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Effectiveness of an HIV-risk reduction intervention to reduce HIV transmission among serodiscordant couples in Durban, South Africa. A randomized controlled trial

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ABSTRACT

Lack of condom use by married or cohabiting couples in populations with high rates of HIV infection has become a significant public health issue. This study investigated whether an HIV risk-reduction intervention (RRI) would increase condom use when delivered to serodiscordant couples as a unit. Of the 62 couples that were screened, 30 serodiscordant couples were enrolled in the study, and randomized 2:1 to an immediate intervention-waitlist control study. The 12-week intervention focused on communication, problem-solving, and negotiation skills. Participants were assessed at baseline, three and six months after the intervention. The main outcome measures were consistent condom use, HIV seroconversion and fidelity to the programme. The use of condoms increased for both the intervention and control groups after receiving a 12-week RRI. Group comparisons showed a significant difference at three months, with a significantly higher mean proportion of condom-protected sex acts ($p=0.0119$) between the control and intervention groups, the later showing an increase in condom use. No seroconversion was detected, and the overall retention rate of participants was 83.33%. Counselling heterosexual couples as a unit prompted an increase in condom use, but sustained condom use remains a challenge.

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Introduction

More than 80% of adults living with the Human Immunodeficiency Virus (HIV) globally reside in sub-Saharan Africa, where the epidemic continues to spread rapidly (UNAIDS, WHO, 2011). Heterosexual HIV transmission is the leading cause of HIV in adult men and women in sub-Saharan Africa (Allen et al., 2003; Jones, Kashy, et al., 2014; Ryder et al., 2000). As the epidemic matures, the risk of infection from regular partners, especially spouses, has increased. This trend has resulted in an increased incidence of serodiscordant couples, where one partner is infected with HIV and the other one is not (McGrath et al., 2007; UNAIDS, WHO, 2011). Serodiscordant couples have historically been considered an ideal group to test new drugs in HIV prevention research, but the high proportion of new infections that needed to be prevented in this group was not appreciated (Carpenter, Kamali, Ruberantwari, Malamba, & Whitworth, 1999; De Boer et al., 1998; N'Gbichi et al., 1995; Skurnick et al., 1998).

In South Africa, the HIV epidemic has been tracked over the past decades through four national surveys in

2002, 2005, 2008 and 2012, with the estimated HIV prevalence of 12.2%, translating to 6.4 million people living with HIV in a population of 52.3 million in 2012 (Zuma et al., 2016). Evidence suggests that the large burden of HIV in South Africa, as with other sub-Saharan countries, is driven predominantly by heterosexual transmission, but few studies have looked at prevalence rates of serodiscordance in the country's nine provinces (Jones, Kashy, et al., 2014; Zuma et al., 2016). A study by Kilembe et al. (2015), undertaken in Umlazi, one of the largest townships in Durban, reported a serodiscordance prevalence rate of 29.5% in a cross-sectional survey of 317 black South African couples seeking couples' voluntary testing and counselling (CVCT) services (Kilembe et al., 2015).

Many programmes designed to reduce the risk of HIV transmission have been conducted with individuals, while other prevention efforts have focused on premarital and extramarital sex. Research has shown that in areas of high HIV prevalence, the protective needs of married and cohabiting couples are unmet (Maharaj & Cleland, 2005). Recent studies strongly recommend the inclusion

of both partners in counselling and testing procedures (Allen et al., 2003; Burton, Darbes, & Operario, 2010; Jones, Weiss, Arheart, Cook, & Chitalu, 2014; Kilembe et al., 2015), as condom use by these couples is generally low, with resistance from men and cultural norms commonly cited as barriers to increased use (Maharaj & Cleland, 2005).

Evidence-based behavioural HIV prevention interventions developed in Western countries have been translated and culturally adapted to a variety of contexts across sub-Saharan Africa, to improve the practice of protective behaviours (Burton et al., 2010). These interventions have been associated with the reduced transmission of HIV (Jones, Kashy, et al., 2014; Burton et al., 2010), suggesting that adjustments to different contexts are often necessary to successfully implement and sustain interventions in diverse resource-limited settings. In sub-Saharan Africa (SSA), couples face many obstacles to condom use, and it is not clear how accurate self-reported measures are or how long behaviour change is maintained (Allen et al., 2003). Several studies have assessed the reliability of self-reporting in couples, while very few have attempted to validate these measures with biological markers (Lagarde, Enel, & Pison, 1995; Padian, Aral, Vranizan, & Bolan, 1995).

This study describes a couples' group intervention, Eban South Africa, which is an adaptation of the United States of America (USA) Eban intervention (El-Bassel, Jemmott, & Landis, 2010; El-Bassel et al., 2016). The National Institute of Health (NIH) Eban HIV/STD Risk Reduction Intervention (RRI) was developed and evaluated in multiple cities in the USA (El-Bassel et al., 2016), and focused on HIV serodiscordant, heterosexual African-American couples (El-Bassel, Jemmott, & Landis, 2010).

Aim and objectives

The aim of this study was, therefore, to evaluate the feasibility and effectiveness of Eban South Africa using a randomized controlled trial (RCT) of an HIV RRI, the intention being to reduce HIV transmission in serodiscordant couples by increasing condom use.

Methods

Overview of the study

Permission to conduct the study was granted by the Institutional Review Board of the University of California (IRB #14-000854) and the Biomedical Research Ethics Committee of the University of KwaZulu-Natal (BREC #166/15). For ethical reasons, it was important that the comparison intervention participants have as

valuable an experience as that of the intervention group (Shadish, Cook, & Campbell, 2002). Couples were recruited through referral by health professionals around the city of Durban, who were provided with information leaflets to distribute to potential participants. Participants were referred to the study on the basis of their serodiscordant status.

Screening and enrolment procedures

Participant screening and follow-up assessments were conducted by a registered psychiatrist. Serodiscordance was determined by the most recent negative ELISA test (Urassa et al., 1992) in one partner, and a positive ELISA test, CD4 count and viral load (VL) test not older than three months for the HIV infected partner. Written informed consent for participation was obtained from each partner individually. Participants were included if they were 18 years and older, were self-identified heterosexuals who were able to read and write in English, as measured by minimum Grade 8 education; reported having unprotected sex at least once in the past 90 days; were both aware of the HIV status of the other, were in a relationship for at least three months and had no plans to relocate from the study site during the next year. Of the 62 serodiscordant couples that were referred for possible enrolment, only 47 met the inclusion criteria to participate in the study.

Participants were randomized 2:1 for immediate intervention or a 3 month waitlist period followed by the 12-week delayed intervention (DI). Every third eligible couple was allocated to the delayed intervention group. This randomization allowed for comparison of the relative effectiveness of the intervention with couples that received the intervention immediately and those who were waitlisted for three months. Couple members completed paper-based assessments on demographics, health questions, alcohol use, sexual abuse, sexual communication, knowledge of HIV and condom use efficacy at baseline, three and six months.

Statistical procedures

Sample size calculation and power analyses

The sample size was determined from earlier Eban studies conducted on serodiscordant couples, assuming a retention rate of 80–85% (El-Bassel, Jemmott, & Landis, 2010). The sample size calculation was informed using several statistical approaches (Brown & Prescott, 2014; Diggle, Liang, & Zeger, 1994; Hintze, 2008; Liu & Wu, 2005). Using the PASS software, the sample size and power analysis were calculated for 30 couples. Sample size calculation and power analyses were conducted at couple-levels to ensure sufficient statistical

power for all analyses. At the couple level, calculations were carried out based on the comparison of key outcome measures of incidents of unprotected sex and an increase in the proportion of condom use (i.e., the number of times condoms were used during intercourse divided by the number of times sexual intercourse is reported) between intervention and waitlist control. With a repeated measures design, type I error 0.05, type II error 0.20, intra-couple correlation 0.4, the mean number of available repeated measures 2.5 (from baseline, post and 3-month measurements), and a 2:1 ratio of intervention and waitlist control, a total of 30 couples would allow us to detect an effect size to be

0.91 in standard deviation unit for the number of unprotected sexual intercourse acts. This design allowed for a comparison of the relative effectiveness of the intervention with couples that received the intervention immediately and those who were waitlisted for three months.

Intervention

The intervention consisted of sessions with individual couples, single gender and couples groups (Box 1). The first meeting with a couple provided an overview of the group therapy process, after which they were invited to participate in group workshops. The three meetings for

Box 1. Eban SA modules.

Module No	Type	Title	Components
1.	Group session single gender	Preparing for the journey	<ul style="list-style-type: none"> • Introduce group members • Outline the purpose of the journey • Discuss group rules and responsibilities • Learn and apply the 7 principles of healthy living • Enhance gender and cultural pride • Health information • Identify barriers to practicing safe sex
	Individual couples	Enhancing couple communication	<ul style="list-style-type: none"> • The FENCE method • Learn better communication skills • Learn problem solving techniques • Goal setting skills using • Identify triggers to risky behaviours • Improve problem solving skills for good health, better communication and safer sex
	Group session	Tools for the journey	<ul style="list-style-type: none"> • Learn and practice safer sex strategies • Identify male and female sexual anatomy • Identify best barrier methods & related safer sex accessories • Learn, practice and demonstrate correct male & female condom use • Build self-efficacy to engage in safer sex practices • Learn safer strategies to make safe sex fun • Setting homework
2.	Group session	Sharing responsibilities	<ul style="list-style-type: none"> • Use the FENCE problem-solving model to overcome barriers in communication • Identify & build social networks that support safer sex • Problem solve structural barriers to safe sex
	Group session	It takes a village	<ul style="list-style-type: none"> • Identify barriers to practicing safe sex • Problem solve overcoming barriers • Enhance sexual communication skills • Learn how to reframe issues • Develop self-assertiveness skills • Develop strategies to stay connected to the village
	Group session	Strengthening the village	<ul style="list-style-type: none"> • Reinforce communication skills via FENCE • Develop prevention relapse strategies • Re-commit to staying safe
3.	Group session	Expanding the village	<ul style="list-style-type: none"> • Enhance sexual communication skills • Enhance self-assertiveness skills • Enhance strategies to stay connected to the village
	Group session	Celebrating our relationship	<ul style="list-style-type: none"> • Reinforce communication and problem solving skills (individual couples practice skills) • Reinforce prevention relapse & problem solving skills • Re-commit to staying safe • Bring closure to the programme

each group consisted of 6-hour workshops held on Saturdays every four weeks over a period of 12 weeks. Each workshop consisted of three sessions, each lasting 2 hours, with 15-minute tea and comfort breaks in between and lunch at the end of the day. Each group consisted of 3–5 couples, and participants were provided with a workbook for each workshop. The sessions were designed to maximize interaction amongst and between the couples, with a special emphasis on skills-building through modelling and practice problem-solving strategies, using real-life situations that are reported by participants. Each session had a list of objectives that identified a new skill or information that participants needed to gain from the workshop.

Data collection and instruments

Data collection commenced in August 2016 and all the meetings and follow-up assessments were completed by January 2018. Demographic, behavioural, biological and feasibility characteristics were recorded at baseline, three months and final follow-up at six months. A 20 item socio-demographic questionnaire was used to capture socio-demographic information, including age, level of education, profession and relationship characteristics. The reports of condom use and percentage of condom-protected sexual acts in the past 30 days, seven days and last sexual intercourse were recorded at each point of assessment. Concurrency with other partners outside the serodiscordant relationship was also recorded. HIV serostatus, CD4+ count and VL were recorded at baseline and six months post-intervention using the most recent blood results obtained within a month of the assessment date. The feasibility of this intervention was measured by attendance at sessions and fidelity to follow-up visits. Participants were reimbursed for time, discomfort and out of pocket expenses.

Data analysis

The primary behavioural outcomes were measured by the couple's reported proportion of condom-protected intercourse acts. Condom use in the last 30 and seven days, as well as the most recent sexual act, were recorded. Condom use outcomes were compared within and between the groups over time. For within-group analysis, we compared outcomes before the intervention and post-intervention to establish if there were any changes. For between-group comparisons, we compared the baseline, three and 6-month condom use outcomes between the immediate intervention and the waitlisted control groups. Marginal distribution statistics for each variable was calculated through univariate analysis. Bivariate

analysis was conducted using the Chi-square test and the *T*-test.

Results

Demographic data

Table 1 shows the general baseline characteristics of the thirty couples that were enrolled in the study. Randomization was achieved as there were no significant differences between the control and experimental group. The majority of participants (73.3%) were aged between 30 and 49 years, with an average age of 39.3 years (Table 1). More females were HIV positive (60.0%) than males (40.0%), and most participants (88.3%) had Grade 12 level of education. The employment rate was 86.7%, with no significant differences between men and women, and almost half (53.3%) were in the current relationship for over five years. The majority of the HIV positive participants were on ART (93.3%).

Behavioural outcomes

Condom use. The primary behavioural outcome was the couple's reported proportion of condom-protected intercourse over a period of time. The denominator was the sum of vaginal and anal intercourse acts in the last sexual act, 7 days or 30 days reported by each partner. The numerator was the sum of condom-protected vaginal and anal intercourse in the past 7 days or 30 days. Consistent condom use, defined as condom use during every vaginal and anal intercourse was constructed by dichotomizing the proportion of condom-protected intercourse into 2 categories as a unit. Specifically, couples in which both partners independently reported 100% condom use were considered consistent condom users, and all the others were considered inconsistent condom users. Couple-level outcomes were constructed by averaging the partner's responses.

By the end of the intervention, 71.42% of the DI and 77.78% of the II group participants reported condom use in their last sexual activity. Reported condom use in the past seven days increased significantly at three months in the II group (53.0% vs. 86.0%, $p = 0.0086$, respectively), but not in the DI group (40.0% vs. 56.0%, $p = 0.3506$ respectively), which had no intervention from baseline to three months. The reverse was observed at six months follow-up, with the DI group reporting higher condom use from three to six months 56.0% vs. 100%, respectively, $p = 0.0941$ (Table 2).

Concurrent partners. At baseline, 18.33% ($n = 11$) of participants had other partners, at three months post-intervention, 22.22% ($n = 12$) had other partners, and at six months follow-up, 16.0% ($n = 8$) had other partners.

Table 1. Baseline demographic characteristics of 30 serodiscordant couples.

		All N = 30 couples	W.Control N = 10 couples	I.Intervention N = 20 couples
Age		39.3 (9.2)	39.7 (9.4)	39.0 (9.2)
Education*	Less than 12 grade	7 (11.7%)	5 (25%)	2 (5%)
	12 grade and above	53 (88.3%)	15 (75%)	38 (95%)
Employment	Unemployed	8 (13.3%)	1 (5%)	7 (17.5%)
	Employed	52 (86.7%)	19 (95%)	33 (82.5%)
Marital status	Married	28 (46.7%)	7 (35%)	21 (52.5%)
	Not married	32 (53.3%)	13 (65%)	19 (47.5%)
Married to study partner	Yes	35 (58.3%)	10 (50%)	25 (62.5%)
	No	25 (41.7%)	10 (50%)	15 (37.5%)
Length of relationship with study partner (months)		82.7 (61.3)	101.8 (67.9)	73.2 (56.3)
Monthly income ZAR		10106.4 (7707.2)	7705.9 (4011.9)	11466.7 (8947.1)
Number of dependents note: * $p < 0.05$		2.3 (1.6)	2.6 (1.6)	2.1 (1.6)

Table 2. Proportion of couple condom use over time at baseline, three months and six months.

		Baseline	Three months	Six months
Proportion of current condom use	W. control group**	20%	37.50%	71.42%*
	Intervention group	55%	73.68%*	77.78%
Proportion of condom use 7 days	W. control group	40%	56%	100%
	Intervention group	53%	86%*	60%
Proportion of condom use 30 days	W. control group	35%	49%	71%
	Intervention group	58%	68%	66%

Note: *Represents significant change from previous time point. **Represents significant difference between groups at 3 months.

Biological outcomes

Table 3 shows the CD4+ and VL at baseline and six months follow-up, these being the biological outcomes of the study. At baseline, 22.22% of the HIV infected participants ($n = 2$) from the DI group, and 30% ($n = 6$) from the II group had a detectable VL. At six months follow-up, none of the DI group, and 15.0% ($n = 3$) of the II group had detectable VL. There was a significant decrease of detectable VL for the entire sample from baseline (27.59% $n = 8$) to final follow-up (10.34% $n = 3$) overall, $p = 0.0253$. There was a significant increase in the CD4 count in the immediate intervention group from an average count of 558.2 to 629.0 cells/ μL $p = 0.0192$, but no significant changes were observed from baseline to final follow-up for the waitlisted control group, which recorded a reduction from 556.2 to 528.8 cells/ μL . Of

the 30 participants who tested HIV negative at baseline, 25 were re-tested at six months follow-up, with none testing HIV positive.

Feasibility

Of the 47 couples that were eligible to participate, 32 consented but only 30 were randomized and included in the primary analyses (Figure 1). Ninety percent of couples in the intervention and 70% in the control arms completed the study, giving an overall retention rate of 83.33%. Couples in both arms attended 81.25% and 62.5% of the sessions respectively. At baseline, 32 couples had consented but two decided not to participate before the start of the intervention due to discomfort with group processes. At three months, three couples had left, and at six months an additional three couples had left, either because one partner refused to continue or they were relocating to another town or the relationship was unstable.

Discussion

We conducted a study to evaluate the effectiveness of Eban South Africa using a randomized controlled trial of an HIV RRI, the intention being to reduce HIV transmission in heterosexual serodiscordant couples by increasing condom use. This study found that there was a challenge in consistent condom use in established relationships. In the absence of a vaccine or a cure for AIDS, changing risk behaviour, and promoting the use of condoms and other sexual barriers, is the only

Table 3. CD count and viral load at baseline and 6 months post-intervention.

	Baseline			Six months post-intervention		
	Whole sample	W. control group	I. intervention group	Whole sample	W. control group	I. intervention group
CD4	557.6 (274.5)	556.2 (398.7)	558.2 (210.0)	597.9 (273.4)	528.8 (294.5)	629.0 (265.2)
<i>Viral load</i>						
Detectable	8 (26.7%)	2 (20%)	6 (30%)	3 (10%)	0 (0%)	3 (15%)
Non-detectable	21 (70%)	7 (70%)	14 (70%)	26 (86.7%)	9 (90%)	17 (85%)
Don't know	1 (3.3%)	1 (10%)	0 (0%)	1 (3.3%)	1 (10%)	0 (0%)

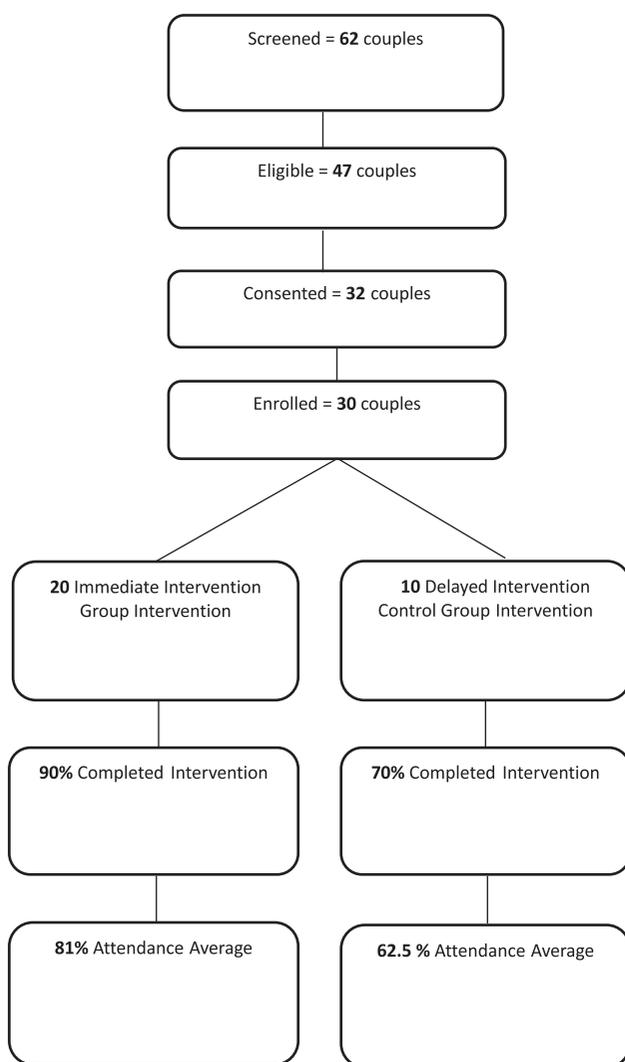


Figure 1. Participant flow diagram of screening, enrolment and participation. *At baseline 30 couples, three months post-intervention 27 couples and six months post-intervention 25 couples.

means available to reduce the sexual transmission of HIV infection (Allen et al., 1992). Consistent use of condoms reduces the risk of infection by blocking the exchange of the virus (Allen et al., 1992; Kamenga et al., 1991), but there are some cases where condom use may not be desirable, e.g., in serodiscordant couples who desire children. In such circumstances, it may be necessary to include other protective measures such as the use of assisted reproductive services and pharmaceutical options such as pre-exposure prophylaxis (PrEP) that prevent sexual HIV transmission (Mmeje et al., 2015).

Our study participants reported an increase in condom use after attending a series of modules that encouraged condom use. The identifiable pattern was that increased condom use was reported more in the recent past, being the last sexual activity and seven days prior to the scheduled assessments. Comparing time frames for the reported changes and significant group

differences between the two groups before and after the delivery of the intervention showed very encouraging results. The waitlisted DI group only started showing an increase in condom use after the intervention was delivered at three months. Our results are comparable to those of a similar RCT conducted in SSA, the *Zambian Partner Project* that enrolled couples into control and intervention groups, and where condom use increased only in the intervention but not the control group (Jones, Weiss, et al., 2014).

However, the finding of great concern in the study was a decline in condom use in the II group at the six months assessment point. This may suggest that the increase in condom use is not sustainable over a period longer than three months, which is a major concern, considering their regular contact with a service provider. These findings are consistent with those reported in other intervention studies of sexual risk behaviour in established relationships, indicating that sustained change can be difficult to achieve (Allen et al., 2003; Kalichman et al., 2005). A study done in Rwanda provided HIV counselling for 963 serodiscordant couples by promoting condom use. At the one year follow-up, only 57% of the discordant couples were using condoms compared to 16% at baseline $p < 0.001$ (Allen et al., 2003), highlighting that consistency remained a challenge despite appropriate counselling.

Research in diverse settings has shown that condoms are often regarded as more appropriate for non-marital than marital relationships (Foss, Hossain, Vickerman, & Watts, 2007; Mehryar, 1995), and are one of the least frequently used contraceptive methods used by married and co-habiting couples in African countries (Gardner, Blackburn, & Upadhyay, 1999). Although the discordant couples in our study increased their usage of condoms, there are still indications that they were underreporting many high-risk exposures, as 16.66% ($n = 5$ females) fell pregnant during the intervention. Of the 5 females, only one reported accidental conception following condom breakage.

Many couples throughout SSA want to have large families, thus the use of condoms, particularly if it is prolonged, may be considered unacceptable (Bankole & Singh, 1998). Notably, one systematic review of condom promotion interventions conducted in SSA and Asia found low evidence of post-intervention change for people with primary partners (Foss et al., 2007). In established serodiscordant relationships, other factors that are likely to influence condom use are personal acquaintance with AIDS sufferers, perceived severity of the consequences of HIV infection, perceived risk of HIV from a partner and perceived self-efficacy to prevent infection (Maharaj & Cleland, 2005). The lack of condom use

may also be attributed to the fatalistic mind-set of not worrying about contracting HIV (Eaton, Flisher, & Aarø, 2003; Marston & King, 2006), such ideas possibly reducing the effectiveness of condom use promotion efforts.

It is also important to note that the Eban South Africa intervention did not reduce multiple partner concurrency. Locally, there has been ongoing debate about the contribution of multiple concurrent partners to the spread of HIV, with a recent population-based data from KwaZulu-Natal Province reporting that such relationships are not an important driver of the high incidence of HIV in this area, and that concurrency among men was decreasing steadily (McGrath, Eaton, Bärnighausen, Tanser, & Newell, 2013; Tanser et al., 2011).

There was no seroconversion in the couples that completed this study and the zero percent transmission rate of HIV could have several explanations. The interplay of condom use, viral suppression, natural immunity to some HIV strains and the use of PrEP by some couples may be the most plausible reasons. Most of the HIV infected partners in our study were virally suppressed at the six months post-intervention period, while some HIV negative participants started taking PrEP during the intervention. The use of PrEP in high-risk groups can reduce the acquisition of HIV infection (Lingappa et al., 2008; Ware et al., 2012; WHO, 2012). A placebo-controlled study that sought to investigate the levels of treatment adherence to PrEP on heterosexual serodiscordant couples ($n = 1147$) in Zambia, reported zero percent seroconversion rates in the active group and 14 new infections in the placebo group (Haberer et al., 2013). Advocating for the use of PrEP in serodiscordant couples may be another strategy to reduce HIV transmission, especially with the evidence indicating that consistent condom use remains a challenge.

Our results also show the feasibility of Eban South Africa as a couple's group-based intervention to address and support the needs of serodiscordant couples. Our retention rate of 83.33% at the end of the pilot study was similar to that of the parent Eban II study, which reported 80.9% retention at the six months follow-up assessment (El-Bassel, Jemmott, & Landis, 2010). This study had a number of strengths, to our knowledge, being the first RCT study design for HIV risk-reduction that allowed for group comparison and was tailored to be culturally appropriate for South African serodiscordant couples. The results of this study confirm that some married and cohabiting couples are willing to use condoms if they perceive the risk of HIV infection, and the messages to increase condom use in this high-risk group need to be intensified.

Limitations

Our results may have been influenced by the small sample size and the short duration of the intervention, and any generalizations may be inappropriate. Further studies are needed to explore the generalizability of the findings to couples in other parts of South Africa and the rest of the continent. The use of sexual diaries to reduce recall bias could have been valuable to minimize some discrepancies that were uncovered in the reports of condom use by the couples (Coxon, 1999; Schroder, Carey, & Vanable, 2003).

Disclosure statement

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