

BACKGROUND

Description of the condition

In 2008, the Joint United Nations Programme on HIV/AIDS (UNAIDS) reported that an estimated 2.7 million people (range 2.4–3.0 million) became newly infected with HIV, bringing the total number of people living with HIV to 33.4 million (range 31.1–35.8 million) worldwide. Overall, 2.0 million (range 1.7–2.4 million) AIDS-related deaths occurred throughout the world (UNAIDS 2009). Most newly acquired infections occurred in low- and middle-income countries, and sub-Saharan Africa remains the most heavily affected region, mainly as a result of heterosexual transmission (WHO 2009).

The high rates of HIV infection among sex workers as compared to most other population groups has affected rates of heterosexual transmission of HIV particularly in low- and middle-income countries (UNAIDS 2009). The term “sex workers” constitutes a meaningful single population for epidemiological purposes, but it encompasses female sex workers, male sex workers, and male-to-female transgender sex workers in a wide variety of settings (e.g. brothels, massage parlours, informal settings, and on the street). Such individuals are often the victims of discrimination (which can sometimes lead to violence), trafficking, legal persecution and societal ambivalence (UNAIDS 2002), are socially stigmatised (Padilla 2008) and often have a precarious lifestyle due to economic difficulties (Gu 2008). Sex workers and their clients, who typically include people such as truck drivers, security workers, sailors, dock workers, police, migrant workers and businessmen, are at high risk for HIV exposure. Moreover, previous research suggests that the numbers of their clients per night can have an effect on heterosexual transmission of HIV particularly in low- and middle-income countries (Ruxrungtham 2004). The lifetime probability of a sex worker becoming infected with HIV is high due to multiple risk factors, including a large number and high turnover of partners, low levels of condom use, a high prevalence of STIs, and unsafe practices such as douching and use of inappropriate lubricants (UNAIDS 2002).

The number of countries reporting on indicators relating to sex workers significantly increased between 2005 and 2009. In sub-Saharan Africa, HIV prevalence among sex workers ranged from zero in Comoros and Sierra Leone to 49% in Guinea-Bissau. Seven African countries (Benin, Burundi, Cameroon, Ghana, Guinea-Bissau, Mali and Nigeria) have reported that more than 30% of all sex workers had HIV (UNAIDS 2009; Gomes do Espirito Santo 2005). Recently, about one quarter of all sex workers (26%) in Lesotho were reported to have had a symptomatic STI (Khobotlo 2009). In Swaziland, transmission during heterosexual contact (including sex within stable couples, casual sex and sex work) is estimated to account for 94% of incident infections (Mngadi 2009). In 2008, Lowndes et al reported that between 13% and 29% of men in West Africa may have paid for sex in the previous year (Lowndes 2008). Surveys in Kenya (Gelmon 2009), Uganda

(Wabwire-Mangen 2009) and Rwanda (Asiimwe 2009) suggested that sex workers and their clients accounted for an estimated 14%, 10% and 46% of incident HIV infections, respectively. Results from an RCT in Jamaica have shown that 25% of AIDS patients had had exposure to sex workers (Weir 2008).

Unprotected commercial sex is the most important risk factor for the spread of HIV in several parts of Asia. In Vietnam, 33% of male sex workers recruited from more than 70 sites in Ho Chi Minh City tested positive for HIV (Nguyen 2008). The prevalence of HIV among male sex workers is more than twice that of their female counterparts and is currently rising in Thailand and Indonesia (UNAIDS 2009). Sex work is common among male-to-female transgender people in Pakistan (Khan 2008) and high HIV prevalence has also been reported among transgender sex workers in studies conducted in Phnom Penh, Cambodia (22%) in 2003 (Girault 2004) and Jakarta, Indonesia (59%) (Pisani 2004). In India, high HIV and STI prevalence were found among street-based FSWs (30% and 27%, respectively) and among those who work in brothels (34% and 13%, respectively) (Buzdugan 2010). Clients of commercial sex workers are also at high risk of transmission. Given their high mobility and frequent sexual encounters with sex workers in other parts of Indonesia, these men could be the agents of the rapid spread of the HIV virus throughout Indonesia (Fajans 1995).

In the Middle East and North Africa, surveys of bar-based sex workers in Djibouti have found HIV prevalence as high as 26%, while in Yemen it has ranged from 1% to 7% (UNAIDS 2009); in Egypt, 1% (Shawky 2009); while in Algeria, Morocco and Yemen, the figures are 4%, 2% and 2% of their national populations respectively (UNAIDS 2009). The percentage of sex workers who report having used a condom during the most recent episode of intercourse ranged from 44% in Jordan to 61% in Yemen (UNAIDS 2009).

Surveys in the Caribbean undertaken in 2005 identified high infection rates in Guyana and Jamaica (27% and 9%, respectively) (UNAIDS 2009). In Latin America, particularly in Peru, 44% of men reported having had sex with a sex worker (Caceres 2009). Surveys in Guatemala and El Salvador have determined HIV prevalence among FSWs to be 4% and 3%, respectively (Soto 2007).

Description of the intervention

Several successful interventions have been reported among sex workers and their clients to reduce the heterosexual spread of HIV, including interventions to change behavior, promote the use of condoms, improve condom availability, introduce voluntary HIV counselling and testing (VCT), and educate about sexual health and the effective management of STIs. The effectiveness of behavioral interventions could be increased by aiming for important goals, such as a delay in the onset of first intercourse, a reduction in number of sexual partners, an increase in condom use, that could

be achieved using multi-level approaches (e.g. targeting couples, families, social and sexual networks, institutions, and entire communities) with both HIV-uninfected and -infected populations (Coates 2008).

Female condom interventions may help empower women to protect themselves when they are unable to avoid sexual relations with HIV-infected partners or cannot persuade their partners to use a condom.

Management of STIs was based on clinical diagnosis and serologic tests for herpes simplex virus type 2 (HSV-2) (Kamali 2003).

Peer education enlists members of a specific group to encourage effective behavioral change among their peers (Cornish 2009, Steen 2009). Its initial goal is usually to modify individuals' knowledge, attitudes and beliefs to bring about healthy behavior.

Structural interventions which mobilize sex workers to engage in HIV prevention may address other factors, such as economic security, reducing stigmatization, community-based organizing (Ghose 2008) and rights-based advocacy (Wolffers 2003).

How the intervention might work

A decline in HIV prevalence in Cambodia occurred when rates of consistent condom use during commercial sex rose from 53% in 1997 to 96% in 2003 (Gorbach 2006); and in China, consistent use of condoms resulted in a 70% reduction in HIV infections (Wang 2009). Other countries with epidemics driven by the sex work industry, such as Kenya and Uganda (Morris 2006), Chile (Barrientos 2007) and India (Basu 2004), have experienced declines in HIV prevalence when sex workers and their clients used condoms consistently. Increasing condom use, however, depends very much on condom availability (Bradley 2010). Therefore, making condoms available in rooms where commercial sex occurs is the most effective strategy to increase condom use (Egger 2000). In addition, consistent condom use was significantly greater among males who perceived that some or all of the members of their male social networks used condoms consistently (Barrington 2009). These results suggest that interventions to increase condom use are more effective when implemented in conjunction with social, network- and/or community-targeted interventions that change the environment in which decisions about safe sex behavior are taken.

Treatment for STIs was found to be more effective in reducing HIV and STI transmission when combined with the consistent and correct use of condoms (Laga 1994; Ghys 2001), suggesting that behavioral interventions for primary prevention may also serve to enhance the effectiveness of secondary prevention activities.

Peer education has resulted in substantial increases in STI and HIV knowledge and use of condoms, and in the reduction of HIV and STIs (Ford 2000).

Why it is important to do this review

Research in some countries has suggested that prevention projects resulting in increased condom use during paid sex could significantly reduce HIV transmission.

Various intervention strategies have been adopted to reduce HIV transmission among sex workers and their clients in low- and middle-income countries, and their results suggest that these interventions may play a significant role in preventing the spread of HIV; however, the effectiveness of these strategies has not been assessed rigorously through meta-analysis of randomised controlled trials. Given the potential effectiveness and low cost of these interventions, it is important to conduct a systematic review of their implementation in low- and middle income countries.

OBJECTIVES

1. To evaluate the studies conducted on behavioral interventions for reducing the transmission of HIV and STIs among sex workers (male, female, and transgender) and their clients in low- and middle-income countries.
2. To assess whether behavioral interventions such as condom use and behavior modification are effective in reducing the HIV/STI incidence and prevalence when the interventions are delivered in sex worker settings.
3. To investigate behavioral interventions to reduce risk of HIV/STIs transmission among sexual workers that have been tested in RCTs.

METHODS

Criteria for considering studies for this review

Types of studies

Randomized or quasi-randomized trials were considered for inclusion if they described behavioral interventions on any one of the outcome measures specified below, occurring in sex worker settings in low- and middle-income countries. Studies relevant to outcome measures, whether primary or secondary outcomes were included. The unit of randomization could be individual or cluster level. Studies that were not eligible, for example studies that did not randomly assign the sex workers in to the behavioral interventions and control groups, targeted not specifically sex workers population, assessed other interventions rather than behavioral interventions, or studies those not related to specified primary and secondary outcome measures were excluded.

Low- and middle-income countries were defined based on World Bank criteria and there are currently about 125 of these low- and middle-income countries with populations of over one million;

in 1997, their combined population was more than 4.89 billion (World Bank).

Types of participants

Sex workers and their clients regardless of age, ethnicity, gender identity, language and nationality are the target population:

Sex workers are defined as female, male and transgender, whether adults or young people (including adolescents), who receive money, goods or protection directly or indirectly in exchange for indoor or outdoor sexual services, such as in a brothel, street or home, either regularly or occasionally, and who may or may not consciously define those activities as income-generating“.

Clients of sex workers were defined as female, male and transgender adults or young people who give money, goods or protection in exchange for sexual services to sex workers (defined above), either regularly or occasionally.

Types of interventions

Intervention: Behavioral interventions, including social or policy interventions to reduce the transmission of HIV in sex worker settings. Behavioral interventions were defined in this systematic review as interventions that aim to change not only individual behavior to prevent HIV infection but also peer and social norms, including strategies such as community mobilization and structural and resource support, and through administrative or legal decisions, such as promoting condom availability.

Control: Studies having no interventions or any other behavioral interventions for preventing the spread of HIV among sex workers and their clients.

Types of outcome measures

Primary outcomes

Change in biological variables for HIV/STI prevention among sex workers and their clients, including:

- a) HIV incidence
- b) HIV prevalence
- c) STI incidence
- d) STI prevalence

Secondary outcomes

Change in self-reported or observed behavior, including:

- a) Condom use (male/female)
- b) HIV/STI-related knowledge
- c) Types of sexual practice, such as vaginal, oral, or anal
- d) Sexual risk behavior, such as having unprotected sex and multiple partners
- e) Frequency of sexual encounters
- f) STIs treatment-seeking behavior
- g) Psychosocial barriers to condom use
- h) Drug and alcohol risk behavior

Search methods for identification of studies

Many different sources of published and unpublished research literature were searched for studies of behavioral interventions to reduce HIV infection among sex workers and their clients. Reporting strategies of the effect of these interventions might not be uniform, and there may be much grey literature and many local publications reporting on this issue. The following databases and conference proceedings were searched using a comprehensive search strategy without restrictions on the language or country or publication status of relevant trials. The date range of the search was 01 January 1980 to the search date. The search was conducted on 28 September 2010.

1) Electronic databases

Relevant databases were identified in consultation with the HIV/AIDS Review Group Coordinator and the Trials Search Coordinator for the Cochrane HIV/AIDS Group's Trials Register, experts in HIV/AIDS research and service projects working in low- and middle-income countries, policy makers and healthcare administrators. This list served as the key document for the extraction of data from electronic databases.

Cochrane Central Register of Controlled Trials (CENTRAL), the Cochrane HIV/AIDS group specialized register, the Cochrane Database of Systematic Reviews, MEDLINE, PsycINFO, Sociological Abstracts, CINAHL, Dissertation Abstract International (DAI), EMBASE, LILACS, BIOSIS, SciSearch, INDMED, Proquest, and various South Asian abstracting databases were included in the database list. The publication sites of the World Health Organization, the US Centers for Disease Control and Prevention, and other international research and non-governmental organizations also appeared in the database list.

An extensive search strategy string was developed in consultation with the Trial Search Coordinator of the HIV/AIDS Review Group. All possible keywords were included in the string to enable an exhaustive electronic literature search. For further details see the Appendices.

2) Hand searching

A hand search of key HIV/AIDS research journals was conducted because many publications from low- and middle-income countries might not have appeared in electronic databases.

3) Personal communication

Key personnel and organizations working in HIV/AIDS intervention programs in low- and middle-income countries were contacted for published and unpublished references and data.

4) Conferences proceedings

Conference proceedings were searched for relevant abstracts. Conferences included the Conference on Retroviruses and Opportunistic Infections (CROI), 1996-2010; International AIDS Conference (IAC), 1985-2010; and International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention (IAS), 2001-2009.

5) Cross-references

The bibliographies of studies identified by the procedures de-

scribed above were further scrutinized to locate additional studies. The search strategy was iterative, in that bibliographies of the included studies were searched for additional references.

Data collection and analysis

The methodology for data collection and analysis was based on the Cochrane Handbook of Systematic Reviews of Interventions (Higgins 2009).

Selection of studies

Using the inclusion criteria described above, two of the review authors (WW and EO) independently assessed the potential studies that were identified as a result of the search strategy. Scrutiny for inclusion was based on the type of study, type of participants, type of interventions, and outcome measures. Any disagreements were resolved through discussion and a third reviewer (RM) was consulted. For all excluded studies a summary statement about the exclusion reasons was made. Four authors (KS, RM, AK and NH) who are experts were informed of the included studies and conducted the data extraction independently.

Data extraction and management

Data was extracted independently using data collection forms. For eligible studies, two review authors (WW and EO) extracted data on trial characteristics including methods, participants, interventions, and outcomes. Discrepancies were resolved through discussion or by consulting with another review author (RM). Data were entered into the Review Manager software (Revman 2008) and checked for accuracy. When information regarding any of the above was unclear, contact with the authors of the original reports was attempted in order to elicit further details.

Assessment of risk of bias in included studies

Two review authors (WW and EO) independently assessed the risk of bias for each study using the criteria outlined in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2009). Discrepancies were resolved by discussion or by involving an additional assessor (RM). Standard guidance was followed for the assessment of the adequacy of methods to reduce the risk of bias across seven domains:

1) Sequence generation (checking for possible selection bias)

For each included study the method used to generate the allocation sequence was described in sufficient detail to allow an assessment to be made of whether it would have produced comparable groups.

2) Allocation concealment (checking for possible selection bias)

For each included study the method used to conceal the allocation sequence was described and a judgment made as to whether the intervention allocation could have been foreseen in advance of or during recruitment, or changed after assignment.

3) Blinding (checking for possible performance bias)

A description was provided of the methods used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. Studies were judged to be at low risk of bias if they were blind, or if the lack of blinding could

not have affected the results. Blinding was assessed separately for different outcomes or classes of outcomes.

4) Incomplete outcome data (checking for possible attrition bias through withdrawals, dropouts, protocol deviations)

For each included study, and for each outcome or class of outcome, completeness of the data was assessed including checking attrition and exclusions was noted, along with the numbers included in the analysis at each stage (compared with the total number of randomized participants), reasons for attrition or exclusions where reported, and whether missing data were balanced across groups or were related to outcomes. Where sufficient information was reported, or was supplied by the trial authors, missing data was included in the analyses.

5) Selective reporting bias

For each included study the possibility of selective outcome reporting bias was investigated and a conclusion reported.

6) Other sources of bias

For each included study all other possible sources of bias, including study design and early trial cessation due to data-dependent processes or extreme baseline imbalance were reported.

7) Overall risk of bias

Explicit judgments were made about whether studies were at high risk of bias, according to the criteria given in the Handbook (Higgins 2009). With reference to (1) to (6) above, the likely magnitude and direction of the bias and its likely impact on the findings was assessed and reported.

Measures of treatment effect

1) Dichotomous data

For dichotomous data, results are presented as summary risk ratios (RR) with a 95% Confidence Interval (CI).

2) Continuous data

For continuous data, the mean difference (MD) was used if outcomes were measured in the same way among trials. Standardized mean differences were used to combine trials that measured the same outcome with different methods.

Unit of analysis issues

All RCTs, cluster-RCTs, and quasi-RCTs were identified.

Dealing with missing data

For included trials, attrition levels were noted and the impact of including trials with high levels of missing data in the overall assessment of the treatment effect was checked through a sensitivity analysis. For all outcomes analyses were conducted on an intention-to-treat basis. The denominator for each outcome in each trial was the number randomized minus any participants whose outcomes were known to be missing.

Assessment of heterogeneity

Heterogeneity amongst trials was tested using an I^2 statistic in each analysis. A value of $I^2=0\%$ indicates no observed heterogeneity. Where substantial heterogeneity ($I^2 >50\%$) was identified, a prespecified subgroup analysis was conducted. Subgroup analyses were planned based on the extent of control for selection bias. However, subgroup analysis considered the effects of different du-

rations of follow-up or different routes that were not included due to a lack of available data.

Assessment of reporting biases

Where reporting bias was suspected (see "Selective reporting bias" above), attempts were made to contact study authors, asking them to provide missing outcome data. Where this was not possible and the missing data were thought to introduce serious bias impact of including such studies in the overall assessment of results was explored through sensitivity analysis.

Data synthesis

A meta-analysis was conducted using the Review Manager software (Revman 2008). Fixed-effect inverse variance meta-analysis was used for combining data where trials were examining the same intervention and the trials' populations and methods were judged sufficiently similar. Where heterogeneity between trials' treatment effects was suspected, random-effect meta-analysis was used. The criteria of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) to evaluate the quality of the evidence by outcome was performed (Guyatt 2008).

Subgroup analysis and investigation of heterogeneity

Subgroup analysis was conducted for the primary outcomes of HIV incidence, HIV prevalence, STI incidence and STI prevalence. For the fixed-effect meta-analysis, a planned subgroup analysis was conducted, classifying whole trials by interaction tests as described by Deeks (Deeks 2001).

Sensitivity analysis

Sensitivity analyses were not performed.

Results

RESULTS

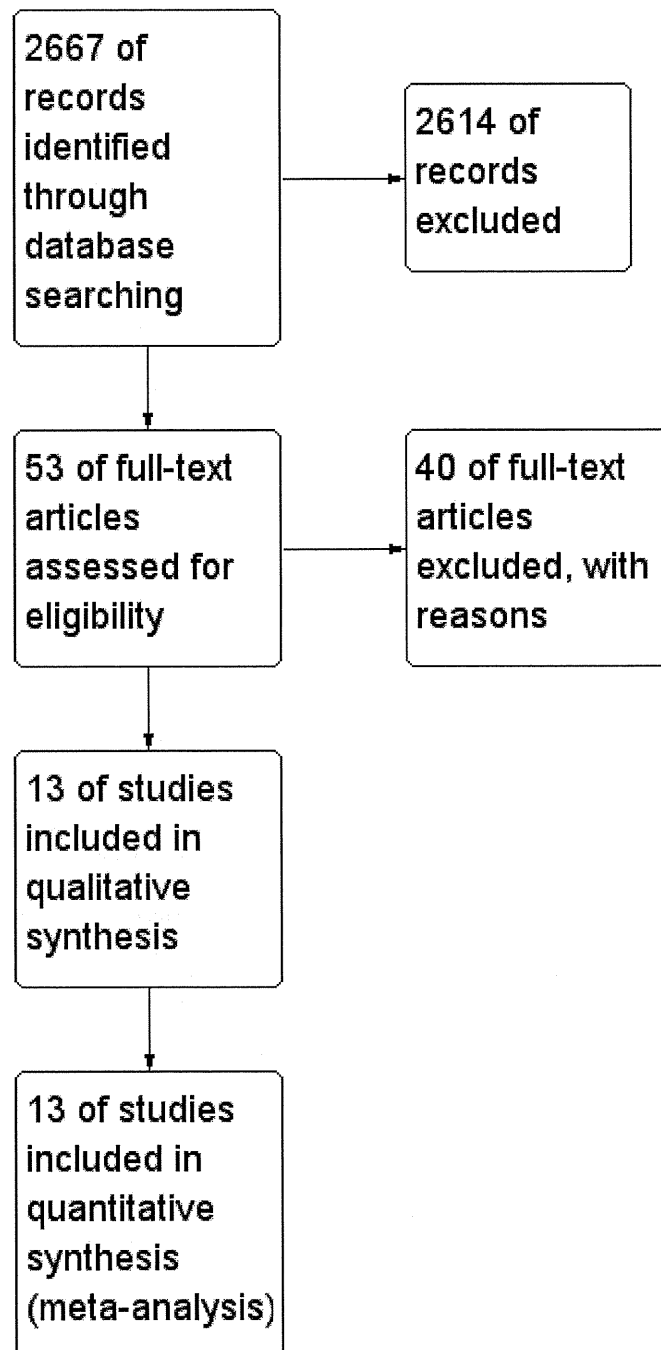
Description of studies

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

See Characteristics of included studies; Characteristics of excluded studies

A total of 2667 citations published between 1980 and 2010 were obtained. Of these, 53 potential studies were identified for consideration. Overall, 13 trials with 8,698 participants were analysed. Of these, two studies in Madagascar (Feldblum 2005, Hoke 2007) used the same population, as did two studies in Mexico (Patterson 2006, Patterson 2008). Two studies using previously published data (Hoke 2007, Patterson 2008) were included because they included outcomes, which were not previously reported. The remaining 40 not eligible studies were excluded (Figure 1).

Figure 1. Study flow diagram.



Seven RCTs (Ghys 2001, Ray 2001, Feldblum 2005-Hoke 2007, Patterson 2006- Patterson 2008, Wechsberg 2006, Markosyan 2010 and Sherman 2010), two cluster-RCTs (Fontanet 1998 and Gutierrez 2010) and four quasi-RCTs (Basu 2004, Li 2006, Swendeman 2009 and Chiao 2009) met the inclusion criteria. The process of randomizations in the two cluster-RCTs (Fontanet 1998 and Gutierrez 2010) was done by using clusters rather than individuals. However, we nevertheless included them because individual data was used as the unit of data analysis.

Seven out of 13 trials were conducted in Asia (four trials in India (Basu 2004, Swendeman 2009, Gutierrez 2010, and Sherman 2010), one in Thailand (Fontanet 1998), and one in China (Li 2006), one in the Philippines (Chiao 2009), and one in Armenia (Markosyan 2010). Four trials were evaluated in Africa (one in Madagascar (Feldblum 2005-Hoke 2007), one in Cote d'Ivoire (Ghys 2001), one in Zimbabwe (Ray 2001), and one in South Africa (Wechsberg 2006). The remaining one trial was conducted in Latin America (Patterson 2006-Patterson 2008).

Primary outcomes were identified in seven trials (Patterson 2008, Gutierrez 2010, Feldblum 2005-Hoke 2007, Ray 2001, Fontanet 1998, Ghys 2001, and Li 2006). Of these, three trials measured HIV incidence (Patterson 2008, Ghys 2001, and Ray 2001), two trials measured the incidence of STIs (Patterson 2008 and Fontanet 1998) and four trials measured the prevalence of STIs (Gutierrez 2010, Feldblum 2005-Hoke 2007, Ghys 2001 and Li 2006). There were no trials that measured HIV prevalence. Secondary outcomes were identified in all studies.

Although most trials provided a follow-up period of at least 6 months to assess outcomes (Ghys 2001, Feldblum 2005, Patterson 2008, Markosyan 2010, Sherman 2010) the duration of the follow-up varied across studies. The shortest was a 3-month trial that occurred in Thailand (Fontanet 1998) whereas the longest follow-up was up to three years in a trial conducted in India (Gutierrez 2010).

Interventions

1) Social cognitive theory

Social cognitive theory identifies human behavior as a personal, behavior, and the environment factors interact (Bandura 1986). Person and environment interaction involves human beliefs and cognitive competencies. Social influences and structures within the environment were developed and modified by this interaction. The third interaction, between the environment and behavior, involves a person's behavior determining the aspects of their environment. The behavior also being modified by that environment. Despite behavior may varies from situation to situation, behavior is not controlled by situation itself rather than person. It means different responses can come from different people or from the same person at different times (Jones 1989). Therefore, this theory is useful to understand and predict both individual and group behavior, and identify strategies in which behavior can be changed.

2) Community empowerment

Community empowerment (also called community organization, -mobilization, or -action research) is a strategy used in public health, behavioral sciences, and social movements, that can mobilize people for recognizing structural barriers to improve health, and empower them to change these barriers. This method is distinguished from behavioral change, because it addresses behaviours through the active involvement of community members to design, execute, and evaluate their empowerment projects. Community involvement in the evaluation directly contributes to capacity-building and increased awareness in the target community (Stevens 1998).

3) Microenterprise

Microenterprise intervention empowers individuals through micro-finance, teaching basic literacy, and training in specific economic livelihoods (e.g., tailoring, computer literacy). Microenterprise programs (e.g., micro-finance, micro-credit) have been reported effective in increasing women's economic well-being, in reducing interpersonal violence, in increasing reproductive health decision-making power, and broaden their role in household decision making (Kim 2007, Hashemi 1996, Schuler 1997).

4) Peer education

This intervention provides training and support to community members and is usually conducted to effect change at both the individual and the group level, with the aim to modify the person's knowledge, attitudes, beliefs, or behaviours. This strategy may effect change by modifying norms that contribute to individual change as well as changes in programs and policies.

5) Manager training

Manager training focuses on providing specialized, HIV-based information and education, reinforcing positive STI prevention behavior that addresses the managerial class, to increase their influence through providing positive reinforcement of their employee's safer sex practices.

6) Promotion of female condom use

This intervention promotes the use of female condoms properly, enhancing condom self-efficacy and negotiation skills and knowledge of HIV/STI transmission, HIV/STI risk assessment, and safer sex options. Early female condom introduction efforts were targeted to FSWs, because they are at high risk for HIV and other STIs and have an obvious need for a female-initiated method of protection. Introduction of the female condom has been more successful in shorter-term programs, particularly among sex workers and members of women's groups (PATH and UNFPA 2006).

7) STI screening

The systematic strategy of providing STI antibody testing to a population of apparently healthy people without signs and symptoms of that disease for the purpose of detecting the number of people (or blood samples) infected with an STI. The primary aim

is not to diagnose STI in a specific person. Screening programs might direct additional resources to groups with the most risky sexual behavior -e.g., sex workers, their clients, migrant workers, and those attending STI clinics (WHO 2006).

8) VCT

VCT provides individuals with knowledge of their HIV infection status, risk assessment, and promotes risk reduction. This intervention may be effective in reducing the risk of further transmission of HIV by promoting safer sex (Nelson 2007).

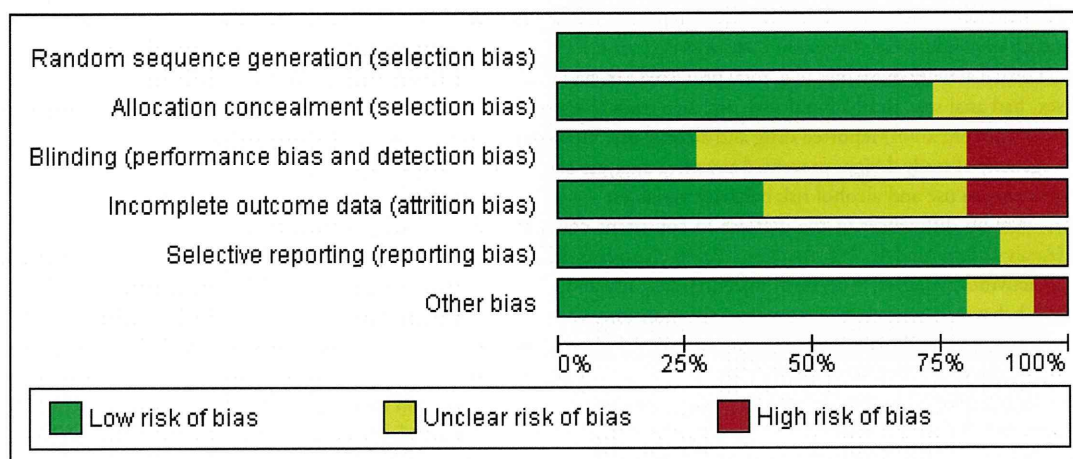
Risk of bias in included studies

Assessment of the risk of bias in the included studies is summarized in Figure 2 and Figure 3.

Figure 2. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding (performance bias and detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Basu 2004	+	+	?	?	+	+
Chiao 2009	+	+	-	?	+	?
Feldblum 2005	+	+	+	?	+	+
Fontanet 1998	+	+	?	+	+	+
Ghys 2001	+	?	?	+	+	+
Gutierrez 2010	+	?	-	-	?	+
Hoke 2007	+	+	+	?	+	+
Li 2006	+	?	?	+	+	-
Markosyan 2010	+	+	+	?	+	+
Patterson 2006	+	+	?	+	+	+
Patterson 2008	+	+	?	?	+	+
Ray 2001	+	+	?	+	+	+
Sherman 2010	+	+	+	+	?	+
Swendeman 2009	+	+	?	-	+	+
Wechsberg 2006	+	?	-	-	+	?

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



Allocation

Generation of the randomisation sequence was judged to be at low risk of bias for all trials. Allocation concealment was judged to be at low risk of bias in 13 trials and unclear in four trials (Ghys 2001, Li 2006, Wechsberg 2006, Gutierrez 2010). Descriptions which included the following details were accepted as being adequate for concealment: a random number table (Fontanet 1998, Basu 2004 and Swendeman 2009), the flip of a coin (Markosyan 2010), a computer generated random allocation list (Feldblum 2005-Hoke 2007, Patterson 2006-Patterson 2008), opaque sealed envelopes (Sherman 2010), numbered sealed envelopes (Ray 2001), and numbers placed in a box (Chiao 2009).

Blinding

Of the included studies only three trials (Feldblum 2005-Hoke 2007, Markosyan 2010, Sherman 2010) were judged to be at low risk of bias due to adequate blinding.

Incomplete outcome data

The proportion of participants in each intervention arm for whom an outcome was not available was reported. Five trials (Basu 2004, Feldblum 2005-Hoke 2007, Patterson 2008, Chiao 2009, Markosyan 2010) were judged to be at high risk of bias due to moderate missing data that had the potential to alter the results, while most of the trials did not address the reasons for the incomplete outcome data.

Selective reporting

Eleven trials were assessed as being free of selective reporting bias. The remaining two studies (Gutierrez 2010, Sherman 2010) did

not present the study outcome completely and were judged to be at high risk of bias.

Other potential sources of bias

Three studies (Wechsberg 2006, Li 2006, Chiao 2009) were judged to be at high risk of bias due to an imbalance of baseline characteristics between the intervention group and the control group.

Effects of interventions

See: **Summary of findings for the main comparison** Social cognitive theory compared to standard counseling for promotion of condom use; **Summary of findings 2** Social cognitive theory for promotion of condom use compared to no intervention; **Summary of findings 3** Promotion of female and male condom compared to promotion of male condom; **Summary of findings 4** VCT compared to standard care of STI for increasing condom use

Comparison 1. Social cognitive theory versus standard care (Analysis 1)

This comparison included two trials (Wechsberg 2006 and Patterson 2006-Patterson 2008) comprising 1017 FSWs.

1. Primary outcomes

One trial conducted in Mexico (Patterson 2008) reported HIV incidence. After a 6-month follow-up period, the risk ratio of HIV incidence was 0.12 (95% CI 0.01 to 2.22; Analysis 1.1) indicating a reduction in HIV incidence. Patterson 2008 also reported STI

incidence and showed a significant decrease in the cumulative incidence of any STIs among the intervention group (RR 0.57, 95% CI 0.34 to 0.96; Analysis 1.2) compared to the control group.

2. Secondary outcomes

Two trials (Wechsberg 2006, Patterson 2008) reported consistent condom use and one trial (Patterson 2006) reported the mean frequency of condom use. Patterson 2006 and Patterson 2008 reported sexual activity outcomes (e.g. total protected sex, had vaginal sex, had anal sex, and had oral sex), and two trials (Patterson 2006, Wechsberg 2006) reported drug and alcohol use. However, heterogeneity of study designs prevented any meta-analyses of consistent condom use and alcohol risk behavior variables.

There were no differences in the increase in consistent condom use (Analysis 1.3; Analysis 1.4; Analysis 1.5), in changes in FSWs sexual activities (Analysis 1.6), or in injecting drug use and alcohol risk behavior (Analysis 1.7; Analysis 1.8), indicating that the intervention had no impact. However, this intervention did show a decrease in drug use among FSW (RR 0.65, 95% CI 0.36 to 1.16, *p* for heterogeneity=0.15, *I*²=52%; Analysis 1.9).

Comparison 2. Social cognitive theory versus no intervention (Analysis 2)

Only one trial of 120 FSWs examined this comparison (Markosyan 2010).

1. Primary outcomes

None reported.

2. Secondary outcomes

Consistent condom use, HIV knowledge, and psychosocial mediators of HIV prevention behavior were assessed. However, social cognitive theory was found not to increase reported condom use, including barriers to condom use and condom use self-efficacy, or HIV-related knowledge (Analysis 2.1; Analysis 2.2; Analysis 2.3)

Comparison 3. Community empowerment versus standard care (Analysis 3)

There were three trials assessing this comparison (Basu 2004, Swendeman 2009, and Gutierrez 2010) involving a total of 3,858 FSWs.

1. Primary outcomes

One trial reported the prevalence of STIs (Gutierrez 2010). However, after a follow-up assessment the risk ratio of syphilis and HSV-2 were 1.26 and 1.38, respectively (Analysis 3.1), indicating that there was no effect in reducing the prevalence of STIs. Moreover, none of the studies reported on the other primary outcomes.

2. Secondary outcomes

Both trials (Basu 2004, Gutierrez 2010) reported on consistent condom use with clients and HIV-related knowledge. One trial (Gutierrez 2010) reported consistent condom use with regular partners, one trial (Basu 2004) reported changes in 100% condom use and changes in any condom use, condom availability, type of sexual practices, and drug and alcohol use. One trial (Gutierrez 2010) reported HIV testing.

A trial in India (Gutierrez 2010) was successful at reduction in non-condom use with regular partners over a 3-year follow-up

period (RR 0.55, 95% CI 0.48 to 0.64; Analysis 3.2). However, a community empowerment intervention showed no increase in condom use with clients (Analysis 3.3; Analysis 3.4; Analysis 3.5), HIV-related knowledge (Swendeman 2009; Analysis 3.6), HIV testing (Gutierrez 2010; Analysis 3.7), risk management skills and protective factors (Swendeman 2009; Analysis 3.8).

Comparison 4. Microenterprise plus education intervention versus education alone (Analysis 4)

There was only one trial (Sherman 2010) consisting of 128 FSWs, which assessed this comparison.

1. Primary outcomes

None.

2. Secondary outcomes

There was no increase in condom use after a 6 month follow-up period (Analysis 4.1). This trial reported that the mean number of sex partners (MD -6.90, 95% CI -10.02 to -3.78) and number of exchange sex partners (MD -2.00, 95% CI -3.01 to -0.99) was smaller for those who experienced community empowerment plus education rather than education alone (Analysis 4.2).

Comparison 5. Peer education versus standard care (Analysis 5)

There was only one trial (Chiao 2009) of 980 FSWs that assessed the effect of peer education compared with standard care.

1. Primary outcomes

This study did not report primary outcomes.

2. Secondary outcomes

This intervention had no effect on self-reported consistent condom use (Analysis 5.1), HIV-related knowledge (Analysis 5.2) or perceived need for HIV testing (Analysis 5.3). However, a peer-led intervention was effective and increased self-regulatory factors, such as perceived control over risk of HIV acquisition (RR 0.74, 95% CI 0.84 to 0.99; Analysis 5.4) and perceived severity (Analysis 5.5), whether in relation to the chance of acquiring HIV (MD -1.47, 95% CI -1.83 to -1.11) or worry about acquiring HIV (MD -1.02, 95% CI -1.50 to -1.00).

Comparison 6. Peer education plus clinic-based counselling versus peer education only (Analysis 6)

There was one trial (Feldblum 2005, Hoke 2007) involving 1000 FSWs.

1. Primary outcomes

The addition of clinic-based counselling to a peer education intervention decreased the prevalence of STIs (Analysis 6.1), particularly Chlamydia at 6-month follow-up (RR 0.70, 95% CI 0.50 to 0.97) and any STIs at 6-month follow-up (RR 0.78, 95% CI 0.65 to 0.93), but the intervention was found to have no effect in reducing the prevalence of all types of STIs after 12 months' and 18 months' follow-up. Other primary outcomes were not assessed by this intervention.

2. Secondary outcomes

Feldblum 2005 reported that FSWs who were administered peer education plus clinic-based counselling were less likely to report overall male condom use, whether with clients (Analysis 6.2) or

non-paying partners (Analysis 6.3) compared with FSWs assigned to the peer education intervention only. In addition, Hoke 2007 reported there was no increase in the use of female condoms after 12 months' and 18 months' follow-up (Analysis 6.4), indicating that there was no effect of this intervention. Hoke 2007 also found that FSWs assigned to the combined interventions were less likely to use male or female condoms with clients (Analysis 6.5) and non-paying partners (Analysis 6.6).

Comparison 7. Peer education plus manager training versus standard care (Analysis 7)

One study (Chiao 2009) of 980 FSWs.

1. Primary outcomes

None of the primary outcomes were reported.

2. Other outcomes

This trial examined consistent condom use, HIV-related knowledge, HIV testing and protective behavior, such as perceived control over AIDS and perceived AIDS severity. However, the intervention had no effect in increasing condom use (Analysis 7.1) and HIV-related knowledge (Analysis 7.2). At a 3-month follow up assessment, manager training in addition to peer education increased the likelihood of seeking HIV testing by 67% (95% CI 59% to 73%; Analysis 7.3).

Comparison 8. Manager training versus standard care (Analysis 8)

One study (Chiao 2009) of 980 FSWs.

1. Primary outcomes

None.

2. Secondary outcomes

This trial reported on consistent condom use, HIV-related knowledge, HIV testing and protective behavior, such as perceived AIDS control (Analysis 7.4) and severity (Analysis 7.5). The intervention had no effect on condom use (Analysis 8.1), HIV-related knowledge (Analysis 8.2), and the likelihood of having an HIV test (Analysis 8.3), and had not reduce the AIDS perceived control (Analysis 8.4). However, the manager training intervention was found to increase the FSWs perceived severity of acquiring HIV (MD -0.43, 95% CI -0.80 to -0.06; Analysis 8.5).

Comparison 9. Promotion of female and male condom versus promotion of male condom (Analysis 9)

Two studies (Fontanet 1998; Ray 2001) involving 653 FSWs.

1. Primary outcomes

Ray 2001 reported HIV incidence. After a 3-month follow-up, the risk ratio of HIV incidence was 0.07 (95% CI 0.00 to 1.38; Analysis 9.1) indicating a large reduction in HIV incidence. Fontanet 1998 reported a decrease in the incidence of STIs (Analysis 9.2), in particular, the incidence of chlamydia and gon-

orrhoea (RR 0.71, 95% CI 0.52 to 0.98 and RR 0.63, 95% CI 0.45 to 0.88, respectively).

2. Secondary outcomes

Two trials (Fontanet 1998, Ray 2001) reported on consistent female and male condom use. Meta-analyses showed a decrease in male condom at 3-month follow-up (RR 0.83, 95% CI 0.65 to 1.05, P for heterogeneity=0.09, I^2 =65%; Analysis 9.3) and overall non-usage of the female (RR 0.12, 95% CI 0.09 to 0.17, p =<0.001, P for heterogeneity=0.78, I^2 =0%; Analysis 9.4). A decrease was also seen in non-usage of the female condom at 24-months follow-up (RR 0.15, 95% CI 0.09 to 0.28; Analysis 9.5), but there was no effect for the male condom at 24-months follow-up (RR 0.91, 95% CI 0.82 to 1.02; Analysis 9.6).

Comparison 10. Intensive STI screening versus basic STI screening (Analysis 10)

One study (Ghys 2001) including 542 FSWs.

1. Primary outcomes

After a 6-month follow-up period, the risk ratio of HIV incidence was 0.65 (95% CI 0.24 to 1.73; Analysis 10.1) indicating a reduction in HIV incidence. This trial also reported a positive effect of intensive STI screening in reducing STI prevalence at 6-months follow-up (Analysis 10.2) compared with basic STI screening. In particular, it reduced the prevalence of gonorrhoea and chlamydia trachomatis (RR 0.38, 95% CI 0.19 to 0.77, and RR 0.23, 95% CI 0.07 to 0.79, respectively). Other primary outcomes were not reported.

2. Secondary outcomes

There was no increase in consistent condom use after a 6-month follow-up assessment (RR 1.04, 95% CI 0.96 to 1.13; Analysis 10.3).

Comparison 11. Voluntary HIV counselling and testing versus the standard care of STIs (Analysis 11)

We identified one trial (Li 2006) involving 400 FSWs.

1. Primary outcome

This trial reported a positive effect of VCT compared with standard STI management in reducing STI prevalence at 6-months follow-up (Analysis 11.1). In particular, the intervention was effective in reducing the prevalence of genital warts (RR 0.22, 95% CI 0.05 to 0.98). Other primary outcomes were not reported.

2. Secondary outcomes

This trial assessed the effect of the intervention on consistent condom use and HIV/STI related knowledge. However, after 6-months follow-up, there was no increase in either consistent condom use (RR 2.05, 95% CI 1.48 to 2.85; Analysis 11.2) or HIV/STI related knowledge (RR 1.28, 95% CI 0.81 to 2.04; Analysis 11.3).

ADDITIONAL SUMMARY OF FINDINGS *[Explanation]*

Social cognitive theory for promotion of condom use compared to no intervention for sex workers						
Patient or population: sex workers Settings: low- and middle-income countries Intervention: Social cognitive theory for promotion of condom use Comparison: no intervention						
Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	no intervention	Social cognitive theory for promotion of condom use				
Consistent condom use by FSWs with clients at 6-month	Study population		RR 0.89 (0.61 to 1.30)	98 (1 study)	⊕⊕⊕○ moderate ^{1,2,3,4,5}	
	560 per 1000	498 per 1000 (342 to 728)				
	Medium risk population					
	560 per 1000	498 per 1000 (342 to 728)				
Consistent condom use by FSWs with clients in the past 7-day	Study population		RR 0.92 (0.68 to 1.24)	98 (1 study)	⊕⊕⊕○ moderate ^{1,2,3,4,5}	
	660 per 1000	607 per 1000 (449 to 818)				
	Medium risk population					
	660 per 1000	607 per 1000 (449 to 818)				

Consistent application of condom by FSWs	Study population		RR 0.65 (0.23 to 1.85)	98 (1 study)	⊕⊕⊕○ moderate ^{1,2,3,4,5}
	160 per 1000	104 per 1000 (37 to 296)			
	Medium risk population				
	160 per 1000	104 per 1000 (37 to 296)			
HIV knowledge among FSWs at 6-month	Study population		RR 2.08 (0.4 to 10.85)	98 (1 study)	⊕○○○ very low ^{1,2,5,6,7}
	40 per 1000	83 per 1000 (16 to 434)			
	Medium risk population				
Psychosocial barriers to condom use among FSWs at 6-month	Study population		RR 0.83 (0.36 to 1.93)	98 (1 study)	⊕⊕⊕○ moderate ^{1,2,3,4,5}
	200 per 1000	166 per 1000 (72 to 386)			
	Medium risk population				
	200 per 1000	166 per 1000 (72 to 386)			
Psychosocial barriers to condom use self-efficacy among FSWs at 6-month	Study population		RR 1.56 (0.85 to 2.89)	98 (1 study)	⊕○○○ very low ^{1,2,5,6,7}
	240 per 1000	374 per 1000 (204 to 694)			
	Medium risk population				

	240 per 1000	374 per 1000 (204 to 694)	
<p>*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).</p> <p>CI: Confidence interval; RR: Risk ratio;</p>			
<p>GRADE Working Group grades of evidence</p> <p>High quality: Further research is very unlikely to change our confidence in the estimate of effect.</p> <p>Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.</p> <p>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.</p> <p>Very low quality: We are very uncertain about the estimate.</p>			

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

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

⁶ Serious indirectness: There is considerable variability in the effect of control which makes extrapolation of result to other setting unreliable.

⁷ Very serious imprecision: The 95% CI of estimate includes appreciable benefit to control group over intervention group.

Promotion of female and male condom compared to promotion of male condom for sex workers						
Patient or population: sex workers Settings: low- and middle-income countries Intervention: Promotion of female and male condom Comparison: promotion of male condom						
Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	promotion of male con- dom	Promotion of female and male condom				
HIV incidence among FSWs at 3-month	Study population		RR 0.07 (0 to 1.38)	149 (1 study)	⊕⊕○○ low ^{1,2,3,4,5}	
	60 per 1000	4 per 1000 (0 to 83)				
	Low risk population					
Chlamydia incidence among FSWs at 3-month	Study population		RR 0.71 (0.52 to 0.98)	504 (1 study)	⊕⊕⊕⊕ high ^{1,2,3,5,6}	
	282 per 1000	200 per 1000 (147 to 276)				
	Medium risk population					
	282 per 1000	200 per 1000 (147 to 276)				
Gonorrhoea incidence among FSWs at 3-month	Study population		RR 0.63 (0.45 to 0.88)	504 (1 study)	⊕⊕⊕⊕ high ^{1,2,3,5,6}	

	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 VCT increasing condom use					
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)			