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A cluster randomized-controlled trial to determine the effectiveness of Stepping Stones in preventing HIV infections and promoting safer sexual behaviour amongst youth in the rural Eastern Cape, South Africa: trial design, methods and baseline findings

R. Jewkes[1], M. Nduna[2], J. Levin[3], N. Jama[1], K. Dunkle[4], N. Khuzwayo[1], M. Koss[5], A. Puren[6], K. Wood[7] and N. Duvvury[8]

1 *Gender and Health Research Unit, Medical Research Council, Pretoria, South Africa*
2 *Population Council, Johannesburg, South Africa*
3 *Bio-statistics Unit, Medical Research Council, Pretoria, South Africa*
4 *Behavioral Sciences and Health Education, Emory University, Atlanta, GA, USA*
5 *College of Public Health, University of Arizona, Tucson, AZ, USA*
6 *National Institute for Communicable Disease, Sandringham, South Africa*
7 *Thomas Coram Research Unit, Institute of Education, London, UK*
8 *International Center for Research on Women, Washington, DC, USA*

Summary

OBJECTIVE To describe the study design, methods and baseline findings of a behavioural intervention trial aimed at reducing HIV incidence.

METHOD A cluster randomized-controlled trial (RCT) conducted in 70 villages in rural South Africa. A behavioural intervention, Stepping Stones, was implemented in 35 communities in two workshops of 20 men and 20 women in each community who met for 17 sessions (50 h) over a period of 3–12 weeks. Individuals in the control arm communities attended a single session of about 3 h on HIV and safer sex. Impact assessment was conducted through two questionnaire and serological surveys at 12-month intervals. The primary outcome was HIV incidence and secondary measures included changes in knowledge, attitude and sexual behaviours. Qualitative research was also undertaken with 10 men and 10 women from two sites receiving the intervention (one rural and one urban) and five men and five women from one village in the control arm. They were interviewed individually three times prior to the workshops and then 9–12 months later.

RESULTS A total of 2776 participants (1409 intervention and 1367 control) were enrolled at baseline and had an interview, and HIV sero-status was established. HIV baseline prevalence rates in women were 9.8% in the intervention arm and 12.8% in the control arm. In men the prevalence was 1.7% in the intervention arm and 2.1% in the control arm. Demographic and behavioural characteristics were similar in the two arms. In the intervention groups 59.9% of participants attended more than 75% of the sessions. In the control group 66.3% attended the control session.

CONCLUSION This is the third RCT to be conducted in sub-Saharan Africa evaluating a behavioural intervention using HIV incidence as a primary outcome. It is of particular interest as the intervention in question is used in many developing countries. There is good baseline comparability between the study arms and the process data on the workshops suggested that the interventions were feasible and adequately implemented.

keywords cluster randomized-controlled trial, South Africa, human immunodeficiency virus prevention, behavioural intervention evaluation

Introduction

Ten years after South Africa achieved democracy, HIV is arguably the most important problem facing the country and threatens to undermine many recent social achievements. Considerable efforts have been directed at harnessing the preventive potential of biotechnology in combating the epidemic, yet best estimates are that there

will be no HIV vaccine for at least another 10 years (Esparza 2004) and no marketable vaginal microbicide for at least 5 years (Rosenberg 2004). Sexual behaviour change is the only current option for HIV prevention and it is likely to remain the central plank of prevention strategies in the decades to come. Whilst there is evidence that voluntary counselling and testing may have an important impact on sexual behaviour (The Voluntary HIV-1 Counselling and Testing Efficacy Study Group 2000), it is essential that other approaches to HIV prevention are evaluated. Developing an evidence base for HIV behavioural intervention in sub-Saharan Africa and other regions severely affected by the epidemic should be a very high priority.

In comparison with the vast investment in efforts to develop more complex biotechnology to combat HIV there has been relatively little research and development on behavioural interventions, particularly those designed for sub-Saharan Africa. Only one randomized-controlled trial has sought to evaluate the effectiveness of a behavioural change intervention, alone or in combination with a sexually transmitted disease (STD) management, in a general population in sub-Saharan African (Kamali *et al.* 2003). This study used a range of approaches including videos, small group meetings, one-to-one discussions, dramas and information leaflets. The intervention had no impact on HIV incidence or the incidence of sexually transmitted infections apart from herpes simplex type 2 and had no impact on measures of reported sexual behaviour. A large school-based behavioural intervention in Mwanza, Tanzania was evaluated and shown not to be effective (DFID Briefing Note 2 2004). There have been several less rigorous evaluations of interventions in schools in Africa. A recent review demonstrated some impact on knowledge and attitude but very little evidence of impact on sexual behaviours (Gallant & Maticka-Tyndale 2004).

There is clearly a need to enhance empirically based behavioural HIV prevention in sub-Saharan Africa. Available evidence suggests that many approaches may not be very effective. Without evidence from rigorously conducted evaluations, it will not be possible to develop and improve the scientific basis of behavioural interventions in Africa. This study describes the trial design, methods, intervention activities and baseline findings for HIV prevalence and sexual behaviour by study arm of an HIV behavioural intervention evaluation that is being conducted in the rural Eastern Cape province of South Africa.

Aims and objectives

The aim was to determine the effectiveness of the Stepping Stones behavioural intervention in preventing HIV infections among youth in the rural Eastern Cape Province of South Africa. The specific objectives were to compare the impact of Stepping Stones intervention with a short HIV focused intervention (the control) on intermediate- and long-term outcome indicators included HIV incidence, sexual behaviour and aspects of gender dynamics in relationships 2 years after the baseline.

Methods

Study area and population

The study area was in the Eastern Cape Province of South Africa within a radius of about 1.5 h drive of Umtata. The local economy of the region is traditionally based on subsistence farming, but increasingly households are primarily supported by remittances from family members living elsewhere, social grants and pensions. The province has the highest unemployment rate in South Africa at 48.5% (Statistics South Africa 2004). There are two sizable towns, Butterworth and Umtata (250 000 population), seven or eight smaller towns and many villages in this area. It includes seven health districts and rural councils. The area is served by 12 hospitals and most villages have a clinic.

Principal design of the trial

Clusters. Villages or residential areas of towns formed the basic unit of randomization. Eligible villages were within the study area, located approximately 10 km from the nearest study village or town (to minimize contamination of study arms), contained a senior or junior secondary school and had a community* that was willing to participate. Seventy villages were identified and then grouped into seven strata according to common features. Six were residential areas of towns and these formed one stratum, the other villages were grouped into six strata according to geographical area, which was defined by proximity to particular parts of the main roads, or location in their immediate hinterland. Each village was numbered and listed, and the study arm allocation was determined using computer-generated randomization with equal numbers of villages allocated to each arm in each stratum.

Participants. Within each village we recruited approximately 20 men and 20 women for the study. The entry criteria were that the youth should be aged

* We use the term 'community' refer to the people living within a particular traditional administrative or local municipal area.

16–23 years, normally resident in the village where they were schooling (i.e. not a migrant scholar) and mature enough to understand the study and the consent process. Most of the youth were recruited from schools. This was strictly a study of volunteers and the processes of recruitment meant that it was impossible to quantify the potential pool from which participants were drawn and to assess biases in this process. More information on participant selection and possible implications of this is provided below.

Sample size. The sample size was calculated using the method of Hayes and Bennett (1999). This method requires an estimate of k, the between-cluster coefficient of variation of the response variable. Such estimates are difficult to obtain. In the Mwanza study referred by Hayes and Bennett (1999) they used $k = 0.25$, and subsequent studies have used a similar value (Kamali *et al.* 2003); however, we used $k = 0.35$ to reflect possibly higher levels of clustering of HIV infection, and this leads to a more conservative sample size calculation. The assumptions made for the calculation were that the 2-year cumulative HIV incidence rate in the control arm would be 12% and the 2-year incidence results would be obtained for at least 14 females and 14 males per cluster (thus allowing up to 30% of females and 30% of males to be either lost to follow up or HIV-positive at baseline). A sample size of 35 clusters would then give more than 80% power to detect as statistically significant at the 5% level a 50% reduction in HIV incidence, assuming that the data for each gender will be analysed separately.

Design of main intervention

The main intervention being evaluated is called Stepping Stones. The first edition of Stepping Stones was developed by Alice Welbourn from work in Uganda and published by Strategies for Hope (Welbourn 1995). In 1998, this edition was adapted for South Africa by the principal investigator (Jewkes & Cornwall 1998). In 2002, a second South African edition was produced (Jewkes *et al.* 2002), drawing on 4 years of experience of Nduna and Jama in using the intervention. The 2002 version was used in the study.

Stepping Stones is an approach to HIV prevention that aims to improve sexual health through building stronger, more gender-equitable relationships with better communication between partners. It does this through building knowledge of sexual health and providing opportunity for facilitated self-reflection on behavioural motivations. It is provided in single sex peer groups, as this format gives the best opportunity for frank discussion and a supportive environment for exploring behaviour change. Male and female groups are paired and conducted in parallel sessions. Stepping Stones uses adult education methods, including role play, spider diagrams and similar exercises (Pretty *et al.* 1995; Mukherjee 2002). A trained, gender-matched facilitator implements the intervention, as described in the manual.

The manual has 13 core sessions and three meetings where the peer groups come together and present exercises that they have been working on to promote dialogue. At the end of the programme there is a community meeting and a special request is presented from each peer group to the broader community. Each session lasts about 3 h, and in our study as supported by refreshments. The issues covered in the 13 sessions include reflecting on love, sexual health joys and problems, body mapping, menstruation, contraception and conception (including infertility), sexual problems, unwanted pregnancy, HIV, STDs, safer sex, gender-based violence, motivations for sexual behaviour, and dealing with grief and loss. Three sessions build assertive communication skills.

Stepping Stones is based on several theories of behaviour change (Welbourn 1996). Fundamentally it follows adult education theory, which tells us that people learn better if the learning is based from their own starting point. According to this theoretical perspective, it is necessary to draw out what people know before building new knowledge or correcting ideas. It is also based on empirical findings that people learn better experientially, hence teaching should draw on people's life experiences and provide them with opportunities to try new ideas and skills in the context of their lives. For this reason the sessions of Stepping Stones are ideally delivered over several weeks, allowing participants ample opportunity to test new skills. The approach also draws on Freirian models of critical reflection and the use of theatre (Boal 1992), as well as techniques from assertiveness training (Willis & Daisley 1990).

Eleven facilitators delivered this intervention. They were young men and women who were slightly older than the study participants. They had a post-school qualification and were selected in part for their demonstration of open-mindedness and gender sensitivity. They were trained for 3 weeks. They first went through the course as participants and then received a week of didactic presentation on multiple aspects of sexual health. Finally, they used the manual to facilitate practice groups involving their peers for which they were observed and given feedback. Before the main study started they had each facilitated two groups. To prevent drift away from standardization in delivery of the intervention, 1 day of in-service training was provided per month for the facilitators throughout the

active phase of the study. Staff kept attendance registers and encouraged attendance by sending messages to people who were not attending but did not make exceptional efforts to secure attendance or offer repeat sessions as we sought to keep as close to what might be standard practice in delivery of community-based interventions as possible.

Intervention in the comparison arm

The second intervention was a single 2–3 h session with exercises about HIV and safer sex practices drawn from the Stepping Stones curriculum. A same sex facilitator also delivered the control intervention to single sex peer groups. The facilitators were trained for 4 days in their intervention and ran one practice group before the main study started. The four facilitators for this intervention interacted with the other facilitators at monthly meetings but did not have the full Stepping Stones training nor did they attend the additional in-service training hours.

Community mobilization, access and consent processes

Successful implementation of the study rested significantly on the success of community mobilization, the process of gaining community support for the study. We initially identified all possible villages by studying a map and driving in the areas. In each potential location, we identified the most important local figures and went to visit them to explain the study. We started with the Chief (or his representative) of the area or Ward Counsellor, and would also visit the principal of the school and nurses in the clinic. In most villages there was a monthly community meeting called by the Chief (or his representative). Typically the staff member attended and made a brief presentation and then took questions from the community. Many of the people attending this were parents of potential participants.

After the community meeting project staff went to the school to raise interest in the study and invite possible participants to a meeting. Here, they explained the study to a group of about 60 young men and women in the targeted age group. Names were taken and the group was asked to debate amongst themselves and decide on 40 people who were most likely to be able to participate in the study, for example, those who lived a little closer to the school and would be more likely to be able to attend the intervention. The presenter would then read aloud the study's consent form to the 40. The form explained the procedures that would occur in some detail, and the presenter then provided an opportunity to ask questions. We observed that our target age group was more comfortable asking questions in a group than in one-to-one meetings. Therefore, group meetings were used to explain what study participation entailed and, on the day of interviews, to provide pre-HIV test counselling. After the group presentation we asked for confirmation that there was still general interest in participation, and requested that the young people talk with their families before committing themselves. Each potential participant received a Xhosa-language leaflet describing the study using terms understandable to a lay audience. This also included the telephone numbers of staff and toll-free helplines. Those who decided to participate were asked to report at an assigned time anywhere from 2 to 7 days later. At that time, formal informed consent was provided and signed and study recruitment finalized. Ethical approval for the study was given by the University of Pretoria Ethics Committee.

The study had a very active community advisory board with representatives from the Department of Health, the Department of Education, Mzimvubu Municipality (the district of one of the clusters), local traditional leaders, the National Association for People with HIV/AIDS, the University of Transkei (UNITRA) and young people approximately the same age as study participants. The board initially met fortnightly to give members greater familiarity with the study and thereafter met bimonthly. In addition, informational meetings were held for local stakeholders at the start of the study including the Department of Health's District Mangers for HIV/AIDS services, and the Department of Health and Department of Education of Eastern Cape Province. After the first year of the project, a series of meetings were organized to which all traditional leaders were invited. Some of the pooled findings on sexual behaviour and characteristics of the people who had HIV from the baseline study were presented at these meetings.

Design of the impact evaluation

The primary outcome measure was HIV incidence, which was determined by carrying out blood tests at baseline, after 1 year and after 2 years. At each point HIV status was assessed using two rapid tests of a venous blood sample using the World Health Organization's (WHO) testing algorithm (WHO 2004). The Determine (Abbott Diagnostics, Johannesburg, South Africa) test was used as a screening test. It has a sensitivity of 99.6–100%, and a specificity of 98–99.5% (Dinat *et al.* 2000; Sauer *et al.* 2000; Stakteas *et al.* 2002; Ziyambi *et al.* 2002). Specimens that tested positive with Determine were retested with Uni-gold™ (Trinity Biotech, Dublin, Ireland), which has a sensitivity of 97–99.5% and specificity of 100% (Stakteas *et al.* 2002; Ziyambi *et al.* 2002). An enzyme-

linked immunosorbent assay (ELISA) was performed to clarify any indeterminate results.

The HIV pre-test counselling was provided by a trained nurse counsellor to groups of 8–10 people after they had enrolled for the study, signed consent for the interview and completed the baseline questionnaire. Counselling typically involved 5 min of information provided by the nurse followed by 20 min of questions. Afterwards participants signed consent for the HIV test (they could raise issues privately then if they so wanted) and were asked to choose whether they wanted to receive notification of their results (cf. Temmerman *et al.* 1995). If so, test results were given with post-test counselling some weeks later by a study nurse. Participants could change their mind and get their results at any stage of their participation. Those collecting positive results were given their CD4 counts and screened for medical problems. They were also referred to local health services and HIV support groups according to a referral algorithm that took into account their clinical condition and the available community services as well as locally accepted standards of care. The study nurses supported participants with social problems and HIV-related problems throughout the course of the study, referring to social workers, or health facilities, as appropriate. Although the rapid HIV tests could in theory have been conducted in the field and participants given their results at the same time, we did not as we could not mask the giving of HIV-positive results in that setting.

The impact of the intervention on behaviour, attitude and beliefs was assessed with a structured questionnaire administered by an interviewer in face-to-face interviews. Interviewers were sex-matched to participants and were roughly the same age. The timing of the intervention and data collection points is illustrated in Figure 1. The start of fieldwork and the intervention in each village was staggered over 12 months. Data were collected prior to the intervention (baseline), after 6–8 months, after 1 year and after 2 years. We had no additional contact with participants in the period between interviews. All participants were paid an incentive of R20 (approximately £2) for each interview.

The questionnaire was developed to measure knowledge, attitudes and behaviours that Stepping Stones was expected to change and some potential confounders of these intermediate outcomes and the final outcomes. The draft of the structured questionnaire consisted almost entirely of questions that had been previously used in surveys in South Africa or were components of standard instruments. Information was collected on background social and demographic factors (age, education, current schooling, earnings in last year or ever, socio-economic status), perceptions of the community and experience of trauma in childhood. The complete list of scales and their properties is presented in Table 1.

Socio-economic status was measured on a scale derived for the study after extensive discussion of the problems with use of standard measures (such as housing quality indices) in the study area. The scale captured household goods ownership (TV, radio and car), frequency of hunger, frequency of having meat and perceived difficulty accessing a fairly small (but not trivial) sum of money for a medical emergency (R100 which is £9). Childhood trauma was measured on a modified version of the short form of the Childhood Trauma Questionnaire (Bernstein *et al.* 1994). The measure covered five dimensions of trauma: emotional neglect, emotional abuse, physical neglect/hardship, physical abuse and sexual abuse.

We collected detailed information on the current or most recent main partnership. This included when it started (and ended, if not ongoing), social and demographic characteristics of the partner (age, education, schooling, employment status), whether the relationship involved sex and when first sex took place. We asked if people knew someone who had HIV/AIDS, had had a sexual partner who developed HIV/AIDS or had a partner who had had a partner with HIV/AIDS.

Women were asked about experiences of emotional abuse, physical violence and sexual violence from any male relationship partner using a slightly adapted version of the WHO violence against women instrument (WHO 2000), which was designed for use in developing countries. Men were asked parallel questions about perpetration of violence against female partners. Questions contained specific, objective descriptions of violent behaviour by men and asked about perceived frequency. Women were asked additional questions about experience of sexual violence perpetrated by a non-partner. Men were asked about perpetration of sexual violence against women who were not girlfriends, and also about their experiences of sexual victimization. The scale measuring relationship control was based on Pulerwitz *et al.* (2000) and Dunkle *et al.* (2004a).

We asked about last sex, including who this was with and whether a condom was used. We assessed condom use in the past year by asking separately about the frequency of condom use with main partners and casual partners; further questions covered barriers to condom use. We asked about numbers of primary and non-primary partners and history of transactional sex. Non-primary partners were defined as *makhwapheni* (concurrent with main partners) and people with whom an interviewee had sex only once. According to Dunkle *et al.* (2004b), transactional sex was defined as sex with a partner which was primarily motivated by material gain, defined as provision

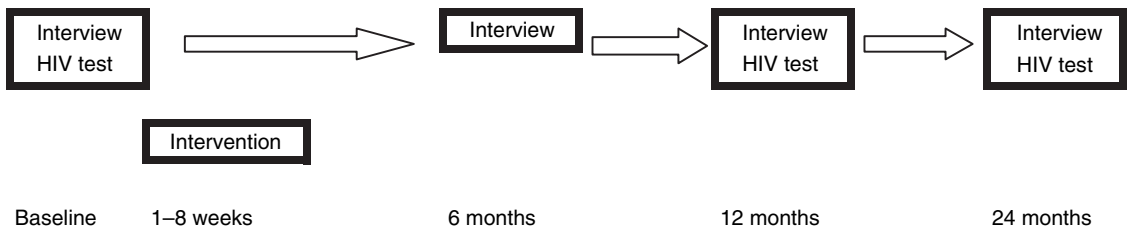

Figure 1 Timeline for research and intervention for each cluster (start of each is staggered).

of food, cosmetics, clothes, transportation, items for children or family, school fees, somewhere to sleep, or cash. Men were asked about experiences giving and receiving these items for sex. Women were asked about dry sex practices. Men were asked about circumcision, sex with other men, and experiences getting into fights and sustaining injuries in the previous 3 months.

Alcohol use and dependence was assessed using the Alcohol Use Disorders Identification Test (AUDIT) scale (Saunders *et al.* 1993). Male participants were asked if they had ever used marijuana, mandrax, injectable drugs, substances that were sniffed or other substances. We asked women if their male partners used drugs as we found almost no drug use amongst women in the pilot study. Depression and suicidal thoughts were measured with the Centre for Epidemiologic Studies Depression Scale (CES-D) and assessment of suicidal thoughts was limited to the past month. The CES-D scale cut-off score of 16 differentiates the depressed from those with symptoms suggestive of depression, a score over 21 is regarded as indicating a high probability of clinical depression. The scale has a high sensitivity and specificity in otherwise well individuals (Weissman *et al.* 1977). In addition, we used a 3-item scale of psychological distress framed around indigenous idiom.

The draft questionnaire was refined through extended discussion and revision of the items by the nine members of the research team who were young people of the approximate age of study participants and who resided in or near the research sites. The team began with an initial draft Xhosa translation of the questionnaire and then debated the meaning of each question and refined the translation until they were satisfied with it. A formal pre-test with Stepping Stones participants was also undertaken. All work in the study with participants was performed in Xhosa, which is the only primary language in the study area.

Data handling and quality control

All items were pre-coded. All questionnaires were edited in the field and then re-edited in the office prior to data entry. Data were double entered and verified. The performance of the laboratory in HIV testing was checked at intervals using panels. All questionnaire errors were shown to the fieldworker involved and corrected immediately if the informant was still available. The interviewers attended biweekly meetings discussing questionnaire errors detected at editing. All study participants were given photo identity cards to enable positive identification before participation in the study components after baseline interviews. At the annual interviews the dates of birth participants had given in previous rounds were compared and in cases of discrepancy, the actual dates of birth established. This revealed that a small group of participants had given an inaccurate date of birth at baseline in order to be included in the study, which led to some participants being older and some younger than the target age range of 16–23 years. At the baseline interview a few participants did not give blood for HIV testing due to a failure of research team logistics. Thirty-three of them were interviewed and tested HIV-negative at 12 months follow up. These have been included in the baseline sample with the inference that they would have been HIV-negative at baseline had they given a blood sample.

Data analysis

The internal consistency of scales which were to be used with factor weighting was assessed by examining the Cronbach's-α and items were removed if necessary to maximize the α for the scale. Scales were derived from the items by carrying out a principal component analysis and saving the first principal component – this leads to using as the scale the linear combination of items that maximizes the variability between respondents. Scales measuring knowledge and those measuring experience of acts, which were to be used as outcome variables, were not handled in this way. Their response categories were summed. No scale had more than 1% missing data and so no efforts were made to replace missing data.

We compared socio-demographic and outcome variables between the two study arms at baseline using procedures

Table 1 Properties of scales used in the structured questionnaire

Scale	Typical item	Response categories	Number of items	Women's Cronbach's-α	Men's Cronbach's-α	Method of scaling
Socio-economic status	Would you say people in your home often, sometimes, seldom or never go without food?	a	6	0.55	0.60	Factor
Community cohesiveness	In this area do most people trust each other in matters of lending and borrowing?	b	5	0.67	0.64	Factor
Childhood trauma (excluding sex abuse)	I was punished at home by being beaten	c	14	0.73	0.72	Factor
Childhood trauma (above scale including sex abuse)	I had sex with someone because I was threatened, frightened or forced	c	17	0.74	0.72	Factor
Knowledge of sexual and reproductive health	The most common cause of infertility is a sexually transmitted disease	d	11			Sum
Knowledge of HIV	People can protect themselves from HIV by choosing their partners well	d	9			Sum
Condom attitudes	If a man and woman trust each other they do not need to use a condom	e	8	0.72	0.65	Factor
Anticipated responses to discovering HIV	I would keep it secret from my main partner	b	10 men; 11 women	0.67	0.69	Factor
Peer pressure resistance	I have to have sex because all my friends are doing it	e	3 men; 4 women	0.80	0.72	Factor
Relationship control scale	When (NAME) wants me to sleep over he expects me to agree	e	10 (women only)	0.73		Factor
Attitudes towards gender relations	A woman should listen to her husband	e	6 (women only)	0.62		Factor
Gender attitudes and partner control	Combined previous two scales with variables adjusted to maximize internal consistency	e	13 (men only)		0.69	Factor
Communication skills and openness	When I disagree with (NAME) I say what I feel	e	6	0.68	0.68	Factor
Communication content	Do you and (NAME) ever discuss together methods to protect each other from HIV?	Yes/no	4	0.60	0.52	Factor
Relationship conflict	How often do you argue about money?	a	6	0.75	0.72	Factor
Intimate partner violence	Before the past 12 months did you ever force (NAME) or any other girlfriend to have sex with you when she did not want to?	f	28			Sum
Alcohol use and abuse (AUDIT scale)	How often do you have six or more drinks on one occasion?					Sum
Depression (CES-D)	During the past week I felt fearful		20			Sum
Indigenous psychological distress scale	During the past week I have been thinking too much		3			Sum

Response categories – a: often, sometimes, seldom, never; b: definitely yes, probably yes, probably no, definitely no; c: never, sometimes, often, very often; d: true, probably true, probably false, false; e: strongly agree, agree, disagree, strongly disagree; f: never, once, few, many.

that took into account the clustering of participants in the study design. For categorical variables the Pearson chi-square statistic for two-way tables was adjusted into an *F*-statistic with non-integer degrees of freedom using a second-order correction due to Rao and Scott (1981, 1984). For continuous variables a *t*-test was carried out by finding the ratio of the difference of the subgroup mean values to the standard error of this difference with the standard error being estimated using standard methods for variances in complex surveys. All analyses were carried out

using the statistical package STATA release 8 (Statacorp 2003).

Qualitative research

The evaluation also included a nested qualitative study. Data were collected to contextualize the quantitatively assessed effects of Stepping Stones on participants' lives, with pre-intervention and post-intervention phases focusing on a small group of young people in both study arms. In addition, a broad group of stakeholders were interviewed on community perceptions of the intervention and the study.

Results

Village recruitment

Three randomized villages had to be replaced. In one case this was because the school did not have enough young people in the age group to permit recruitment, in a second it was because we discovered that it was really part of another village that we had already performed fieldwork in and in a third place it was because hostility to the study from local clinic nurses prevented fieldwork. In each case the next accessible village in the area of that stratum was chosen as a replacement. No areas declined to participate because they had a preference for a different study arm.

Comparison of the baseline results between arms

Table 1 shows Cronbach's-α for the scales used in the study. Table 2 gives the social and demographic characteristics of participants recruited in each arm. These were very similar between men and women and between study arms. About 1320 (98.8%) men and 1371 (97.6%) women were in the intended age group of 16–23 years. Eleven (0.8%) men and 32 (2.3%) women were aged 15 years, and five (0.4%) men and two (0.1%) women were aged 24–26 years. Whilst no differences between the treatment arms were significant at the 5% level, there may have been differences in education in both men and women between the two arms (P-value: <0.1). The study population was generally poor. About a third of women (35.5% intervention arm and 32.7% control arm) and men (28.2% intervention arm and 31.7% control arm) said people at home often or sometimes went without food. The proportion saying that it would be very or quite difficult for their household to find R100 (£9) for a medical emergency was even higher. About two-thirds of women (62.1% intervention arm and 62.9% control arm) and men (63.7% intervention arm and 59.6% control arm) said this would be difficult. Study participants had commonly spent much of their childhood without one or both parents. Women were less likely than men to have lived with their fathers. Over two-thirds of women (70.4% intervention arm and 68.9% control arm), and somewhat fewer men (53.6% intervention arm and 57.2% control arm) had either never, or only sometimes, lived with their father during their childhood. Women were also less likely to have lived with their mothers. Over a third of women (40.3% intervention arm and 44.4% control arm), and a fifth of men (19.8% intervention arm and 22.7% control arm) had either never, or only sometimes, lived with their mother during their childhood.

Table 3 shows a comparison of HIV serostatus and sexual risk taking behaviours between the two study arms. Sexual risk taking behaviours were highly prevalent in the study population (Table 3). Consistent condom use was low, a substantial proportion of the sample reported casual partners and multiple partners, intimate partner violence was highly prevalent, and transactional sex was commonly reported. All of these behaviours are targeted by the Stepping Stones intervention. There were no significant differences between the treatment arms for any variable; all analyses were carried out separately for males and females.

Operational observations

Facilitators submitted detailed attendance registers for 52 of 70 groups having the Stepping Stones workshops, including 27 of 35 male groups and 25 of 35 female groups. Attendance registers were available for 64 of 70 groups having the short intervention, 32 of 35 male and 32 of 35 female groups. These show that 16.8% (90 of 534) of men and 12.5% (63 of 504) of women did not participate in any of the Stepping Stones sessions. About 31.7% (189 of 597) of men and 35.7% (228 of 639) of women did not attend the short intervention. About 60.7% (324 of 534) of men and 59.1% (298 of 504) of women attended 75% or more of the Stepping Stones sessions. About 27.5% (147 of 534) of men and 25.4% (128 of 504) of women attended the complete Stepping Stones programme. There was no evidence of difference in the proportion of women and men attending 75% or more of the programme by age group, HIV serostatus, socio-economic status and number of partners in the past year. For men there was very strong evidence ($P = 0.007$) of an association between educational level and attending 75% or more, with the highest proportion attending 75% or more being in grade 10 at school (70.7% of whom were in this attendance group) compared with those below grade 9 and the grade 11 where attendance at this level was below 50%. For women there was no evidence of an association between educational level and attending 75% or more.

Table 2 Social and demographic characteristics of the two study arms

	Women			Men		
	Intervention ($n = 715$), *n* (%)	Control ($n = 701$), *n* (%)	*P*-value	Intervention ($n = 694$), *n* (%)	Control ($n = 666$), *n* (%)	*P*-value
Age (years)						
15–17	329 (46.0)	289 (41.2)	0.25	234 (33.7)	182 (27.3)	0.19
18 and 19	261 (36.5)	250 (35.7)		259 (37.3)	264 (39.8)	
20 and 21	102 (14.3)	128 (18.3)		160 (23.1)	164 (24.6)	
22–26	23 (3.2)	34 (4.8)		41 (5.9)	56 (8.4)	
Education (grade)						
<9	67 (9.4)	40 (5.7)	0.088	112 (16.1)	79 (11.9)	0.08
9	343 (48.0)	248 (35.4)		335 (48.3)	243 (36.5)	
10	243 (34.0)	279 (39.8)		188 (27.1)	229 (34.4)	
11	58 (8.1)	121 (17.3)		55 (7.9)	105 (15.8)	
>11	4 (0.6)	13 (1.8)		4 (0.6)	10 (1.5)	
Currently schooling	707 (98.9)	678 (96.7)	0.13	680 (98.0)	640 (96.2)	0.31
SES score (mean)	−0.026	0.041	0.54	−0.056	0.064	0.40
Childhood trauma score	0.028	−0.03	0.44	0.024	−0.034	0.33
Community cohesiveness score	−0.0071	0.097	0.78	0.007	−0.012	0.80

Just over a third of study participants received their HIV results (905 of 2631 or 34.4%). In the Stepping Stones arm, 38.7% (520) got results, compared with 29.9% (385) in the short intervention arm. Stratifying by sex, those in the long arm were significantly more likely to take their results (OR: 1.47, 95% CI: 1.05–2.07, $P = 0.027$). Thirteen (4.7%) of the women who got their results in the Stepping Stones arm received HIV-positive results and 7.4% (16) of those in the short arm. For men, five (2.1%) of those who got their results in the long arm were positive compared with only one (0.6%) in the short arm. Participants with HIV were significantly less likely to receive their result than those without HIV (19.0% *vs.* 35.6%). Stratifying by sex, this difference was highly significant (OR: 0.41, 95% CI: 0.27–0.61, $P < 0.001$). In some cases people were unable to get their results because of logistical

Table 3 A comparison of HIV serostatus, knowledge and attitudes related to sexual and reproductive health and some HIV-related sexual behaviour risk factors between the two study arms

	Women			Men		
	Intervention, *n* (%)	Control, *n* (%)	*P*-value	Intervention, *n* (%)	Control, *n* (%)	*P*-value
HIV seroprevalence	70 (9.8)	90 (12.8)	0.13	12 (1.7)	14 (2.1)	0.65
SRH knowledge score	22.8	23.0	0.39	21.9	21.8	0.65
Condom attitudes score	−0.60	0.064	0.12	0.057	−0.059	0.15
HIV knowledge score	24.2	24.4	0.67	24.1	23.8	0.38
Ever had sex	655 (91.6)	633 (90.3)	0.47	654 (94.2)	624 (93.7)	0.75
Used a condom on last sex	266 (40.7)	288 (45.6)	0.20	292 (44.6)	303 (48.6)	0.37
>2 sexual partners in past year	62 (9.5)	71 (11.2)	0.27	317 (48.5)	314 (50.3)	0.58
Casual partner in last 12 months	138 (21.1)	146 (23.1)	0.43	379 (58.0)	378 (60.6)	0.41
Ever transactional sex	177 (27.1)	141 (22.3)	0.14	200 (30.6)	168 (26.9)	0.30
Intimate partner violence: none	377 (55.8)	409 (61.0)	0.13	456 (69.8)	429 (66.8)	0.63
Physical only	173 (25.6)	169 (25.2)		138 (21.2)	156 (24.3)	
Sexual only	42 (6.2)	27 (4.0)		23 (3.5)	24 (3.7)	
Physical and sexual	84 (12.4)	65 (9.7)		35 (5.3)	33 (5.2)	
Always condom use in past year	136 (21.1)	140 (22.4)	0.69	145 (22.5)	152 (24.6)	0.55
Problem drinking (AUDIT cut point)	28 (3.9)	19 (2.7)	0.27	170 (24.5)	171 (25.7)	0.70

reasons so the comparison of those who did and did not receive them in the baseline year should be treated with caution. Men who received results were younger than those who did not (OR: 0.87), but no other differences were seen.

The research team was able to re-interview 2139 participants (1047 control and 1092 intervention) at 12 months, which is 77.1% of the total sample.

Discussion

The risk of HIV among the general population of youth in the rural Eastern Cape is high. The goal of the trial is to evaluate an intervention that has been widely acclaimed, is used in many countries in the world, and has been adapted for many settings. Determining whether it is effective in reducing HIV infections and positively influencing HIV risk in this population is a matter of considerable importance for South Africa and of interest to others working with the materials. The data on attendance at the workshops indicated that the intervention was highly feasible and the proportion of study participants attending 75% or more of the workshops in the intervention was approximately the same as that of participants attending the single intervention in the control arm. This suggests that the length of Stepping Stones was not a major barrier to attendance and that overall the programme was highly acceptable.

The prevalence of HIV at baseline and overall pattern of sexual practices were very similar to those of the national survey of 15–24-year-olds HIV and sexual behaviour (Pettifor *et al.* 2005). They found the HIV prevalence in women to be 15.5% and in men 4.8%, which is similar, if slightly above, our rates. Seventy-one percent of African youth had ever had sex. This is substantially below the proportion of sexually active youth in our study. It seems likely that there may have been bias towards self-selection of the sexually active for our programme, and may also reflect under-reporting of sensitive behaviours in large surveys. Pettifor *et al.* 2005 also found somewhat lower levels of sexual risk taking, with 12% of women and 44% of men having more than one sexual partner in the last year. The proportion reporting condom use at last sex was similar to ours; however, with 57% of men and 48% of women reporting this.

The study was designed as an effectiveness trial aimed to enhance the generalizability of its findings. The intervention was implemented using documentation that will permit it to be replicated in other settings in South Africa. We sought to apply principles of best practice to selection and training of facilitators, but in other respects the implementation of the intervention arms of the study very closely followed normal practice of non-governmental organizations (NGO) such as the Planned Parenthood Association that have used Stepping Stones. Over the years of working with Stepping Stones we have learnt that facilitators are better if they have attitudes that are supportive of gender equity and non-judgemental regarding sexuality. One deviation from usual NGO selection practices is that we assessed these attitudes during the selection process and recruited more open-minded facilitators. However, we were working in an area with predominantly conservative views on gender and so most of the facilitators held views that were considerably more conservative than those of the project investigators. A second difference was that staff were trained for longer than is common practice in most NGOs. The Planned Parenthood Association of South Africa; however, has quite an extensive in-service training element for its staff so our training was ultimately not very different. Supervision of staff was very similar to normal practice for NGOs with which we are familiar. Our staff made *ad hoc* visits to workshops that were in progress. They observed all facilitators and discussed issues related to workshops; however, there was no attempt to micro-manage the progress of intervention delivery.

We sought to reduce contamination between the study arms by ensuring that villages were at least 10 km apart and did not share a school or traditional leadership. Unfortunately the requirement that all participants be normally resident in their village was unfeasible to implement as there are a very large number of migrant scholars in the area and we could not recruit sufficient numbers without including them. There was thus some residual potential for contamination caused by people returning to villages in other study arms for holidays or moving to schools in other arms in subsequent years. It is hard to estimate the possible impact of this at this stage, but we are monitoring mobility and will explore its impact in future analysis.

We were concerned about the potential for differential exposure to other HIV prevention interventions between the two study arms. However, the study is being conducted in a rural area in which there are few other HIV prevention programmes. There was little actively being undertaken in schools. Some mass media interventions, such as the edutainment television programme Soul City (http://www.soulcity.org.za) or the Lovelife (http://www.lovelife.org.za) materials may have been available to some participants but this is unlikely to have differentially affected the study arms unless interest in these was differentially influenced by exposure to Stepping Stones, in which case this would be a legitimate impact of Stepping Stones and not a confounder.

The approach used in the study to recruit villages and participants should enhance the generalizability of findings

at least to other rural areas of South Africa. Study participants were volunteers, but participants in these sorts of programmes implemented by NGOs are always volunteers. The study was implemented in amenable villages, which again is similar to normal practice. About 67/70 (95.7%) of initially selected villages participated and the three non-participating villages were replaced with another in the same stratum. Non-participation was not related to factors, which would be expected to influence the outcome of the study, and we hope the bias introduced by replacement will be minimal.

The greatest area of deviation from normal practice of NGOs in the implementation of Stepping Stones was the voluntary counselling and testing element of the study design. HIV testing was conducted for evaluation purposes and has essentially made our study one of 'Stepping Stones plus VCT'. This may impact on the generalizability of the results and the impact of differential uptake of results between the study arms will need to be explored in the final analyses. The need to give a blood specimen did discourage some potential trial participants from joining the trial and influenced levels of participation in subsequent rounds of interviews. The methods used in participant recruitment meant that it was not possible to give estimates of the number of people thus affected. There were problems in some areas with rumours that the Medical Research Council was 'buying blood' as financial incentives were given for interviews and a considerable amount of time was needed to explain the situation. The timing of the study also coincided with media activity around new vaccine trials. The rumours were sustained through subsequent rounds of interviews.

The most important lessons learnt by the research team in the course of undertaking the study are summarized in Table 4. The most important underlying lesson is the need to allocate sufficient time to the processes of community mobilization, participant recruitment and retention and building an effective community advisory board. The latter was particularly helpful during difficult periods in the study, such as when we faced many rumours that we were injecting people with HIV (after publicity about HIV vaccine trials) and in organizing meetings with traditional leaders in all districts. Time spent meeting parents, when there were opportunities, was a good investment and very few parents were unwilling to support their children's participation in the study after it was explained to them in person. Time spent building teams was also invaluable. Using staff as key informants in questionnaire validation and translation resulted in a high degree of investment in the instrument and the data. It also helped the staff feel valued and that they had a stake in the research rather than just being people doing a job. The impact of this has been seen in the very small proportion of missing data in the questionnaires (very much <1%).

Table 4 Key lessons

1. Rural African communities will support a research project of this nature if they feel it is addressing an issue they are concerned about and will be of value to them. Researchers must invest time in explaining the proposed study; building a strong Community Advisory Board with a range of stakeholders can be of great assistance.
2. Community mobilization must be viewed as ongoing process and not a once-off task. Resources for community mobilization should be adequate for the entire duration of the planned project, and allocated independently of fieldwork.
3. Local community politics may be complicated, and there may be many different interest groups with differing concerns and priorities with respect to the research. Establishing good relations with as many groups as possible takes time and is very important for success of the project.
4. It is important to understand how local communities view giving blood samples to researchers. The meanings attached to giving blood and the uses to which blood may be put should be investigated rather than assumed and communication should build on locally prevalent ideas around this. Some communities may feel more comfortable with smaller blood volumes or finger prick specimen collection.
5. Informed consent should be seen as a process to maximize freedom of choice around research participation and levels of commitment to the study.
6. Instruments, which have been validated in other settings, must have their validity established in the local settings. Cross-cultural validity should not be assumed.
7. Involving field workers in validating and translating instruments greatly increases their depth of understanding of the instrument and resultant data quality.
8. Projects of this nature in rural areas often employ many staff who have not worked in the formal sector before. Extra time needs to be provided for problem solving and team building with inexperienced staff.
9. All training in the project should be ongoing throughout the project including that of fieldworkers and intervention facilitators.
10. Rural youth may be highly mobile, especially if they have to travel for school. Arrangements for follow up should include ascertaining when youth will return home for interviews, using peers or other community members to help the team determine when young people return. More resources are needed to trace mobile populations but investment in can result in high levels of retention in the study.

This is the first RCT evaluating a community-based behavioural intervention in southern Africa. The intervention being evaluated is widely promoted in developing countries and thus the forthcoming results will be of great interest to understanding the impact of this intervention on a group of rural African young people. We have demonstrated that Stepping Stones is a feasible intervention in rural communities, our next challenge is to determine its effectiveness.

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Corresponding Author
R. Jewkes, Gender and Health Research Unit, Medical Research Council, Private bag X385, Pretoria 0001, South Africa. Tel.: +27 12 339 8525; Fax: +27 12 339 8582; E-mail: rjewkes@mrc.ac.za

Etude randomisée contrôlée en grappe pour déterminer l'efficacité de la méthode Stepping Stones dans la prévention des infections VIH et dans la promotion d'un comportement sexuel plus protégé chez des jeunes dans la zone rurale de l'Eastern Cape, en Afrique du Sud: plan de l'étude, méthodes et observations de base

OBJECTIF Décrire le plan de l'étude, les méthodes et les observations de base dans une étude d'intervention comportemental visantà réduire l'incidence du VIH.

MÉTHODE Une étude randomisée contrôlée a été menée dans 70 villages en zone rurale en Afrique du Sud. Le mode d'intervention comportementale dite de Stepping Stone a été appliqué dans 35 communautés, sous forme de deux ateliers composés de 20 hommes et 20 femmes (dans chaque communauté) qui se sont rencontrés pendant 17 sessions (50 heures) sur le VIH et la protection sexuelle, sur une période de 3 à 12 semaines. Les individus dans le groupe de communautés contrôles ont suivi une seule session d'environ 3 heures. L'évaluation de l'impact a été menée sous forme de deux questionnaires et des suivis sérologiques ont été menés à des intervalles de 12 mois. L'objectif primaire était l'incidence VIH et les mesures secondaires comportaient les changements dans la connaissance, l'attitude et les comportements sexuels. Une recherche qualitative a aussi été menée sur 10 hommes et 10 femmes dans deux sites (rural et urbain) où l'intervention était appliquée et un groupe contrôle composé de 5 hommes et 5 femmes dans un village. Les participants ont été interviewés individuellement, trois fois de suite avant le début des ateliers et 9 à 12 mois plus tard.

RÉSULTATS 2776 participants ont été recrutés au début de l'étude (1409 dans le groupe recevant l'intervention et 1367 dans le groupe contrôle) où un entretien ainsi qu'une prise de sang ont été menées. Les taux de base de la prévalence du VIH étaient de 9,8% chez les femmes dans le groupe recevant l'intervention et 12,8% dans le groupe contrôle. La prévalence chez les hommes était de 1,7% dans le groupe recevant l'intervention et 1.7% dans le groupe contrôle. Dans le groupe d'intervention, 59,9% des individus ont participé à plus de 75% des sessions. Dans le groupe contrôle, 66,3% des individus ont participé à la session contrôle.

CONCLUSION Cette étude est la troisième du genre, conduite en Afrique sud-Saharienne pour évaluer l'intervention comportementale avec utilisation de l'incidence du VIH comme objectif primaire. Cette étude est d'un intérêt particulier car ce type d'intervention est appliquée dans plusieurs pays en développement. Elle permet une bonne comparaison à la base entre les deux groupes et les résultats obtenus par les ateliers suggéraient que l'intervention était faisable et a été bien appliquée.

Mots clés Etude randomisée contrôlée en grappe, Afrique du sud, prévention hiv, évaluation de l'intervention comportemental

Ensayo clínico randomizado por clusters para determinar la efectividad del 'Stepping Stones' en la prevención de infecciones por VIH y promover un comportamiento sexual más seguro entre jóvenes de la zona rural del Cabo del Este, Sur África: Diseño del estudio, métodos y hallazgos basales.

OBJETIVO Describir el diseño del estudio de un ensayo clínico randomizado para determinar la efectividad de una intervención de comportamiento en la prevención de infecciones por VIH.

MÉTODOS Ensayo clínico, aleatorizado por clusters (RCT), conducido en 70 poblados rurales de Sur África. Se implementó una intervención de comportamiento, 'Stepping Stones', en 35 comunidades en cada una de las cuales se realizaron dos talleres de 20 hombres y 20 mujeres cada una, que atendieron 17 sesiones (50 horas) en un periodo de 3–12 semanas. Los individuos en las comunidades control atendieron una sesión única de cerca de 3 horas sobre VIH y sexo seguro. La evaluación del impacto se hizo a través de dos cuestionarios y estudios serológicos a los 12 meses de la intervención. El resultado primario fue la incidencia de VIH y las medidas secundarias incluyeron cambios en el conocimiento, actitud y comportamiento sexual. Se realizaron también pruebas cualitativas con 10 hombres y 10 mujeres de dos lugares en los que se realizaba la intervención (uno rural y uno urbano), así como en 5 hombres y 5 mujeres de un poblado del brazo control. Estos individuos fueron entrevistados de forma individual tres veces antes de los talleres y de 9 a 12 meses después de los mismos.

RESULTADOS 2776 participantes fueron reclutados inicialmente (1409 en el brazo intervención y 1367 en el brazo control) y dieron una entrevista y una muestra de sangre. La prevalencia basal de VIH en mujeres fue de 9.8% en el brazo de la intervención y 12.8% en el brazo control. En los hombres, la prevalencia fue de 1.7% en el brazo de la intervención y 2.1% en el brazo control. Las características demográficas y de comportamiento fueron similares en ambos brazos. En los grupos de intervención, el 59.9% de los participante atendieron a más del 75% de las sesiones. En el grupo control, un 66.3% asistio a la sesión de control.

CONCLUSIÓN Este es el tercer estudio controlado, aleatorizado, realizado en el África sub-Sahariana evaluando una intervención en el comportamiento y utilizando la incidencia de VIH como resultado primario. Es de particular interés que la intervención en cuestión es utilizada en muchos países en vías de desarrollo. Hay una buena comparabilidad basal entre los dos brazos del estudio y los datos procesados de los talleres sugieren que las intervenciones eran factibles y fueron implementadas adecuadamente.

Palabras clave Estudio controlado aleatorizado por clusters, SurÁfrica, Prevención de VIH, evaluación de una intervención en el comportamiento