Biological and Behavioural Impact of an Adolescent Sexual Health Intervention in Tanzania: A Community-Randomized Trial

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Biological and behavioural impact of an adolescent sexual health intervention in Tanzania: a community-randomized trial

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Objective: The impact of a multicomponent intervention programme on the sexual health of adolescents was assessed in rural Tanzania.

Design: A community-randomized trial.

Methods: Twenty communities were randomly allocated to receive either a specially designed programme of interventions (intervention group) or standard activities (comparison group). The intervention had four components: community activities; teacher-led, peer-assisted sexual health education in years 5–7 of primary school; training and supervision of health workers to provide 'youth-friendly' sexual health services; and peer condom social marketing. Impacts on HIV incidence, herpes simplex virus 2 (HSV2) and other sexual health outcomes were evaluated over approximately 3 years in 9645 adolescents recruited in late 1998 before entering years 5, 6 or 7 of primary school.

Results: The intervention had a significant impact on knowledge and reported attitudes, reported sexually transmitted infection symptoms, and several behavioural outcomes. Only five HIV seroconversions occurred in boys, whereas in girls the adjusted rate ratio (intervention versus comparison) was 0.75 [95% confidence interval (CI) 0.34, 1.66]. Overall HSV2 prevalences at follow-up were 11.9% in male and 21.1% in female participants, with adjusted prevalence ratios of 0.92 (CI 0.69, 1.22) and 1.05 (CI 0.83, 1.32), respectively. There was no consistent beneficial or adverse impact on other biological outcomes. The beneficial impact on knowledge and reported attitudes was confirmed by results of a school examination in a separate group of students in mid-2002.

Conclusion: The intervention substantially improved knowledge, reported attitudes and some reported sexual behaviours, especially in boys, but had no consistent impact on biological outcomes within the 3-year trial period.

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Keywords: adolescents, HIV, pregnancy prevention, sexually transmitted infections, Tanzania

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Introduction

Youth (15–24 years) in sub-Saharan Africa account for almost one quarter of those living with HIV worldwide [1–3], and several studies have demonstrated high rates of sexually transmitted infections (STI), pregnancy, and their complications [4,5]. In the absence of a vaccine or cure, preventive behavioural interventions have been advocated as the most effective HIV control strategy, especially among youth [1,6]. Even in the worst affected countries, prevalences of HIV and STI are very low in 15 year olds, but rise steeply thereafter [3,7,8]. Interventions focusing on adolescents might therefore have a substantial impact on the HIV epidemic, but evidence on the efficacy of behavioural interventions is contradictory [9–17]. Whereas most programme evaluations in developing countries have shown an improvement in knowledge, reported communication about sexual matters and reported attitudes, most showed no changes in reported sexual behaviours or changes that were demonstrated only in subgroups [16].

Few previous trials have measured biomedical endpoints, and this is the first to measure the impact on HIV as well as other STI and pregnancy. The inclusion of such outcomes is critically important because of known limitations in the validity of reported sexual behaviour, particularly in young people [18–23]; the potential for interventions to increase bias in reported behaviour towards more socially desirable behaviours; and because reductions in HIV, STI and pregnancy are usually the ultimate objectives for these interventions.

We conducted a community-randomized trial to evaluate the impact of the *MEMA kwa Vijana* ('Good things for young people') intervention on HIV incidence, the prevalence or incidence of other STI and pregnancy, and sexual health knowledge, attitudes and reported sexual behaviour.

Methods

The design of the trial [24] and of the intervention [25] are described in detail elsewhere.

Study population

The trial was conducted in 20 well-separated rural communities in Mwanza Region, Tanzania, (Fig. 1). The study communities were grouped into three risk strata using data from a previous population-based survey [5]. Restricted randomization was used to balance HIV and chlamydia prevalence between the two trial arms [24]. Ten communities (58 primary schools, 18 health facilities) received the intervention, the other 10 (63 primary schools, 21 health facilities) acting as comparison communities.

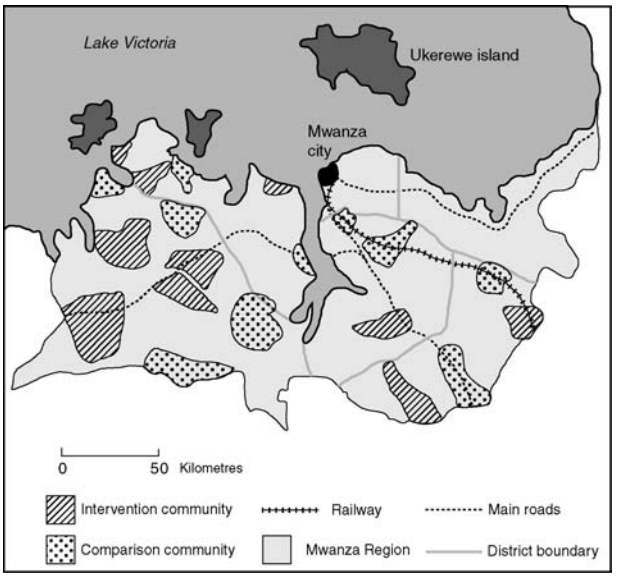

Fig. 1. Map of Mwanza Region, Tanzania, showing intervention and comparison communities.

Intervention design

To ensure sustainability and replicability, the intervention was delivered by government workers through existing structures and supervision systems, who were trained and supported by eight staff from the African Medical and Research Foundation. The main aims of the intervention were to provide young people with the knowledge and skills to enable them to delay sexual debut, reduce sexual risk-taking by sexually active youth (including reducing numbers of sexual partners and promoting condom use) and increase their appropriate use of sexual health services (e.g. STI treatment, family planning). It had four major components [25].

The most intensive component was a participatory, teacher-led, peer-assisted, in-school programme, comprising an average of 12 40-min sessions per year, held in normal school hours in years 5–7 of primary school. The programme built on the experience of adolescent reproductive health projects in Tanzania [26–28] and elsewhere [29–31], and aimed to include all 10 characteristics previously identified as associated with effective programmes [11].

Second, two to four health workers per government facility were trained for one week in the provision of youth-friendly sexual and reproductive health services, and were supervised quarterly. This was in addition to the provision of family planning services and improved case management of STI, which were available in all facilities in both intervention and comparison communities throughout the trial, with drugs and other supplies ensured.

The third component, community-based condom promotion and distribution by youth, was introduced

early in the second year of the trial in response to the results of process evaluation. Four to five youth per village were elected by their peers and trained in the social marketing of condoms.

Finally, community-wide activities included initial community mobilization followed by annual youth health weeks focused around interschool competitions and performances by local youth groups, twice-yearly youth health days at health facilities, and quarterly video shows linked to discussions that were open to all community members.

Surveys in the trial communities showed that sexual health activities in the comparison communities were very limited, and similar to non-*MEMA kwa Vijana* activities in the intervention communities.

Process evaluation

Extensive process evaluation of the intervention was conducted and fed back to the intervention team throughout the trial. This included questionnaires to trainees before and after all training courses; quarterly supervision visits to every intervention school and clinic; observation of in-class sessions, clubs and clinic sessions; checks on exercise books to see which sessions had been taught; annual feedback workshops with teachers; two externally conducted evaluation surveys with interviews and data collection from district to community levels [32]; regular feedback from the social science team who were studying the social and sexual norms of local young people (J. Wamoyi, D. Wight, M. Plummer, G. Mshana, D. Ross, Exchanging sex for gifts or money among young people in rural northern Tanzania, in preparation) [33]; and evaluations of programme components by international and national experts (D. Kirby, The *MEMA kwa Vijana* curriculum: a review, 2001, unpublished report; W. Lugoe. Evaluation of the teachers' training sessions for the *MEMA kwa Vijana* teacher-led component, 2001, unpublished report) [34].

Impact evaluation

The impact of the intervention was evaluated in a cohort of 9645 adolescents. All those aged 14 years or more (mean 15.7 years) in late 1998, who were in years 4–6 of all 121 government primary schools within the 20 trial communities (and about to enter years 5–7) were eligible for enrolment. An interim follow-up survey was conducted in 2000 and final follow-up between October 2001 and April 2002, approximately 3 years after recruitment. Strenuous attempts were made to locate cohort members. These included up to six household visits, and attempts to trace out-migrants using address information supplied by household members. Cohort members who were in year 7 when the intervention commenced (January 1999) could only receive one year of the in-school programme, those in year 6 2 years, and those in year 5 the full 3 years.

The predefined primary trial outcomes were HIV seroincidence during follow-up and HSV2 seroprevalence at final survey. Secondary outcomes were six further biological, five behavioural, one attitudinal and three knowledge outcomes (see Table 3). Each of the attitudinal and knowledge outcomes was based on the answers to three questions (Table 1). After registration, detailed identity checks and informed consent, and data on knowledge, attitudes and sexual behaviour were collected through a 15–25 min interview administered by a same-sex, 20–24-year-old research assistant. Laboratory specimens were then collected by trained technicians, and a clinician checked for clinical symptoms (male and female participants) and signs (male participants only) of sexually transmitted diseases and offered HIV counselling and testing.

Table 1. Questions used in the composite knowledge and attitudes scores.

Question	Correct answer
1. Knowledge on acquisition of HIV	
1.1 Can HIV be caught by sexual intercourse (making love) with someone?	Yes
1.2 Can you catch HIV by sharing a plate of food with an HIV-positive person?	No
1.3 Can a person who looks strong and healthy have HIV?	Yes
2. Knowledge on acquisition of sexually transmitted diseases	
2.1 Can pus or abnormal fluids coming out of the private parts be caught by sexual intercourse (making love) with someone?	Yes
2.2 Can schistosomiasis be caught by sexual intercourse (making love) with someone?	No
2.3 Can an ulcer on the private parts be caught by sexual intercourse (making love) with someone?	Yes
3. Knowledge on pregnancy prevention	
3.1 Is it possible for a girl to become pregnant the first time she makes love?	Yes
3.2 Is it possible for a person to prevent pregnancy by using a condom while having sexual intercourse (making love)?	Yes
3.3 Is it possible for a person to prevent pregnancy by not having sexual intercourse (making love) at all?	Yes
4. Sexual attitudes	
4.1 If a man or youth wants to have sexual intercourse (make love) with a girl, can she refuse to have sexual intercourse (make love) with him if he is older than her?	Yes
4.2 If a man or youth wants to have sexual intercourse (make love) with a girl, can she refuse to have sexual intercourse (make love) with him if he is her lover?	Yes
4.3 If a girl accepts a gift from a boy, must she agree to have sexual intercourse (make love) with him?	No

In addition to the cohort evaluation, a formal test of knowledge and attitudes was carried out in July 2002 among all 4707 pupils who were in year 7 in the intervention and comparison schools. These were pupils in the year below the youngest group in the study cohort, and so were not cohort members. All pupils taking the test in the intervention schools had received all 3 years of the in-school intervention, which continued to be implemented after the trial period in the 10 intervention communities only. Tests were administered under examination conditions, supervised by a teacher from a different school.

Laboratory methods

Only urine specimens were collected at the baseline survey, and tested for HIV-1 antibodies using a semiquantitative particle agglutination test (GACPAT; Central Public Health Laboratory, Colindale, London, UK) [35]. Reactive specimens were tested with Wellcozyme HIV1+2 GAC enzyme-linked immunosorbent assay (ELISA; Murex Biotech Ltd., Dartford, UK) [36], which provided the definitive result. Urine was also tested for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* by polymerase chain reaction (PCR; Amplicor, Roche Diagnostics, Branchburg, New Jersey, USA). Samples were pooled for PCR, with a pool size of five, with samples from reactive pools then tested individually [37]. Urine specimens from female participants were tested for pregnancy using an IPAS dipstick (Quickstick One Step HCG Pregnancy Test; IPAS/Pharmatech Inc., Denver, Colorado, USA).

At the final survey, serum and urine were collected from all participants and two self-administered vaginal swabs were collected by female subjects. Sera were tested for HIV-1 and HIV-2 using the Murex HIV Ag/Ab Combination ELISA (Murex Biotech). No specimen was reactive for HIV-2. Specimens reactive in the Murex HIV Ag/Ab ELISA were sent to the UK Central Public Health Laboratory for confirmation using a battery of antibody and antigen assays, including PCR when necessary. Full details of the HIV testing algorithm are given elsewhere [38]. Fifteen positive baseline HIV results (based on urine testing) were reclassified as negative when serum testing at the final survey showed these participants to be HIV negative.

Sera were tested for antibodies to HSV2 using a monoclonal enzyme immunoassay (HSV2 IgG; Kalon Biological Ltd., Ash Vale, Surrey, UK) [39]. Lifetime exposure to syphilis was examined using a *Treponema pallidum* particle agglutination (TPPA) test (Serodia TPPA; Fujirebio Inc., Tokyo, Japan). Urine from male subjects and vaginal swabs from female subjects were tested for *C. trachomatis* and *N. gonorrhoeae* using the same PCR methods as at baseline. Each vaginal swab was also tested for *Trichomonas vaginalis* using two independent sets of PCR primers [40–42]. A specimen was only defined as *T. vaginalis* positive if it was positive by both PCR assays. Urine specimens from female participants were tested for pregnancy using the same dipstick method as at baseline.

Statistical considerations

Based on previous survey data from the study communities [5], cumulative HIV sero-incidence over the 3 years of the trial was expected to be 1.6%. Assuming a between-community coefficient of variation for HIV incidence of 0.2 and 30% loss to follow-up, the sample size of 9645 would have given 75% power to detect a 50% reduction in HIV incidence in intervention communities if this had been the incidence rate within the trial.

Impact measures were based on ratios of prevalences, risks or rates in the intervention and comparison arms. For risks, the geometric mean risk for the 10 communities in each arm was computed, and the unadjusted risk ratio (RR) was calculated as the ratio of these geometric means. An approximate variance for the log(geometric mean) in each arm was obtained based on the residual mean square from a two-way analysis of variance (ANOVA) of community log-risk on stratum and study arm. A 95% confidence interval (CI) for the RR was calculated from this variance using a *t*-statistic with 14 degrees of freedom [43]. Analogous methods were used for prevalences and rates.

Logistic or Poisson regression were used to adjust for individual-level covariates [43]. The regression model included terms for risk stratum and predefined adjustment factors, but not study arm. For each community, the fitted model was used to compute the ratio of observed to expected events (O/E). The adjusted RR was obtained as the ratio of the geometric mean of these O/E estimates for the two study arms, and variances and CI were obtained from an ANOVA of log(O/E) on stratum and study arm.

For outcomes with zero cases in some communities, unadjusted and adjusted RR were obtained as the ratios of arithmetic mean risks and O/E, and approximate variances and CI were obtained from ANOVA of untransformed community risk or O/E on stratum and study arm.

Intervention impact was also analysed separately among those who were in years 4, 5 and 6 at baseline. The trend in adjusted RR with school year was assessed by regression of O/E on study arm and school year as a linear variable. A random effects model was used to allow for clustering by community. The statistical significance of the trend was obtained from the interaction between study arm and school year. A similar method was used to assess the interaction between study arm and marital status.

The analytical plan was approved by the trial's data and safety monitoring committee before the impact analysis commenced.

Ethical considerations

The trial protocol received ethical and research clearance from the Tanzanian National Medical Research Coordinating Committee and the Ethics Committee of the London School of Hygiene and Tropical Medicine. Primary school committees (which include parent representatives) gave written approval for schools to participate. Before each survey round, the study was explained to teachers and students, who were given a leaflet to take home to their parents that included notice of a meeting for parents and the right to inform the school if they did not want their child to take part. Signed informed consent was obtained from each student on the day of the survey round. At each round, cohort members could opt to receive their HIV test result after pretest and posttest counselling.

Results

Process evaluation

The results of the process evaluation are described elsewhere [25]. Briefly, these showed that the intervention had been delivered to a high standard and with high coverage. For example, supervision visits to the schools showed that most teachers taught the sessions well, most class peer-educators ably performed brief dramas that were used as discussion starters, and a qualitative study confirmed that the teaching was well received by most pupils and communities [44]. Over 80% of sessions had already been taught 2–3 months before the end of each school year during the trial [45]. A simulated patient study found that health workers in intervention facilities were more respectful and empathic to youth than in comparison facilities [46]. Over 57 500 condoms were sold by the youth condom promoters/distributors in the 2 years of this intervention component.

Baseline characteristics

The baseline characteristics of the intervention and comparison groups were generally similar (Table 2). Slight baseline imbalances in ethnic group and lifetime number of partners were adjusted for in all analyses of trial outcomes. There were substantial differences between male and female participants, so outcomes were analysed separately by sex.

Completeness of follow-up

This is shown in Fig. 2. In summary, 7040 (73%) of the 9645 eligible cohort members were seen at the final survey. Follow-up rates were similar in intervention (72%) and comparison (74%) communities, higher among male (77%) than female (69%) participants ($P < 0.001$), and higher in younger participants (age at recruitment: 14 years, 74%; 15 years, 73%; 16+ years, 71%; P value for trend < 0.001).

Impact on knowledge and reported attitudes

At the final survey, there were substantial and statistically significant differences in the proportions of both male and female participants who answered all three questions 'correctly' for each of the three knowledge outcomes, and for the reported attitude outcome (Table 3, Fig. 3). The adjusted RR for these four outcomes ranged from 1.28 to 1.77 for male and from 1.41 to 1.58 in female participants. These results were independently confirmed by the results of a school examination administered to year 7 students in July 2002 (Table 4).

Impact on reported sexual behaviours

The proportion of young men reporting sexual debut during follow-up was 60% in the intervention and 72% in the comparison communities (adjusted RR 0.84, CI 0.71, 1.01). There was little difference among young women (adjusted RR 1.03, CI 0.91, 1.16; Table 3, Fig. 3). Similarly, the proportion of male subjects reporting more than one sexual partner in the past year was significantly lower in the intervention (19%) than in the comparison communities (28%; adjusted RR 0.69, CI 0.49, 0.95), but no significant difference was seen in female participants (adjusted RR 1.04, CI 0.58, 1.89).

The proportions who reported initiating condom use during follow-up were substantially and significantly higher in intervention communities among both male and female participants. The proportions reporting condom use at last sex were higher in intervention communities in both sexes, but this was only significant in young men, and absolute levels of condom use at last sex remained relatively low (< 30%; Table 3).

Impact on clinical symptoms and signs

At the final survey, the proportion of participants reporting genital pus or abnormal genital discharge during the past year was substantially lower in intervention communities, both among male (adjusted RR 0.58, CI 0.41, 0.83) and female (adjusted RR 0.59, CI 0.43, 0.80) participants. Among those reporting STI symptoms, however, there was no significant difference in the proportion who reported having sought care at a local health facility for their most recent STI episode during the past year, in either sex (Table 3).

Impact on HIV, sexually transmitted infections and pregnancy

The two primary outcomes of the trial, HIV incidence and HSV2 prevalence, were based on biological tests. Only 45 participants (five boys and 40 girls) seroconverted to HIV during 23 730 person-years of follow-up. After adjustment, HIV incidence in female subjects was 25% lower in the intervention communities, but this

Table 2. Baseline characteristics of the cohort.

	Young men ($n=5103$)				Young women ($n=4116$)			
	Intervention $N=2607$		Comparison $N=2496$		Intervention $N=2083$		Comparison $N=2033$	
Demographic								
Age (years)								
14	875	34%	840	34%	1048	50%	980	48%
15	677	26%	638	26%	609	29%	631	31%
16	567	22%	514	21%	294	14%	327	16%
17	278	11%	246	10%	86	4%	72	4%
≥18	210	8%	258	10%	46	2%	23	1%
Sukuma tribe	1901	73%	1982	79%	1545	74%	1609	79%
Religion								
Christian	1952	75%	1868	75%	1795	86%	1717	85%
Muslim	130	5%	143	6%	88	4%	100	5%
Other/none	525	20%	485	19%	199	10%	214	11%
School year (1998)								
4	780	30%	697	28%	482	23%	498	25%
5	830	32%	842	34%	663	32%	598	29%
6	997	38%	957	38%	938	45%	937	46%
Knowledge								
HIV acquisition[a]	514	20%	424	17%	410	20%	290	14%
STD acquisition[a]	439	17%	468	19%	192	9%	175	9%
Pregnancy prevention[a]	581	22%	554	22%	459	22%	382	19%
Reported attitudes								
Attitudes to sex[a]	114	4%	103	4%	261	13%	238	12%
Reported sexual behaviour								
Lifetime partners								
0	1328	51%	1164	47%	1700	82%	1557	77%
1	372	14%	347	14%	204	10%	259	13%
2	274	11%	322	13%	127	6%	149	7%
3+	633	24%	662	27%	52	2%	68	3%
>1 Partner in past 12 months	360	14%	416	17%	95	5%	114	6%
Ever been pregnant	NA	–	NA	–	2	<1%	7	<1%
Condom use	$N=1279$		$N=1331$		$N=383$		$N=476$	
Ever used[b]	39	3%	60	5%	24	6%	33	7%
Used at last sex[b]	28	2%	39	3%	17	4%	24	5%
Biological								
HIV	1	0.04%	1	0.04%	4	0.19%	2	0.10%
Chlamydia	9	0.35%	7	0.28%	39	1.88%	26	1.28%
Gonorrhoea	2	0.08%	0	0.00%	5	0.24%	5	0.25%
Any STI	12	0.46%	8	0.32%	46	2.21%	31	1.53%
Pregnancy	NA	–	NA	–	19	0.92%	12	0.59%

STD, Sexually transmitted disease; STI, sexually transmitted infection.
[a]Proportion with maximum score (three 'correct/desired' answers).
[b]Among those who had ever had sex.

difference was not statistically significant (adjusted RR 0.75, CI 0.34, 1.66; Table 3). Overall, 12% of male and 21% of female participants were HSV2 seropositive at the final survey, but there was no difference by trial arm for either male (adjusted RR 0.92, CI 0.69, 1.22) or female (adjusted RR 1.05, CI 0.83, 1.32) participants (Table 3, Fig. 3).

Secondary biological outcomes included TPPA seroprevalence (syphilis), the prevalence of *C. trachomatis* and *N. gonorrhoeae*, and, in young women only, the prevalence of *T. vaginalis* and pregnancy, and the reported incidence of pregnancy during follow-up. There was no evidence of a protective effect of the intervention on any of these outcomes. In female participants, the prevalence of *N. gonorrhoeae* was higher in the intervention arm, and this difference was of borderline significance (Table 3). This difference was, however, only seen in those who were in year 6 at enrolment, who only had the potential to receive one year of in-school intervention (Table 5). A substantial proportion of young women were pregnant at the final survey (19%), and 46% reported having been pregnant for the first time during the 3-year follow-up period.

Trends by year of enrolment

In general, intervention/comparison differences in knowledge, reported attitudes and reported risk behaviours were greater among participants with more years of potential exposure to the in-school intervention, especially in young men (Table 5).

Impact by marital status

The impact of the intervention on pregnancy prevention knowledge was greater for those never married, among

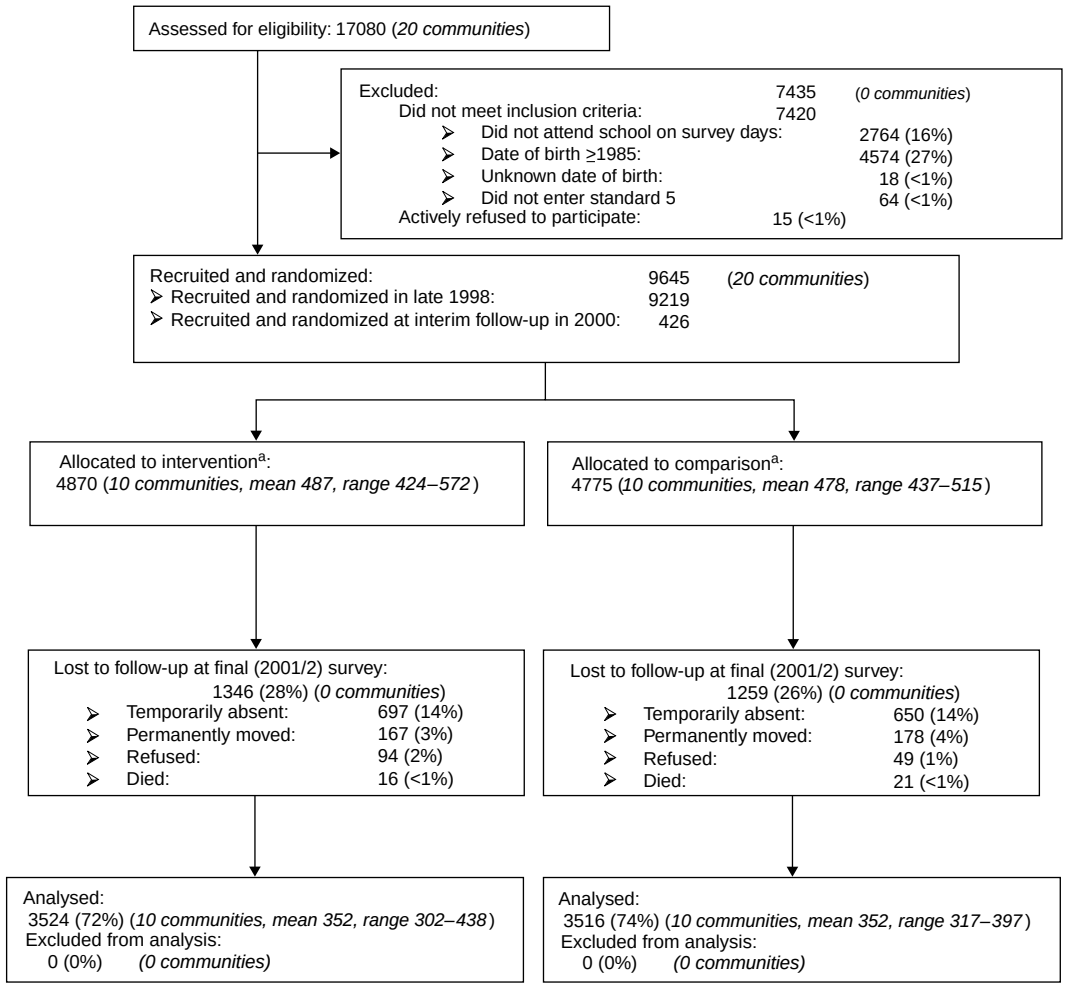

Fig. 2. Trial cohort and follow-up. [a]Although the interventions were available to all cohort members, there was no way of recording each individual's receipt of each of the components of the intervention.

both female and male participants ($P = 0.06$ and $P = 0.01$, respectively), and there was some evidence of a greater impact on STI knowledge among never-married women ($P = 0.07$). The effect on HIV incidence was substantially greater in never married women (adjusted RR 0.40, CI 0.10–1.59) than ever-married women (adjusted RR 0.98, CI 0.47–2.03), although this was not statistically significant. There was no consistent difference by marital status for any of the behavioural or other biological outcomes (results not shown).

Discussion

The study has confirmed that young people in this rural African population were at high risk of adolescent pregnancy and STI, with a low incidence of condom use and a high proportion of the cohort reporting sexual debut during 3 years of follow-up. There is, therefore, an urgent need for effective and affordable preventive interventions.

This trial has demonstrated the feasibility of large-scale implementation of an adolescent sexual health intervention using existing government staff and structures in sub-Saharan Africa. External evaluations of this multicomponent package of interventions showed that they were of high quality, well implemented and achieved high coverage. The average annual cost of the intervention was almost US$30 000 per trial community (approximately equivalent to an administrative ward, mean total population approximately 15 000) during the trial phase, including all start-up and capital costs, approximately equivalent to US$10 per adolescent per year within the primary target age range (12–19 years). Within a district-wide programme, first-year costs are projected to be US$22 000 per ward (US$7.30 per 12–19 year old), decreasing to US$3600 per ward (US$1.20 per 12–19 year old) in subsequent years [47].

Important limitations of the trial were that the interventions were deliberately constrained to be affordable and replicable on a large scale, and that the trial cohort included some young people who only received

Table 3. Impact of intervention on knowledge, reported attitudes, reported behaviours, and biological outcomes by sex.

Outcome	Young men			Young women		
	Frequency[a]			Frequency[a]		
	Intervention ($N=2076$) n (%)	Comparison ($N=2024$) n (%)	Adjusted RR[b] (CI)	Intervention ($N=1448$) n (%)	Comparison ($N=1492$) n (%)	Adjusted RR[b] (CI)
Knowledge (% with all three responses 'correct')						
HIV acquisition	1356 (65%)	908 (45%)	1.44 (1.25, 1.67)	832 (58%)	601 (40%)	1.41 (1.14, 1.75)
STD acquisition	1074 (52%)	807 (40%)	1.28 (1.07, 0.54)	522 (36%)	376 (25%)	1.41 (1.06, 1.88)
Pregnancy prevention	1746 (84%)	1018 (50%)	1.66 (1.55, 1.78)	1047 (72%)	688 (46%)	1.58 (1.26, 1.99)
Reported attitudes (% with all three responses 'correct')						
Attitudes to sex	454 (22%)	247 (12%)	1.77 (1.42, 2.22)	383 (27%)	283 (19%)	1.42 (1.11, 1.81)
Reported sexual behaviour (% with outcome)						
Sexual debut during follow-up[c]	638 (60%)	677 (72%)	0.84 (0.71, 1.01)	801 (68%)	763 (67%)	1.03 (0.91, 1.16)
More than 1 partner in past 12 months	394 (19%)	556 (28%)	0.69 (0.49, 0.95)	123 (9%)	116 (8%)	1.04 (0.58, 1.89)
First used condom during follow-up[d]	548 (39%)	427 (28%)	1.41 (1.15, 1.73)	387 (38%)	297 (28%)	1.30 (1.03, 1.63)
Used condom at last sex[e]	431 (29%)	326 (20%)	1.47 (1.12, 1.93)	284 (27%)	238 (22%)	1.12 (0.85, 1.48)
Went to health facility for most recent STI symptoms within past 12 months[f]	26/91 (29%)	52/150 (35%)	0.84 (0.50, 1.41)	33/93 (36%)	54/160 (34%)	1.02 (0.62, 1.70)
Primary biological outcomes						
HIV incidence (/1000 person-years)	3 (0.43)	2 (0.30)	NA	16 (3.18)	24 (4.73)	0.75 (0.34, 1.66)
HSV2 prevalence	234 (11.3%)	251 (12.5%)	0.92 (0.69, 1.22)	305 (21.3%)	309 (20.8%)	1.05 (0.83, 1.32)
Secondary biological outcomes						
Syphilis prevalence	28 (1.4%)	37 (1.8%)	0.78 (0.46, 1.30)	47 (3.3%)	54 (3.6%)	0.99 (0.67, 1.46)
Chlamydia prevalence	11 (0.5%)	11 (0.5%)	1.14 (0.53, 2.43)	71 (4.9%)	54 (3.6%)	1.37 (0.98, 1.91)
Gonorrhoea prevalence	8 (0.4%)	2 (0.1%)	NA	35 (2.4%)	18 (1.2%)	1.93 (1.01, 3.71)
Trichomonas prevalence[g]				413 (28.6%)	383 (25.8%)	1.13 (0.92, 1.37)
Pregnancy (test) prevalence[g]				277 (19.2%)	268 (18.0%)	1.09 (0.85, 1.40)
Reported pregnancy during follow-up[g,h]				489 (46.9%)	489 (45.5%)	1.03 (0.89, 1.20)

CI, 95% Confidence interval; HSV2, herpes simplex virus 2; NA, number of cases too small to justify comparison (<10 in each group); RR, rate ratio (prevalence, risk or rate ratio); STD, sexually transmitted disease; STI, sexually transmitted infection.

[a]Prevalence, risk or rate depending on outcome.

[b]Adjusted for: age group (≤17, 18, ≥19 years at final survey), stratum, tribe (Sukuma versus non-Sukuma), number of lifetime partners at baseline (0, 1, 2, ≥3).

[c]Among those who reported never having had sex at recruitment.

[d]Among those who reported having had sex at the final round, who had not reported ever using a condom at recruitment.

[e]Among those who reported having had sex at the final round.

[f]Among those reporting STI symptoms within the past 12 months.

[g]Young women only.

[h]Among those who reported never having been pregnant at recruitment.

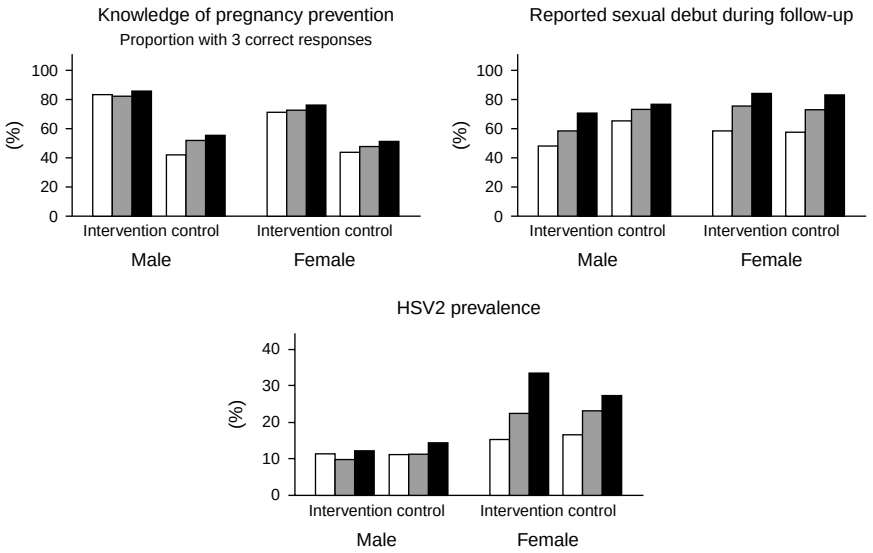

Fig. 3. Selected outcomes by age, intervention and sex. □ Age ≤17 years; ▒ age 18 years; ■ age ≥19 years.

one or 2 years of the main, in-school component, rather than the full 3 years. The trial design also meant that mass media and other national or region-wide approaches could not be included. HIV incidence was much lower than predicted based on a previous survey of 15–19 year olds in the same communities [5]. This may have been a result of the closed nature of the cohort, which excluded in-migrants, whereas those who were lost to follow-up may have been at higher risk than those followed up. Despite considerable efforts to trace cohort members who were absent during the follow-up rounds, 27% were lost to follow-up (Fig. 2). As follow-up rates were very similar in the intervention and comparison arms, it is unlikely that this would have biased the results.

The intervention led to substantial and statistically significant improvements in knowledge and reported sexual attitudes in both sexes. There was no evidence that the intervention increased sexual activity. On the contrary, young men reported delayed sexual debut and a reduction in the reported number of partners in the past year. Reported behavioural effects were stronger in male than female participants, possibly because young women were exposed to older male partners who had not benefited from the programme, or because young men understood the intervention messages better or were better able to act on them. For some outcomes, especially among male participants, the data suggested a dose–response effect with greater impact among those receiving 2 or 3 years of the in-school programme (Table 5). Previous studies have shown that youth interventions can improve knowledge and attitudes in the short-term (< 6 months) [16]; this study has shown a strong and sustained impact on knowledge and reported attitudes, especially in young men. Young people in the intervention communities were also less likely to report STI symptoms within the past year.

Table 4. Year 7 sexual health examination results (July 2002).

	Total	Pass (≥50%) *n* (%)	Distinction (≥80%) *n* (%)
Young men			
Intervention	1233	1083 (88%)	398 (32%)
Comparison	1162	680 (59%)	9 (<1%)
P value		<0.001	<0.001
Young women			
Intervention	1205	958 (80%)	237 (20%)
Comparison	1093	449 (41%)	4 (<1%)
P value		<0.001	<0.001

Despite these differences in knowledge, and reported attitudes and behaviours, there was no consistent impact on biological outcomes, including HIV incidence, the prevalence of other STI or pregnancy rates. There are several potential explanations for this discrepancy.

First, such interventions may only change knowledge and reported attitudes, but not actual risk taking, at least in the short term. Reported behaviour can be unreliable in young people [23], and may be subject to differential reporting bias in intervention and comparison arms. Therefore, observed differences in reported behaviour may have reflected a better knowledge of the promoted behaviours rather than changes in actual behaviour.

Second, it may be that the differences in reported sexual behaviour were valid, but the behavioural changes were not large enough to impact significantly on biological outcomes, at least within the follow-up period.

Third, young people may need longer exposure to such interventions. Overall, 42% of the cohort only had the

Table 5. Impact of intervention on knowledge, reported attitudes, reported behaviours, and biological outcomes, by school year at baseline.[a]

	Young men				Young women			
School year at baseline (1998)	Y4	Y5	Y6	P^b	Y4	Y5	Y6	P^b
HIV knowledge[c]	1.82	1.41	1.27	<0.01	1.56	1.51	1.31	0.16
STD knowledge[c]	1.39	1.37	1.10	0.01	1.27	1.77	1.33	0.62
Pregnancy prevention knowledge[c]	1.97	1.64	1.47	<0.01	2.01	1.70	1.37	<0.01
Attitudes to sex[c]	2.23	2.12	1.30	<0.01	1.60	1.78	1.20	0.08
Sexual debut during follow-up[d]	0.81	0.79	0.91	0.18	1.00	1.01	1.04	0.92
More than 1 partner in past 12 months	0.50	0.59	0.84	<0.01	1.01	1.61	0.82	0.55
First used condom during follow-up[e]	1.33	1.59	1.29	0.83	1.41	1.50	1.29	0.50
Used condom at last sex[f]	1.35	1.89	1.29	0.99	1.34	1.28	0.98	0.06
Went to health facility for most recent STI symptoms within past 12 months[g]	1.31	1.06	0.77	0.27	1.52	0.79	1.31	0.91
Primary biological outcomes								
HIV incidence (rate ratio)	NA	NA	NA	NA	0.60	1.04	0.94	0.55
HSV2 prevalence	0.85	0.92	1.04	0.10	0.98	1.12	1.08	0.33
Secondary biological outcomes								
Syphilis prevalence	0.27	1.30	0.89	0.12	0.79	1.24	0.95	0.70
Chlamydia prevalence	NA	NA	NA	NA	1.94	1.47	1.20	0.29
Gonorrhoea prevalence	NA	NA	NA	NA	0.99	0.80	4.90	0.05
Trichomonas prevalence[h]					1.18	1.17	1.06	0.40
Pregnancy (test) prevalence[h]					0.99	0.98	1.15	0.62
Reported pregnancy debut during follow-up[h,i]					1.51	0.92	1.05	0.14

HSV2, Herpes simplex virus 2; NA, number of cases too small to justify comparison (<10 in each group); STD, sexually transmitted disease; STI, sexually transmitted infection.
[a]Prevalence, risk or rate ratio depending on outcome, adjusted for: age group (≤17, 18, ≥19 years at final survey), stratum, tribe (Sukuma versus non-Sukuma), number of lifetime partners at baseline (0, 1, 2, ≥3).
[b]*P* value for linear trend of rate ratio with standard.
[c]Outcome is proportion with three 'correct/desired' responses.
[d]Among those who reported never having had sex at baseline.
[e]Among those who reported having had sex at the final round, who had not reported ever using a condom at baseline.
[f]Among those who reported having had sex at the final round.
[g]Among those reporting STI symptoms within the past 12 months.
[h]Young women only.
[i]Among those who reported never having been pregnant at baseline.

potential to receive one year of the in-school intervention, and a further 32% could only have received 2 years. The tendency for greater beneficial impact on knowledge and reported attitudes among those who had the potential to receive 3 years of in-school intervention lends some support to this hypothesis.

Fourth, young men have considerably more decision-making power within sexual partnerships than young women [33]. Our study cohort were on average several years older than the young women [48], and would not have benefited from the school-based intervention.

Fifth, those youth who leave school early or attend irregularly may be at disproportionately high risk, but would miss the in-school component of the intervention.

Finally, it may be that additional interventions are needed to make an impact within the short term. The interventions that were tested within this trial were all directly targeted to adolescents themselves. Cultural norms, however, such as gendered and age-related power relationships and marriage and fertility norms within the wider community, compromise the ability of adolescents to change their sexual behaviour [33]. Community-wide interventions aimed at changing societal norms may be particularly important [49].

Accurate knowledge and skills are a prerequisite for young people who want to change their behaviour to reduce their risk of HIV and other sexual health problems. This trial has shown that it is possible for a large-scale intervention, implemented through local government workers and supervision structures, substantially to improve knowledge, reported attitudes, and reported behaviours. The effects on these outcomes were at least as great as those recorded in previous studies in Africa [15–17], and there was no evidence of increased risk-taking behaviour. Furthermore, these effects were present after a relatively long follow-up period (approximately 3 years) after the interventions were initiated.

It has often been assumed when interpreting the results of previous studies that improvements in self-reported sexual behaviours can be used as a proxy for reductions in true behaviour and hence reductions in HIV, other STI or pregnancy [9–12,15–17]. The lack of any consistent effect on the biological outcomes measured in our trial,

despite substantial impacts on knowledge, reported attitudes and self-reported sexual behaviours, raises serious questions about the interpretation of previous studies, and argues strongly for the inclusion of biological outcomes in future programme evaluations.

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Appendix

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data management and analysis from 1997 to 2000, and played a leading role in the design and implementation of the initial survey and baseline and interim follow-up survey rounds. M.L. Plummer led the team that conducted detailed qualitative social research that contributed to the design of the interventions and the interpretation of the findings, and played a leading role in the design and implementation of the final follow-up survey round. B. Cleophas-Mazige was directly responsible for the design and implementation of the health services component of the intervention, and led the intervention team during 2002. A. Anemona was in charge of the data management and analysis from 2000 to 2002. M. Makokha was actively involved in the implementation of the intervention from 2001 onwards, and played a major role in the design of the in-school component in 2001 and 2002. R. Balira played a major role in the data management for the trial. D. Everett co-supervised the laboratory testing of the interim and final follow-up survey rounds. H. Weiss took the lead in the analysis of the trial results. D. Wight contributed to the design of the intervention and interpretation of the trial results, and supervised the qualitative social research. F. Mosha was in charge of the field data collection teams throughout the trial. J. Parry was responsible for external quality control on the HIV testing, and for resolving the HIV status of problem sera from the final survey. F. Terris-Prestholt was responsible for the costing of the intervention. A. Gavyole was AMREF's Programme Coordinator for the Lake Zone of Tanzania throughout the trial, and advised on the design and implementation of the intervention and the interpretation and policy implications of the findings. D.C. Mabey contributed to the design of the trial and supervised the laboratory procedures. H. Grosskurth contributed to the design of the trial and the intervention, and advised on other aspects of the study. R.J. Hayes took the lead on the design of the trial and the interpretation of the results, and contributed to all other aspects of the study. All co-authors contributed to the writing of the report.