

	275 per 1000	173 per 1000 (124 to 242)			
	Medium risk population				
	275 per 1000	173 per 1000 (124 to 242)			
Consistent male condom use at 3-month	Study population		RR 0.88 (0.83 to 0.92)	572 (2 studies)	⊕⊕⊕⊕ high ^{3,6,7,8,9}
	968 per 1000	852 per 1000 (803 to 891)			
	Medium risk population				
	913 per 1000	803 per 1000 (758 to 840)			
Consistent female condom use by FSWs at 3-month	Study population		RR 0.12 (0.09 to 0.17)	564 (2 studies)	⊕⊕⊕⊕ high ^{3,6,7,9,10}
	968 per 1000	116 per 1000 (87 to 165)			
	Medium risk population				
	913 per 1000	110 per 1000 (82 to 155)			
Consistent female condom use by FSWs at 24-month	Study population		RR 0.15 (0.09 to 0.28)	128 (1 study)	⊕⊕⊕⊕ high ^{1,2,3,5,6}
	950 per 1000	143 per 1000 (86 to 266)			
	Low risk population				
	147 per 1000	22 per 1000 (13 to 41)			

Consistent male condom use at 24-month	Study population		RR 0.91 (0.82 to 1.02)	128 (1 study)	⊕⊕⊕○ moderate ^{1,2,3,5,11}
	950 per 1000	865 per 1000 (779 to 969)			
	Low risk population				
	868 per 1000	790 per 1000 (712 to 885)			

*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; **RR:** Risk 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 No serious limitations: Allocation concealment was judged to be at 'low risk of bias' in this trial.

² Single study.

³ No serious indirectness: Result is likely to be reliable.

⁴ Very serious imprecision: The 95% CI of estimate is wide and crosses the line of no effect.

⁵ Bias was judged to be at 'low risk' in this trial.

⁶ No serious imprecision: The 95% CI of estimate includes appreciable benefit to intervention group over control group.

⁷ No serious limitations: Allocation concealment was judged to be at 'low risk of bias' in two trials.

⁸ No serious inconsistency: May represent substantial heterogeneity (65%).

⁹ Bias was judged to be at 'low risk' in two trials.

¹⁰ No serious inconsistency: Heterogeneity (0%) might not be important.

¹¹ Serious imprecision: The 95% CI of estimate crosses the line of no effect.

VCT compared to standard care of STI for increasing condom use for sex workers						
Patient or population: sex workers Settings: low- and middle income countries Intervention: VCT Comparison: standard care of STI for increasing 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				
	standard care of STI for increasing condom use	VCT				
Syphilis prevalence among FSWs at 6-month	Study population		RR 0.52 (0.23 to 1.18)	278 (1 study)	⊕○○○ very low ^{1,2,3,4,5}	
	109 per 1000	57 per 1000 (25 to 129)				
	Medium risk population					
	110 per 1000	57 per 1000 (25 to 130)				
Gonorrhoea prevalence among FSWs at 6-month	Study population		RR 0.83 (0.4 to 1.74)	278 (1 study)	⊕○○○ very low ^{1,2,3,4,5}	
	102 per 1000	85 per 1000 (41 to 177)				
	Medium risk population					
	102 per 1000	85 per 1000 (41 to 177)				
Chlamydia prevalence among FSWs at 6-month	Study population		RR 0.67 (0.4 to 1.13)	278 (1 study)	⊕○○○ very low ^{1,2,3,4,5}	

	212 per 1000	142 per 1000 (85 to 240)			
	Medium risk population				
	212 per 1000	142 per 1000 (85 to 240)			
Trichomonas prevalence among FSWs at 6-month	Study population		RR 0.52 (0.23 to 1.18)	278 (1 study)	⊕○○○ very low ^{1,2,3,4,5}
	109 per 1000	57 per 1000 (25 to 129)			
	Medium risk population				
	110 per 1000	57 per 1000 (25 to 130)			
Genital warts prevalence among FSWs at 6-month	Study population		RR 0.22 (0.05 to 0.98)	278 (1 study)	⊕⊕○○ low ^{1,2,3,5,6}
	66 per 1000	15 per 1000 (3 to 65)			
	Medium risk population				
	66 per 1000	15 per 1000 (3 to 65)			
Consistent condom use by FSWs with clients at 6-month	Study population		RR 2.05 (1.48 to 2.85)	278 (1 study)	⊕○○○ very low ^{1,2,5,7,8}
	255 per 1000	523 per 1000 (377 to 727)			
	Low risk population				
	255 per 1000	523 per 1000 (377 to 727)			

HIV/STI knowledge among FSWs at 6-month	Study population		RR 1.28 (0.81 to 2.04)	278 (1 study)	⊕○○○ very low ^{1,2,5,7,8}
	182 per 1000	233 per 1000 (147 to 371)			
	Low risk population				
	182 per 1000	233 per 1000 (147 to 371)			

*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; **RR:** Risk 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 Serious limitations: Allocation concealment was judged "unclear" in this trial.

² Single study.

³ No serious indirectness: Result is likely to be reliable.

⁴ Serious imprecision: The 95% CI of estimate crosses the line of no effect.

⁵ Bias was judged to be at "high risk" in this trial.

⁶ No serious imprecision: The 95% CI of estimate includes appreciable benefit to intervention group over control group.

⁷ Serious indirectness: There is considerable variability in the effect of control which makes extrapolation of result to other settings unreliable.

⁸ Very serious imprecision: The 95% CI of estimate include appreciable benefit to control group over intervention group.

DISCUSSION

Summary of main results

The current review addressed a number of HIV behavioral prevention interventions intended to reduce the transmission of HIV among FSWs in low- and middle-income countries. The review used comprehensive search strategies encompassing both published and non-published studies. In addition, strict inclusion criteria were followed to ensure that the review was focused on behavioral interventions among sex workers. The review's conclusions are weakened by the small number and size of the potential trials and by the insufficiency of the reported data for the pre-specified primary and secondary outcomes.

Thirteen trials were identified which fulfilled the inclusion criteria for this review, involving 8,698 participants. Of the interventions assessed, seven studies identified the primary outcomes but only three trials examined HIV incidence. Moreover, there was no strong evidence that these interventions reduced HIV prevalence. Nonetheless, results of meta-analyses of primary outcomes found that the interventions did have an effect in reducing HIV incidence among FSWs assigned to a social cognitive intervention compared with those received standard counselling for HIV/STIs (Patterson 2008) and interventions promoting the use of female and male condoms were more effective compared than those that promoted male condoms only (Ray 2001). Furthermore, other primary outcomes, such as the incidence of STIs, were assessed by various interventions such as:

- Social cognitive theory, which was found to be effective in reducing the incidence of any STIs in India by 43% (Patterson 2008);
- Promotion of condom use, which reduced gonorrhoea and chlamydia incidence in Thailand by 37% and 29%, respectively (Fontanet 1998)
- Peer education intervention in addition to clinic-based counselling conducted which reduced prevalence of chlamydia and of any STIs by 30% and 20%, respectively in Madagascar (Feldblum 2005)
- Intensive STI screening, which reduced HIV incidence by 35%, and chlamydia trachomatis and gonorrhoea prevalence by 77% and 62%, respectively in Cote d'Ivoire (Ghys 2001)
- VCT intervention, which led to a 78% reduction in prevalence of genital warts among FSWs in China (Li 2006)
- Prevalence of STIs was also reported by a community empowerment intervention in India (Gutierrez 2010), but no intervention effect was found.

Meta-analyses also were performed for two secondary outcomes; changes in behavior outcomes such as consistent condom use,

including female and male condom use; and drug use risk behavior. These meta-analyses showed strong effects of the promotion of condom use in intervention and control groups, including increases in female condom use rather than male condom use. However, this was positively correlated with increased condom use by clients, a finding not repeated in other results from the meta-analysis. There was a difference between social cognitive theory and standard care in the reduction of illicit drug use among FSWs. Substantial heterogeneity ($I^2 > 50\%$) in this review were identified in two meta-analyses assessed consistent condom use through community empowerment intervention (81%; Analysis 3.3) and through promotion of female and male condom use (65%; Analysis 3.4) indicated that variability in methodological, implementation of interventions, settings or populations may be differ. No observed heterogeneity were observed among studies whether evaluated consistent condom use through social cognitive intervention (Analysis 1.3) or through promotion of condom use (Analysis 9.4) indicated studies contributed for meta-analysis is a similar way.

The effectiveness of behavioral interventions for other secondary outcomes was analysed. Results were

- A positive increase in the rate of consistent use of condoms with regular partners by 45% as a result of a community empowerment intervention (Gutierrez 2010)
- The addition of an education intervention to a microenterprise intervention conducted in India was associated with a reduction in the number of sex exchange partners (Sherman 2010)
- The addition of manager training to peer education was found to increase the likelihood of HIV testing among FSWs in the Philippines (Chiao 2009)

It is not possible to conclude definitively that no positive effect has been achieved by some interventions, either due to small sample size or failure in the design of the studies, or both. This clearly highlights of the need to clarify these issues for policy-makers and researchers considering affordable options for improving the quality of interventions to reduce the transmission of HIV in resource-limited settings. It also indicates the importance of good study design when implementing behavioral intervention programs of previously unknown quality.

This review was limited to examining the available literature on female sex workers. Given their high mobility and high risk of HIV exposure, male and transgender sex workers and their clients should also be taken into account when considering the spread of STIs. In spite of limited data, a number of non-RCTs have determined the effect of HIV/AIDS behavioral interventions in preventing HIV/STIs among targeted male sex workers (Maticka-Tyndale 1997 in Thailand), male transgender sex

workers (Khan 2008 in Pakistan), and male clients of sex workers (Leonard 2000 in Senegal, Barrington 2009 in Dominican Republic, and Hoque 2009 in Bangladesh), however, this systematic review did not include non-RCTs, so these studies and the evidence from them were not available to support the results in this review.

Although some trials provided only minimal details of follow-up length, the length or intensity of the interventions varied across trials. It is important to note that follow-up assessments over six months might have seen a reduction in the incidence rates of STIs in Thailand, Madagascar and Mexico (Fontanet 1998, Feldblum 2005, Patterson 2008) and STI prevalence in China (Li 2006), and in the number of sex exchange partners in India (Sherman 2010) compared with shorter or longer follow-up assessments. Conversely, the results from the current review of consistent condom use did not depend on the duration of the follow-up period. For example, results from an RCT in Thailand (Fontanet 1998) showed effective use of female condoms after a 6-month follow up period and after a 24-month follow up period, but the intervention failed to increase male condom use after a 24-month assessment period, which means this phenomenon was not specific enough to measure the reduction of HIV/STI incidence and prevalence. This indicates that effective behavioral change interventions to increase condom usage may be long-lasting and sustainable, which is an important consideration in dealing with hard-to-reach, hidden and mobile populations such as sex workers.

Despite its limitations, our review provides scientific evidence to support social cognitive theory intervention and the promotion of male and female condom use in order to reduce the transmission of HIV/STIs in vulnerable populations, especially FSWs, when compared with other behavioral approaches or no interventions. This meta-analysis also could inform the design and implementation of future studies, especially in terms of the choice of target population, setting, intensity of assessment, and the content of the intervention, and the findings of the studies included in this review, as well as the methods that were successful, should be considered by policy-makers, health workers and researchers in designing new interventions for these communities.

Overall completeness and applicability of evidence

A total of 13 trials were selected for review. However, the available data are limited for some outcomes and the results should thus be interpreted with caution. Although the data is available, it is not clear how easy it would be to apply the interventions to other settings, or to generalize the findings to other population groups. Studies identifying the effects of behavioral interventions on HIV prevalence were not considered in this review although this outcome is undoubtedly important in the reduction of HIV transmission among sex workers. The interventions for all sex workers were reviewed but only FSW programs were eligible based on randomised methods. Male and transgender sex workers and their

clients were not included in the review due to the unavailability of data and due to these factors the results of the meta-analyses can only be applied to FSWs. Also, there was heterogeneity in the intervention effects for many of the outcomes, and there is no information as to the specific factors that might have caused the differences between the intervention and control groups. However, with regard to our objective, the findings of the review indicate that the use of social cognitive-based theory and the promotion of female and male condom use as HIV behavioral prevention strategies play an important role in reducing HIV/STI incidence, along with increasing condom use consistently and reducing illegal drug use risk behavior among FSWs in low- and middle-income countries. Because these interventions are likely to be low-cost, capable of being implemented by relatively unskilled workers, and can be easily maintained over long periods, they provide an important tool for controlling the spread of HIV amongst high-risk groups in low- and middle-income countries.

Quality of the evidence

The quality of the evidence has been assessed using the GRADE process (Guyatt 2008), and the results are presented in the Summary of findings for the main comparison, Summary of findings 2, Summary of findings 3, and Summary of findings 4. The GRADE approach uses four levels of quality (very low, low, moderate and high) over several domains covering limitations in the design and implementation of studies, indirectness of evidence, unexplained heterogeneity or inconsistency in results, imprecision of results and high probability of publication bias. The highest quality rating was found in six trials (Fontanet 1998, Ray 2001, Hoke 2007, Patterson 2008, Chiao 2009, Sherman 2010). The assessment of the risk of bias in these trials suggests concern regarding insufficient information of sequence generation, allocation concealment and failure to adequately address incomplete outcome data. Methodological quality was rated as "high" for only four of the thirteen trials (Fontanet 1998, Ray 2001, Patterson 2006, Sherman 2010), .

Potential biases in the review process

All authors have an interest in HIV behavior prevention interventions, and each brings a different perspective to the methods used. However, we made efforts to limit the bias in several ways: two review authors assessed eligibility for inclusion and assessed the risk of bias independently. Although the authors' views varied, after extensive discussion and achieving a consensus, we decided to accept the final conclusions. We knew that a meta-analysis might be vulnerable to publication bias in the review process. However, we were not able to use funnel plots due to the heterogeneity of the study designs. But we did try to ensure that our eventual conclusion arose solely from the data. Feedback from readers internationally will serve to improve the next review update.

Agreements and disagreements with other studies or reviews

These results indicate that combined HIV behavioral prevention strategies have a greater potential for positive results than single interventions such as peer education or manager training alone (Chiao 2009). These results are consistent with those from cluster non-RCTs that tested the combined effects of educational interventions and the promotion of condom use in reducing HIV and STI incidence in India (Bhave 1995) and Indonesia (Ford 2002). However, when a health education intervention was combined with the promotion of condoms, it resulted in the intervention having either no effect or in an increase in condom use among FSWs in Nicaragua (Egger 2000). The effectiveness of these interventions, moreover, may not be assumed when the objective is, for example, to improve the knowledge of HIV/STI, or to change self-reported or observed behavior, such as sexual risk behavior and the frequency of sexual encounters. Our systematic review in low- and middle income countries shows that not all behavioral interventions have a positive impact when it comes to preventing HIV/STI infections or other secondary outcomes. This finding is consistent with the systematic review of interventions for sex workers in high-income countries, in which the effect of behavioral interventions did not significantly reduce the STI incidence and increase the use of condoms (Ota 2011).

AUTHORS' CONCLUSIONS

Implications for practice

HIV transmission among sex workers and their clients helps to drive a broader epidemic of heterosexually-acquired HIV (UNAIDS 2009), resulting in transmission even among individuals who engage in low levels of risk behavior. Interventions to reduce the risk of HIV transmission amongst these high-risk groups are therefore an important part of the international response to the HIV epidemic, and should be assessed carefully for their suitability, cost and effectiveness. This review strongly considers the effectiveness of several ongoing behavioral interventions that are likely to be available to policy makers and healthcare workers in low- and middle-income nations. Policy makers, practitioners and researchers therefore have a greater range of choice of potential interventions to reduce HIV transmission risk among high-risk groups. Before making a practice decision based on the current review, further information from other reviews considering how the role of combining sexual risk reduction, condom promotion and improved access to STI treatment reduces HIV and STI acquisition in sex workers receiving these interventions (Shahmanesh 2008) should be taken into account. Nevertheless, given the observed effectiveness of social cognitive theory and the promo-

tion of condom use in reducing transmission of HIV/STIs, and the clear need for a reduction in transmission, these behavioral interventions should be considered for implementation in high-risk FSW communities in low- and middle-income countries. This decision should be supported, however, by the knowledge that there is lack of information about most other outcomes and target populations, and although there is evidence in favour of their implementation amongst other high-risk populations (such as transgender sex workers) the quality of this evidence is not currently sufficient to conclude that they will be effective amongst these populations. The studies reviewed here did not cover the full range of developing nations, but were spread across three continents and so be sufficient to inform policy-makers from nations not represented in the current review. This review finds that the effects of some interventions were sustained in radically different national and local settings, indicating that the interventions be suitable in most low- and middle-income countries.

Implications for research

Researchers designing new RCTs in to measure intervention effects should strongly consider measuring HIV incidence and prevalence as outcomes, and assess risk-factors for the spread of this infection. More high quality RCTs are urgently needed to further clarify which behavioral interventions are most effective in reducing the transmission of HIV among high-risk, hidden or marginalized populations in low- and middle-income countries. Moreover, because sub-Saharan Africa remains the most heavily affected region of heterosexual transmission, including among sex workers, critical evaluation of interventions there should be conducted. Furthermore, the cost-effectiveness of these interventions, particularly social cognitive behavioral interventions and the promotion of condom use as effective strategies targeted at vulnerable populations should be a priority area for research. Therefore, detailed data on the cost of interventions should be collected and analysed in a standardized format, and future implementation programs should consider enhanced study design and collection methods, to ensure that key findings from those studies are valid, generalizable and of high quality.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Basu 2004

Methods	Design: Quasi-randomized controlled trial Random allocation: means of a random number table Date: unclear (15 months)	
Participants	Number: Each community consisted 350 sex workers. 100 FSWs were randomly selected in each area (n=200) using a two-stage randomisation process. 10 sex workers in each area were over sampled at baseline to account for refusal and loss at the first follow-up Inclusion criteria: FSWs those who live and work in selected communities and provided informed consent Setting: Community-based Country: India	
Interventions	"Community empowerment" versus "standard care" Intervention: FSWs received basic STI information. Additionally, health clinics were established in the centre of both communities' red light areas to improve existing care for sex workers. They also received training by a team of local peer educators to build skills and confidence in providing education and to foster empowerment and advocacy for local sex workers. The training comprised empowerment and advocacy, included sustained engagement with local sex workers, showed interest in sex workers' health and well-being and that of their children, nurtured group solidarity among them, and raised consciousness about sex worker rights Control: FSWs did not receive the enhanced intervention to prevent HIV and STIs	
Outcomes	1. Consistent condom utilization 2. Change in condom use	
Notes		
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Communities were randomly assigned to an intervention and control condition"
Allocation concealment (selection bias)	Low risk	"First, the brothel rooms in each red-light. ...using a random number table"
Blinding (performance bias and detection bias) All outcomes	Unclear risk	The study did not address this
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Insufficient reporting of attrition/exclusions; no reasons for missing data provided

Basu 2004 (Continued)

Selective reporting (reporting bias)	Low risk	The study protocol is available and the study's outcome have been reported
Other bias	Low risk	Baseline characteristics were comparable

Chiao 2009

Methods	Design: Quasi-randomized trial Random allocation: sequential random selection of study sites Date: unclear	
Participants	Number: 980 FSWs at baseline and 903 at posttest FSWs. Inclusion criteria: FSWs who were employed at establishment and who were self-reported ever engaging in commercial sex Exclusion criteria: FSWs who failed to provide key information about HIV testing and condom use behavior Setting: Establishment-based Country: Philippines	
Interventions	Intervention: (1) peer education, (2) manager training, (3) a combination of peer education and manager training 1) The peer education intervention was implemented in Legaspi. A 5-day training included basic information on STIs and HIV, modes of transmission, interpersonal relationship with peers and clients in the work establishment, sexual negotiation, and role playing/modelling was implemented to all participants 2) Manager training intervention was conducted in Cagayan de Oro, consisted of the same topic as the peer education intervention, and training on the manager's social influence role was added 3) The combined intervention of peer education and manager training was implemented to all participants in two contiguous cities in Cebu Control: Usual care was conducted in Ilo-Ilo. Participants received standard treatment which consisted of regular examinations at the health centers	
Outcomes	1. HIV testing changes 2. Consistent condom use 3. HIV-related knowledge 4. AIDS perceived control 5. AIDS perceived severity	
Notes		
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"The research design was a simple randomised quasi-experimental approach..."

Chiao 2009 (Continued)

Allocation concealment (selection bias)	Low risk	"...number for each of the four sites were placed in a box...."
Blinding (performance bias and detection bias) All outcomes	High risk	Either participants or some key study personnel were not blinded
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	"24/1,004 (2%) missing data" was reported but reasons for missing data were not described
Selective reporting (reporting bias)	Low risk	The study protocol is available and all of the study's outcome have been reported
Other bias	Unclear risk	"The participant rates of FSWs at baseline and posttest assessments were over 95%, reducing the likelihood of a biased participant pool" but Table 1 shows the baseline and posttest were imbalance

Feldblum 2005

Methods	Design: Randomized controlled trial Random allocation: Computer-generated list stratified by study site was created by using a block permuted approach with block size of 20, 10 and 4 Date: February to August 2001, and follow-up visits extended to June 2002
Participants	Number: 1000 FSWs (500 FSWs at each site) Inclusion criteria: 18 years or older, self identified active sex workers with no signs of pregnancy Setting: Dispensary-based Country: Madagascar
Interventions	"Peer education plus clinic based counselling" versus "peer counselling only" Intervention: FSWs received three bimonthly clinic counselling sessions. A 15-minute counselling session involved a two way exchange of information on the following components: individual risk assessment; transmission and verification of basic knowledge about STIs and HIV; dual protection; demonstration of condom use with opportunity to practice using models; counselling tailored to individual circumstances; reinforcement of skill for negotiating condom use; and promotion of the "no condom = no sex" policy Control: FSWs received condom promotion and risk reduction counselling delivered by peer educators
Outcomes	1. STI prevalence 2. Consistent male/female or male and female condom use
Notes	

Feldblum 2005 (Continued)

<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Participants were individually randomised to receive condom counselling...."
Allocation concealment (selection bias)	Low risk	A computer generated random allocation list stratified by study site was created at FHI using a block permuted approach with block sizes of 20, 10 and 4
Blinding (performance bias and detection bias) All outcomes	Low risk	"....STI testing and reporting were done by laboratory staff blinded to group assignment"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No reasons for missing data provided
Selective reporting (reporting bias)	Low risk	The study protocol is available and all the study's outcome have been reported
Other bias	Low risk	The intervention and control groups are balance

Fontanet 1998

Methods	Design: Randomized controlled trial Random allocation: numbered table Date: October 1994 to January 1995
Participants	Number: 504 FSWs working at 71 sex establishments Inclusion criteria: Women were at least 18 years of age, were not using a diaphragm, a cervical cap nor vaginal spermicides, had no evidence of intravenous drug use, were willing to use the condoms as instructed, and were willing to keep a pictorial coital log recording all sexual acts with clients and non-commercial sexual partners Setting: Sex establishments Country: Thailand
Interventions	"Promotion of female and male condom use" and "promotion of male condom use" Intervention: FSWs proposed a male condom to their clients as a first choice, but have the option of using a female condom when clients refused or could not use a male condom Control: FSWs proposed a male condom to their clients, and, if clients refused or could not use male condoms, they were instructed not to have sex
Outcomes	1. STIs incidence 2. Consistent condom use

Fontanet 1998 (Continued)

Notes		
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"The randomisation was into two groups.."
Allocation concealment (selection bias)	Low risk	"The randomisation procedure relied on a table of random numbers matched with the list of sex establishments, and took into account..."
Blinding (performance bias and detection bias) All outcomes	Unclear risk	The study did not address this.
Incomplete outcome data (attrition bias) All outcomes	Low risk	4.3% (11) in female/male group and 11.7% (33) in male condom group were loss to follow up, but no statistically significant differences on the baseline characteristics of the FSWs without follow-up in the two trial groups
Selective reporting (reporting bias)	Low risk	Study procedure and all study's outcome have been reported
Other bias	Low risk	Intervention and control groups comparable at baseline are balance

Ghys 2001

Methods	Design: Randomized controlled trial Random allocation: unclear Date: June 1994 to November 1997
Participants	Number: 542 FSWs Inclusion criteria: HIV negative or HIV-2 seropositive when tested in the first the screening Setting: HIV/STD clinic Country: Cote d'Ivoire
Interventions	"Intensive STI screening" versus "basic STI screening" Intervention: FSWs randomised to the intensive STI screening and treatment strategy were examined every month, regardless of the presence of symptoms Control: FSWs randomised to the basic STI screening and treatment strategy were examined only if they reported following symptoms: vaginal discharge, lower abdominal

Ghys 2001 (Continued)

	pain or a genital ulcer	
Outcomes	1. HIV incidence 2. STI prevalence 3. Consistent condom use	
Notes		
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"...women were randomised to either an intensive or a basic STI screening and treatment strategy"
Allocation concealment (selection bias)	Unclear risk	The study did not address this
Blinding (performance bias and detection bias) All outcomes	Unclear risk	The study did not address this
Incomplete outcome data (attrition bias) All outcomes	Low risk	Reason for missing outcome data unlikely to be related to true outcome
Selective reporting (reporting bias)	Low risk	The study protocol is available and all the study's outcome have been reported
Other bias	Low risk	The intervention and control groups comparable at baseline are balance

Gutierrez 2010

Methods	Design: Cluster-randomized controlled trial Random allocation: unclear Date: Between 2003/2004 and 2007
Participants	Number: 3,442 FSws and 2,786 MSM; we excluded MSM data. Setting: Community-based. Country: India.
Interventions	"Community empowerment" versus "standard care" Intervention: The community-based (<i>Frontiers Prevention Project</i>) set out to empower target populations by improving advocacy within these groups, and increasing community awareness, by combining the provision of a comprehensive package of prevention interventions implemented on the appropriate scale Control: Participants in the control group received intervention but not intensive