey was conducted in this cohort March–June 2003. An interim survey was conducted among cohort members in 12 of 30 randomly selected communities in 2006, in order to re-ascertain the likely power of the trial by determining HIV prevalence and rates of loss to follow-up at year 3. The final evaluation survey was run in 2007 (year 4). The results of the interim and final survey will be published elsewhere.

### Community mobilisation, access and consent processes

Community sensitisation took place at national, provincial and district levels before entering study communities. The study was approved by the Zimbabwe Ministry for Health and Child Welfare and the National AIDS Council. Ethical approval was obtained from the Medical Research Council

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of Zimbabwe and the ethics committees of University College London and the London School of Hygiene and Tropical Medicine. Strong links were established with other relevant ministries and community stakeholders.

Five people from each community were trained as community advisory board (CAB) members (150 in all) and were crucial to successful community sensitisation and cohort recruitment. A list of potential study participants (all Form 2 students attending study schools) was drawn up from school registers. Community meetings were held to inform the community about the study and to obtain written consent from parents for their child's participation in the research (consent was not sought for participation in the intervention itself). If parents failed to attend these meetings, home visits were undertaken to obtain consent.

### The randomisation process

In February 2003, a meeting was held at which randomisation of the 30 communities to early or deferred intervention implementation took place. More than 100 provincial, district and community representatives attended the meeting. Restricted randomisation was used to ensure balance between arms of the study (see below) (Hayes *et al.* 2000).

The process of randomisation was as follows. The communities were placed into three strata based on the distance of the clinic from a tarred road. There were 16 299 360 ways that the 30 communities could be allocated to the two arms ensuring balance across these strata. Randomisation was then restricted to ensure an equal number of schools in each arm; balance across districts; and an average sample size per community between 255 and 261 in each arm. The 8575 allocations satisfying these conditions were listed, and one was selected randomly at the randomisation meeting.

### The baseline survey of the study cohort

The baseline survey took place between March 2003 and June 2003. Young people whose parents had consented were asked to sign to confirm their assent or refusal to take part.

Participants in the baseline survey were asked to self-complete a questionnaire as it was read out loud in Shona (the indigenous language) by a trained surveyor. Participants provided a finger-prick blood sample for HIV & HSV-2 antibody testing and girls provided a urine sample for pregnancy testing. The questionnaire collected information on socio-demographic characteristics, socio-economic status (SES) of their household (using questions from the Zimbabwe census), self-esteem, self-efficacy, sexual knowledge and attitudes, sexual behaviour including sexual intercourse, other risky behaviours and their hopes and aspirations for the future.

### Design of main intervention

The intervention is theoretically based in social learning theory and the stages of change model (Prochaska & DiClemente 1992; Bandura *et al.* 1997). It aims to achieve change in societal norms within communities. The intervention has three components described in detail in Table 1:

- *The youth programme* for in- and out-of-school youth is delivered by carefully selected and trained Zimbabwean school leavers in the year between leaving school and starting university. These school leavers work as volunteers and go to live and work in the rural communities for 8–10 months of the year. They act both as role models for young people and as

**Table 1** The Regai Dzive Shiri intervention

Youth	<p>In-school programme (First 3 years of the intervention; delivered to all students in years 1–4)            The 3 year MEMA kwa Vijana curriculum (Hayes <i>et al.</i> 2005; Obasi <i>et al.</i> 2006; Plummer <i>et al.</i> 2007) was adapted for use in Zimbabwe. Additional introductory sessions on self-awareness and communication were added in year 1 and on self belief and gender issues in year 2.            Supplemented with materials developed locally by the Zimbabwe CDC AIDS Project (Talktime and Mopani Junction), Training and Research Support Centre (Auntie Stella – <a href="http://www.auntiestella.co.zw">http://www.auntiestella.co.zw</a>) and JSI UK (Young People We Care – an innovative programme which integrates HIV prevention for young people into a broader package of providing treatment and care for those affected/infected by HIV).            In year 4, the programme became entirely community based.</p> <p>Out-of-school programme            In years 1–3, community groups were established, which undertook HIV prevention activities using the supplementary materials outlined above.            In year 4, a 24-session out-of-school youth programme based on the ‘Stages of Change’ theoretical model was developed and implemented <i>de novo</i>. This is a highly participatory course which uses techniques developed for rural development, including risk and body mapping, drama, story telling and role play. The programme is run with groups of 20–30 participants over 4 weeks and groups are then encouraged to continue with community outreach to families and young people affected by HIV. Participants who attend at least 75% of sessions received an attendance certificate and a project T-shirt.</p>
Clinic	<p>Five day residential youth-friendly clinic staff training for at least one nurse in each clinic with refresher training after 2 years. On-site training was provided for remaining clinic staff.            Monthly support visits by project staff when key features of clinic accessibility were assessed and on-site training tailored to any deficiencies noted.            Standards for youth-friendly services provision were developed by clinic nurses, who are independently assessed against these standards at 6 monthly intervals. Prizes are awarded to clinics performing well. Each clinic receives detailed independent feedback on their performance at these standard assessments. The district nursing leadership is an integral part of this process.</p>
Community	<p>The community component aims to (i) raise awareness of issues relating to adolescent sexuality among parents and other adults in the community; (ii) improve communication between parents and their children; (iii) make the community a safer place for young people to be and (iv) enable adults to support young people to reduce their reproductive health risk.            The community intervention comprises two modules (eleven 3-h sessions for each module) delivered by carefully selected, trained and supported community facilitators. The sessions are designed to be as participatory as possible in order to maximise ownership of the learning points, encourage development of life skills, encourage internalisation of attitude change and be more enjoyable for participants. It is hypothesised that people will be more likely to accept new ideas if they come from within the community.            In addition to participatory techniques, the sessions use proverbs and bible verses to support new ideas that community members may be wary of or have difficulty understanding. Traditional games are also used to help support and clarify learning points. Participants can only progress to Module 2 if they have completed at least 75% sessions in Module 1.</p>

a bridge between adults and youth within communities. These professional peer educators (PPEs) use well-structured, theoretically-based materials which they deliver in a highly participatory way. The programme is delivered to all students and out-of-school youth who want to take part and not just those enrolled in the trial cohort.

- The *programme for parents and community stakeholders* is a 22-session community-based programme, which aims to improve knowledge about reproductive health, communication between parents and their children and community support for adolescent reproductive health. The community component arose from focus group discussions held with parents during the feasibility study (Cowan *et al.* 2002; Power *et al.*

2004). Parents lamented the collapse of traditional communication structures and acknowledged their lack of communication skills. Interestingly young people also said that they struggled to communicate with their parents especially about reproductive health issues and that they saw this as an important barrier to staying safe.

- The *programme for nurses and other staff working in rural health clinics* aims to improve accessibility of clinics for out-of-school youth.

These three components are highly integrated. For example, nurses trained to run the clinic intervention also run sessions within the youth and parents programmes and in so doing publicise the accessibility of the clinic. PPEs

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help run the 'youth corners' at the clinics and help facilitate sessions in the parents programme. Integrating the three components in this way makes them mutually supportive and reinforcing. By living and working so closely with the community, it is hypothesised that the PPEs are able to change the norms of that community through challenging the norms that may be detrimental to adolescent reproductive health and reinforcing those that are beneficial.

**Intervention in the deferred intervention arm**

No specific intervention was introduced into the deferred intervention arm, but standard HIV prevention activities were implemented through the District AIDS Action Committees by local and international governmental and non-governmental organisations across both early and deferred intervention communities. Details of these activities are being recorded. The intervention was delivered in these communities in 2007 after final survey completion.

The project provided voluntary HIV counselling and testing through rural health clinics in all 30 communities on 1 day a month for the duration of the study. Uptake and acceptability was recorded and will be reported elsewhere.

**Process evaluation of the intervention**

Monitoring and evaluation data were collected throughout the study to document the study and non-study activities underway in communities, the number of people attending these activities and the frequency of their attendance. Clinic attendance figures were collected from study clinics. A team of social scientists undertook regular assessment of the intervention to assess whether each component was being delivered as intended. The results of these evaluations were fed back to the intervention teams who modified the intervention and or its delivery as necessary.

**Laboratory analysis**

Blood samples were collected onto filter paper [US National Committee for Clinical Laboratory Standards (NCCLS), unpublished observation]. The samples were tested for HIV-1 antibody at the National Microbiology Reference Laboratory in Harare using a validated testing algorithm (US Department of Health and Human Services *et al.*, unpublished observation). All specimens were tested using two ELISA tests (Vironostika® HIV Microelisa System BioMerieux, Inc., Durham, NC) and AniLabsystems EIA kit (AniLabsystems Ltd, Vantaa, Finland), with western blot used in the case of discrepant results. Dried blood spot (DBS) samples were tested for antibodies to HSV-2 using a type-specific HSV-2 assay (Focus

HerpeSelect EIA, Focus Technologies, Cypress CA) with the index for diagnosing positive samples raised to >3.4 to minimise the number of false positives (Morrow *et al.* 2006). Urine samples were tested on-site for pregnancy using Cortez OneStep hCG Rapidip InstaTest®.

**Data handling and analysis**

All questionnaire data from the baseline survey were double-entered into an Access database and range and consistency checks were performed. An overall SES scale was created from household asset data. Each item was coded on a scale of 0 to 1 where 0 was considered to be the poorest SES category and 1 the richest. The scores were then added and the sum of each scale used to calculate a mean score for each participant. SES categories were then created by dividing this mean score distribution into quintiles. All statistical analyses were performed using STATA 9.2 (College Station, TX).

On completion of the trial, the primary analysis will be based on the cumulative incidences of HIV, HSV-2 and unintended pregnancies at the final follow-up survey, at median age 19 years. Statistical methods that allow for clustering of events within community will be used for the analysis (Donner & Klar 2000; Hayes *et al.* 2000). Further analyses will be carried out to adjust for covariates showing baseline imbalance.

Secondary analysis to compare HIV incidence by different levels of intervention intensity will be undertaken, adjusting for potential confounding. Incidence rates will be compared both within the intervention communities (e.g. comparing those with limited exposure to those who had reasonable exposure to the intervention) and to control communities where intervention was not implemented. Rates of losses to follow-up, and the characteristics of those lost, will be examined to investigate bias.

Similar methods will be used to analyse the cumulative incidence of HSV-2 and unintended pregnancies. We will also examine the factors associated with the acquisition of HIV, using logistic regression on individual-level data. Terms will be included in the model to adjust for communities.

**Sample size justification**

The sample size calculations made the following assumptions: 15 communities per arm from which an average of 220 Form 2 students would be enrolled, 4% of students would be excluded from analysis because they are HIV-infected at baseline and 25% would be lost to follow-up by the end of the trial.

Assuming that the cumulative incidence of HIV in the 'deferred intervention' arm would be 4% over the 4 years

of the study (National AIDS Council *et al.* 2002) and a coefficient of variation of cumulative incidence between communities within strata of  $k = 0.2$ , we will have 80% power to detect as statistically significant (at the 5% two-sided significance level) a cumulative incidence of 2.4% or lower in the 'early intervention' arm (reduction of 40%) (Hayes *et al.* 2000). As cumulative incidence of HSV-2 and unintended pregnancy will likely be higher than 4%, we will have greater power to detect a smaller difference in these factors.

## Results

### Participation rate

There were 7885 Form 2 students eligible for inclusion in the cohort. Parents/guardians of 91.5% ( $n = 7215$ ) of these agreed to their child's participation, 8.1% declined (mostly because of religious beliefs around blood draw) and 0.2% of parents were not contactable. 94.1% of young people whose parents had given consent agreed to participate ( $n = 6791$ ), giving an overall consent rate of 86.3%.

### Baseline characteristics of participants

The baseline characteristics of study participants are shown in Table 2. Boys were 6 months older than girls ( $P < 0.001$ ). While both girls and boys reported relatively low levels of knowledge about sexual matters, girls reported poorer knowledge than boys ( $P < 0.05$ ). For example, 78% girls compared with 71% of boys ( $P < 0.001$ ) said they knew little or nothing about preventing pregnancy (including two girls who were pregnant); 70% of girls compared with 62% of boys ( $P < 0.001$ ) said they knew little or nothing about HIV [including 32 (63%) of those infected]; and 81% of girls compared with 68% of boys ( $P < 0.001$ ) said they knew little or nothing about other sexually transmitted infections. Girls were also significantly less likely than boys ( $P < 0.001$ ) to report that they would find it easy to access condoms (7% compared with 24%), or to use a condom in the future (17% compared with 46%), and to tell their partner he must use condoms (24% compared with 49%).

Twenty (0.6%) boys and 31 (1.0%) girls had HIV-1 antibody detected (Table 3). Only 12 had HSV-2 antibody (0.2%). Four (0.12%) girls were pregnant. There was excellent balance between early and deferred intervention arms in terms of rates of HIV-1 infection and other behavioural and socio-demographic variables.

Overall, 2.9% of the girls reported being sexually active compared with 11.9% of the boys ( $P < 0.001$ ) [median age

at first intercourse 12 years for both males (range 3–21 years) and females (range 3–16 years)]. On the whole, 1% of female respondents consistently reported having had sex and 86% consistently reported not having sex. Among male respondents, 5% consistently reported having sex and 67% consistently reported not having sex. Girls appeared more likely to under-report their sexual activity. Overall they had higher rates of HIV infection but reported less sexual activity. Additionally, none of the four pregnant girls reported that they had sex in the questionnaire.

Thirty-five per cent (95% CI: 33.9–36.2%) of the cohort reported having lost one or both parents, with 9.5% (95% CI: 8.8–10.2%) indicating that they had lost both, 19.9% (95% CI: 19.0–20.9%) reporting having lost their father only and 5.6% (95% CI: 5.0–6.1%) having lost their mother only. Orphaned participants were at increased risk of HIV [age–sex and clustering adjusted odds ratio 3.4 (95% CI: 1.7–6.5;  $P < 0.001$ )]. Majority of the HIV-positive participants reported having lost one or both parents (65%; 95% CI: 51–78%).

Based on the individual question items relating to self-esteem, it appears that young women generally have higher self-esteem than men ( $P < 0.05$  for all items – data not shown). Likewise, females were more likely to perceive that they mattered to people ( $P < 0.05$  for all items).

## Discussion

In this paper, we outline the design of a community randomised trial of a multi-component community-based adolescent HIV prevention intervention. The study is being conducted in rural Zimbabwe. We intend to evaluate the effectiveness of the intervention by measuring its impact on HIV incidence, HSV-2 incidence and prevalence and incidence of unintended pregnancy among a cohort of young people who were enrolled in Form 2 of secondary school in 2003. In addition we will measure impact on reported behaviour, self-efficacy and self-esteem and on attitudes to gender issues. Over the first 3 years of the study, the intervention has evolved from a primarily school-based intervention supported by an out-of-school youth programme and a programme for parents to using a broader community-based approach. The intervention has evolved in this way in response to the economic climate in Zimbabwe which has impacted severely on rural secondary school attendance. Importantly, while the site of intervention delivery has changed, the target population (in- and out-of-school youth), the delivery method (carefully selected, recruited and trained PPEs) and the theoretical basis for the intervention have remained constant, thus maintaining the integrity of the intervention (Hawe *et al.* 2004) and thereby its replicability and generalisability.

**Table 2** Baseline characteristics of respondents by intervention arm

Characteristic	Male				Female			
	Early ( <i>n</i> = 1777)		Deferred ( <i>n</i> = 1744)		Early ( <i>n</i> = 1604)		Deferred ( <i>n</i> = 1666)	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
<b>Age (years)</b>								
Mean age	15.4		15.5		14.8		15.0	
<15 years	370	20.8	310	17.8	574	35.8	530	31.8
15 years	593	33.4	574	32.9	676	42.1	697	41.8
16 years	518	29.2	544	31.2	289	18.0	339	20.4
17–18 years	275	15.5	285	16.3	65	4.1	95	5.7
19 years and over	21	1.2	31	1.8	0	0.0	5	0.3
<b>Province</b>								
Manicaland	604	34	577	33.1	549	34.2	580	34.8
Mashonaland East	462	26	401	23	418	26	386	23.2
Masvingo	711	40	766	44	637	39.7	700	42
<b>Religion</b>								
Catholic	454	26.0	487	28.3	394	24.8	419	25.4
Protestant	559	32.0	549	31.8	528	33.3	572	34.6
Apostolic/Pentecostal	561	32.2	468	27.2	578	36.4	539	32.6
Other	122	7.0	123	7.1	62	3.9	106	6.4
None	49	2.8	97	5.6	24	1.5	17	1.0
<b>Sex of head of household</b>								
Male	935	62.7	921	64.5	775	56.9	810	58.8
Female	556	37.3	508	35.6	586	43.1	568	41.2
<b>Orphanhood</b>								
Both parents alive	1148	64.8	1140	65.4	1044	65.3	1073	64.4
Mother died	104	5.9	94	5.4	84	5.3	96	5.8
Father died	356	20.1	333	19.1	321	20.1	342	20.5
Both parents dead	165	9.3	175	10.1	151	9.4	154	9.3
<b>Economic status</b>								
Overall SES score (quintiles)								
SES1 – Lowest	337	19.0	380	22.0	312	19.5	345	20.8
SES2	431	24.3	439	25.4	400	24.9	415	25.0
SES3	504	28.4	443	25.7	412	25.7	454	27.3
SES4	281	15.8	291	16.9	277	17.3	261	15.7
SES5 – Highest	224	12.6	174	10.1	203	12.7	187	11.3
<b>Sexual behaviour</b>								
Ever had sex								
No	1525	87.6	1509	88.6	1544	97.1	1601	97.2
Yes	216	12.4	195	11.4	47	2.9	47	2.8
Number of lifetime partners								
Only 1 partner	163	9.2	175	10.1	40	2.5	34	2.0
2 partners	31	1.8	33	1.9	4	0.3	3	0.2
3 or more partners	39	2.2	30	1.7	2	0.1	8	0.5
Age at 1st sex								
Under 15 years	189	11.2	176	10.6	32	2.1	44	2.7
15 or older	44	2.6	61	3.7	9	0.6	12	0.7
Ever used a condom								
No	141	8.0	139	8.0	60	3.7	58	3.5
Yes	126	7.1	135	7.8	11	0.7	14	0.8
Used a condom at last sex								
No	143	8.1	150	8.6	58	3.6	36	2.2
Yes	99	5.6	94	5.4	10	0.6	13	3.8

**Table 2** (Continued)

Characteristic	Male				Female			
	Early ( <i>n</i> = 1777)		Deferred ( <i>n</i> = 1744)		Early ( <i>n</i> = 1604)		Deferred ( <i>n</i> = 1666)	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
<b>Knowledge &amp; Attitudes</b>								
Condoms can prevent HIV								
No or don't know	1027	58.1	970	55.8	1219	76.2	1252	75.4
Yes	742	41.9	768	44.2	381	23.8	409	24.6
Condoms can prevent pregnancy								
No or don't know	969	54.7	908	52.2	1312	81.9	1346	81.0
Yes	803	45.3	831	47.8	290	18.1	316	19.0
<b>Self Esteem &amp; Mattering</b>								
I am a failure								
Agree	607	34.2	659	37.8	551	34.4	615	36.9
Neither agree or disagree	646	36.3	587	33.7	488	30.4	559	33.6
Disagree	524	29.5	498	28.6	565	35.2	492	29.5
I do lots of things well								
Disagree	177	10.0	220	12.6	145	9.0	172	10.3
Neither agree or disagree	337	19.9	365	20.9	204	12.7	263	15.8
Agree	1263	71.1	1159	66.5	1255	78.2	1231	73.9
People do not care what happens to me								
Agree	481	27.1	484	27.8	375	23.4	430	25.8
Neither agree or disagree	622	35.0	618	35.4	520	32.4	564	33.9
Disagree	674	37.9	642	36.8	709	44.2	672	40.3

**Table 3** Baseline survey results: prevalence of HIV and HSV-2 infection by gender and pregnancy in girls only

Number	Early			Deferred			Total		
	Male	Female	Total	Male	Female	Total	Male	Female	Total
	1777	1604	3381	1744	1666	3410	3521	3270	6791
HIV-positive	10 (0.6)	15 (0.9)	25 (0.7)	10 (0.6)	16 (1.0)	26 (0.8)	20 (0.6)	31 (1.0)	51 (0.8)
<i>n</i> (%) [95% CI]	[0.3–1.0]	[0.5–1.6]	[0.5–1.1]	[0.3–1.1]	[0.6–1.6]	[0.5–1.1]	[0.4–0.9]	[0.7–1.4]	[0.6–1.0]
HSV-2-positive	2 (0.1)	2 (0.1)	4 (0.1)	2 (0.1)	6 (0.4)	8 (0.2)	4 (0.1)	8 (0.2)	12 (0.2)
<i>n</i> (%) [95% CI]	[0.0–0.3]	[0.0–0.3]	[0.0–0.2]	[0.0–0.3]	[0.1–0.6]	[0.1–0.4]	[0.0–0.2]	[0.1–0.4]	[0.1–0.3]
Pregnant (%)	–	3 (0.18)	–	–	1 (0.06)	–	–	4 (0.12)	–
[95% CI]		[0.00–0.39]			[0.00–0.19]			[0.03–0.31]	

It is encouraging to note that our intervention fulfils many of the criteria outlined for potentially effective community-based interventions in the systematic reviews of HIV prevention among young people in developing countries (United Nations General Assembly Special Session on HIV/AIDS 2001). A cornerstone of the intervention is that its facilitators are very carefully selected, trained and supported. The facilitators who implement the intervention with parents go through a similarly rigorous selection process and undergo 2 weeks of residential training on the course materials and facilitation skills. Both

groups are supported by the project intervention team who provide ongoing mentoring. Although the initial recruitment and training of facilitators is time consuming (and accounts for the bulk of intervention delivery costs), it is a manageable and easily replicable activity that then forms the backbone of the intervention.

Baseline data suggest that there is good balance between trial arms in terms of both biological and behavioural markers at the start of the study. The levels of HIV, HSV-2, pregnancy and reported sexual behaviour in both arms were remarkably low before the intervention was



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implemented, suggesting that the intervention started before the majority of young people in our target population became sexually active. HSV-2 antibody was detected using DBS samples. In our pre-study evaluation of the assay, we found that sensitivity of DBS specimens was 91% compared with sera suggesting that HSV-2 seroprevalence may be slightly underestimated in our baseline survey. Specificity was high compared with sera at 99.3% (data not shown). While communities are well separated from each other, the high rates of mobility in Zimbabwe make it impossible to prevent the possibility of contamination between communities. While other HIV prevention programmes may be implemented within study communities, all prevention activities are coordinated by the District AIDS Action Committee (DAAC). Project staff work closely with the DAAC and in this way we hope to minimise the risk of differential implementation of other programmes by study arm. All non-study HIV prevention activities that take place in study communities are recorded.

As others have found when using quantitative survey methods to measure sexual behaviour in young people, there was considerable inconsistency in reporting (Plummer *et al.* 2006). While young women were more consistent in their reporting, they were also more likely to under-report the extent of their sexual experience; for example, none of the four women who were pregnant reported having had sexual intercourse. This finding underscores the importance of using externally valid outcomes measures when assessing the effectiveness of sexual behavioural interventions especially as reporting bias may be *differential* in the context of these interventions. Nonetheless, understanding behaviours and their determinants is important for designing and implementing appropriate and effective reproductive health interventions and finding methods to improve the validity of these data is critical.

After many years of very high prevalence of HIV, data suggest that the tide has turned and that rates of infection in Zimbabwe are now falling (UNAIDS 2005). Evidence from one study in eastern Zimbabwe indicates that this is likely the result of behaviour change (specifically reduction in casual partners and delay in sexual debut) (Gregson *et al.* 2006). Rates of HIV among our study participants were lower than we were anticipating based on our pilot study data (Cowan *et al.* 2002) and data from a large national representative survey of young people conducted in 2001 (National AIDS Council, Ministry of Health & Child Welfare & Zimbabwe National Family Planning Council 2002). This encouraging trend in HIV incidence may have implications for the power of this study to detect a difference in cumulative HIV incidence between arms, although it is likely that the study will still be adequately

powered to detect a difference in cumulative incidence of HIV when combined with incidence of HSV-2 and unintended pregnancy.

Data from this study suggest that HIV is not distributed uniformly across the population. Orphans had higher rates of HIV than non-orphans. Household structure also seemed to be important. A nested qualitative study has been conducted to explore this vulnerability in more depth and has been linked to expanded data collection as part of the interim survey data so that these causes of vulnerability can be quantified. These data will be important for more effectively targeting HIV prevention in this rapidly changing environment.

Few rigorous evaluations of HIV prevention in young people have been conducted in Africa. The MEMA kwa Vijana trial is evaluating the impact of a package of interventions on HIV, other STIs, pregnancy, reported sexual behaviours, reported attitudes towards sexual risk and knowledge of sexual and reproductive health among young people (Hayes *et al.* 2005; Ross *et al.* 2007). In South Africa, Jewkes *et al.* (2006) have evaluated the effect of the Stepping Stones intervention on HIV and HSV-2 incidence.

In summary, this is one of the few rigorous evaluations of a community-based HIV prevention intervention for young people to take place in southern Africa. The intervention being evaluated targets both young people and their parents and adults in the community, and aims to change behaviour at an individual level in addition to changing societal and cultural norms surrounding adolescent sexuality more broadly in order to reduce their environment of risk. The UNAIDS Interagency Taskforce on Youth has advised against further expansion of community-based HIV prevention in youth without more rigorous evaluation of the processes and outcomes of such programmes. We believe that this study will make an important contribution to the evidence base required by policy makers on the likely effectiveness and costs of such programmes.

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