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Behavioral interventions to promote condom use among women living with HIV (Review)

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[Intervention Review]

Behavioral interventions to promote condom use among women living with HIV

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ABSTRACT

Background

High rates of HIV infection among women of reproductive age have dramatic consequences for personal and public health. Prophylaxis during sexual intercourse in the form of condoms has been the most effective way to prevent both STI and HIV transmission among people living with HIV.

Objectives

To investigate the effectiveness of behavioral interventions in promoting condom use among women living with HIV.

Search methods

We conducted a comprehensive literature search in several scientific databases, clinical trials databases, conference proceedings, and conference websites to identify studies produced between 1980 and May 2010 that met our selection criteria.

Selection criteria

Studies were included in the analysis if they conducted a randomized controlled trial that examined the effects of behavioral interventions on condom use among HIV-positive women; considered at least one HIV-related behavioral outcome (e.g., reported protected anal, vaginal, or oral sex) or biological outcome (e.g., acquisition of STIs); and one follow-up assessment three months or more after the intervention. Studies were assessed irregardless of language or publication status.

Data collection and analysis

We used random effects models to summarize odds ratios (ORs) that compared intervention and control groups with respect to a dichotomous outcome (consistent *versus* inconsistent condom use). We used funnel plots to examine publication bias and a χ^2 statistic to test for heterogeneity. The methodological and evidence quality was evaluated through risk of bias criteria and the GRADE system, respectively.

Main results

Five primary studies that collectively researched a total of 725 women living with HIV were analysed. When compared to standard care or minimal HIV support intervention, meta-analysis showed that behavioral interventions had no effect on increasing condom use among

HIV-positive women. This finding was consistent at 3 (OR= 0.72; 95% CI 0.43-1.20; p=0.21), 6 (OR= 0.96; 95% CI 0.66-1.40; p=0.83) and 12-months follow-up meetings (OR= 0.75; 95% CI 0.51-1.11; p=0.15). Only one study presented adequate data to analyze the relationship between behavioral interventions and STI incidence. Studies included in this analysis demonstrated low risk of bias based on the risk of bias criteria. However, sample size was considered inadequate across all studies.

Authors' conclusions

Meta-analysis shows that behavioral interventions have little effect on increasing condom use among HIV-positive women. However, these findings should be used with caution since results were based on a few small trials that were targeted specifically towards HIV-positive women. To decrease sexual transmission of HIV among this population, we recommend interventions that combine condom promotion, family planning provision and counselling, and efforts to reduce viral loads among HIV-positive women and their partners (e.g., HAART treatment provision). New research is needed to address the needs of HIV-positive women, including an assessment of the impact of interventions that combine safer sexual behavior and harm reduction approaches.

PLAIN LANGUAGE SUMMARY

Behavioral interventions to promote condom use among women living with HIV

Behavioral interventions to promote condom use and/or to modify HIV sexual risk behaviours include individual counseling, skills training, coping strategies, peer education, and social and educational support. This systematic review of randomized controlled trials assessed the effects of behavioral interventions on promoting condom use among women living with HIV, a population at higher risk to other sexually transmitted infections (STIs). Based on five eligible studies, we found that behavioral interventions promoting consistent condom use in HIV-positive women did not have a significant impact on outcomes, when compared to standard care or minimal HIV-related support. However, these findings should be used with caution since they are based on a few small trials that were targeted specifically towards HIV-positive women. New research is needed to assess the potential personal and public health gains that could arise from a combination of interventions that promote safe sexual behavior and adopt a harm reduction approach, particularly in developing countries, where HIV infection rates among women remain high.

Summary of findings for the main comparison. Behavioral intervention to promote condom use for women living with HIV

Behavioral intervention to promote condom use for women living with HIV

Patient or population: patients with women living with HIV
Settings: Health Care Settings
Intervention: Behavioral intervention to promote condom use

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	Behavioral intervention to promote condom use				
Consistent condom use - 3 months Self-report Follow-up: mean 3 months	**Study population**		**OR 0.72** (0.43 to 1.2)	272 (3 studies)	⊕⊕⊝⊝ **low** [1,2]	
	431 per 1000	**353 per 1000** (245 to 476)				
	Moderate					
	426 per 1000	**348 per 1000** (242 to 471)				
Consistent condom use - 6 months Self-report Follow-up: mean 6 months	**Study population**		**OR 0.96** (0.66 to 1.4)	637 (4 studies)	⊕⊕⊝⊝ **low** [1,2]	
	673 per 1000	**664 per 1000** (576 to 743)				
	Moderate					
	632 per 1000	**622 per 1000** (531 to 706)				
Consistent condom use - 12 months Self-report Follow-up: mean 12 months	**Study population**		**OR 0.75** (0.51 to 1.11)	487 (2 studies)	⊕⊕⊝⊝ **low** [1,2]	
	684 per 1000	**618 per 1000** (524 to 706)				
	Moderate					

	626 per 1000	**557 per 1000** (461 to 650)			
Incidence of STI [3] - not reported	See comment	See comment	Not estimable[3]	-	See comment

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: Confidence interval; **OR:** Odds ratio;

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] Generalization can not be reached to diverse population of women with HIV.
[2] Trials are underpowered due to inadequate sample size.
[3] Results from two studies could not be pooled due to different follow-up assessments and insuficient data.

BACKGROUND

HIV infection rates among women greatly increased in the 1990s, and have remained stable since then. In 2009, women accounted for half of the 33.3 million global total cases of infection, primarily as a result of heterosexual transmission (UNAIDS 2010).

The large number of HIV infection among women in reproductive age has dramatic consequences for both their own health and public health. HIV-positive women are at increased risk for sexually transmitted infections (STIs), such as *Treponema pallidum*, *Trichomonas vaginalis*, *Chlamydia trachomatis*, human papillomavirus (Landes 2007; McClelland 2005), and for cervical dysplasia and genital cancer (Jong 2008; Lehtovirta 2008; Oliveira 2010). As an example, in a European sample of 1,050 HIV pregnant women, 25% had a diagnosis with at least one bacterial or viral STI (Landes 2007). In addition to HIV infection, sexual risk behaviours (e.g., inconsistent condom use, large number of sexual partners and high-risk sexual behavior of the partner) significantly increase the risk of STI among women (Almonte 2008; Oliveira 2010).

In the context of pregnancy, the presence of STIs can also increase the risk for mother-to-child HIV transmission. High maternal viral RNA level and cervical or vaginal ulcers are significantly associated with infant infection (John 2001). The presence of maternal syphilis is also associated with mother-to-child transmission (Mwapasa 2006). Finally, infants can be at increased risk for adverse outcomes, including congenital infection, due to the strong association between STIs and HIV in seropositive pregnant women (Landes 2007).

Although women are approximately twice as likely as a men to contract HIV infection during vaginal intercourse (Nicolosi 1994), female-to-male transmission rates increase in the presence of some factors such as: high viral loads; concurrent STI; genital trauma to the uninfected partner; and poor immune responses from the uninfected partner (Galvin 2004; O'Farrell 2001;McClelland 2005; Quinn 2000).

Protected sexual intercourse through consistent condom use has been described as the most effective way to prevent both STI and HIV transmission among people living with HIV. While the prevalence of sexual risk behavior generally declines following HIV diagnosis, a substantial group of HIV-positive people continue to engage in unprotected intercourse (Marks 2005; Wilson 2004). For example, in an American sample, 36.5% of HIV-positive women have engaged in any unprotected sexual intercourse during the last 3-months (Weinhardt 2004).

Many reasons may account for unprotected sexual practices among HIV-positive women, including difficulties in negotiating condom use, domestic violence, alcohol abuse, and reproductive intentions (Finocchario-Kessler 2010; Murphy 1998; Peretti-Watel 2006). HIV-positive women are also less likely to use a condom when they have a HIV-positive partner. Findings showed that 51% of unprotected sexual intercourse among HIV-positive women in the past 3 months involved a HIV-positive partner (30% of unprotected sexual intercourse was reportedly with HIV-negative partner, and 26% with a partner of unknown serostatus) (Weinhardt 2004). Beliefs regarding lower levels of infectivity under antiretroviral therapy also are associated with less condom use. Studies reported higher levels of unprotected sex among women after antiretroviral treatment initiation, which not vary with the therapeutic response (Wilson 2004). Moreover, social determinants (e.g., precarious socioeconomic conditions, low educational level, and gendered power imbalances) are associated with lower likelihood of women using condoms (Ghosh 2009; Santos 2009).

Reducing sexual risk behaviours, as well as coping with other challenges from living with HIV, have been the focus of many behavioral interventions (Faria 2010;Crepaz 2006). Interventions to increase antiretroviral adherence (Johnson 2007), disclosure of HIV diagnosis to sexual partner (Serovich 2009), and reductions in anxiety and depression (Balfour 2006; Blanch 2002) also have been successfully addressed by behavioral interventions.

Regarding sexual risk behaviours, studies showed that behavioral interventions tailored specifically to HIV risk groups can reduce unprotected sexual practices among people living with HIV (Kalichman 2001; Gore-Felton 2005; The Healthy Living 2007). This effectiveness is also attested by meta-analysis studies, especially when an intervention includes skills training (Crepaz 2006, Johnson 2006). Those interventions that were guided by behavioral theories, were more intensive, and were undertaken with longer duration were found to be more effective at promoting protected sexual intercourse. Those interventions delivered by health-care providers, on a one-to-one basis, and in medical care settings were also associated with reductions in unprotected sex (Crepaz 2006). Meta-analysis also found that behavioral interventions were more successful in increasing condom use if younger participants and fewer men who have sex with men were included in the sample (Johnson 2006).

Behavioral interventions appear to hold public health promise; however, to date, few intervention studies have comprehensively addressed the effects of gender, culture, and power imbalances on HIV risk behavior (Quadagno 1996; Wingood 2004). Interventions designed specifically for HIV-positive women demonstrated divergent results on reducing sexual risk behavior. While two studies reported increases in condom use among HIV-positive women in the intervention group compared with a control group (Wingood 2004; Wyatt 2004), the same result was not found in a third study with a similar design and purpose (Saleh-Onoya 2009).

Although an emerging body of evidences indicates that behavioral interventions can be effective, the absence of a solid evidence base in this area presents barriers for designing and implementing effective interventions that can increase condom use among HIV-positive women. This is a missed opportunity to promote the health of these women and to reduce the spread of HIV. The current review addresses a gap in the existing literature because no systematic review has been published evaluating the empirical evidence on behavioral interventions among HIV-positive women.

OBJECTIVES

To investigate the effectiveness of behavioral interventions in promoting condom use among women living with HIV.

METHODS

Criteria for considering studies for this review

Types of studies

Studies included in this analysis were randomized controlled trials (RCTs) that investigated HIV or STI behavioral interventions

designed for people living with HIV. Trials had to include women, have outcomes presented by gender, and have sufficient data to calculate effect sizes. Authors were contacted for additional information if their study performed analysis by gender but did not publish results by gender.

We excluded studies that lacked a control group, used a pre- and post-intervention design, or allowed participants to self-select into the intervention.

Types of participants

All studies included adult women living with HIV who know their HIV diagnosis at baseline. Studies targeting women at risk of but not infected by HIV were excluded. Interventions could be carried out in a variety of settings (e.g., clinic, home, community).

Types of interventions

Only studies concerned with behavioral interventions that promote condom use and/or modify HIV sexual risk behaviours among people living with HIV were included. Interventions could focus on providing information, counseling, individual cognition, emotional well-being, skills training, coping strategies, or peer education related to HIV risk behaviours. There were no restrictions as to the intervention theoretical approach, setting, frequency, or duration. Studies that focused on biomedical interventions (e.g., vaccines, HIV testing, or administering HAART) were excluded unless behavioral intervention effects were described separately.

Types of outcome measures

Studies included in the analysis had to include data on at least one HIV-related behavioral outcome (e.g., reported unprotected/protected anal, vaginal, or oral sex) or biological outcome (e.g., acquisition of STIs, including hepatitis B) and at least one follow-up assessment at three months or more post-intervention. Protected sexual intercourse (or consistent condom use) was described as use of condoms in all vaginal, anal or oral sexual relationships with casual and/or steady partners. All other situations were considered inconsistent condom use (e.g. "almost always" or "sometimes" condom use).

Search methods for identification of studies

We searched the following electronic databases irregardless of language or publication status using the optimal sensitive search strategy developed by The Cochrane Collaboration (Higgins 2008):

- Cochrane Central Register of Controlled Trials (CENTRAL)
- MEDLINE (PubMed)
- EMBASE
- Latin American and Caribbean Health Sciences Literature (LILACS)
- PsycInfo
- Social Science Citation Index (SocINDEX and CINAHL through EBSCO)

We used specific search terms to identify relevant studies from January 1980 to May 2010. Appendix 1describes the search strategy applied to CENTRAL, EMBASE and PubMed which was also applied to other search engines without substantial modifications.

In addition, we examined reference lists of all pertinent reviews and studies for published studies; the WHO International Clinical Trials Registry Platform and the Clinicaltrials.gov database for unpublished studies; and the International AIDS Conferences, National HIV Prevention Conference (through Meeting Abstracts Database - NLM Gateway), the International Society for Sexually Transmitted Disease Research, and the Conference on HIV Pathogenesis and Treatment (through Conferences' website) for conference proceedings. Finally, experts in the field were contacted for recommendations about additional intervention research reports and unpublished sources.

Data collection and analysis

The search was completed by one author (TG) with the assistance of the Cochrane HIV/AIDS Group (San Francisco). Citations retrieved from electronic searches were inspected by two authors (FC and EF) who independently screened studies for inclusion. Any uncertainties were resolved by consensus.

Selection of studies

Following an initial screening, all potentially eligible studies were independently read by at least two authors (EF, FC, or TG) who assessed in detail the study design, types of participants, types of interventions, and outcome measures. The Kappa coefficient indicated a good agreement across those rating the study (K=0.76).

Data extraction and management

Using a standardized data extraction form, EF, FC, and TG extracted the following characteristics from each study that met the inclusion criteria:

1. Description of study participants (e.g., sample size, demographic characteristics, country where study was performed);
2. Eligibility criteria for enrolment (e.g., HIV+ diagnosis);
3. Details about the intervention (e.g., length of intervention and follow-up, individual or group modality, behavioral techniques);
4. Assessment of risk of bias (e.g., study design, generation of allocation sequence, allocation concealment, blinding, loss to follow-up, inclusion of all randomized participants, incomplete outcome data addressed, and sample size calculation);
5. Outcome measures (e.g., acquisition of STI or hepatitis B, self-reported protected anal, vaginal, or oral sexual intercourse) and data analysis strategy.

Methodological quality was assessed through RevMan5 and in accordance with the recommendations of the Cochrane Handbook of Systematic Reviews of Interventions (Higgins 2008). Quality was categorized as either "Low risk", "High risk", or "Unclear", and was listed in risk of bias tables broken down by trial. Sample size was calculated by the authors according to Hulley 2001 using the earliest study that met the inclusion criteria (Wingood 2004). From this calculation it was concluded that a sample size of 1,133 participants per group was necessary to adequately compare proportions of dichotomous variables. See Appendix 2 for further information on the sample size calculation. In the case of missing data, authors were contacted directly.

Finally, the GRADE system was used to evaluate the overall evidence quality for the outcome.

Measure of treatment effect

Statistical analysis was conducted according to Cochrane guidelines and compared the impact of distinct treatments (Higgins 2008). For the dichotomous outcome (consistent *versus* inconsistent condom use), the absolute numbers of participants reporting consistent condom use in each group (intervention and control) was extracted. Results for the effect of each intervention were expressed as odds ratios (ORs) with 95% confidence intervals and were combined for meta-analysis using a random-effects model in the RevMan 5.0 software. This strategy accounts for any potential heterogeneity that may occur following unique intervention approaches developed in various study settings.

Statistical heterogeneity between results of different studies was examined by χ^2 tests. A *P* value for a χ^2 test of less than 0.10 indicated heterogeneity. An alternative approach to quantify the effect of heterogeneity is assessing the inconsistency among the results of studies with 95% uncertainty intervals. A value of 0% indicates no observed heterogeneity and a value greater than 50% indicates the presence of substantial heterogeneity. Condom use was estimated using an intention-to-treat analysis and included all subjects who had undergone randomization, regardless of their baseline condom use behavior. Reporting bias was assessed by examining a funnel plot graphic which can detect small trial effects even those resulting from publication bias.

Subgroup and sensitivity analyses were not feasible given the small number of trials included in the assessment.

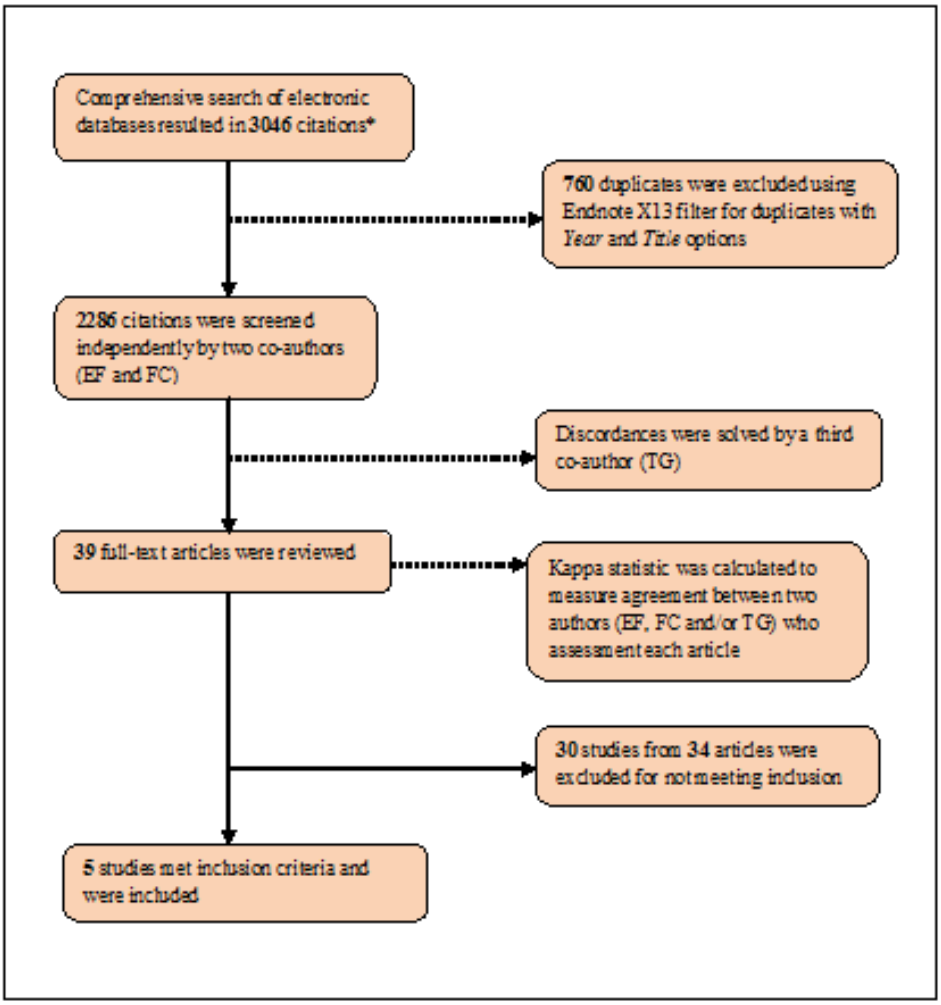
RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies.

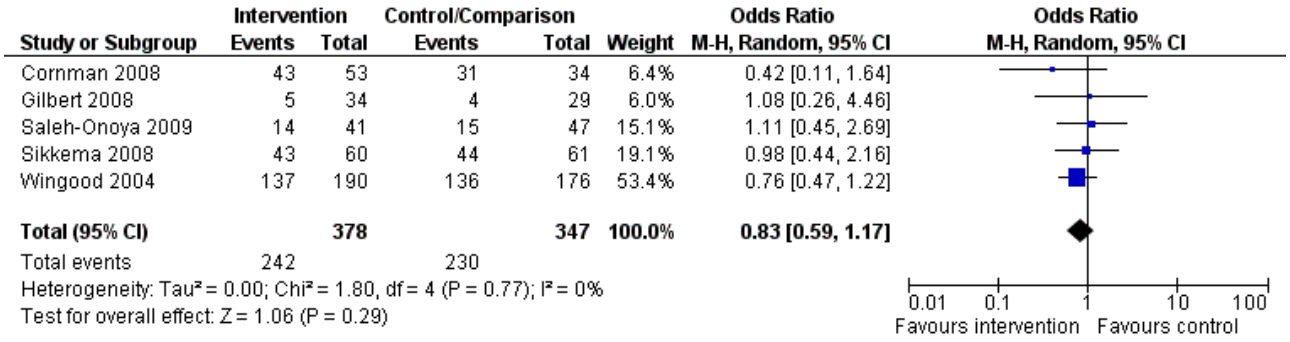
The study selection process is summarized in Figure 1. Out of 3,046 citations, 35 potentially relevant studies and their full-text version were extracted. After assessment, the following 30 studies were excluded: 10 that did not consider gender and/or age in their outcomes analyses (Kalichman 2005; Lightfoot 2007; Naar-King 2006; Olley 2006; Patterson 2003; Purcell 2007; Rotheram-Borus 2001; Rotheram-Borus 2004; Rotheram-Borus 2009; The Healthy Living 2007); 3 that included strategies to promote condom use in control groups (Cosio 2010; Fogarty 2001; Jones 2005); 4 that were not RCT studies (Bunnell 2006; Fisher 2006; Jones 2006; Magnano San Lio 2009); 2 that only described formative analyses of interventions (Holstad 2006; NIMH Multisite Group 2008); 2 that did not describe outcomes and/or analysis by HIV status (Belcher 1998; Bhave 1995); 2 that did not assess the target outcomes (Burman 2008; Carrico 2009); 2 that only included participants at risk for HIV (Champion 2001; Dilley 2008); 1 that assessed the baseline assessment before HIV diagnosis (Cleary 1995); 1 that conducted a control group assessment only in immediate post-intervention follow-up (Wyatt 2004). Even after contact with authors by e-mail, 3 studies could not be included due to lack of information from the authors about absolute number of HIV-positive women engaged in safer sex (Jones 2001; MacNeil 1999) and lack of information on intervention effects by gender (Kalichman 2001).

Figure 1. *Note: Figure shows an integrated view of the screening process considering the first comprehensive searches (performed 26-28 May, 2009) were subsequently updated on 18-21 May, 2010 to complete the review.



Data from five studies (Figure 2) encompassing a total of 725 female respondents living with HIV were analysed. Of these studies, three were carried out in the United States(Gilbert 2008; Sikkema 2008; Wingood 2004) and two in South Africa (Cornman 2008; Saleh-Onoya 2009). Two interventions were developed exclusively for women living with HIV (Saleh-Onoya 2009; Wingood 2004), while the other three targeted both women and men living with HIV (Cornman 2008; Gilbert 2008; Sikkema 2008). All interventions followed the initiation of HAART. The Characteristics of included studies tables show details about methodology, participants, interventions, and outcomes for each study.

Figure 2. Forest plot of comparison: 1 Protected sex among women living with HIV in the baseline.



Risk of bias in included studies

Evidence of selective reporting and other biases were limited across all studies. All authors who were contacted responded with explanations for participant drop out. One study did not include attrition analysis (Saleh-Onoya 2009), and another one (Sikkema 2008) inferred that attrition analysis was made however no further information was provided. All studies performed an intention-to treat analysis except one, (Saleh-Onoya 2009), However the authors of this study did describe the absolute number of participants for each outcome assessed. According to an estimated sample size performed by authors (Appendix 2), sample size was considered inadequate for all studies. A summary of each reviewer's assessment of the studies' methodological qualities is presented in Figure 3 and Figure 4.

Figure 3. Risk of bias graph: review authors' judgments about each risk of bias item presented as percentages across all included studies.

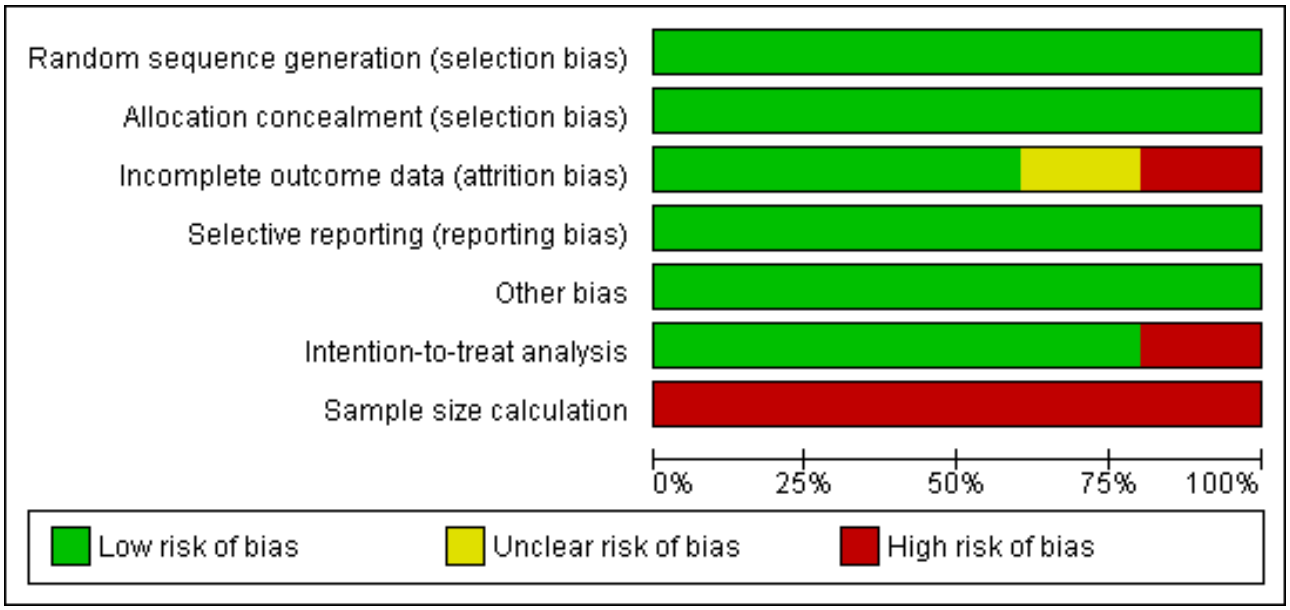
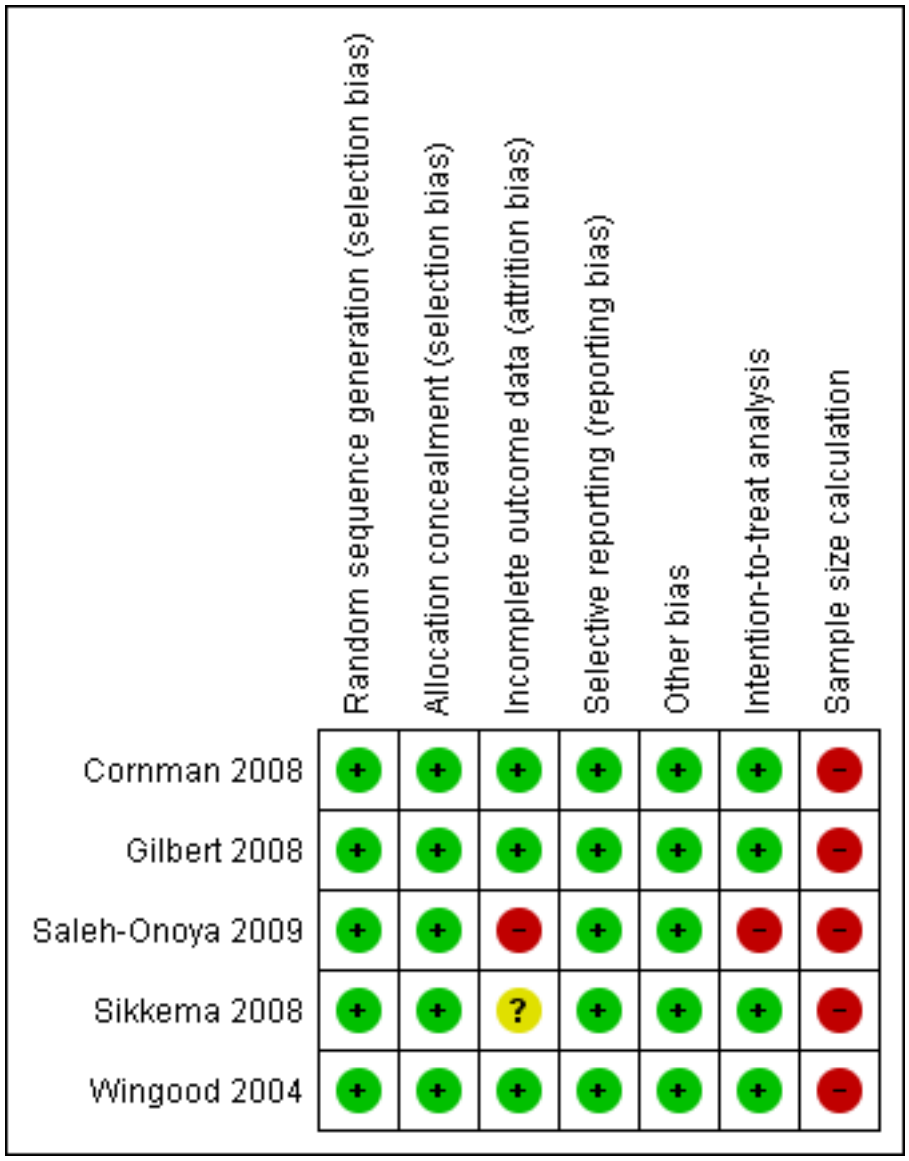


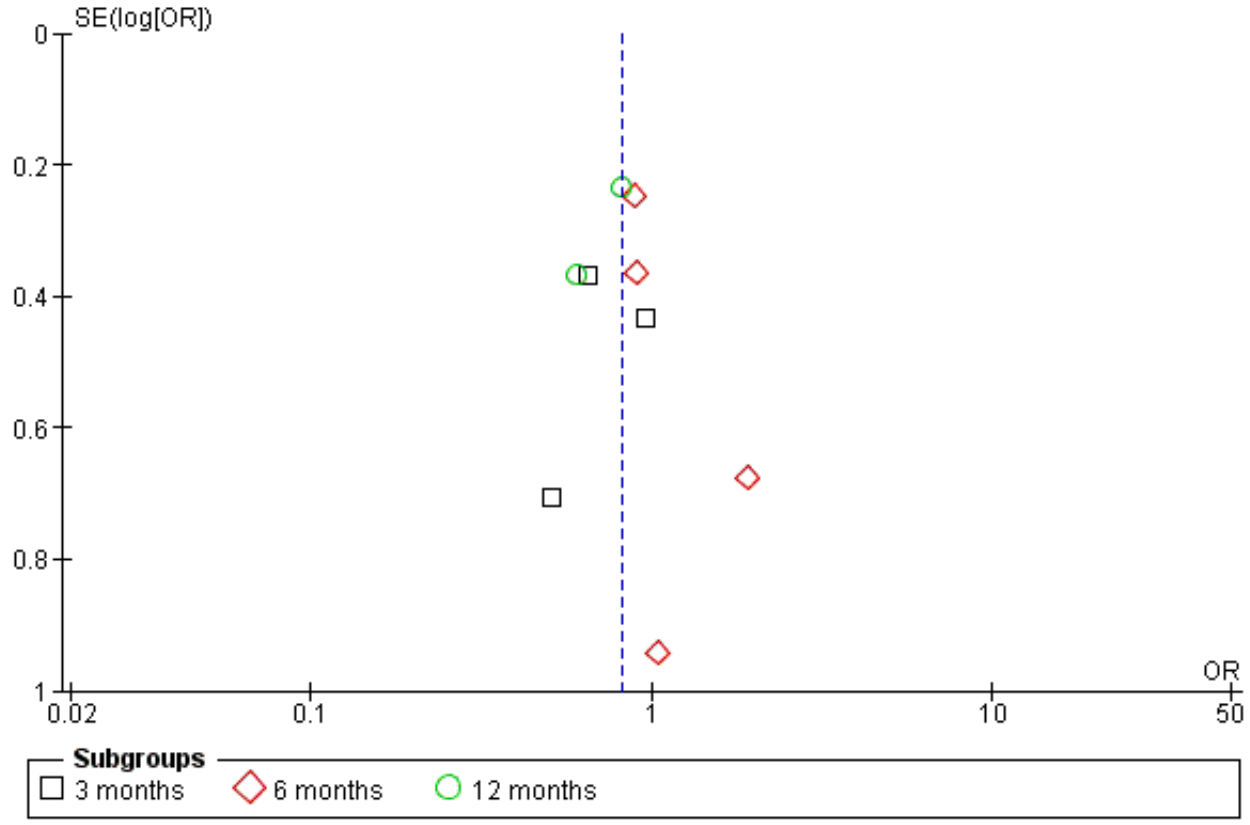
Figure 4. Risk of bias summary: review authors' judgments about each risk of bias item for each included study.



Publication Bias

Meta-analysis may be vulnerable to publication bias if studies with less favorable results are excluded. A useful test for publication bias is based on the funnel plot, which compares intervention effects estimated from individual studies against a measure of study size. In the absence of bias, the plot resembles a symmetrical inverted funnel (Sterne 2001). In the current review, there was no clear evidence of funnel plot asymmetry (Figure 5).

Figure 5. Funnel plot of comparison: 2 Increasing in protected sex among women living with HIV after intervention, outcome: 2.1 Time intervention.



Quality of Evidence

We performed a GRADE evaluation on the quality of evidence for all interventions included in this review (GRADE Working Group 2004).This classification indicated low evidence quality for the specific outcome in the target population (See Summary of findings for the main comparison). We only included randomized controlled trials in this portion of the review. The main methodological limitation among studies was inadequate sample sizes, which may reduce the power of analyses.

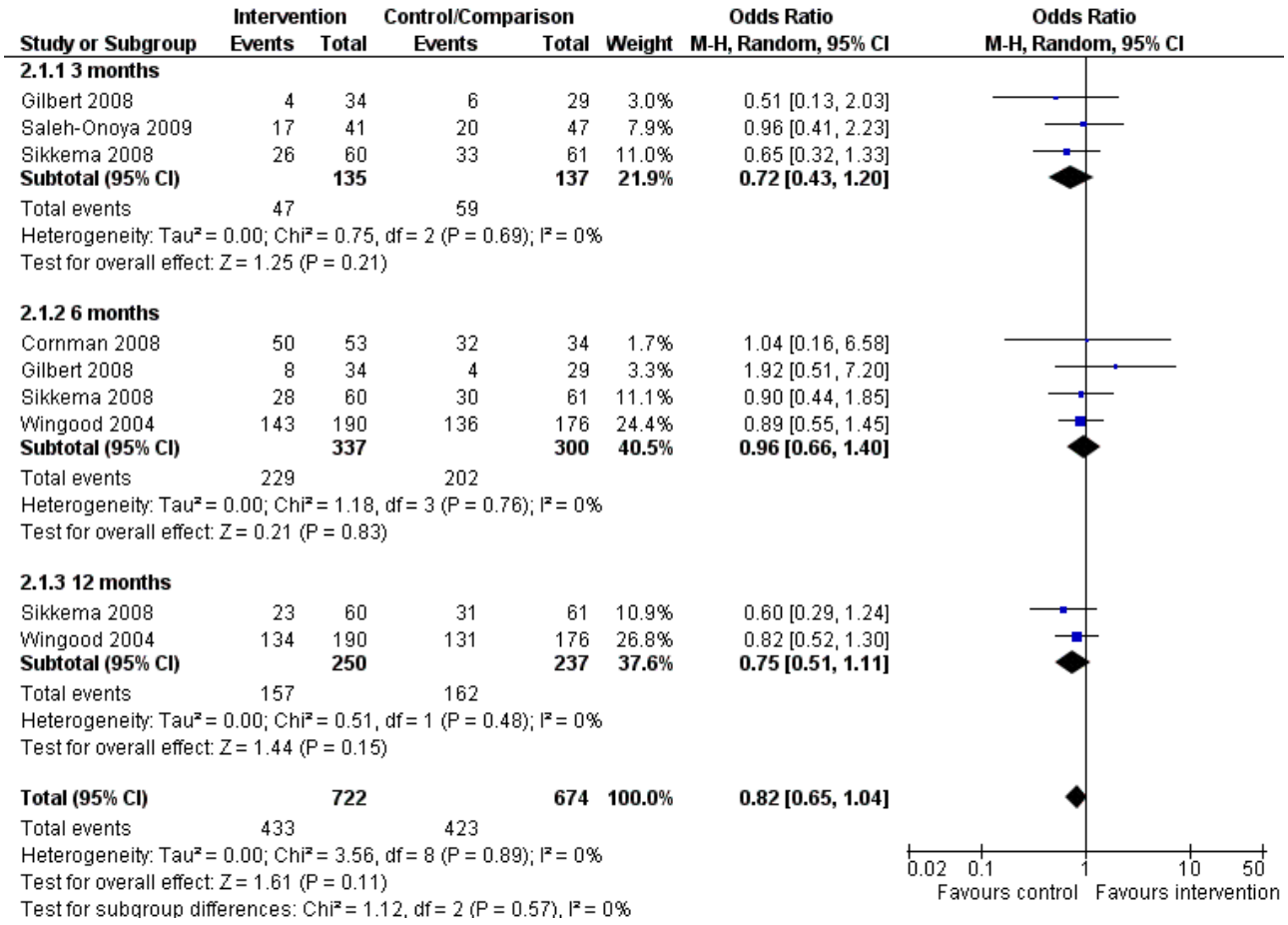
Effects of interventions

See: **Summary of findings for the main comparison** Behavioral intervention to promote condom use for women living with HIV

Meta-analysis conducted on the five studies showed no effect of behavioral interventions on condom use promotion among HIV-positive women when compared to standard care or minimal HIV support interventions. No intervention effects on consistent condom use promotion were noted at the 3 (OR= 0.72; 95% CI 0.43-1.20; p=0.21), 6 (OR= 0.96; 95% CI 0.66-1.40; p=0.83), or 12-month follow up (OR= 0.75; 95% CI 0.51-1.11; p=0.15), nor over the full 12-month follow-up period (OR=0.82; 95% CI 0.65-1.04; p=0.11). Conversely to what was expected, we could also observe a slight trend towards interventions effects being favorable to control groups (condom use being lower among women in intervention groups). Even so, four studies found positive results to increase condom use on their published articles (Cornman 2008; Gilbert 2008; Sikkema 2008; Wingood 2004). Although, three of these studies have considered a combined number of sexual events in which condom were used as their primary outcome instead of consistency on condom use (Cornman 2008; Sikkema 2008; Wingood 2004). Also, other three studies did not originally analyse interventions results by gender (Cornman 2008; Gilbert 2008; Sikkema 2008).

No evidence of heterogeneity was found among studies (Tau^2=0.00; Chi^2=3.56, df=8, p=0.89, I^2=0%), meaning each study contributed results for the meta-analysis in a similar way. These results are shown in Figure 6. We were not able to conduct subgroup analyses due to the small number of studies included in the analysis. For this reason, it was not possible to distinguish effects from different participant characteristics or intervention designs.

Figure 6. Forest plot of comparison: 2 Increase in protected sex among women living with HIV after intervention, outcome: 2.1 Time intervention.



The current review also aimed to assess the effect of behavioral interventions on STI incidence, but only two studies (Saleh-Onoya 2009; Wingood 2004) assessed this outcome. Nevertheless, both studies had different time of follow-up assessments, and only one (Wingood 2004) presented adequate data for grouping by results. Despite limitations, these positive studies results are individually described for the systematic review purpose. One study found significantly higher incidences of *Chlamydia Trachomatis* (CT), *Neisseria Gonorrhoea* (NG) and *Trichomona vaginalis* (TV) in the control group than in the intervention condition at 3-month follow-up assessment (Saleh-Onoya 2009). No significant difference was found for Bacterial Vaginosis (BV) incidence. Wingood 2004 reported that participants in the intervention group were not significantly less likely to have an incident Trichomonas infections, bacterial infection of Chlamydia or gonorrhea at any follow-up assessment, but were significantly less likely to have an incident bacterial STD at the 12-month assessment and over the entire 12-month. These findings indicate that behavior interventions could be a promising strategy to reduce STI incidence. However, these positive results cannot be confirmed through meta-analysis.

DISCUSSION

Previous meta-analyses reported that behavioral interventions are effective in reducing sexual risk behavior among adults living with HIV, however these analysis concentrated primarily on male participants (Crepaz 2006; Johnson 2006). After assessing data on interventions among female participants, different results arose. Our meta-analysis identified no increase in consistent condom use among HIV-positive women following participation in behavioral interventions.

Some issues that may be influencing these findings deserve further mention. First, we found few randomized controlled trials evaluating the effect of interventions on condom use by gender. Second, there is a gap in research on behavioral interventions for HIV-positive women that promote prophylaxis during sexual intercourse; only two interventions were found to be tailored specifically toward HIV-positive women. Despite continued emphasis on the challenges faced by women living with HIV, the research literature has yet to address how various gender-linked factors (e.g., capacity to negotiate condom use, gender power imbalances regarding resources) can impact the ability of behavioral interventions to successfully increase condom use (Finocchario-Kessler 2010; Murphy 1998; Peretti-Watel 2006; Santos 2009). Moreover, none of the included studies explicitly reported the promotion or use of the female condom, leading us to assume that the male condom was the main focus of these interventions. This oversight represents a remarkable limitation in these interventions since the male condom is not a female initiated contraceptive method. To that end, we recommend and advocate for more female condom interventions that can empower women

to independently make decisions in sexual situations, especially among women living with HIV.

Also, it would be useful for future research to better account for the diversity across HIV-positive women, focusing on subgroup analyses that highlight varying intervention effects across heterogeneous samples of women living with HIV (e.g., women planning to become pregnant; women with casual *versus* steady partners; women in a relationship with seronegative *versus* seropositive partner). These analyses would be helpful in identifying specific groups of women who could benefit from these interventions as well as identifying new strategies for tailoring interventions.

The present systematic review holds some limitations which must be considered. The results themselves could be affected by gender-based factors since studies in the analysis described if and how male partners were involved in the intervention strategies; only two of the included studies were focused exclusively on women living with HIV. Taking this into consideration, it would be interesting to systematically review interventions targeted at heterosexual couples where at least the woman lives with HIV. This type of investigation could be used to explore how these interventions encourage condom negotiation, woman's empowerment, or the involvement of men. It is also important to highlight the possibility of self-selection bias in this analysis. All studies included were clinic-based and their participants were already receiving HIV-related care therefore the population does not accurately reflect the general population of HIV positive women.

Another shortcoming of our study results is posed by our outcome – consistent condom use – which was measured as a dichotomous variable. The majority of favorable intervention results were observed among studies that considered frequencies of risk behaviours as the main outcome (Crepaz 2006; Johnson 2006). It implies that HIV-positive people who had never used a condom before and began using one soon after the intervention may have increased the frequency of condom use, however their use is still considered inconsistent. To this end, the condom use outcome measure adopted in our review is so rigorous that positive results could be considered less attainable and it also can be related to the contrary effects (condom use being higher in the control group) found for some behavioral interventions in the meta-analysis. For this reason, significant increasing on frequency of condom use among HIV-positive women reported by some of our included studies (Cornman 2008; Sikkema 2008; Wingood 2004) does not match with our results.

Finally, only two revised studies individually reported positive effects of behavioral intervention on STI incidence among HIV+ women, but their results could not be combined through meta-analysis. STI assessment as a critical outcome to trials on behavioral interventions since strong evidences supports biological mechanisms through which STIs facilitate HIV transmission and the synergistic negative effects of multiple sexually transmitted infections, especially among women (Galvin 2004; McClelland 2005; Landes 2007). Then, we endorse that even small reductions in STI incidence could yield critical reductions in HIV morbidity and its associates treatment cost and more studies are needed to examine behavioral interventions effects.

AUTHORS' CONCLUSIONS

Implications for practice

Our meta-analysis showed behavioral interventions to have little effect on promoting condom use among HIV-positive women. These findings are in contrast to previous analyses which found these interventions to be effective among all adults living with HIV. Since our findings are based on only five studies, we are hesitant to discourage behavioral interventions all together, but instead recommend that behavioral interventions be conducted in conjunction with other strategies such as family planning and contraceptive counseling or biomedical interventions to reduce viral load. We also recommend that future interventions more effectively address gender-linked strategies to promote female condom use and the inclusion of male partners.

Implications for research

None of the studies included in our review had an adequate number of female participants warranting further research using larger female sample sizes. Future studies should also consider assessing STI prevalence outcomes (an important public health indicator), since few studies included in the current review contained data related to STIs. Furthermore, to establish definitively the efficacy of behavioral interventions on condom use among HIV-positive women, more randomized controlled trials designed specifically for this population are needed. Other important intervention research innovations include the ability to address the social context within which this population lives (Finocchario-Kessler 2010; Ghosh 2009; Murphy 1998; Peretti-Watel 2006; Santos 2009), including their position within society and the potential to work with sexual partners where appropriate and feasible.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Cornman 2008

Methods	Randomized controlled trial
Participants	87 women (from a total of 152 HIV-positive patients) receiving clinical care at an urban hospital in South Africa.

Cornman 2008 *(Continued)*

	Intervention condition: 53 HIV-positive women; mean age was 33 years old (SD=8.63); 91% were Zulu; 47% had high school; 76% were unemployed; 81% were single; 28% had learned of their diagnosis within the past 3 years, with 47% diagnosed in the past year. **Control condition:** 34 HIV-positive women; mean age was 33.7 years old (SD=5.42); 91% were Zulu; 41% had high school; 82% were unemployed; 80% were single; 47% had learned of their diagnosis within the past 3 years, with 35% diagnosed in the past year.
Interventions	**Intervention condition:** The Izindlela Zokuphila/Options for Health intervention consisted of brief (15-minute) patient-centered discussions between a counselor and a patient during regular clinical visits (every 3 months), and these discussions were repeated at each visit over an interval of approximately 6 months. The intervention consisted of an 8-step framework used by the counselor to tailor the discussions to a specific patient's HIV risk reduction (or maintenance of safer behavior) needs. The counselor used motivational interviewing techniques to (1) introduce the discussion of safer sex, (2) assess the patient's risk behavior, (3) determine how important it is to the patient to change her risk behavior, (4) determine how confident the patient is that she can change her risk behavior, (5) identify information, motivation, behavioral skills, and other barriers to consistently practicing safer behavior, (6) discuss specific strategies for overcoming these barriers, and (7) negotiate a risk reduction action plan with the patient. The final intervention step was to document the agreed upon goal on the ''Action Plan'' form, which was handed to the patient. Upon completion of the Options for Health visit, the counselor documented what transpired during the discussion (intervention steps completed, risk behaviours identified, agreed upon goal, etc.) on the ''Patient Record Form,'' which was then stored in the patient's medical file. **Control condition:** Standard HIV counseling about infection, ARVs, medication adherence, and nutrition during regularly clinic visits. Standard HIV counseling did not include systematic discussion of HIV prevention, but such discussions were not prohibited and occurred on an ad hoc basis.
Outcomes	Total number of unprotected sex events (vaginal and anal sexual events without condoms) in previous 3 months; number of times condoms were used for each type of sex; number and perceived HIV serostatus of their partners. Outcome assessments were conducted at baseline and 6-month follow-up through self-report questionnaires.
Notes	Participants were not tested to STIs. Estimated means reported in the article. After request, authors provided absolute number of female participants who reported unprotected sexual behavior at baseline and 6-month follow-up.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Information provided by e-mail: *"Since we had two intervention participants to every one control participant 152 small cards were created; 49 with the word "control" and 103 with the word "intervention." The cards were folded so the text could not be seen and placed in a box. A participant would draw one card out of the box which would determine the randomly assigned study condition. Once drawn cards were not replaced."*
Allocation concealment (selection bias)	Low risk	As described in the item above.
Incomplete outcome data (attrition bias) All outcomes	Low risk	
Selective reporting (reporting bias)	Low risk	

Cornman 2008 *(Continued)*

Other bias	Low risk	
Intention-to-treat analysis	Low risk	
Sample size calculation	High risk	Authors did not perform a sample size calculation because it was a preliminary study (information provided by e-mail).

Gilbert 2008

Methods	Randomized controlled trial
Participants	101 women (from a total of 471 HIV-positive adults) reporting substance use or sexual risk behaviours from *Positive Choice trial*, attending on outpatient HIV clinics in the San Francisco Bay Area. Considering the entire sample, 236 were Black or African-American, and 266 had High school diploma or GED. The number of women in intervention and control conditions was 56 and 45, respectively.
Interventions	**Intervention condition:** Participants received a computer based intervention (*The Video Doctor intervention*). Interactive risk reduction messages, based on principles of Motivational Interviewing, were delivered by an actor-portrayed Video Doctor, whose tone was respectful and non-judgmental. These messages simulated an ideal discussion where the health care provider expressed reflexive understanding of the patient's concerns, showed compassion for the patient, and provided nonjudgmental counseling. Using a library of digital video clips, extensive branching logic, and participant input, the program tailored the video clips to the participant's gender, risk profile, and readiness to change. At the conclusion of each session, the program printed 2 documents: 1) an ''Educational Worksheet'' for participants with questions for self-reflection, harm reduction tips, and local resources; and 2) a ''Cueing Sheet'' for providers, which offered an at-a-glance summary of the patient's risk profile and readiness to change, and suggested risk-reduction counseling statements. Intervention participants received ''booster'' Video Doctor counseling at 3-month follow-up, including feedback reflecting changes made since baseline, and updated Cueing Sheets and Educational Worksheets. **Control condition:** Participants did not interact with the Video Doctor and did not receive the Educational Worksheets or the Cueing Sheets. Following completion of the risk assessment they received the clinic's regular care.
Outcomes	Number of drinks per week, number of binge drinking episodes, total days of all drug use, absolute percent change in self-reported condom use with steady and casual partners, and number of casual sex partners. Outcome assessments were conducted at baseline, 3, and 6-month follow-up through self-reported information.
Notes	Participants were not tested to STIs. Absolute number of female participants who reported unprotected sexual behavior at baseline and each follow-up assessment was provided by e-mail.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	
Allocation concealment (selection bias)	Low risk	*"The Video Doctor program was programmed to access the secure file and select the next randomization assignment within that stratum. Thus, stratified randomization was completely concealed from the participants and the study staff. Only the programming staff would have been able to access the program in case of a problem."* (Information provided by e-mail).

Gilbert 2008 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Low risk	Postrandomization exclusion due to no risk event reported.
Selective reporting (reporting bias)	Low risk	
Other bias	Low risk	
Intention-to-treat analysis	Low risk	
Sample size calculation	High risk	

Saleh-Onoya 2009

Methods	Randomized controlled trial
Participants	102 HIV-positive women between 18 and 50 years old, black, isiXhosa speaking, sexually active in the prior 12 months. They were attending primary health clinics in Western Cape Province, South Africa. Participants were on average 29 years old. The number of women in intervention and control conditions was 53 and 49, respectively. The demographic characteristics of the intervention group did not significantly differ from the control group.
Interventions	Each group session comprised of 8 to 10 participants and was implemented by a black, isiXhosa speaking, female health educator and a black isiXhosa speaking HIV-positive woman co-facilitator. **Intervention condition:** Consisted of four four-hour sessions of sexual risk reduction and coping training, implemented weekly. Session 1 focused on enhancing ethnic and gender pride, and self-esteem. The group discussed ways of expanding support networks and maintaining social support. In session 2 participants discussed communication styles and potential outcomes of each option. Role plays were used to demonstrate and reinforce assertive communication skills. Session 3 focused on reinforcing HIV and STI infection and re-infection knowledge, and highlighted personal HIV risk associated to unsafe sexual behavior. Participants discussed and role-played strategies for negotiating condom use with sex partners. They learnt skills for correct condom use by observing demonstrations by health educators and practicing condom application on penis models. In session 4 participants differentiated healthy and unhealthy relationships, and discussed abuse in relationships (emotional, sexual, or physical) and methods for safely resolving relationship problems. Most intervention activities were adopted from the original *WiLLOW* program which was culturally adapted through previous focus group discussions. **Control condition:** Consisted of one four-hour session focusing on reiterating motivational messages about developing a positive outlook on life despite the challenges of living with HIV.
Outcomes	STI prevalence and incidence (vaginal swabs tested for CT, NG, TV and BV); sexual behavior (self-reported information about condom use in the last sexual intercourse, and in the last month); psychosocial determinants of condom use (scales focusing HIV Knowledge, attitude towards condom use, self-efficacy for negotiating and correct condom use, control in relationships, self-esteem, and coping with HIV).
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	

Saleh-Onoya 2009 *(Continued)*

Allocation concealment (selection bias)	Low risk	
Incomplete outcome data (attrition bias) All outcomes	High risk	
Selective reporting (reporting bias)	Low risk	
Other bias	Low risk	
Intention-to-treat analysis	High risk	An ITT analysis was not performed but, in the article, authors reported absolute number of participants for each outcome.
Sample size calculation	High risk	Authors did not perform a power size calculation (information provided by e-mail).

Sikkema 2008

Methods	Randomized controlled trial
Participants	130 women (from a total of 247 HIV-positive adults) with extensive sexual trauma histories, attending AIDS service organizations and community health care clinics in New York City. Considering the entire sample, participants had a mean age of 42.3 years (SD = 6.8) and 12.2 years (SD = 2.4) of education. On average, participants were diagnosed with HIV for 10.0 years (SD =5.8). Authors did not report demographic characteristics by gender but they reported no statistically significant differences by study condition.
Interventions	In both group conditions, co-therapists delivered the interventions in a community health center over a course of 15 weekly 90-minutes sessions. **Intervention condition:** The intervention model integrated the cognitive theory of stress and coping and effective cognitive-behavioral treatment strategies for sexual trauma within a transactional framework for understanding sexual abuse outcomes. Participants identified stressors related to sexual abuse and HIV. Parallels between these traumatic experiences in terms of stress response and coping strategies were addressed. Other therapeutic activities included identification of individual triggers, selection of attainable goals, skill-building exercises, and exposure. Risk reduction skills were addressed in the context of elements necessary for healthy relationships (e.g., safety, intimacy, power, self-esteem), including sexual relations after sexual abuse, re-victimization, and HIV infection. Participants shared experiences and offered mutual support and feedback. **Control condition:** The comparison group paralleled a standard therapeutic support group and was led by experienced co-therapists not trained on the coping intervention model. The purpose of the group was to provide a supportive environment for participants to address issues of HIV and trauma. Because group leaders were skilled clinicians with substantial experience, this treatment condition resembled an interpersonal process group model more than a standard community-based support group. Despite the open format, the group content had a predominant focus on the connections between sexual abuse, HIV/AIDS, current relationships, and life events.
Outcomes	Participants reported the number of times they had engaged in anal and vaginal intercourse in the past 4 months at baseline, 3, 6 and 12-month follow ups. Condom use and partner serostatus were assessed specific to intercourse occasions.
Notes	Absolute number of female participants who reported unprotected sexual behavior at baseline and each follow-up assessment was provided by e-mail. Participants were not tested to STIs.

Sikkema 2008 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	After contact by e-mail, authors clarified that they used block randomization by gender, so each wave or block of approximately 30 female or male participants was randomized independently, with previously prepared sealed envelopes presented to participants following the baseline interview. Both participants and interviewers were blind to condition until after baseline.
Allocation concealment (selection bias)	Low risk	
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Article has referred attrition analysis in the discussion section (p. 511) but did not provide complete information on that.
Selective reporting (reporting bias)	Low risk	
Other bias	Low risk	
Intention-to-treat analysis	Low risk	
Sample size calculation	High risk	Considering power sample calculation, authors answered our request as follow: *"For original proposal, a sample size of 240 HIV-positive women and men to participate in the study; 120 participants randomly assigned to each condition."*

Wingood 2004

Methods	Randomized controlled trial
Participants	366 women receiving medical care for HIV/AIDS in Alabama and Georgia, USA. They were sexually active in the previous 6 months, had been living with HIV for an average of 5 years (SD = 3.8), and had a mean age of 34.7 years (SD = 7.6). 190 were randomized to the WiLLOW intervention, and 176 to the comparison condition. Authors reported no significant group differences on demographic characteristics.
Interventions	**Intervention condition:** The WiLLOW intervention consisted of 4 4-hour interactive group sessions that were implemented over consecutive weeks. Each session included 8 to 10 participants, was implemented by a trained female health educator, and was co-facilitated by an HIV-positive female peer educator. The social cognitive theory and the theory of gender and power were used as theoretic frameworks for the development and implementation of the WiLLOW intervention. Session 1 emphasized gender pride by discussing the joys and challenges of being a woman and by acknowledging the accomplishments of women in society. This session also sought to assist women in identifying people in their social network who have provided social support and in recognizing the essential qualities of supportive network members. Session 2 discussed ways of maintaining supportive network members, encouraged women to seek new network members, and informed participants about how to disengage from network members who were not supportive. Peer educators emphasized that social support could be requested without having to disclose serostatus. Session 3 enhanced awareness of HIV transmission risk behaviours and debunked common myths regarding HIV prevention for people living with HIV (e.g., *"If both partners are HIV-positive, it is okay to have unprotected sex"*). This session also taught participants communication skills for negotiating safer sex and reinforced the benefits of using condoms consistently, and peer educators modeled proper condom use skills. Session 4 taught women to distinguish between healthy and unhealthy relationships, discussed the impact of abusive partners on safer sex, and informed women of local shelters for women in abusive relationships.

Wingood 2004 *(Continued)*

	Control condition: Participants from a health promotion comparison received 4 4-hour interactive group sessions administered over consecutive weeks. These sessions addressed medication adherence, nutrition, and provider interaction skills. Two peer educators co-facilitated implementing the comparison condition.
Outcomes	Sexual behavior (self-reported frequency of unprotected vaginal intercourse in the 30 days and 6 months preceding assessments); psychosocial mediators of condom use (scales focusing HIV transmission risk knowledge, partner communication, perceived partner-related barriers to condom use, beliefs that condoms interfere with sex, and condom use self-efficacy; and STI prevalence and incidence (vaginal swabs tested for CT, NG, TV-entire 12-month follow-up period). Assessment at baseline, 6 and 12-month follow-ups.
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	
Allocation concealment (selection bias)	Low risk	
Incomplete outcome data (attrition bias) All outcomes	Low risk	
Selective reporting (reporting bias)	Low risk	
Other bias	Low risk	
Intention-to-treat analysis	Low risk	
Sample size calculation	High risk	*"Sample size calculations were based on preliminary research with this population. We estimated a moderate effect size, a 35% difference between the study conditions in the number of unprotected vaginal sex acts in the 30 days preceding assessment. Estimating 20% attrition over the 12-month follow-up period and setting the type I error rate at 0.05 for a 2-tailed test (power = 0.80) required a total sample of 185 participants in each study condition to detect the specified effect size." (p. S61)*

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Belcher 1998	Intervention did not target HIV population. Outcomes not reported by HIV status (only 18 HIV-positive women were included)
Bhave 1995	Not randomized study. Outcomes not reported by HIV status. Participants aged between 15-25 - outcomes not reported by age
Bunnell 2006	Not randomized study

Study	Reason for exclusion
Burman 2008	Outcome is not behavioral
Carrico 2009	Outcome does not involve condom use but psychosocial adjustment
Champion 2001	Descriptive study. Participants not HIV-positive
Cleary 1995	Baseline assessment was conducted when participants did not have their HIV diagnosis yet
Cosio 2010	Both groups received intervention for increasing condom use
Dilley 2008	Participants were homosexual men not HIV-infected
Fisher 2006	Not randomized study
Fogarty 2001	Both groups received intervention for increasing condom use. Participants are the same reported in Gielen 2001 (Outcome reported refers to condom use with main partners only)
Holstad 2006	Study in recruitment phase
Jones 2001	Authors were contacted and did not have available data on absolute number of female participants who reported unprotected sexual intercourse in baseline and each follow-up assessment in both groups
Jones 2005	Both groups received intervention for condom use
Jones 2006	Study not controlled
Kalichman 2001	We have tried insistently to contact authors and we had no answer. In spite of the study presents results by gender it does not show absolute results of consistent condom use
Kalichman 2005	Outcomes not reported by gender. Study includes men and women
Lightfoot 2007	Study includes adolescents. Outcomes not reported by age and gender
MacNeil 1999	Authors were contacted and did not have available data on absolute number of female participants who reported unprotected sexual intercourse in baseline and each follow-up assessment in both groups.
Magnano San Lio 2009	Intervention not focused in condom use. Not a clinical trial design
Naar-King 2006	Study includes adolescents. Outcomes not reported by age and gender
NIMH Multisite Group 2008	No outcomes reported.
Olley 2006	Outcomes not reported by gender. Intervention not clearly focused in condom use
Patterson 2003	Outcomes not reported by gender or age. Study includes men and women
Purcell 2007	Outcomes not reported by gender. Study includes men and women
Rotheram-Borus 2001	Study includes adolescents. Outcomes not reported by age and gender
Rotheram-Borus 2004	Outcomes not reported by gender or age. Study includes adolescents
Rotheram-Borus 2009	Outcomes not reported by gender. Study does not examine gender differences.

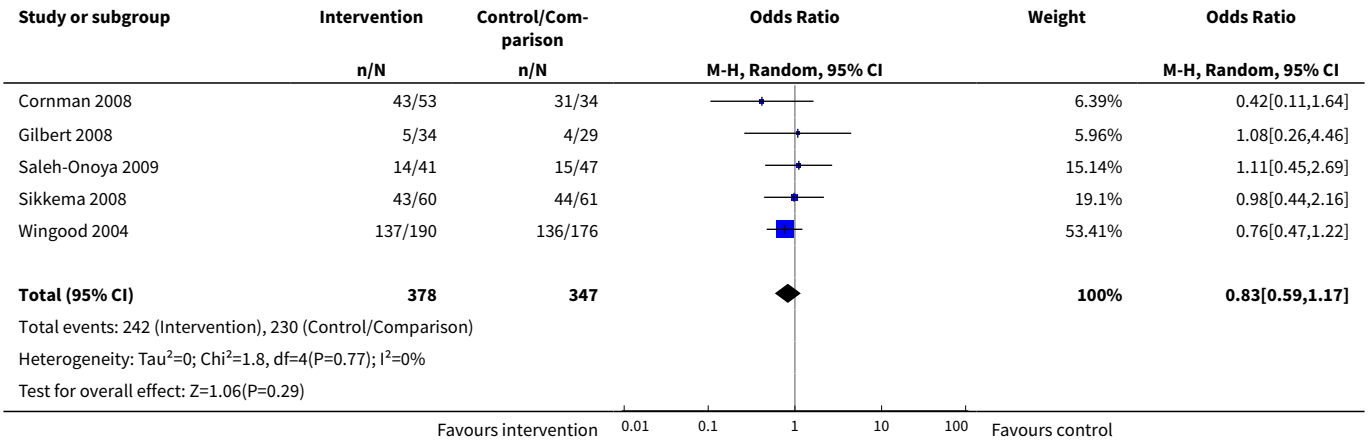
Study	Reason for exclusion
The Healthy Living 2007	Outcomes not reported by gender
Wyatt 2004	Control group assessment was obtained only in an immediately post-intervention follow-up but not at 3 or 6 months follow-up

DATA AND ANALYSES

Comparison 1. Consistent condom use among women living with HIV

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Baseline	5	725	Odds Ratio (M-H, Random, 95% CI)	0.83 [0.59, 1.17]

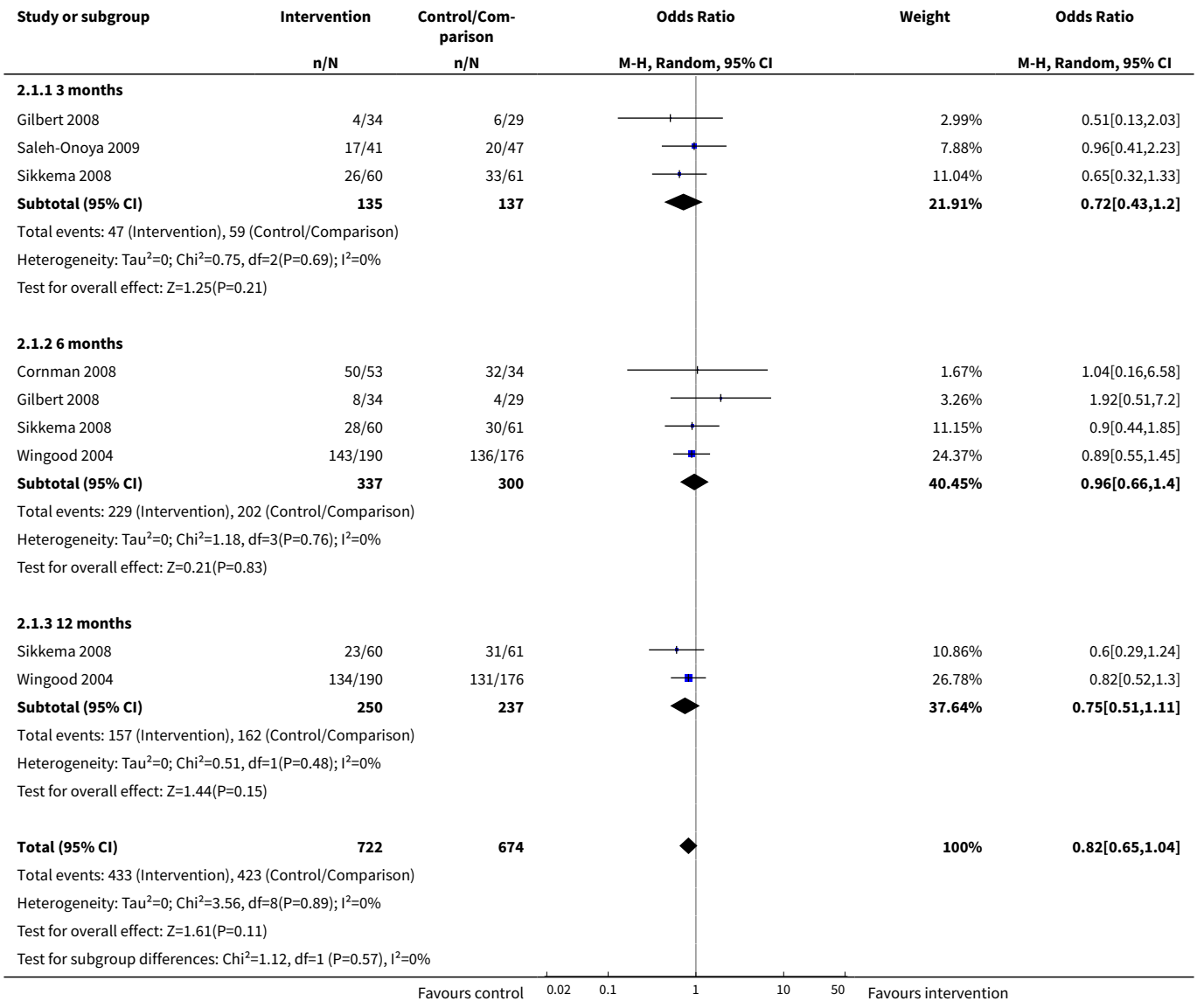
Analysis 1.1. Comparison 1 Consistent condom use among women living with HIV, Outcome 1 Baseline.



Comparison 2. Increasing in consistent condom use among women living with HIV after intervention

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Time intervention	5	1396	Odds Ratio (M-H, Random, 95% CI)	0.82 [0.65, 1.04]
1.1 3 months	3	272	Odds Ratio (M-H, Random, 95% CI)	0.72 [0.43, 1.20]
1.2 6 months	4	637	Odds Ratio (M-H, Random, 95% CI)	0.96 [0.66, 1.40]
1.3 12 months	2	487	Odds Ratio (M-H, Random, 95% CI)	0.75 [0.51, 1.11]

Analysis 2.1. Comparison 2 Increasing in consistent condom use among women living with HIV after intervention, Outcome 1 Time intervention.



APPENDICES

Appendix 1. MEDLINE (PubMed) search strategy queries

Date range: 1 January 1980 18 May 2010

HIV/AIDS terms

#1 “HIV Infections”[MeSH]

#2 “HIV”[MeSH]

#3 hiv[tw]

#4 hiv-1*[tw]

#5 hiv-2*[tw]

#6 hiv1[tw]

#7 hiv2[tw]

#8 hiv infect*[tw]

#9 human immunodeficiency virus[tw]

#10 human immunedeficiency virus[tw]

#11 human immuno-deficiency virus[tw]

#12 human immune-deficiency virus[tw]

#13 ((human immun*) AND (deficiency virus[tw]))

#14 acquired immunodeficiency syndrome[tw]

#15 acquired immunedeficiency syndrome[tw]

#16 acquired immuno-deficiency syndrome[tw]

#17 acquired immune-deficiency syndrome[tw]

#18 ((acquired immun*) AND (deficiency syndrome[tw]))

#19 “sexually transmitted diseases, viral” [MESH:NoExp]

#20 #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7OR #8 OR #9 #10 #11 OR #12 OR #13 OR #14 OR #14 OR #15 OR #16 OR #17OR #18 OR #19

RCT and CCTs terms

#21 randomized controlled trial[pt]

#22 controlled clinical trial[pt]

#23 randomized[tiab]

#24 placebo[tiab]

#25 drug therapy[sh]

#26 randomly[tiab]

#27 trial[tiab]

#28 groups[tiab]

29 #21OR #22 OR #23 #24 OR #25 OR #26 OR #27 OR #28

#30 #29 AND humans[mh]

Sexual behavior terms

#31 sexual[tiab] AND (behavior[tiab] OR behavior[tiab])

#32 sexual[tiab] AND (risk[tiab] OR risk-taking[tiab] OR risk behavior[tiab] OR risk behaviour[tiab] OR risk practice[tiab] OR risky behavior[tiab] OR risky behaviour[tiab] OR risky practice[tiab] OR risky activity[tiab])

#33 unsafe[tiab] AND (sex[tiab] OR intercourse[tiab])

#34 unprotected[tiab] AND (vaginal sex[tiab] OR anal sex[tiab] OR vaginal intercourse[tiab] OR anal intercourse[tiab] OR sexual practice[tiab])

#35 condom*[tiab]

#36 #31OR #32 OR #33 #34 OR#35

Behavioral interventions terms

#37 "Behavior Therapy"[Mesh]

#38 "Cognitive Therapy"[Mesh]

#39 "Imagery (Psychotherapy)"[Mesh]

#40 "Psychotherapy, Rational-Emotive"[Mesh]

#41 cognitive*[tiab] AND (therap*[tiab] OR train*[tiab] OR techni*[tiab] OR question*[tiab] OR approach*[tiab] OR intervention[tiab])

#42 ((behavior*[tiab] OR behaviour*[tiab]) AND (therap*[tiab] OR train*[tiab] OR modif*[tiab] OR experiment*[tiab] OR intervention[tiab] OR coping[tiab]))

#43 ((educat*[tiab]) AND (intervention[tiab] OR therap*[tiab] OR counsel*[tiab] OR program[tiab] OR train*[tiab] OR client[tiab] OR patient[tiab] OR health[tiab]))

#44 ((patient[tiab]) AND (counsel*[tiab] OR compliance[tiab] OR educ*[tiab] OR teach*[tiab]))

#45 ((safer-sex[tiab] OR risk reduction[tiab]) AND (counsel*[tiab] OR intervention[tiab] OR prevention[tiab]))

#46 ((problem solving[tiab] OR self control[tiab]) AND (therap*[tiab] OR intervention[tiab] OR train*[tiab]))

#47 motivation*[tiab] AND (debriefing[tiab] OR interview[tiab])

#48 brief[tiab] AND (psychotherap*[tiab] OR therap*[tiab])

#49 group[tiab] AND (psychotherap*[tiab] OR therap*[tiab])

#50 rational*[tiab] AND emotive*[tiab]

#51 cbt[tiab]

#52 psychoeducation[tiab]

#53 peer-led intervention[tiab]

#54 peer-mentoring intervention[tiab]

#55 social skills train*[tiab]

#56 health promotion[tiab]

#57 HIV prevention intervention[tiab]

#58 #37 OR #38 OR #39 OR #40 OR #41 OR #42 OR #43 OR #44 OR #45 OR #46 OR #47 OR #48 OR #49 OR #50 OR #51 OR #52 OR #53 OR #54 OR #55 OR #56 OR #57

Terms combination

#59 #20 AND #29 AND #36 AND #58

Appendix 2. Sample size calculation for assessment of risk of bias

Based on the results of the first published article in order to determine the efficacy of a behavioral intervention on condom use among women living with HIV (Wingood 2004).

P1 expected proportion in the control group 136/176= 0.77

P2 expected proportion in the treated group 143/190=0.75

Lowest *p*= 0.75

Difference between **P1** and **P2** = 0.02

Table 6.B.1 (pg. 86, Hulley 2001): alpha and beta 0.05 and 0.20 (middle column) 15th line (0.75) and first column (0.05) the middle column in each group = **1.133**

FEEDBACK

Response to feedback, 16 January 2012

Summary

Date of Submission: 06-Jan-2012

Feedback: From David Sinclair and Paul Garner

We are writing to highlight several concerns about the above Cochrane review.

This review is obviously an important topic within HIV and makes what would be very important conclusions: 'Meta-analysis shows that behavioral interventions have little effect on increasing condom use among HIV-positive women'. The summary of findings table states that this is 'High' quality evidence meaning that we can have full confidence in the result and further research is unnecessary.

However there are some major errors in the way the data has been handled:

1. The numbers given in the SoF table for the primary outcome (Consistent condom use: OR 0.83, 95% CI 0.59 to 1.17) are actually the data for the use of condoms at baseline, before the intervention is given (shown in figure 2)
2. The numbers given for the same outcome in the abstract are also incorrect (OR 0.82, 95% CI 0.65 to 1.04). These figures are taken from the meta-analysis in figure 6 which combines data at 3 months, 6 months, and 12 months. It is incorrect to perform this meta-analysis as it triple counts some data.
3. The actual data which should be used in both instances is from 2 trials: OR 0.75, 95% CI 0.51 to 1.11)

There are then some important deficiencies in how the data has been interpreted:

1. This figure suggests that there is a trend towards behavioural interventions actually being harmful (condom use being lower in the intervention group) but this is not adequately discussed.
2. The evidence from 2 small trials (or even 5 small trials) is unlikely to be of high quality, due to concerns about imprecision (the trials are underpowered), and indirectness (can we really generalise this data to all women with HIV?). The authors themselves note several limitations in the data such as 'None of the studies included in our review had an adequate number of female participants warranting further research using larger female sample sizes' and ' Since our findings are based on only five studies, we are hesitant to discourage behavioral interventions all together'. These comments are not consistent with a quality GRADE of high.
3. In addition the results section appear very short. Some positive benefits on the incidence of STI are noted but inadequately reported and inadequately discussed. These are predefined outcomes and should be included in the Summary of findings tables.

We hope this helps in improving the review.

Best wishes,

Paul and Dave

Submitter agrees with default conflict of interest statement:

I certify that I have no affiliations with or involvement in any organization or entity with a financial interest in the subject matter of my feedback.

Reply

We thank Dr. Garner and Dr. Sinclair for their helpful comments and we have corrected their primary points of concern. We plan to update this review in May 2012, when additional modification will be made.

Contributors

Tonantzin Ribeiro Gonçalves

WHAT'S NEW

Date	Event	Description
18 January 2012	Feedback has been incorporated	New feedback, and response to feedback.

CONTRIBUTIONS OF AUTHORS

FC, TG, EF, JS, CP, and MR were involved in the study design and concept. TG conducted the trials search and, together with FC and EF, worked on selection of studies and data extraction. LM collaborated with data extraction and management, and performed the analyses. TG and EF drafted the manuscript. All authors critically revised the manuscript and approved the final version.

DECLARATIONS OF INTEREST

None

SOURCES OF SUPPORT

Internal sources

- No sources of support supplied

External sources

- Conselho Nacional de Desenvolvimento Científico e Tecnológico (CNPq), Brazil.
- Health Ministry, Brazil.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

In the review protocol, we had planned to include CCTs in the review but we identified only one controlled clinical trial (Fisher 2006) that was excluded to avoid potential confounders in the meta-analysis. Moreover, STI outcome could not be considered in the meta-analysis because the outcomes reported in two studies (Saleh-Onoya 2009; Wingood 2004) were not comparable due to distinct follow-up periods, and insufficient data in one case (Saleh-Onoya 2009).

INDEX TERMS

Medical Subject Headings (MeSH)

*Risk Reduction Behavior; Condoms [*statistics & numerical data]; HIV Infections [*prevention & control] [transmission]; HIV Seropositivity [psychology]; Randomized Controlled Trials as Topic; Sexually Transmitted Diseases [prevention & control] [transmission]; Standard of Care

MeSH check words

Adult; Female; Humans