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Culture, Health & Sexuality: An International Journal for Research, Intervention and Care

Publication details, including instructions for authors and subscription information:
http://www.tandfonline.com/loi/tchs20

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Version of record first published: 14 Sep 2012.

To cite this article: Rachel Jewkes, Yandisa Sikweyiya, Mzikazi Nduna, Nwabisa Jama Shai & Kristin Dunkle (2012): Motivations for, and perceptions and experiences of participating in, a cluster randomised controlled trial of a HIV-behavioural intervention in rural South Africa, Culture, Health & Sexuality: An International Journal for Research, Intervention and Care, DOI:10.1080/13691058.2012.717305

To link to this article: http://dx.doi.org/10.1080/13691058.2012.717305



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Culture, Health & Sexuality
2012, 1–16, iFirst

Routledge
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Motivations for, and perceptions and experiences of participating in, a cluster randomised controlled trial of a HIV-behavioural intervention in rural South Africa

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(*Received 16 February 2012; final version received 29 July 2012*)

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Empirical research on ethical issues in HIV-prevention and gender-based violence research, critical for honing ethical and safety guidelines, is limited. In this paper we describe South African young people's motivations for participating in randomised controlled trial, the prevalence of negative occurrences, participation regrets and associated factors. This trial partly followed, but also deviated from, the WHO safety guidelines for research on violence against women. A total of 1085 women and 985 men provided information two years after the trial start. Most participated for HIV testing and to help their community. Fewer reported motivation by the financial incentive. Minor adverse events included upset from questions on childhood experiences and arguments at home with siblings. Just under 1 in 10 (8.1% women, 9.8% men) regretted participation. Factors were associated with this were keeping some questions secret from their partners, feeling sad about questions on childhood, quarrelling at home and, for women, being motivated by the incentive. Men who had been physically violent to a partner were twice as likely to regret participation. There were no recorded adverse effects from the deviations from the ethical guidelines. Participation regrets mostly stemmed from problems in participants' families preceding the research. There was no evidence that the research had been unsafe.

Keywords: research participation; perceptions; experiences; research ethics; South Africa

Introduction

In sub-Saharan Africa, where more than two-thirds (68%) of all HIV infections are located (UNAIDS 2011), very few HIV-prevention behaviour-change interventions have been empirically evaluated, especially using randomised controlled trials (RCTs) (Ross 2010). This limits our ability to identify effective HIV-prevention programmes (Global HIV Prevention Working Group 2008). With gender-based violence identified as a driver of the HIV epidemic in women (Jewkes, Dunkle, et al. 2010), there is an urgent need for more, and more rigorous, evaluations of behaviour-change interventions for HIV and gender-based violence (Jewkes et al. 2006; Ross 2010).

Conducting RCTs, particularly in resource-poor settings, presents numerous challenges. These include: issues of informed consent (Taiwo and Kass 2009) and worries

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ISSN 1369-1058 print/ISSN 1464-5351 online
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http://dx.doi.org/10.1080/13691058.2012.717305
http://www.tandfonline.com

about undue inducement (Emanuel 2004) and coercion (Ashcroft 2001; Vanderpool 2001) of people to enrol and participate in research trials; ensuring that sufficient numbers of willing participants are recruited and retained (Kim et al. 2004; Rosenbaum et al. 2005); and concerns that researching gender-based violence may place participants at risk of further violence or distress from the research questions (Fontes 2004). For research to be conducted ethically, researchers and institutional review boards (IRBs) need enough understanding of the challenges to innovatively navigate them, appreciate the risk-benefit ratio and assess the relative benefits in research planning and protocols. Gaining a better understanding of the experiences of research participants with RCTs of HIV-prevention interventions that also address gender-based violence, may provide us with insight on how to address some of these challenges.

There are very few published studies on participants' motivations for enrolling and experiences of participating in research (Kneipp, Lutz, and Means 2009). This gap in the research literature limits our understanding of: what motivates people to participate (or not) in research (Kneipp, Lutz, and Means 2009); how participants make meaning of studies they partake in (Taiwo and Kass 2009); and their experiences of participating in such research (DePrince and Freyd 2004). Little empirical research has been conducted on the ethics of research into gender-based violence (Fontes 2004; Sikweyiya and Jewkes 2011; Sullivan and Cain 2004) and very few studies have sought to explore longitudinally (Jorm, Kelly, and Morgan 2007) whether respondents experience negative consequences as a result of participating in research that explores violence victimisation (Ellsberg et al. 2001; Griffin et al. 2003; Johnson and Benight 2003).

Most published papers on ethics of research on violence against women have been theoretical or contain researcher's reflections and professional experiences of undertaking research in different regions of the world (see Ellsberg et al. 2001; Ellsberg and Heise 2002; Jewkes et al. 2000; Jewkes and Wagman 2007; Wasunna 2007).

Kuyper et al. (2012) assert that the absence of empirical data on the impact on participants of participation in research may result in a situation where 'judgments about the risks and benefits of research participation are based on political, cultural, religious and emotional grounds' (see also DePrince and Freyd 2004; Kassam-Adams and Newman 2002), rather than empirical evidence (see also Griffin et al. 2003). Research on participants' experiences of participation in research can empirically inform efforts to address these concerns, as well as providing guidance on how to recruit and retain participants without coercion. Similarly, such research can help both future investigators and IRBs better understand the potential risks and benefits for participants when conducting research that address sensitive topics such as sexuality and violence (Kuyper et al. 2012).

The most extensively used ethical guidelines are the WHO Ethical and Safety Recommendations for Research on Domestic Violence Against Women (see Ellsberg and Heise 2005; WHO 2001), which have at times been extrapolated to research with men (Jewkes, Sikweyiya, et al. 2010; Machisa et al. 2011; Wood and Jewkes 2001; Wood, Lambert, and Jewkes 2007). The WHO recommendations emphasise the need to conceal the violence focus of the research in order to protect participants. There are a number of ways in which this is done, including interviewing only one woman per household, not conducting interviews with men and women from the same locale and concealing the focus on violence from non-participants.

This requirement is feasible to implement in survey research (Ellsberg and Heise 2005), but poses problems for intervention evaluation. For example, if the intervention has gender-based violence prevention as a primary objective, it may not be possible to

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conceal a violence focus. If it has men and women in the study, then both will be asked questions on violence. Whilst it may be possible to geographically separate male and female clusters in a cluster trial, in other studies, such as school-based violence intervention evaluations, such separation may be impossible. Inevitably some of the study participants will be involved in relationships. It is very important that we understand whether such deviations from the WHO guidelines in clinical trials place participants at risk, and to understand the implications of this for interpretation of the guidelines in research more generally.

The Stepping Stones programme is a participatory intervention for HIV prevention that seeks to build stronger, more gender equitable relationships, with prevention of violence an important goal (Jewkes, Nduna, and Jama 2002). The intervention was evaluated in South Africa in a cluster RCT with two years of follow up (Jewkes et al. 2006). This provided an opportunity to examine ethical issues related to participation and to reflect on evidence of the impact of protocol deviations from the WHO guidelines. The study had both men and women, recruited from the same locale, who were asked about gender-based violence on multiple occasions. Some of them were involved in intimate relationships and generally the focus on violence was not concealed, although the intervention was seen as predominantly concerned with HIV.

The aim of this paper is to describe participants' motivations for participating in the study and the prevalence of negative reactions from others to participants' involvement in the study. We also explore whether participants' experienced pressure to learn their HIV results and whether there were regrets associated with study involvement. We describe the impact on participants of questions about childhood trauma and violence on people. Finally, we explore factors associated with regretting participation.

Methods

Study setting

The Stepping Stones study (Jewkes et al. 2006) was conducted in the rural Eastern Cape Province of South Africa between 2003 and 2006. The study was a cluster randomised controlled trial conducted in 70 villages or townships around the town of Mthatha. The goal of the Stepping Stones trial was to evaluate the effectiveness of the Stepping Stones behavioral intervention in averting new HIV infections among young people in the rural Eastern Cape Province of South Africa (Jewkes et al. 2006).

Villages were randomly allocated to the two study arms after they were grouped into seven strata (Dunkle et al. 2007; Jewkes et al. 2006; Nduna et al. 2010). In each cluster, about 40 volunteer participants (20 women and 20 men) were recruited, giving a sample of 1367 men and 1415 women. Eligible participants were aged 16 to 23 years, normally resident in the area where they schooled and mature enough to understand the study and consent process. There was a difference between the actual (15–26 years) and intended age of participants, which is discussed in detail elsewhere (Jewkes et al. 2006).

Recruitment was mostly undertaken in schools and followed multiple stages. In each cluster, project staff invited 60 or more young people to a meeting where they were briefed on the study (Dunkle et al. 2007; Jewkes et al. 2006). In most clusters, a list of all eligible prospective participants was generated and 40 people more able to participate in the study were chosen by the project staff after some discussion among the youth about who would more easily participate, for example those who lived nearer the school, as in the area commonly students could live over an hours walk from school (Jewkes et al. 2006). Then a separate meeting was held with the selected people and they were given further

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information about the study and its procedures, allowing them to ask questions and the research staff to provide answers, and thereafter seeking written consent to participate in the study.

Participants were informed that the trial was going to run for two years and would have multiple rounds of data collection (see Jewkes et al. 2006). To maximise the potential for cohort retention, participants were asked to provide their home contact details, telephone numbers of friends or relatives and they were further requested to inform the project staff if they changed their home address or contact details or asked to provide an alternative number on which they can be reached (Jewkes et al. 2006).

The South African 2nd edition of the Stepping Stones programme (Jewkes, Nduna, and Jama 2002), which was evaluated (Jewkes et al. 2006), was adapted from Alice Welbourn's (1995) original Stepping Stones curriculum. It uses participatory learning approaches, including critical reflection, role play and drama, and draws the everyday reality of participants' lives into the sessions. It had 13 main sessions, given in single-sex workshops, each lasting about 3½h, as well as some meetings of both male and female groups, and was held over 6–8 weeks (Jewkes, Nduna, and Jama 2002). The sessions covered: how we act and what shapes it; sex and love; conception and contraception; taking risks and sexual problems; unwanted pregnancy; sexually transmitted diseases and HIV; safer sex and condoms; gender-based violence; motivations for sexual behaviour; dealing with grief and loss; and communication skills. The control clusters received a single 2–3-hour session on HIV and safe sex practices drawn from the Stepping Stones curriculum (Jewkes, Nduna, and Jama 2002).[1]

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Questionnaire

A structured questionnaire was administered by same-sex interviewers, who were the same age or slightly older than the participants. The baseline questionnaire was administered prior to commencing the study and participants also gave blood for HIV testing. The questionnaire asked about age and level of completed education (presented here dichotomised as up to grade 10 and beyond grade 10). Socioeconomic 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 and with the age group. The scale captured household goods ownership (TV, radio and car), frequency of hunger, frequency of having meat to eat and perceived difficulty accessing a fairly small (but not trivial) sum of money for a medical emergency (R100 $\sim$ \$12). This was derived into a scale and factor weighted (Cronbach's alpha for men $= 0.60$ and for women $= 0.55$). Among the background questions was a scale on exposure to childhood trauma, this measured physical, sexual and emotional abuse and neglect and was adapted from Bernstein et al. (1994) (Cronbach's alpha for men 0.73, for women 0.72). The questionnaire had a detailed section on sexual behaviour, including number and types of partners, condom use, contraception use and transactional sex. The questionnaire covered many gender issues, including experience of emotional, physical or sexual intimate partner violence (as a victim for women or, for men, a perpetrator), assessed using a modified version of the WHO multi-country study's instrument (Garcia-Moreno et al. 2005).

Questions on research participation

In the last round of evaluation, 24 months after the study started, the survey instrument included questions that explored motivations for participation, regrets and adverse (and positive) consequences perceived and experienced by the participants. These items

were developed for this study. Each took the form of a statement, scored on a four-point Likert scale, of strongly agree, agree, disagree or strongly disagree. If participants had said they experience of violence as a result of study participation, follow-up questions were asked to probe and the answers recorded in narrative. These were transposed from the questionnaire and analysed as text. Participants were asked a statement to capture their views on research participation in hindsight: 'If I had understood everything about the research and what would happen afterwards I would not have agreed to participate'. This was the main outcome variable for the analysis of participation regrets.

Research ethics

Throughout the trial period, two professional nurses were employed to support the study participants. They carried a cell phone and were available for calls at all times. All participants were given their number and invited to call if anything concerned them. The ethics review committees of the Universities of Pretoria and the Witwatersrand granted ethics approval and monitored the progress of the trial. The Eastern Cape Provincial Department of Education gave approval to recruit through public schools and access to villages was provided by the local traditional and political leadership. Participants gave written informed consent to participate in the study and were given R20 (US$3) as an incentive for participating. A Community Advisory Board was formed comprising stakeholders from various local organisations and its main responsibility was that of advising the investigators on the local context and observing the overall progress of the study. All participants were told that participation was voluntary and that agreement could be withdrawn at any time with no negative consequences.

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Statistical analysis

Analyses were carried out using Stata release 10.0. All procedures used in data analysis took into account the study design, viewing the study as a stratified, two-stage survey with participants clustered within villages. The datasets for men and women were analysed separately. First, descriptive analyses were carried out on background variables collected during the baseline round of data collection, then these were summarised as percentages with 95% confidence limits. Categorical variables were compared using Pearsons Chi. These estimates were carried out using standard methods for estimating confidence intervals from complex multistage sample surveys (Taylor linearization).

To examine the motivations for, and consequences of, participation, responses to each statement were dichotomised so the proportion strongly agreeing or agreeing versus disagreeing or strongly disagreeing could be presented. Responses between men and women were compared using a Pearson's chi.

Generalised linear mixed models (xtlogit) were fitted to account for clustering of respondents within villages in investigating factors associated with regretting study participation. Candidate variables for these models with the social demographic, violence and childhood trauma variables are presented in Table 1 and the variables in Table 2. Modelling fitted followed a process of backwards elimination after all variables were included, with elimination initially at $p < 0.2$ and subsequently at $p \leq 0.05$.

Results

Table 1 describes the characteristics of participants who were retained and interviewed two years after the study commenced and those lost to follow up. Among women, 1085 were

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Table 1. Characteristics of the sample comparing those lost and not lost to follow up.

	Women			Men		
	Retained in sample ($n = 1085$) (%)	Lost to follow up ($n = 332$) (%)	p value	Retained in sample ($n = 985$) (%)	Lost to follow up ($n = 386$) (%)	p value
Mean age (years)	18.54	18.75	0.061	19.11	19.25	0.191
Educated to grade 10	86.4	85.5	0.702	88.7	83.9	0.037
Socioeconomic status (mean)	0.003	0.017	0.879	0.007	-0.018	0.786
Childhood trauma scale (mean)	-0.012	0.031	0.506	-0.029	0.073	0.071
Ever had sex	90.5	92.5	0.197	94.0	93.8	0.863
Intimate partner violence ever: none	59.2	56.1	0.104	68.1	68.0	0.093
Physical	24.1	29.6		22.6	23.6	
Sexual	5.7	3.1		3.3	5.2	
Physical and sexual	11.0	11.2		6.0	3.3	

interviewed and 332 had been lost to follow up. Among men, 985 were interviewed and 386 lost to follow up. There were no significance differences between the women retained and lost in age, education, socioeconomic status, history of exposure to trauma in childhood, sexual activity or in exposure to physical or sexual intimate partner violence. The one area of difference in men was in education: more men who were above Grade 10 (i.e., in the last two years of school) at the time of recruitment were lost to follow up. Overall 6% of participants at baseline said they had partners in the study.

Motivations for participating in the study differed between men and women, but the magnitude of this difference was very small (Table 2). Almost all participants reported that they were motivated by the opportunity to get an HIV test and to have a chance to help their community. Many indicated that the R20 incentive had been a part of the motivation, with many more women (66.9%), than men (40.9%), agreeing with this statement.

Men and women did not differ in their general perceptions of the study (Table 2). They almost all were glad to have had a chance to be in it, felt that the interviews helped them,

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Table 2. Comparison of perceptions and consequences of participation between men and women.

	Women		Men		
	Strongly agree or agree		Strongly agree or agree		
	n	%	*n*	%	*p* value
Motivation to participate					
A chance to help the community	1076	99.2	964	97.9	0.025
Chance to get a HIV test	1053	97.1	920	93.4	0.004
The R20 incentive	723	66.6	403	40.9	< 0.0001
General perceptions of research participation					
Pleased to have had a chance to be in the study	1061	97.8	962	97.8	0.97
Found workshops more interesting than expected	1055	97.2	959	97.4	0.88
The research helped me at school	1006	92.7	891	90.5	0.103
Interviews really helped me	1062	97.9	960	97.6	0.606
Never previously had told someone about some of the things asked in the questionnaire	466	43.0	338	34.4	0.0008
Adverse consequences of research participation					
I had tried to forget painful things asked in interview	611	56.3	594	60.4	0.124
Questions about childhood made me sad	153	14.1	69	7	< 0.0001
I had to keep some of the content secret to avoid getting into trouble with my partner	257	23.7	272	27.6	0.097
Intimate partner became cross after hearing about the questionnaire	124	10.6	46	4.7	< 0.0001
Was pressurised to take HIV results by partner	256	22.9	148	19.7	0.238
Partner tried to prevent me taking HIV test results	94	8.7	23	2.3	< 0.0001
Arguments at home about participation	123	11.3	57	5.8	0.0002
Beaten for participation in the study	10	0.9	2	0.2	0.029
With hindsight, I would have preferred not to have participated	88	8.1	96	9.8	0.204

that the study had helped them at school and that the workshops were more interesting than they had expected. Many of the participants said they had never told anyone about some of the things that were asked them in the questionnaire. This was more common for women (43% of women versus 34% of men, $p = 0.0008$).

More than half of participants said the interviews had asked them about painful things, which they had tried to forget. This proportion did not differ between men and women (60.4 versus 56.3%) (Table 2). More women than men (14 versus 7%, $p < 0.0001$) had found the questions about their childhood made them sad. Whereas about a quarter of participants felt they should keep some of the questions secret from their partner, this proportion did not differ between men and women (27.6 versus 23.7%). Women who had experienced physical or sexual intimate partner violence were not more likely to perceive the need for secrecy ($p = 0.127$), nor were those who had experienced more severe (multiple episodes of) partner violence ($p = 0.304$). In contrast, men who had perpetrated physical or sexual intimate partner violence were more concerned about keeping questions secret from their partner ($p = 0.024$). The correlation was not seen among those perpetrating more severe violence ($p = 0.101$).

The proportion who had told their partner about the questionnaire, resulting in the partner becoming angry, was larger for women than men (10.6 versus 4.7%), but still relatively small. About one in five participants felt they were pressurised by their partner to collect their HIV test results, a proportion similar for men and women (19.7 versus 22.9%). More women than men reported that their partner had tried to stop them collecting their HIV test results, although this was still relatively uncommon (8.7% of women versus 2.3% of men).

Some of the participants had experienced arguments at home as a result of their participation. This was more common for women than men (11.3 versus 5.7%). Significantly more women than men were beaten for participating, although the absolute proportion was less than 1%. All beatings for which the perpetrator was known were meted out by brothers. Participants were asked about their regrets with hindsight, and just under 1 in 10 (8.1% of women and 9.8% of men), a proportion not differing by gender, said they would not have participated if they had known everything they do now.

We examined whether the study arm influenced men and women's experiences of the study and their perceptions and overall assessment of participation (Table 3). Women in the Stepping Stones arm were more positive than those in the control arm about the intervention, the study and its impact on them. They were more pleased to have been in the study (98.9 versus 96.7%), found the workshops more interesting than expected (99.3 versus 95.3%) and felt the interviews had helped them (99.3 versus 96.5%). Fewer said they had never previously told someone about some of the things asked in the questionnaire. For both men and women, more participants in the Stepping Stones arm said participation had helped them at school (94.8 versus 93.7%). There were no differences between study arms for either women or men in perceived adverse consequences or regrets about participation. In all, 9% of men and women in Stepping Stones regretted participation and 7% of women and 11% of men in the control arm.

The factors that were associated with regretting participation for women were having been motivated by a desire for R20 reimbursement, having to keep some of the questions in the questionnaire secret from their partner, feeling sad about questions from childhood and having arguments at home. For men, regretting participation was also associated with having to keep some of the questions in the questionnaire secret from their partner, feeling sad about questions from childhood and having arguments at home but, in addition, having been physically violent to a partner was associated with being twice as likely to regret participation.

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Table 3. Comparison of perceptions and consequences of participation by gender and study arm.

	Women			Men		
	Stepping Stones	Control		Stepping Stones	Control	
	% Strongly agree or agree	% Strongly agree or agree	*p* value	% Strongly agree or agree	% Strongly agree or agree	*p* value
General perceptions of research participation						
Pleased to have had a chance to be in the study	98.9	96.7	0.014	97.6	97.9	0.767
Found workshops more interesting than expected	99.3	95.3	0.0001	97.8	96.9	0.427
The research helped me do better at school	94.8	90.7	0.019	93.7	87.1	0.002
Interviews really helped me	99.3	96.5	0.019	96.8	98.3	0.096
Never previously had told someone about some of the things asked in the questionnaire	41.2	44.7	0.001	30.6	38.3	0.144
Adverse consequences of research participation						
I had tried to forget painful things asked in interview	57.2	55.5	0.648	57.5	63.3	0.422
Questions about childhood made me sad	15.3	13	0.347	6.4	7.7	0.354
I had to keep some of the content secret to avoid getting into trouble with my boyfriend	24.6	22.7	0.522	29	26.2	0.877
Intimate partner became cross after hearing about the questionnaire	10.8	10.4	0.864	4.6	4.8	0.263
Was pressurised to take HIV results by partner	21.2	24.5	0.46	17.3	22.3	0.311
Partner tried to prevent me taking HIV test results	7.3	10	0.142	2.8	1.9	0.418
Arguments at home about participation	12.7	10	0.231	6.8	4.8	0.298
Beaten for participation in the study	0.7	1.1	0.582	0.2	0.2	0.975
With hindsight, I would have preferred not to have participated	8.9	7.3	0.376	8.5	11	0.158

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Discussion

The majority of participants in the Stepping Stones study who completed the interview at 24-months follow-up expressed highly positive views about having participated in the research. As other authors have shown (Olin et al. 2006; Vanderpool and Weiss 1984), they indicated multiple reasons for engaging in research. Most of them had started the trial from altruistic reasons but the offer of R20 for participation was also important, especially for women. The gender difference here may have reflected the local practice of mothers giving pocket money to boy children, whilst expecting girls to make do.

Both men and women found their experience of involvement in the study to be overwhelmingly positive and expressed a perception that it had positively impacted on their schooling. This was higher among those in the Stepping Stones intervention arm, and supports reports from teachers and school principals of the positive effect of the materials on scholars (Jewkes, Wood, and Duvurry 2010). There was no evidence of any serious

Table 4. Logistic regression model of factors associated with regretting participation, by gender adjusted for age and study arm.

	Women ($N = 1030$)				Men ($N = 98$)			
	Odds ratio	95%	CI	p value	Odds ratio	95%	CI	p value
Motivated by R20	3.26	1.63	6.53	0.001				
I had to keep some of the content secret to avoid getting into trouble with my partner	2.39	1.46	3.90	< 0.0001	2.72	1.71	4.30	< 0.0001
Questions about childhood made me sad	2.11	1.22	3.66	0.008	2.81	1.44	5.46	0.002
I had arguments at home about my participation	3.27	1.89	5.66	< 0.0001	2.49	1.19	5.19	0.015
Perpetrated intimate partner violence ever:								
None					1.00			0.004
Physical					2.06	1.26	3.38	
Sexual					1.50	0.48	4.73	
Physical and sexual					0.92	0.31	2.73	

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adverse events related to study participation after all had been scrutinised by the Data Safety and Monitoring Board (Jewkes et al. 2008).

A substantial minority (about one in four) indicated that they felt concerned that their partner would learn what was in the survey, but we did not have information about what they were afraid of sharing. The proportion of participants concerned about sharing with their partner was about the same for men and women. Qualitative research with research participants, undertaken in another province in South Africa, has highlighted concerns related to disclosure of experience of violence and details of sexual relationships by both men (as violence perpetrators) and women (as violence victims). It is possible that these were the concerns of the Stepping Stones study participants (Sikweyiya and Jewkes 2012). Whilst questions on victimisation experience of gender-based violence may have provoked fear of retaliatory violence, our findings suggest that women who were not victims may equally have had other concerns about sections of the questionnaire as violence exposure was not associated with a higher prevalence of concerns. We did have evidence that men who had perpetrated were more likely to fear their partner knowing about what was in the survey. This suggests that men's fear of reputational damage if their violence was known was a particular violence-related concern with respect to questionnaire content that is not much discussed in the literature. The lack of correlation between concerns about content and perpetration of more severe violence furthermore suggests that concerns about reputation may be related to perceptions of non-acceptability of violence among generally less violent men.

The analysis of factors associated with regretting study participation, and the correlation with experiences of violence, reflect this same pattern. Violence victimisation experiences of women were not associated with participation regrets. However, men who had perpetrated physical, but not sexual, intimate partner violence (nor both), were more likely to regret study participation (Sikweyiya and Jewkes 2012). This further supports the idea that an intervention on gender-based violence may be more discomforting for men

who have been violent but are able to feel remorse and regret it, than it is for men who have been more severely violent and, we can speculate, may feel less remorse. We would suggest that these experiences of discomfort and regret should not be reasons to dissuade anyone from providing gender-based violence prevention interventions, or doing research, with men on whom these interventions may be more impactful.

Despite the deviation from some of the WHO guidelines necessary to conduct a behavioural RCT of this nature, the proportion of participants who had experienced serious adverse events or beating due to the study was small. There was no evidence that any participant was beaten by a partner due to study participation, although we acknowledge that many of the original study subjects (23% of women) did not complete the final interview. However, there was no difference in baseline exposure to violence between those who did and did not complete the 24-month interview, suggesting there had not been differential drop out by intimate partner violence exposure. The equally low rates of beating as a result of study participation between study arms suggests that trial participation posed an overall low risk of violence, and this cannot be explained by protection given to participants through the gender-focus of the Stepping Stones intervention.

The overall proportion of participants who, with hindsight, regretted participation was fairly small. Further, many who expressed regret also acknowledged benefits from participation, as have participants in previous research (Edwards et al. 2009). Nonetheless, analysis of factors associated with participation shows that women who participated for money were much more likely to regret it. Similarly those who had had arguments at home as a result of participation and those who had been made sad by questions about childhood were more likely to regret participation. These associations are not explained by an objective assessment of childhood trauma using the study's childhood trauma scale, nor by questions death of parents, nor by an assessment of depression (data not shown). It seems likely, that they reflect slightly different aspects of disharmony and pain at home, which may have been in part triggered by the decision to participate in the study and pertained irrespective of age (most participants were legal adults so did not need parental consent). Qualitative research in the study area has highlighted the severe domestic discord with which many young people like the study participants live (Nduna and Jewkes 2012). It is possible that, for some, study participation was a choice as a distraction from the discord.

Participants who felt they had to keep questions secret from their partner were more likely to regret study participation, although the majority of men and women who kept survey content secret did not do so. Although there is considerable speculation in the literature about the need for women experiencing gender-based violence to keep questions on this secret from their partner (Ellsberg and Heise 2002; Fontes 2004; Jewkes et al. 2000; Jewkes and Wagman 2007), we have no evidence here to support the idea that violence was concealed more often than other questionnaire content. The portion of women who had experienced abuse greatly exceeded those who felt the need to conceal, and many men expressed the same feeling. It is more likely that this variable reflects relative relationship disharmony and distrust, which may provide more fertile ground for arguing over the study or feeling the study was a burden.

This study required HIV testing of school-going (although mostly adult) participants. Whist this is often viewed as problematic, we found it to have been a specific motivator of study participation. This may have reflected the more limited availability of HIV testing in Government clinics in 2003, when the study started. Whilst most participants indicated that their partners had not been told about it, there was pressure from partners to get results in one in

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five of cases. This may have been related to the often reported vicarious HIV testing (i.e. pressuring a partner to test and assuming sero-concordance (Jewkes and Morrell 2010). The small group encouraged not to get their HIV results may have had partner influenced by similar ideas, but ones who were dominantly fearful of being found to be HIV-positive. The gender differences in partners trying to stop HIV test results collection may reflect gender power norms whereby men expect to be able to control their partner (Jewkes and Morrell 2010).

The key strengths of the evaluation presented here include the large size of the study, the inclusion of both men and women, the long follow-up period (24 months) and repeated (usually three) measures of gender-based violence and other sensitive measures of experience of violence and sexual behaviour. However, information on experiences of participation in the study was only available for participants who completed the 24-month interview and so we have no information on the motivations and study experiences of those who were lost to follow up. The main reason for loss to follow up was participants moving to a different school or village. Many also moved to completely different parts of South Africa. Such moves are very unlikely to have been related to study participation experiences. The similarity between those lost to follow up and those retained in all characteristics, including exposure to gender-based violence and childhood trauma, further supports a view that those lost to follow up would be similar to those retained with respect to main areas of concern in this paper.

Our questions about the experience of study participation required retrospection over two years, and this may have led to some recall bias. However, they did allow us to assess participants' long-term reflections on their involvement in our research. The general perception that almost everyone was happy at the end of the study was confirmed when we asked participants if they would be willing to have their details retained by the researchers so they could be invited for further research. Almost everyone agreed (see also Edwards et al. 2009; Griffin et al. 2003).

The quantitative methods used enabled data to be collected from many participants with subgroup comparison and multivariable regression modeling. They do not allow a more nuanced exploration of the issues as available data are necessarily restricted to the largely closed questions that were used.

Conclusion

This study provides valuable insights into research participants' motivations and experiences for enrolling and remaining in a long-term HIV-prevention trial. Importantly, it offers considerable reassurance for those organising evaluation studies that include measures of gender-based violence and stigmatised sexual behaviour. In this study, the risks associated with research on gender-based violence and potentially stigmatised sexual behaviour were few, even though it was necessary to somewhat deviate from the WHO guidelines about concealing the study's interest in violence and not recruiting partners or men and women from one locale because of the nature of the RCT evaluation. This provides considerable reassurance for other researchers who are unable to follow these recommendations. However, we have also provided further evidence that research participants have concerns about their partners learning what they are asked in sensitive questionnaires, and this concern can be mitigated by following the WHO guidance. We thus recommend that in circumstances where it is relatively easy to follow the WHO recommendations, such as in most community survey research, recommendations about

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geographically separating male and female participants, not recruiting partners and concealing questionnaire context should be followed. However, our experience here shows minimal risk associated with careful deviations from these protocols when necessitated by the study design, such as those in this large trial of a community-level HIV-prevention intervention designed to include both male and female participants.

Acknowledgements

Our sincere gratitude goes to the participants who shared their time, thoughts and experiences, which made this analysis possible. The second author acknowledges Fogarty International Center, National Institutes of Health for the training he received on research ethics through the South African Research Ethics Training Initiative.

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Note

1. For a more detailed description of the Stepping Stones curriculum, see Jewkes, Nduna, and Jama (2002) and see Jewkes and associates (Jewkes et al. 2006, 2008; Jewkes, Wood, and Duvurry 2010) for the complete account of the trial design, methods and results.

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Résumé

Les recherches empiriques sur les questions éthiques dans la prévention du VIH et dans les études sur les violences fondées sur le genre sont peu nombreuses, bien qu'elles soíent critiques pour l'amélioration des recommandations sur les principes d'éthique et de sécurité. Dans cet article, nous décrivons les motivations de jeunes sud-africains pour participer à des essais randomisés, la prévalence des incidents négatifs, les regrets associés à leur participation et les autres facteurs associés. Cet essai a en partie suivi les directives de l'OMS sur la sécurité dans la recherche sur la violence contre les femmes et s'en est également écarté. 1085 femmes et 985 hommes ont fourni des informations deux ans après le démarrage de l'essai auquel la plupart d'entre eux ont participé pour bénéficier du dépistage du VIH et aider leur communauté. Ceux qui ont déclaré avoir été motivés par l'incitation financière à leur participation ont été moins nombreux. Les effets indésirables mineurs comprennent le malaise provoqué par les questions relatives aux expériences vécues dans l'enfance et les disputes au foyer avec les frères. La proportion de personnes ayant exprimé des regrets concernant leur participation n'est que de un peu moins de 1 sur 10 (8,1 % des femmes, 9,8 % des hommes). Les facteurs associés à ces regrets ont été le désir de ne pas communiquer aux partenaires les réponses à certaines questions, la tristesse suscitée par des questions se rapportant à l'enfance, les disputes au foyer et, pour les femmes, la motivation suscitée par l'incitation financière. Les hommes qui avaient fait preuve de violences envers leurs partenaires étaient deux fois plus susceptibles de regretter leur participation. Aucun impact négatif de l'écart de l'étude par rapport aux directives sur l'éthique n'a été relevé. Les regrets ont principalement émergé des problèmes dans la famille, dont

l'existence était préalable à la participation de ces jeunes. La non-sécurité de la recherche n'a pas été démontrée.

Resumen

Son pocas las investigaciones empíricas realizadas sobre temas éticos en relación con la prevención de VIH y la violencia de género, aunque éstas son básicas para determinar normas éticas y de seguridad. En este artículo, los autores describen los motivos que condujeron a jóvenes sudafricanos a participar en un ensayo aleatorio controlado (EAC), la frecuencia de ocurrencias negativas, de personas que se arrepintieron de participar y de otros factores asociados. El ensayo acató, aunque sólo en parte, las normas de seguridad de la OMS para investigaciones sobre violencia contra las mujeres. Durante los dos años que duró el ensayo, 1,085 mujeres y 985 hombres facilitaron información. La mayoría participó porque se les aplicó la prueba de VIH y también para ayudar a sus comunidades. Un número menor participó por motivos económicos. Hubo incidentes menores, como molestias derivadas de las preguntas sobre experiencias de la infancia y sobre disputas familiares con los hermanos. Menos de uno de cada 10 (8.1% de las mujeres, 9.8% de los hombres) se arrepintió de participar. Algunos factores asociados a lo anterior son: la obligación de no comentar algunas de las preguntas con sus parejas, la aflicción que provocaron algunas preguntas sobre su infancia, las peleas domésticas y, para algunas mujeres, haber participado por el incentivo. Entre los hombres que habían sido violentos con sus parejas se registró un índice de arrepentimientos en la participación dos veces mayor. No se registraron efectos adversos derivados de desviaciones de las normas éticas. La mayoría de los arrepentimientos se debió a problemas familiares de los participantes previos a la investigación. No se registraron pruebas de que la investigación hubiera sido insegura.

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