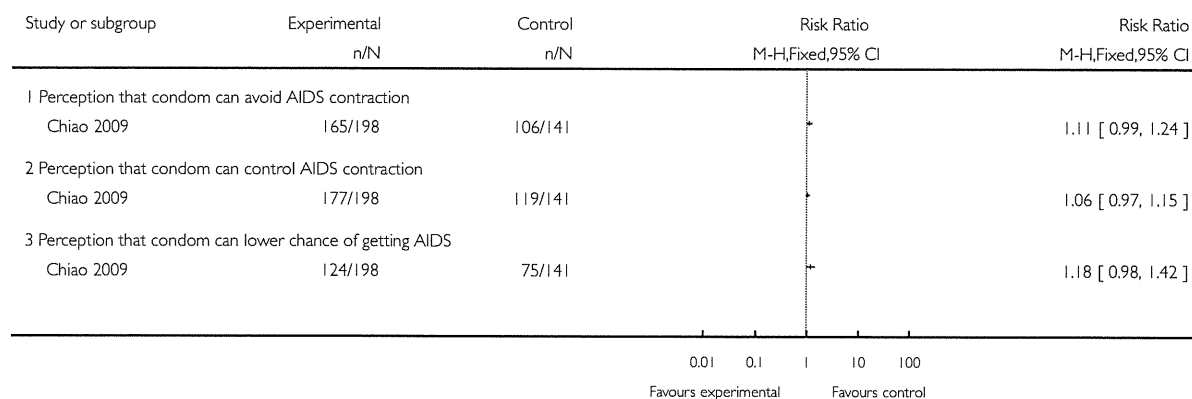


Analysis 8.4. Comparison 8 Manager training versus standard care for promoting HIV testing and condom use, Outcome 4 AIDS perceived control by FSWs at 6-month.

Review: Behavioral interventions to reduce the transmission of HIV infection among sex workers and their clients in low- and middle-income countries

Comparison: 8 Manager training versus standard care for promoting HIV testing and condom use

Outcome: 4 AIDS perceived control by FSWs at 6-month

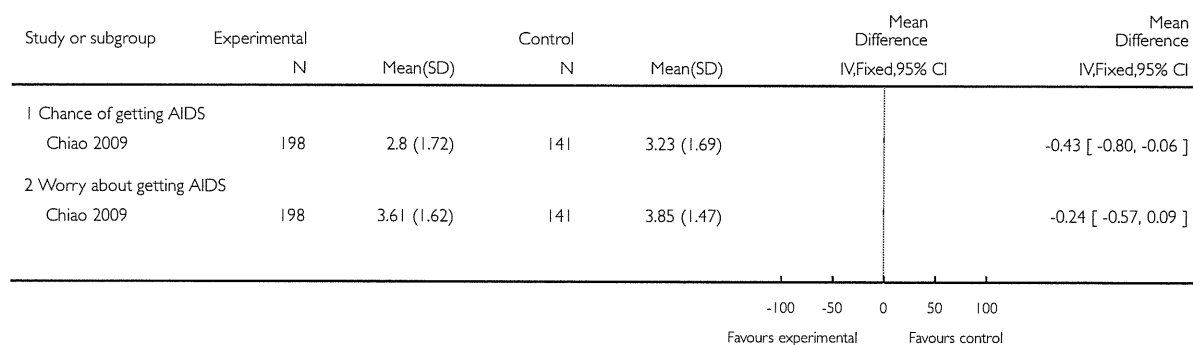


Analysis 8.5. Comparison 8 Manager training versus standard care for promoting HIV testing and condom use, Outcome 5 Mean score of perceived themselves at greater risk (by FSWs at 6-month).

Review: Behavioral interventions to reduce the transmission of HIV infection among sex workers and their clients in low- and middle-income countries

Comparison: 8 Manager training versus standard care for promoting HIV testing and condom use

Outcome: 5 Mean score of perceived themselves at greater risk (by FSWs at 6-month)

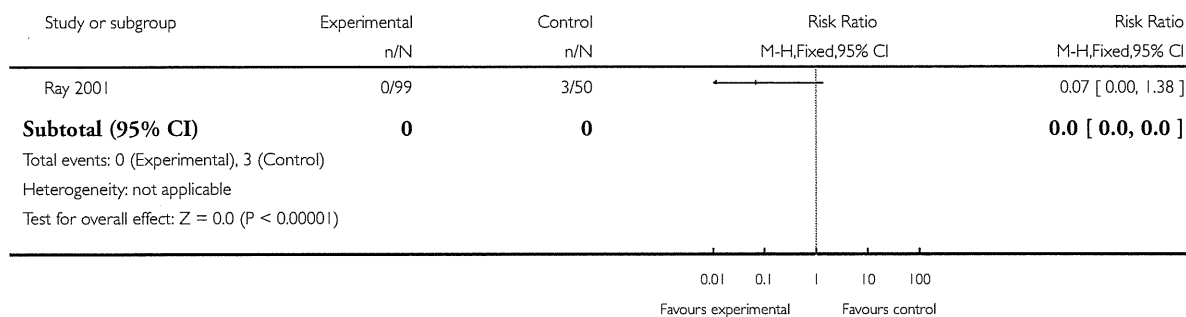


Analysis 9.1. Comparison 9 Promotion of female and male condom versus promotion of male condom, Outcome 1 HIV incidence among FSWs at 3-month.

Review: Behavioral interventions to reduce the transmission of HIV infection among sex workers and their clients in low- and middle-income countries

Comparison: 9 Promotion of female and male condom versus promotion of male condom

Outcome: 1 HIV incidence among FSWs at 3-month

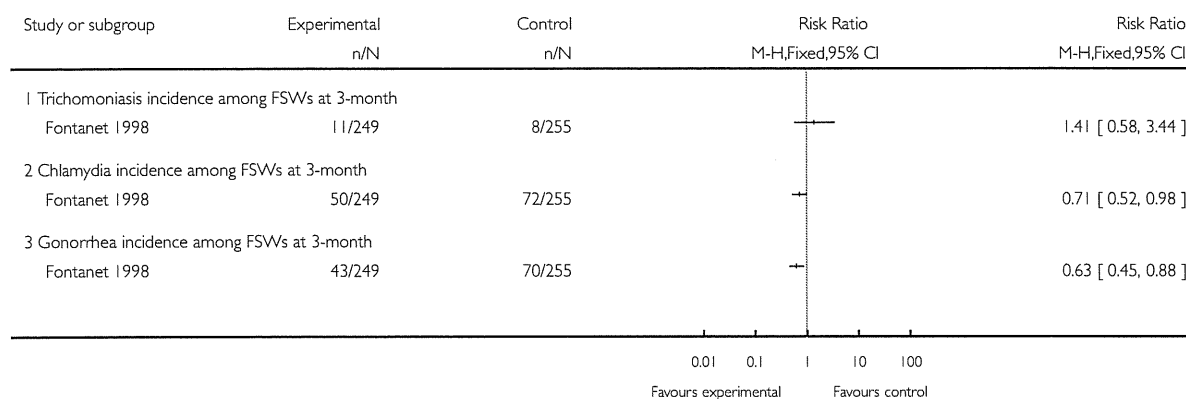


Analysis 9.2. Comparison 9 Promotion of female and male condom versus promotion of male condom, Outcome 2 STIs incidence among FSWs at 3-month.

Review: Behavioral interventions to reduce the transmission of HIV infection among sex workers and their clients in low- and middle-income countries

Comparison: 9 Promotion of female and male condom versus promotion of male condom

Outcome: 2 STIs incidence among FSWs at 3-month

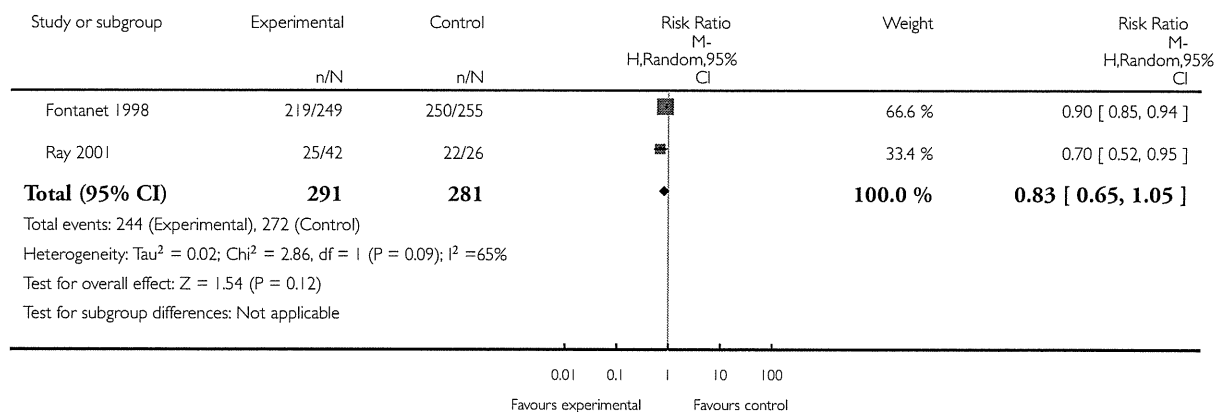


Analysis 9.3. Comparison 9 Promotion of female and male condom versus promotion of male condom, Outcome 3 Consistent male condom use at 3-months.

Review: Behavioral interventions to reduce the transmission of HIV infection among sex workers and their clients in low- and middle-income countries

Comparison: 9 Promotion of female and male condom versus promotion of male condom

Outcome: 3 Consistent male condom use at 3-months

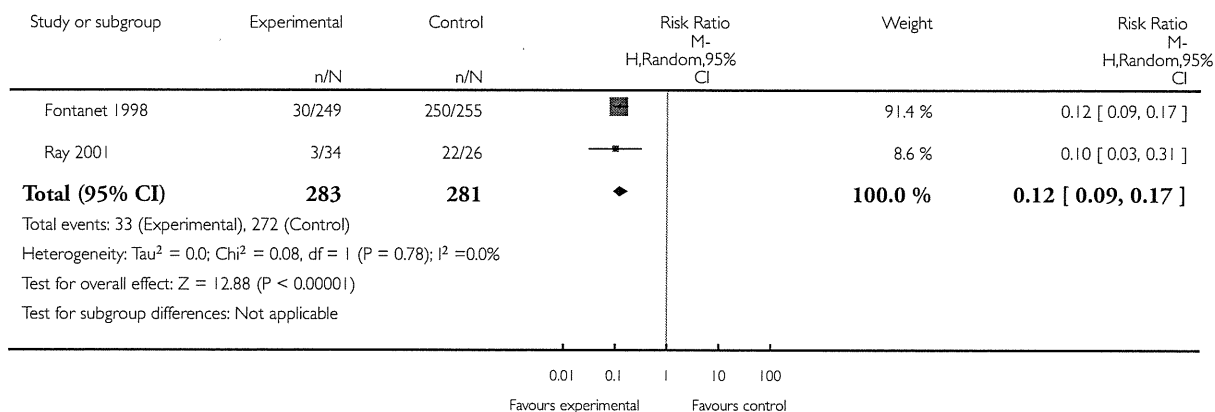


Analysis 9.4. Comparison 9 Promotion of female and male condom versus promotion of male condom, Outcome 4 Consistent female condom use by FSWs at 3-month.

Review: Behavioral interventions to reduce the transmission of HIV infection among sex workers and their clients in low- and middle-income countries

Comparison: 9 Promotion of female and male condom versus promotion of male condom

Outcome: 4 Consistent female condom use by FSWs at 3-month

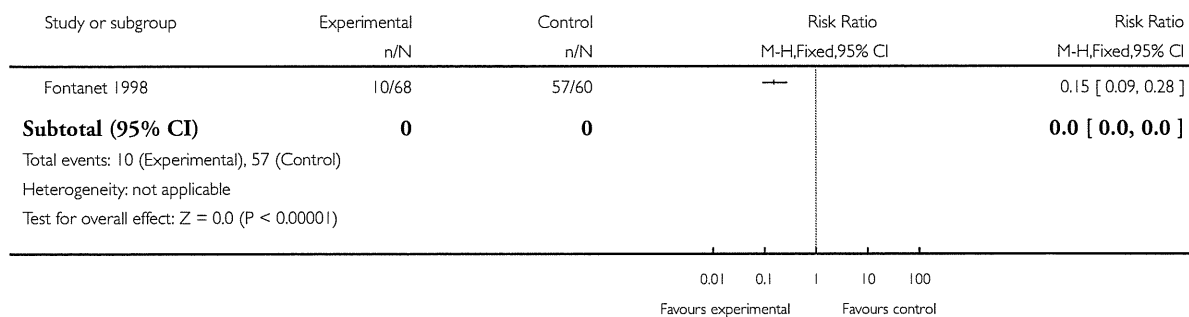


Analysis 9.5. Comparison 9 Promotion of female and male condom versus promotion of male condom, Outcome 5 Consistent female condom use by FSWs at 24-month.

Review: Behavioral interventions to reduce the transmission of HIV infection among sex workers and their clients in low- and middle-income countries

Comparison: 9 Promotion of female and male condom versus promotion of male condom

Outcome: 5 Consistent female condom use by FSWs at 24-month

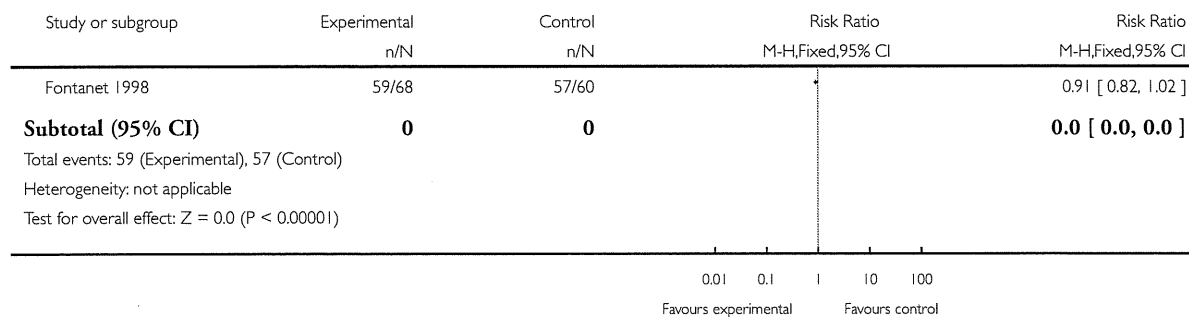


Analysis 9.6. Comparison 9 Promotion of female and male condom versus promotion of male condom, Outcome 6 Consistent male condom use at 24-month.

Review: Behavioral interventions to reduce the transmission of HIV infection among sex workers and their clients in low- and middle-income countries

Comparison: 9 Promotion of female and male condom versus promotion of male condom

Outcome: 6 Consistent male condom use at 24-month

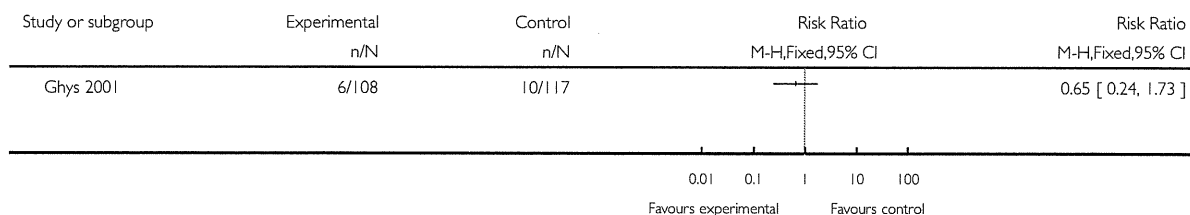


Analysis 10.1. Comparison 10 Intensive STI screening versus basic STI screening to control STI, Outcome 1 HIV incidence among FSWs at 6-month.

Review: Behavioral interventions to reduce the transmission of HIV infection among sex workers and their clients in low- and middle-income countries

Comparison: 10 Intensive STI screening versus basic STI screening to control STI

Outcome: 1 HIV incidence among FSWs at 6-month

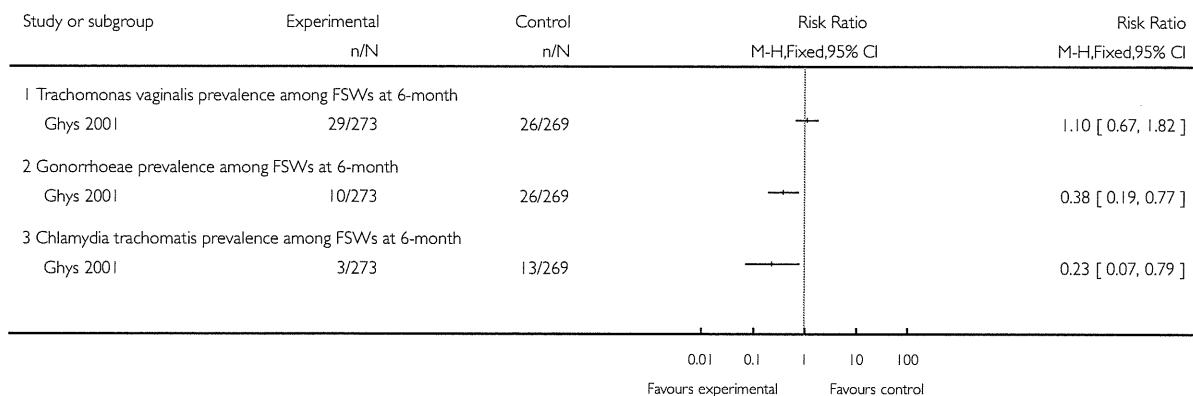


Analysis 10.2. Comparison 10 Intensive STI screening versus basic STI screening to control STI, Outcome 2 STIs prevalence among FSWs at 6-month.

Review: Behavioral interventions to reduce the transmission of HIV infection among sex workers and their clients in low- and middle-income countries

Comparison: 10 Intensive STI screening versus basic STI screening to control STI

Outcome: 2 STIs prevalence among FSWs at 6-month

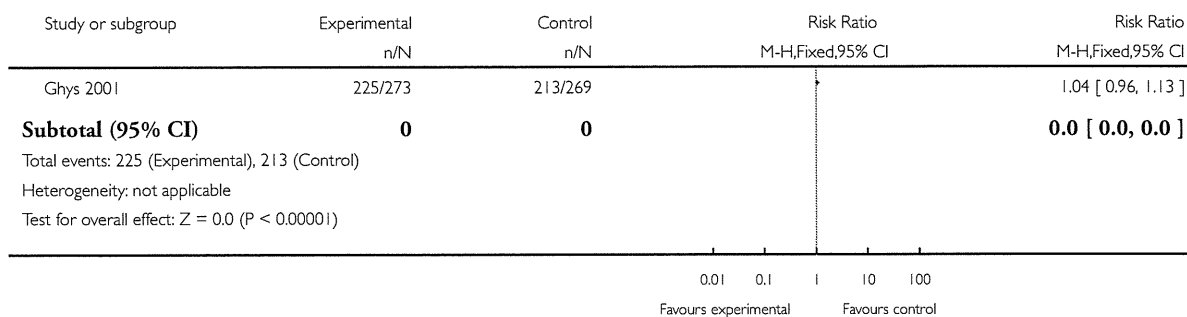


Analysis 10.3. Comparison 10 Intensive STI screening versus basic STI screening to control STI, Outcome 3 Consistent condom use by FSWs at 6-month.

Review: Behavioral interventions to reduce the transmission of HIV infection among sex workers and their clients in low- and middle-income countries

Comparison: 10 Intensive STI screening versus basic STI screening to control STI

Outcome: 3 Consistent condom use by FSWs at 6-month

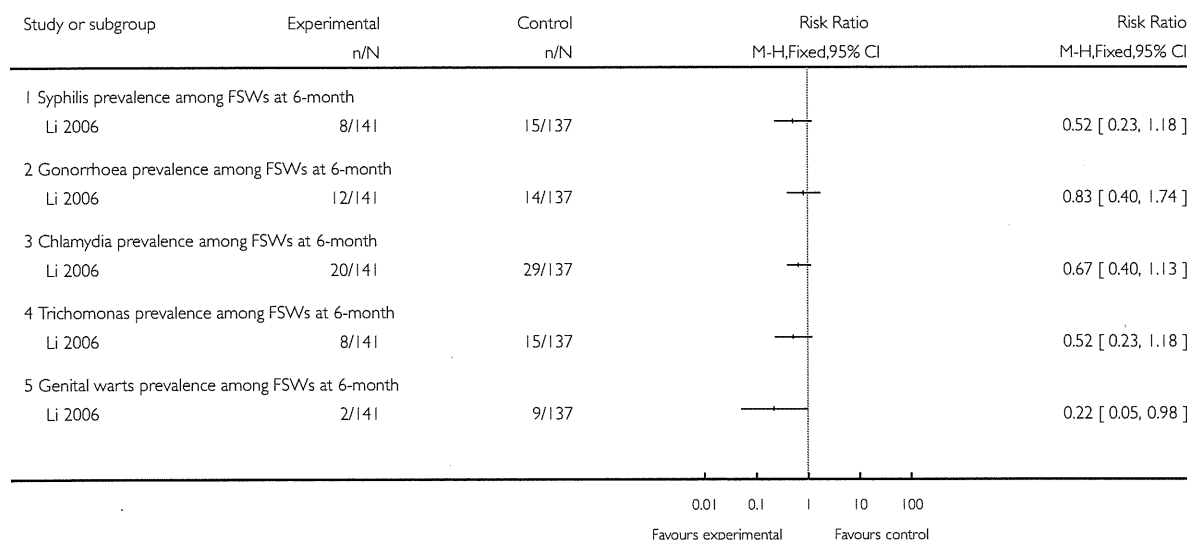


Analysis 11.1. Comparison 11 VCT versus standard care of STI for increasing condom use, Outcome 1 STIs prevalence among FSWs at 6-month.

Review: Behavioral interventions to reduce the transmission of HIV infection among sex workers and their clients in low- and middle-income countries

Comparison: 11 VCT versus standard care of STI for increasing condom use

Outcome: 1 STIs prevalence among FSWs at 6-month

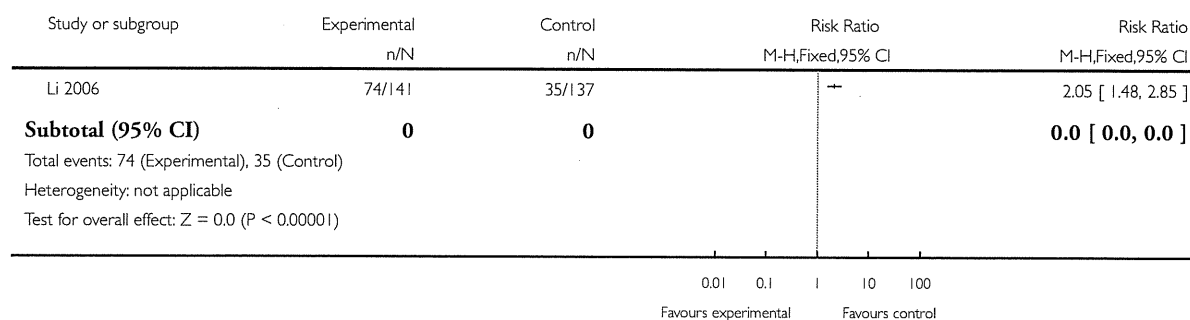


Analysis 11.2. Comparison 11 VCT versus standard care of STI for increasing condom use, Outcome 2 Consistent condom use by FSWs with clients at 6-month.

Review: Behavioral interventions to reduce the transmission of HIV infection among sex workers and their clients in low- and middle-income countries

Comparison: 11 VCT versus standard care of STI for increasing condom use

Outcome: 2 Consistent condom use by FSWs with clients at 6-month

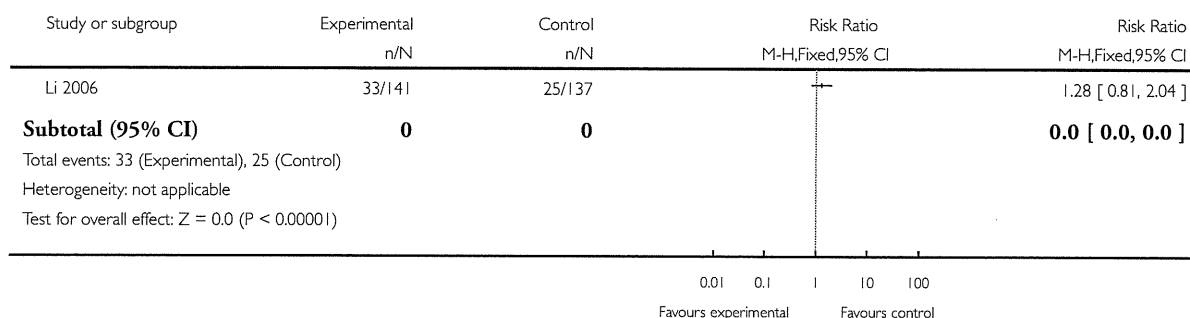


Analysis 11.3. Comparison 11 VCT versus standard care of STI for increasing condom use, Outcome 3 HIV/STI knowledge among FSWs at 6-month.

Review: Behavioral interventions to reduce the transmission of HIV infection among sex workers and their clients in low- and middle-income countries

Comparison: 11 VCT versus standard care of STI for increasing condom use

Outcome: 3 HIV/STI knowledge among FSWs at 6-month



APPENDICES

Appendix I. PUBMED SEARCH STRATEGY

Search	Most Recent Queries	Time	Result
#44	Search #39 AND #40 AND #41 AND #42 Limits: Publication Date from 1980/01/01 to 2010/09/28	08:29:05	1005
#43	Search #39 AND #40 AND #41 AND #42	08:27:24	1007
#42	Search intervention[tiab] OR interventions[tiab] OR risk reduction behavior[mh] OR risk reduction[tiab] OR risk reducing[tiab] OR Health Knowledge, Attitudes, Practice[mh] OR incidence[mh] OR incidence[tiab] OR prevalence[mh] OR prevalence[tiab] OR sexual behavior[mh] OR sexual behavior[tiab] OR sexual behaviour[tiab] OR intervention studies[mh]	08:27:05	1153751
#41	Search prostitute[tiab] OR prostitutes[tiab] OR sex worker[tiab] OR sex workers[tiab] OR prostitution[mh] OR prostitution[tiab]	08:26:54	6708
#40	Search (randomized controlled trial [pt] OR controlled clinical trial [pt] OR randomized [tiab] OR placebo [tiab] OR drug therapy [sh] OR randomly [tiab] OR trial [tiab] OR groups [tiab]) NOT (animals [mh] NOT humans [mh])	08:26:34	2267836
#39	Search HIV Infections[MeSH] OR HIV[MeSH] OR hiv[tw] OR hiv-1*[tw] OR hiv-2*[tw] OR hiv1[tw] OR hiv2[tw] OR hiv infect*[tw] OR human immunodeficiency virus[tw] OR human immunodeficiency virus[tw] OR human immunodeficiency virus[tw] OR human immunodeficiency virus[tw] OR ((human immun*) AND (deficiency virus[tw])) OR acquired immunodeficiency syndrome[tw] OR acquired immunodeficiency syndrome[tw] OR acquired immunodeficiency syndrome[tw]	08:26:21	267057

(Continued)

deficiency syndrome[tw] OR acquired immune-deficiency syndrome[tw] OR ((acquired immun*) AND (deficiency syndrome[tw])) OR "sexually transmitted diseases, viral"[MH]		
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Appendix 2. EMBASE SEARCH STRATEGY

No.	Query	Results	Date
#6	#1 AND #2 AND #3 AND #4 AND [humans]/lim AND [embase]/lim AND [1980-2010]/py	146	28 Sept 2010
#5	#1 AND #2 AND #3 AND #4	181	28 Sept 2010
#4	intervention OR interventions OR 'risk reduction'/de OR 'risk reduction' OR 'risk reducing' OR 'attitudes to health' OR 'prevalence'/de OR prevalence OR 'incidence'/de OR incidence	1321732	28 Sept 2010
#3	'prostitute'/de OR prostitute OR prostitutes OR 'prostitution'/de OR prostitution OR 'sex worker' OR 'sex workers' OR 'callgirl'/de OR callgirl OR callgirls	7014	28 Sept 2010
#2	random*:ti OR random*:ab OR factorial*:ti OR factorial*:ab OR cross?over*:ti OR cross?over*:ab OR crossover*:ti OR crossover*:ab OR placebo*:ti OR placebo*:ab OR (doubl*:ti AND blind*:ti) OR (doubl*:ab AND blind*:ab) OR (singl*:ti AND blind*:ti) OR (singl*:ab AND blind*:ab) OR assign*:ti OR assign*:ab OR allocat*:ti OR allocat*:ab OR volunteer*:ti OR volunteer*:ab OR 'crossover procedure'/exp OR 'crossover procedure'/de OR 'crossover procedure' OR 'double-blind procedure'/exp OR 'double-blind procedure'/de OR 'double-blind procedure' OR 'single-blind procedure'/exp OR 'single-blind procedure'/de OR 'single-blind procedure' OR 'randomized controlled trial'/exp OR 'ran-	999275	28 Sept 2010

(Continued)

	domized controlled trial'/de OR 'randomized controlled trial'		
#1	'human immunodeficiency virus infection'/exp OR 'human immunodeficiency virus infection'/de OR 'human immunodeficiency virus infection' OR 'human immunodeficiency virus'/exp OR 'human immunodeficiency virus'/de OR 'human immunodeficiency virus' OR hiv:ti OR hiv:ab OR 'hiv-1':ti OR 'hiv-1':ab OR 'hiv-2':ti OR 'hiv-2':ab OR 'human immunodeficiency virus':ti OR 'human immunodeficiency virus':ab OR 'human immunodeficiency virus':ti OR 'human immunodeficiency virus':ab OR 'human immunodeficiency virus':ti OR 'human immunodeficiency virus':ab OR 'human immunodeficiency virus':ti OR 'human immunodeficiency virus':ab OR 'acquired immune-deficiency syndrome':ti OR 'acquired immune-deficiency syndrome':ab OR 'acquired immunodeficiency syndrome':ti OR 'acquired immunodeficiency syndrome':ab OR 'acquired immunodeficiency syndrome':ti OR 'acquired immunodeficiency syndrome':ab OR 'acquired immunodeficiency syndrome':ti OR 'acquired immunodeficiency syndrome':ab OR 'acquired immunodeficiency syndrome':ti OR 'acquired immunodeficiency syndrome':ab	315753	28 Sept 2010

HISTORY

Protocol first published: Issue 2, 2005

Review first published: Issue 2, 2012

Date	Event	Description
15 February 2010	New citation required and major changes	Made protocol a "clean slate" for new author team.
11 November 2008	Amended	Converted to RevMan 5, and re-published without new citation

CONTRIBUTIONS OF AUTHORS

WW designed, set up, analysed, interpreted the data and drafted the review. EO designed, set up, and analysed the data. RM, AK, NH, and KS revised the article. All authors read and approved the final version to be published.

DECLARATIONS OF INTEREST

We declare that we have no conflict of interest.

SOURCES OF SUPPORT

Internal sources

- Health Labour Sciences Research Grant, Japan.

External sources

- No sources of support supplied

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

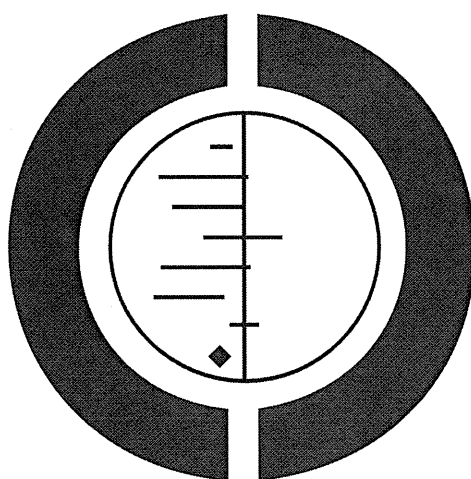
Ai Koyanagi was involved as a co-author. She revised the draft and approved the final draft.

HIV/STI-related knowledge, sexual risk behavior, psychosocial barriers to condom use, drug and alcohol risk behavior were not listed in the protocol. These were added as secondary outcomes as relevance to the review question regarding change individual behaviours to prevent HIV infection.

Sensitivity analyses were not performed as there were too few trials under each comparison.

Structural and community-level interventions for increasing condom use to prevent HIV and other sexually transmitted infections. (Protocol)

Nababan H, Ota E, Wariki WMV, Koyanagi A, Ezoe S, Shibuya K, Tobe-Gai R



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Structural and community-level interventions for increasing condom use to prevent HIV and other sexually transmitted infections. (Protocol)

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[Intervention Protocol]

Structural and community-level interventions for increasing condom use to prevent HIV and other sexually transmitted infections.

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Editorial group: Cochrane HIV/AIDS Group.

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

The objective of this review is to assess the effects of structural and community-level interventions for increasing condom use in the general population and population at-risk, by comparing alternative strategies or by assessing the effects of a strategy compared with a control.

BACKGROUND

Description of the condition

In 2009 UNAIDS estimated that globally there were 2.6 million people who were just infected with HIV, and as many as 33.3 million people were living with AIDS by the end of the same year (UNAIDS 2010). Condom use is one of the most efficacious available means for reducing the risk of transmission of sexually transmitted infections (STIs), including HIV (Sarkar 2008). Laboratory and epidemiological studies have demonstrated that condom use is effective against a number of STIs, such as gonorrhoea, non-gonococcal urethritis, trichomoniasis, and genital herpes (da Silveira 2005). Hence condom use remains the keystone of HIV and STIs prevention worldwide (Matson 2010).

Nevertheless, the impact of condom use may be limited by its inconsistent and low use (Hearst 2004). Several factors are known to be associated with condom non-use during sexual intercourse and individual perception of risk or pleasure often affects condom use (Sarkar 2008). One third of the study participants in a study of 206 university students reported discomfort (tightly fitting condoms, vaginal irritation, and loss of sensation) as reasons for less motivation to use condom (Crosby 2005). In addition, the result of a study among truck drivers in Nigeria also revealed similar results where the major barrier to condom use were reduction in sexual satisfaction which hindered their sexual interests (Sunmola 2005).

Furthermore, the dissemination of the information that highly active antiretroviral therapy (HAART) may reduce infectiousness of HIV has resulted in an increase in unprotected sex (Akinyemi 2010). This was demonstrated in a meta-analysis including 25 studies which was conducted to assess the association between HAART and sexual risk behavior among men who have sex with men (MSM) where regardless of HIV serostatus, the likelihood of unprotected sex was higher in people who believed that receiving HAART or having undetectable viral load protects against HIV transmission (Crepaz 2004).

In many societies, moral values, ethnic and religious factor also play a role. For Roman Catholics for example, the application of contraceptive measure is considered a transgression of divine law and a sin against nature. This belief also applies to condoms even if it were to be used to avoid HIV infection (Lefkowitz 2004).

The availability of and accessibility to condom is often the most fundamental barrier to condom use. In most low-and middle-income countries, cost is known to be a barrier among the poor (Essien 2005). Even if they were to incur no cost, non-availability often results in engagement in unprotected sexual practice (Kumar 2006). Not only in low-and middle-income countries, but even in high-income countries such as the USA, many African-Americans are unable to purchase condoms due financial barriers (Essien 2005).

Among female sex workers (FSW), lack of knowledge about HIV transmission, poverty, client's refusal or coercion and control by

pimps or establishment owners can act as barriers to condom use (Xia 2005). For men who have sex with men (MSM), negative attitudes about homosexuality have been translated into legal and policy restrictions on their sexual behaviour and official relationship. These restrictions tend to marginalize and exclude MSM and drive their relationship underground, which result in risky sexual behaviour (Adimora 2010).

Among other social factors, gender inequality, lack of dialogues among partners regarding condom use, and the stigma associated with condom use could all lead to unsafe sexual practices (Pulerwitz 2006). The violent behaviour of male partner within the relationship is predictive of a more coercive response to a woman's negotiation to use condoms (Sarkar 2008). As regard to stigma, lack of privacy in stores and the social stigma associated with condom were the most significant barriers to their use (Sri 2007). Lack of condom use is also closely correlated with lack of knowledge about HIV prevention which is fuelled by lack of education (Dandona 2005). Those factors reflect norms, cultures and practices that provide entry into better targeted interventions through structural approaches.

Description of the intervention

Among public health researchers and practitioners, there is an increasingly shared understanding that age and the environments in which people are born, live, and work significantly influence health (Adimora 2010). Those environments are shaped by structural factors which, in HIV epidemics in particular, are defined as physical, social, cultural, organizational, communal, economic, legal, or policy aspects of the environment that impede or facilitate efforts to avoid HIV infection (Gupta 2008). Therefore structural approaches aim to modify those underlying factors in order to promote health and reduce risks in specific contexts (Auerbach 2009).

Structural interventions for condom use have focused on three kinds of contextual factors that determine health (Blankenship 2000). The first of the three is "availability", which emphasizes on behaviours, tools, equipments, materials, or settings that are necessary to prevent individuals from being exposed to the particular health problem. Community campaigns to place condom machines in bathrooms or bars or 100% condom-use policies in brothels are example of this. The second factor is "acceptability", which locates the source of public health problems in the normative structure, and focuses on manipulating social norms in order to have an influence on health of the public. Anti-prostitution stigmatisation campaigns and social marketing of condoms are examples. The last one is "accessibility" which locates problems related to public health in the unequal distribution of resources and power, which in turn limits the accessibility of health care for marginalized populations. Examples of this factor include distribution of free condoms and establishment of female-controlled prevention methods such as female condom use (Blankenship 2000).

Structural approaches typically involve at least one of the following: influencing policy or legal changes; enabling environmental changes; shifting harmful social norms; catalysing social and political change; and empowering communities and groups (Adimora 2010).

Structural intervention can be implemented in three levels: individual, group (organisational), and community (environment) level (Charania 2010). Individual and group-level interventions directly address knowledge, attitude, skills, and behaviours related to condom use of the participant in one-on-one settings and in existing (e.g. couple) or newly formed groups respectively (Charania 2010). Community-level interventions have typically been conceptualised as geographic units (e.g. cities, counties, villages), although alternative conceptualisations of smaller units also exist (e.g. workplace and schools) (Atienza 2002). Community-level interventions both directly and indirectly address knowledge, attitudes and behaviours with focus on the entire community and often involves strong emphasis on alteration of social norms Charania 2010(). Potentially, interventions of this level may have a significant impact on the physical and social determinants of health across the organizations and communities involved (Swerissen 2004).

How the intervention might work

As has been explained above, individual's health including the risk of being infected by HIV is influenced by structural factors which are outside an individual's control. An individual's behaviour which favours healthy behaviour, in this case protected sex to prevent HIV and other sexually transmitted infections, therefore can be influenced indirectly through changes in structural factors which affect behavior or directly when the structural factors operate in the more proximal level or more closely linked to a specific behaviour. One evidence originates from a meta-analysis of US and other international studies during 1998-2007 which concluded that structural-level condom distribution intervention is an efficacious approach to increase condom use and reduce HIV and STI risk (Charania 2010).

Experience further shows that structural factors can act as barriers to individually oriented HIV prevention and care services and the adoption of HIV-preventive behaviours. For instance, fear of HIV/AIDS related stigma and discrimination discourages people from seeking HIV counselling and testing (Blankenship 2010) and from disclosing their status to their sexual partners which then hinder them from using condoms as preventive measure (Medley 2004). Women who regularly experience gender-related violence might be unable to negotiate condom use (Jewkes 2006).

Structural approaches that have aimed to reduce HIV infection of sex workers ranges from policies to enforce condom use to programs that seek to enhance solidarity and empowerment among sex workers (Gupta 2008). In 1995, two Dominican Non-Governmental Organizations (NGOs) began exploring the possibility

of adapting elements of the Thai 100% condom program to the Dominican context. This included solidarity and collective commitment toward HIV and STI preventions, environmental cues to promote condom use, clinical services, monitoring and encouraging adherence of condom use among establishment owners, and policies and regulations to ensure the establishment of the program (Kerrigan 2006). Assessment of this program revealed that condom use did increase subsequent to introduction of this intervention. Another program in India called "Sonagachi" which consisted of community mobilization within the FSW community itself, where the sex workers were allowed to decide what they needed and take action accordingly, also resulted in reduction of risky sexual behaviour (Basu 2004).

Dealing with inequitable gender norms, especially those that define masculinity, was an important component of HIV prevention strategies in BRazil. This program gained success in influencing young men's attitude toward gender roles and improved their relationship and sexual behavior which was reflected in the increase of condom use (Pulerwitz 2006). Furthermore in South Africa, a different type of gender-based HIV prevention strategy was implemented by partnering with a local micro-finance institution to enable women pursuing micro-enterprises to receive HIV education and to create opportunities to discuss and mobilize local action against gender-based violence. With greater ownership and control over economic assets, program participants may have greater capacity to negotiate abstinence, fidelity, and safer sex (Jan 2010). Apart from the above mentioned interventions, media campaigns promoting condom use also has the potential to influence norms and change values, expectations, and behaviour (Cohen 2006).

Individual-targeted interventions which focus on behavioral change have been responsible for the success of HIV prevention to date (Coates 2008). Therefore to mitigate and eventually eliminate HIV epidemics around the world, it remains essential to develop and implement HIV prevention interventions that modify individuals' behaviours and practices (Auerbach 2009). Nevertheless, although some individually oriented interventions have shown positive results in reducing risk behavior, their success is substantially improved when HIV prevention addresses the broader structural factors that shape or constrain individual behavior (Coates 2008, Pisani 2003). In the famous example of 100% Condom Program in Thailand, sex workers had been assisted to consistently engage in safe sexual practices by the policies that enforced requiring condom use (Kerrigan 2006). In addition, even though costly, financial analyses demonstrate that structural changes may have the greatest impact in the long term in decreasing the number of new HIV infections, and producing other social advantages, such as improvements in economic productivity and advances in human rights (Hecht 2009). Theoretically structural interventions are promising because they have the ability to reach large number of people in contrast to individually focused methods which rarely can be scaled up to large numbers because they are often labor-intensive and require complex logistic planning to bring clients and

counsellors together to work on behavior change (Cohen 2006).

Why it is important to do this review

Despite decades of experience with HIV prevention programs, the number of people living with HIV infection continue to rise (Pisani 2003). Some people suggest that behaviours that spread HIV is overemphasized, compared to the social and economic conditions that promote such behaviours (Barnett 2006). The awareness in recent years that social, economic, political, and environmental factors directly affect HIV transmission and risky sexual behaviours has fuelled interest in structural approaches to HIV prevention (Gupta 2008). However, progress in incorporating structural approaches into HIV prevention has been limited due to lack of conceptual and technical consensus on definition and implementation, and limited data on the effectiveness of structural approaches to the reduction of HIV incidence (Gupta 2008). Behavioral interventions aiming to encourage individual attitude change toward safer sexual practice play an important role in overall HIV prevention efforts. However, behavioral interventions alone are inadequate to produce substantial and lasting reductions in HIV transmission (Coates 2008). As a result, consistent condom use has not reached a sufficiently high level, even after many years of widespread and often aggressive promotion (Potts 2008). Structural interventions represent a potentially powerful approach to HIV prevention, especially those that promote community mobilization (Blankenship 2010). Currently, the Cochrane Library has no reviews or protocols focusing specifically on structural and community-level intervention for increasing condom use to prevent HIV and other sexual transmitted diseases both in low-middle income and high-income countries. Program planners and policy makers need descriptions of interventions and quantitative estimates of the effects of various interventions to make informed decisions concerning prevention funding and research (Johnson 2008). This review will help generate knowledge on how structural and community-level interventions might impact on condom use.

OBJECTIVES

The objective of this review is to assess the effects of structural and community-level interventions for increasing condom use in the general population and population at-risk, by comparing alternative strategies or by assessing the effects of a strategy compared with a control.

METHODS

Criteria for considering studies for this review

Types of studies

Randomized controlled trials (RCTs), including cluster-randomised controlled trials, that compare either two or more alternative condom promotion strategies, or one condom promotion strategy with a control (i.e., no condom promotion strategy), will be included.

Types of participants

Studies that include the following types of participants will be included in the review:

1. General population (adolescents and adults)
2. STIs patients, including HIV-positive patients and/or sero-discordant couples
3. Drug users, including IDUs as well as other drug-using populations
4. Sex workers (male and female)
5. MSM

Types of interventions

The interventions may include the following types:

1. Interventions focusing on changing condom use behaviours by altering social norms, such as social-cognitive theory intervention, mass media campaigns, the use of public opinion, social marketing strategies, and women empowerment.
2. Interventions focusing on altering economic situations which impact condom use, such as condom taxes or tariffs removal, or condom subsidization (either total subsidization, as in free condoms distributed through the public sector, or partial subsidization, as in social marketing approaches)
3. Interventions which improve condom accessibility, or change or improve distribution, whether through the public sector, the private sector, or NGOs (including social marketing operations)
4. Interventions derived from legislative support for condom use, such as mandating condom use among sex workers
5. Combinations of the above

Types of outcome measures

Primary Outcome:

1. Reported condom use (male or female condoms)
2. HIV incidence / prevalence
3. STI incidence / prevalence

Secondary Outcome:

1. Knowledge about condom use (both self-reported and tested)
2. Attitudes towards condom use (both self-reported and tested)

3. Condom acquisition/procurement
4. Stated intention to use condoms
5. Negotiation skills around condom use (both self-reported and tested)
6. Changes of other STI risk-related practices, including number of partners
7. Process indicators reporting on satisfaction with and/or acceptability of aspects of the intervention (including the mode of condom distribution as well as the structure and/or content of the condom promotion strategy)
8. Reported harms related to condom use, such as domestic violence or abuse or allergic reactions to latex
9. Comparative costs of interventions

Search methods for identification of studies

Electronic searches

A MEDLINE search will be conducted. The Cochrane search strategy will be used to identify appropriate studies within electronic databases (Higgins 2009). We will not restrict any languages or publication status. The precise search strategy to be employed will be developed with the assistance of the Cochrane HIV/AIDS Review Group. The Cochrane Central Register of Controlled Trials (CENTRAL), EMBASE, Psychological Abstracts and Sociological Abstracts will be searched using a search strategy similar to that outlined for MEDLINE. The sensitivity of the search strategies will be improved if possible by including text and key words from relevant trials accessed by the authors that were not detected by earlier searches. In order to maximize the sensitivity of these searches, searches will be run both with and without keywords referring to study design.

Searching other resources

Hand searching of the following will be conducted as available:

1. Proceedings of the International AIDS Conferences (before 1989, as abstracts from 1989-present are included in AIDSLINE)
2. Proceedings of the International Society of STD Research (ISSTD)
3. Other proceedings, including those of major behavioral studies conferences focusing on HIV/AIDS, STIs, or other reproductive health issues
4. Key journals in this field, including AIDS

Bibliographies of studies and previous reviews will be examined to find other relevant evaluation studies. Professionals in the field (e.g. authors of previous reviews or investigators on prior primary research) will be contacted to identify continuing studies. Internet sites which are concerned with HIV-prevention as well as reproductive health in general, will be explored for condom-promotion intervention information. Other relevant organizations

which may possibly involved in condom promotion interventions will be contacted. These may include: international agencies (e.g., UNAIDS, WHO, UNFPA, World Bank), national public health agencies with projects in the developing countries (Centers for Disease Control and Prevention), major NGOs (e.g., International Planned Parenthood Federation, Population Services International, Family Health International), and major academic centres. These contacts will be utilised to assist in identifying existing sources of data as well as the prospective tracking of studies either planned for the near future or still in progress.

Data collection and analysis

Selection of studies

The search for trials will be performed with the assistance of the Cochrane HIV/AIDS Group. The two authors would critically appraise all identified citations independently to establish their relevance for inclusion into the review. Studies will be reviewed for relevance based on study design, types of participants, interventions and outcome measures. Any disagreement will be resolved by discussion or by contacting an independent author. We will give reasons for excluding potentially relevant trials in an excluded studies table.

Data extraction and management

A standardized form will be used for data abstraction. At least two reviewers will independently abstract study characteristics and outcomes including information on:

1. Contexts of study setting, including background attitudes towards and/or levels of use or condoms as well as other forms of contraception, awareness of HIV/AIDS or STIs, and prevalence of HIV/AIDS or STIs
2. Populations involved (including socio-cultural and economic characteristics and possible previous exposure to similar interventions)
3. Duration of exposure (or 'dose') involved in the intervention, such as measurements of total time period over which the intervention took place, and the cost of the intervention per individual or group 'treated' (if available)
4. Type of intervention
5. Outcome measures
6. Study quality
7. Findings

Assessment of risk of bias in included studies

The quality of all selected studies will be assessed independently by both the authors using the following:

1. Allocation concealment

- Adequate allocation concealment: participants and researchers were unaware of participants' future allocation to condition until after decisions about eligibility were made and informed consent was obtained

- Unclear concealment: allocation concealment measures were not described in detail

- Inadequate allocation concealment: allocation was not concealed from either participants before informed consent or from researchers before decisions about inclusion were made

2. Blinding of participant, assessors and providers of care

- Yes: assessor blind to condition

- Unclear: blinding of assessor not reported and information not available from researchers

- No: assessor not blind to condition

3. Loss to follow up

- Adequate: losses to follow up were equally distributed

between treatment and comparison groups

- Unclear: information about losses to follow up unavailable

- Inadequate: losses to follow up in excess of 30% or unevenly distributed between treatment and comparison groups

4. Method of generation of the randomisation sequence

5. The description of the completeness of outcome data for each main outcome

For each trial the authors will categorise the risk of bias as high, moderate, or low. Scores will be allotted to each component, and studies will be categorized to be of adequate, inadequate or unclear quality, depending on the total score calculated. If there is any disagreement between two authors regarding the quality of a particular study, a third reviewer will reconcile the disagreement. The quality of evidence will be evaluated using the GRADE approach (Guyatt 2008).

Measures of treatment effect

Measures of effect of the interventions will be assessed according to the outcomes of interest for this review.

Unit of analysis issues

Studies with similar units of analysis will be grouped together for the purposes of analysis. Studies with different units of analysis will not be pooled for analysis.

Dealing with missing data

Should there be missing or inadequate data, three attempts will be made to obtain the data by contacting authors.

Assessment of heterogeneity

We anticipate substantial heterogeneity across studies, and thus meta-analysis of these studies will be undertaken with caution, if at all. For studies that are homogenous with respect to types of populations, the interventions that are compared, and outcome measures, overall relative risks will be calculated and translated into relative risk reductions and NNTs. If there is no statistically significant heterogeneity ($p < 0.10$) in results, a fixed effect model (Mantel-Haenszel) will be used. If there is statistically significant heterogeneity we will identify possible explanations and a random effects model (DerSimonian and Laird method) will be used; this will be compared with the corresponding results of the fixed effect model. The following factors will be considered as possible explanations for differences in effects: study quality, patients' gender, age, and the study setting (low- and middle income or high-income countries). To test for robustness of results, sensitivity analyses will be done in which studies using less rigorous methods will be excluded.

Given the likelihood of substantial heterogeneity across studies, and subsequently insufficient data for meta analysis, we intend to include in this review a qualitative overview of the studies and their findings. This may also draw on high-quality studies which did not meet the full selection and/or methodological criteria for various reasons. The main aim of the analysis will be to identify interventions that have been shown to be effective in developing countries, the circumstances under which they have been shown to be effective, and the specific effects that have been measured. We will also identify patterns of intervention strategies which appear ineffective, as well as important gaps in existing knowledge.

Assessment of reporting biases

Funnel plots will be generated to assess for the presence of reporting bias. The presence of asymmetry will suggest that there is reporting bias. We will conduct a thorough evaluation to determine if there are other reasons for asymmetry. If no other reasons for asymmetry are found, we will document the possible presence of reporting bias.

Data synthesis

All eligible studies will be summarized in RevMan. The two authors will extract the data and enter all data into RevMan, and all the entries will be rechecked by both authors. Disagreements will be resolved by discussion. If no consensus is reached, the HIV/AIDS mentor for this review will be contacted.

Subgroup analysis and investigation of heterogeneity

If possible, stratified analysis will be undertaken among participant subgroups. Subgroupings will include age of target population (adolescent versus adult); among general population; or among population at-risk), gender of population, and primary motivation

for condom use (contraception and prophylaxis versus prophylaxis only), whether individually or cluster. Additional stratified analyses will divide studies according to methodological quality, if sufficient numbers are available.

Sensitivity analysis

If the number of studies and data available allows for sensitivity analysis, we shall perform a sensitivity analysis by using one or all of the following strategies

1. Removing studies with high risk of bias to see if there will be any effect on the results of the meta analysis
2. Studies with missing data may be re-analysed using a reasonable range of missing values
3. Data may be re-analysed using different statistical approaches

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