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Structural and community-level interventions for increasing condom use to prevent the transmission of HIV and other sexually transmitted infections (Review)

Moreno R, Nababan HY, Ota E, Wariki WMV, Ezoe S, Gilmour S, Shibuya K

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Structural and community-level interventions for increasing condom use to prevent the transmission of HIV and other sexually transmitted infections (Review)

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TABLE OF CONTENTS

ABSTRACT	1
PLAIN LANGUAGE SUMMARY	2
SUMMARY OF FINDINGS	3
BACKGROUND	6
OBJECTIVES	7
METHODS	8
Figure 1.	10
RESULTS	11
Figure 2.	12
Figure 3.	14
Figure 4.	15
Figure 5.	16
Figure 6.	17
Figure 7.	18
Figure 8.	19
Figure 9.	20
Figure 10.	20
Figure 11.	20
Figure 12.	21
Figure 13.	21
Figure 14.	21
Figure 15.	22
Figure 16.	22
Figure 17.	22
Figure 18.	23
Figure 19.	23
DISCUSSION	23
AUTHORS' CONCLUSIONS	26
ACKNOWLEDGEMENTS	27
REFERENCES	28
CHARACTERISTICS OF STUDIES	35
DATA AND ANALYSES	50
Analysis 1.1. Comparison 1 Interventions to increase condom use versus standard care, Outcome 1 HIV incidence (person/years).	52
Analysis 1.2. Comparison 1 Interventions to increase condom use versus standard care, Outcome 2 HIV prevalence.	52
Analysis 1.3. Comparison 1 Interventions to increase condom use versus standard care, Outcome 3 HSV-2 incidence (person/years).	53
Analysis 1.4. Comparison 1 Interventions to increase condom use versus standard care, Outcome 4 HSV-2 prevalence.	53
Analysis 1.5. Comparison 1 Interventions to increase condom use versus standard care, Outcome 5 Syphilis incidence, 1:8 dilutions (person/years).	53
Analysis 1.6. Comparison 1 Interventions to increase condom use versus standard care, Outcome 6 Syphilis prevalence (1:8 dilutions).	54
Analysis 1.7. Comparison 1 Interventions to increase condom use versus standard care, Outcome 7 Gonorrhoea prevalence. ..	54
Analysis 1.8. Comparison 1 Interventions to increase condom use versus standard care, Outcome 8 Chlamydia prevalence. ...	55
Analysis 1.9. Comparison 1 Interventions to increase condom use versus standard care, Outcome 9 Trichomona prevalence (only in women).	55
Analysis 1.10. Comparison 1 Interventions to increase condom use versus standard care, Outcome 10 Trichomona prevalence (both sexes).	55
Analysis 1.11. Comparison 1 Interventions to increase condom use versus standard care, Outcome 11 Composite score 1: HIV, HSV-2, syphilis, gonorrhea, chlamydia, trichomonas (in women).	56
Analysis 1.12. Comparison 1 Interventions to increase condom use versus standard care, Outcome 12 Composite score 2: HIV, syphilis, gonorrhea, chlamydia, trichomonas.	56

Analysis 1.13. Comparison 1 Interventions to increase condom use versus standard care, Outcome 13 Composite score 3: gonorrhea, chlamydia and trichomonas (all results assessed in women).	56
Analysis 1.14. Comparison 1 Interventions to increase condom use versus standard care, Outcome 14 Two or more sexual partners in last year.	57
Analysis 1.15. Comparison 1 Interventions to increase condom use versus standard care, Outcome 15 Use of condom during last sexual intercourse.	57
Analysis 1.16. Comparison 1 Interventions to increase condom use versus standard care, Outcome 16 Use of condom during last sexual intercourse with non-regular partner.	57
Analysis 1.17. Comparison 1 Interventions to increase condom use versus standard care, Outcome 17 Unprotected sex with regular partner in past three years.	58
Analysis 1.18. Comparison 1 Interventions to increase condom use versus standard care, Outcome 18 Correct condom use at last sexual intercourse at 12 months.	58
Analysis 1.19. Comparison 1 Interventions to increase condom use versus standard care, Outcome 19 Correct condom use at last sexual intercourse 24 months.	58
Analysis 1.20. Comparison 1 Interventions to increase condom use versus standard care, Outcome 20 Consistent condom use at 6 months.	59
Analysis 1.21. Comparison 1 Interventions to increase condom use versus standard care, Outcome 21 Consistent condom use at 12 months.	59
Analysis 1.22. Comparison 1 Interventions to increase condom use versus standard care, Outcome 22 Knowledge: Condom can prevent HIV.	59
Analysis 1.23. Comparison 1 Interventions to increase condom use versus standard care, Outcome 23 Knowledge: Condom can prevent STIs.	60
Analysis 1.24. Comparison 1 Interventions to increase condom use versus standard care, Outcome 24 Condom self efficacy. ...	60
Analysis 1.25. Comparison 1 Interventions to increase condom use versus standard care, Outcome 25 HIV self efficacy.	60
Analysis 1.26. Comparison 1 Interventions to increase condom use versus standard care, Outcome 26 Self efficacy.	61
Analysis 2.1. Comparison 2 Stratified analysis: Condom promotion along with free massive condom distribution, Outcome 1 HIV incidence (person/years).	61
Analysis 2.2. Comparison 2 Stratified analysis: Condom promotion along with free massive condom distribution, Outcome 2 HIV prevalence.	62
Analysis 2.3. Comparison 2 Stratified analysis: Condom promotion along with free massive condom distribution, Outcome 3 HSV-2 prevalence.	62
Analysis 2.4. Comparison 2 Stratified analysis: Condom promotion along with free massive condom distribution, Outcome 4 Syphilis prevalence (1:8 dilutions).	62
Analysis 2.5. Comparison 2 Stratified analysis: Condom promotion along with free massive condom distribution, Outcome 5 Gonorrhoea prevalence.	63
Analysis 2.6. Comparison 2 Stratified analysis: Condom promotion along with free massive condom distribution, Outcome 6 Chlamydia prevalence.	63
APPENDICES	63
HISTORY	68
CONTRIBUTIONS OF AUTHORS	69
DECLARATIONS OF INTEREST	69
SOURCES OF SUPPORT	69
DIFFERENCES BETWEEN PROTOCOL AND REVIEW	69
INDEX TERMS	70

[Intervention Review]

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

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ABSTRACT

Background

Community interventions to promote condom use are considered to be a valuable tool to reduce the transmission of human immunodeficiency virus (HIV) and other sexually transmitted infections (STIs). In particular, special emphasis has been placed on implementing such interventions through structural changes, a concept that implies public health actions that aim to improve society's health through modifications in the context wherein health-related risk behavior takes place. This strategy attempts to increase condom use and in turn lower the transmission of HIV and other STIs.

Objectives

To assess the effects of structural and community-level interventions for increasing condom use in both general and high-risk populations to reduce the incidence of HIV and STI transmission by comparing alternative strategies, or by assessing the effects of a strategy compared with a control.

Search methods

We searched the Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library*, from 2007, Issue 1), as well as MEDLINE, EMBASE, AEGIS and ClinicalTrials.gov, from January 1980 to April 2014. We also handsearched proceedings of international acquired immunodeficiency syndrome (AIDS) conferences, as well as major behavioral studies conferences focusing on HIV/AIDS and STIs.

Selection criteria

Randomized control trials (RCTs) featuring all of the following.

1. Community interventions ('community' defined as a geographical entity, such as cities, counties, villages).
2. One or more structural interventions whose objective was to promote condom use. These type of interventions can be defined as those actions improving accessibility, availability and acceptability of any given health program/technology.

3. Trials that confirmed biological outcomes using laboratory testing.

Data collection and analysis

Two authors independently screened and selected relevant studies, and conducted further risk of bias assessment. We assessed the effect of treatment by pooling trials with comparable characteristics and quantified its effect size using risk ratio. The effect of clustering at the community level was addressed through intra-cluster correlation coefficients (ICCs), and sensitivity analysis was carried out with different design effect values.

Main results

We included nine trials (plus one study that was a subanalysis) for quantitative assessment. The studies were conducted in Tanzania, Zimbabwe, South Africa, Uganda, Kenya, Peru, China, India and Russia, comprising 75,891 participants, mostly including the general population (not the high-risk population). The main intervention was condom promotion, or distribution, or both. In general, control groups did not receive any active intervention. The main risk of bias was incomplete outcome data.

In the meta-analysis, there was no clear evidence that the intervention had an effect on either HIV seroprevalence or HIV seroincidence when compared to controls: HIV incidence (risk ratio (RR) 0.90, 95% confidence interval (CI) 0.69 to 1.19) and HIV prevalence (RR 1.02, 95% CI 0.79 to 1.32). The estimated effect of the intervention on other outcomes was similarly uncertain: Herpes simplex virus 2 (HSV-2) incidence (RR 0.76, 95% CI 0.55 to 1.04); HSV-2 prevalence (RR 1.01, 95% CI 0.85 to 1.20); syphilis prevalence (RR 0.91, 95% CI 0.71 to 1.17); gonorrhoea prevalence (RR 1.16, 95% CI 0.67 to 2.02); chlamydia prevalence (RR 0.94, 95% CI 0.75 to 1.18); and trichomonas prevalence (RR 1.00, 95% CI 0.77 to 1.30). Reported condom use increased in the experimental arm (RR 1.20, 95% CI 1.03 to 1.40). In the intervention groups, the number of people reporting two or more sexual partners in the past year did not show a clear decrease when compared with control groups (RR 0.90, 95% CI 0.78 to 1.04), but knowledge about HIV and other STIs improved (RR 1.15, 95% CI 1.04 to 1.28, and RR 1.23, 95% CI 1.07 to 1.41, respectively). The quality of the evidence was deemed to be moderate for nearly all key outcomes.

Authors' conclusions

There is no clear evidence that structural interventions at the community level to increase condom use prevent the transmission of HIV and other STIs. However, this conclusion should be interpreted with caution since our results have wide confidence intervals and the results for prevalence may be affected by attrition bias. In addition, it was not possible to find RCTs in which extended changes to policies were conducted and the results only apply to general populations in developing nations, particularly to Sub-Saharan Africa, a region which in turn is widely diverse.

PLAIN LANGUAGE SUMMARY

The effectiveness of community interventions to promote condom use in the prevention of HIV and sexually transmitted infections

Background

Since the advent of the HIV/AIDS epidemic in the 1980s, condom promotion has become one of the most widely used interventions to prevent transmission of HIV and sexually transmitted infections (STIs). However, despite widespread promotion of condom use globally, new cases of HIV and other STIs either remain high or continue to rise in some particular regions and settings across the world. It is believed that by modifying the environment in which people live, it is possible to improve access and use of condoms on a large scale so that the transmission of HIV and other STIs decreases. This review aimed to assess if this theory was correct.

Methods

We screened all relevant literature from January 1980 to April 2014. Two independent authors selected and assessed the trials.

Results

We obtained nine studies, involving 75,891 participants and with a duration ranging from one to nine years. Seven of these studies were conducted in Sub-Saharan Africa, one in Peru, and one in a multi-country location. Condom promotion was implemented in all the studies. Our results did not provide clear evidence that condom promotion in these specific contexts led to a decrease in the transmission of HIV and other STIs. However, knowledge about HIV and other STIs increased, as did reported condom use. A likely reason for the negative results in this review is that sexual behaviors are difficult to change. For example, we found no difference in the number of sexual partners after the intervention was implemented. Also, if there is not consistent condom use the risk of transmission remains for HIV and other STIs. The quality of the evidence was deemed to be moderate.

Conclusions

Our findings should be interpreted with caution since most of the studies in the present review were carried out in Sub-Saharan Africa, region that is very diverse, and whose social and cultural characteristics are different from those in other developing nations. Thus, our results present a limited generalizability.

SUMMARY OF FINDINGS

Summary of findings for the main comparison. Structural and community-level interventions for increasing condom use versus standard care to prevent the transmission of HIV and other sexually transmitted infections

Structural and community-level interventions for increasing condom use versus standard care to prevent the transmission of HIV and other sexually transmitted infections

Patient or population: low and high-risk populations

Settings: community-based

Intervention: structural and community-level interventions to increase condom use

Comparison: standard care

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	Structural and community-level interventions to increase condom use				
HIV incidence (per-son/years) Follow-up: 2 to 4 years	Study population		RR 0.90 (0.69 to 1.19)	14279 (4 studies)	⊕⊕⊕⊖ moderate ^{1,2}	
	14 per 1000	13 per 1000 (10 to 17)				
	Moderate					
	11 per 1000	10 per 1000 (8 to 13)				
HIV prevalence Follow-up: 3 to 9 years	Study population		RR 1.02 (0.79 to 1.32)	9042 (3 studies)	⊕⊕⊖⊖ low ^{3,4}	
	24 per 1000	25 per 1000 (19 to 32)				
	Moderate					
	29 per 1000	30 per 1000 (23 to 38)				
Herpes Simplex Virus 2 (HSV-2) incidence (per-son/years)	Study population		RR 0.76 (0.55 to 1.04)	3877 (2 studies)	⊕⊕⊕⊖ moderate ⁵	
	44 per 1000	33 per 1000				

Follow-up: 2 to 4 years	(24 to 45)				
	Moderate				
	41 per 1000	31 per 1000 (23 to 43)			
HSV-2 prevalence Follow-up: 4 to 9 years	Study population		RR 1.01 (0.85 to 1.20)	2974 (2 studies)	⊕⊕⊕⊖ moderate ⁶
	130 per 1000	131 per 1000 (110 to 156)			
	Moderate				
	202 per 1000	204 per 1000 (172 to 242)			
Two or more sexual partners in last year Follow-up: 3 to 9 years	Study population		RR 0.90 (0.78 to 1.04)	4008 (5 studies)	⊕⊕⊕⊖ moderate ⁷
	156 per 1000	140 per 1000 (121 to 162)			
	Moderate				
	173 per 1000	156 per 1000 (135 to 180)			
Use of condom during last sexual intercourse Follow-up: 3 to 9 years	Study population		RR 1.20 (1.03 to 1.4)	1898 (3 studies)	⊕⊕⊕⊖ moderate ⁸
	221 per 1000	265 per 1000 (228 to 309)			
	Moderate				
	217 per 1000	260 per 1000 (224 to 304)			
Knowledge: condom can prevent STIs Follow-up: 3 to 9 years	Study population		RR 1.23 (1.07 to 1.41)	1231 (3 studies)	⊕⊕⊕⊖ moderate ⁸
	368 per 1000	452 per 1000 (393 to 518)			
	Moderate				

372 per 1000	458 per 1000 (398 to 525)
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*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; **HIV:** human immunodeficiency virus; **RR:** Risk ratio; **STI:** sexually transmitted infection

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 Although there was attrition bias higher than 30% in one study, it was the only one classified as high risk among a total of four studies assessing this outcome.
- 2 Wide confidence intervals (null effect with a confidence interval that goes beyond 0.75) and a total number of events inferior to 300 with a small risk ratio reduction (< 20%).
- 3 High risk of incomplete outcome data in two studies, and unknown in 1 study.
- 4 Wide confidence intervals (null effect with a confidence interval that goes beyond 1.25) and a total number of events inferior to 300 with no risk ratio reduction.
- 5 Wide confidence intervals, few number of events (< 100).
- 6 Both studies with high risk of incomplete outcome data.
- 7 Three studies with high risk of incomplete outcome data and two studies with unknown technique for randomisation.
- 8 Two studies with high risk of incomplete outcome data and two studies with unknown technique of randomisation.

BACKGROUND

Description of the condition

HIV is a virus that attacks the immune system, weakening it progressively and leading some years later to the onset of opportunistic infections, a stage that is known as acquired immunodeficiency syndrome (AIDS). If not treated, the natural progression of this syndrome winds up in death (Weiss 1993). HIV's routes of transmission are sexual intercourse through contact of mucosae with semen or vaginal fluids, exchange of intravenous syringes, blood transfusion, hemodialysis, and mother-to-child transmission via blood transfer and breastfeeding.

In 2012 the World Health Organization (WHO) and the Joint United Nations Programme on HIV/AIDS (UNAIDS) estimated that globally 2.3 million people were newly infected with HIV, 35.3 million people were already living with the virus, and 1.6 million people died from AIDS-related causes (UNAIDS 2013). Moreover, the HIV/AIDS pandemic affects disproportionately low- and middle-income countries (LMICs), with several regions in Sub-Saharan Africa facing the highest burden of the disease (Ortblad 2013).

Since the onset of the pandemic, condoms have been considered one of the most effective biological mechanisms for reducing the transmission of HIV (Holmes 2004). Laboratory and epidemiological studies have demonstrated that condoms are effective against a number of sexually transmitted infections (STIs), such as gonorrhoea, non-gonococcal urethritis, trichomoniasis, genital herpes (da Silveira 2005), and HIV (Weller 2002). Of the many strategies to reduce infection, promotion of condom use continues to be the keystone of HIV and STI prevention worldwide (Matson 2010). However, the positive impact of condoms may be limited by their inconsistent or low use (Hearst 2004). Several factors are known to be associated with condom non-use during sexual intercourse, including perception of reduced pleasure (Sarkar 2008; Sunmola 2005), discomfort (Crosby 2005), partner trust (Abdullah 2002; Jadack 1997), use of other contraceptives (Abdullah 2002), fear of revealing HIV status to partners (Medley 2004), and religious beliefs (Thomsen 2004). It has also been suggested that the spread of information about highly active antiretroviral therapy (HAART) reducing the infectiousness of HIV may be a potential hindrance to condom use (Akinyemi 2010); nonetheless, evidence supporting this theory is mixed (Berhan 2012; Crepaz 2004).

The availability of and accessibility to condoms is often a major obstacle to condom use. In most low- and middle-income countries cost is a barrier to purchase condoms among the poor (Essien 2005). Even when cost is not an issue, non-availability of condoms often results in unprotected sexual practices (Kumar 2006). This problem affects not only LMICs, but also high-income countries such as the United States, where many African-Americans are unable to purchase condoms due to financial barriers (Essien 2005). Other authors have also mentioned that in certain societies, the setting in which condoms are provided, commercialized and purchased may hinder their acquisition from possible buyers/consumers (e.g. buying them in a public place (Roth 2001)). Also, in many societies moral values and ethnic and religious factors play an important role in health behaviors and health promotion policies (Koenig 2012). For example, the Catholic Church considers any contraceptive method as a transgression of divine law (HUMANAE VITAE 1968), a mandate that some devout Catholics observe (Lefkowitz 2004).

Moreover, lack of condom usage is also a consequence of limited knowledge about HIV prevention and a low level of education (Dandona 2005). Other social determinants such as women's lack of empowerment, scarce dialogue within couples, domestic violence, and prejudice related to condom use could increase the risk of unsafe sexual practices (Sarkar 2008).

Among female sex workers (FSW), limited knowledge about HIV transmission, a client's refusal to use condoms, or coercion and control by pimps or brothel owners act as barriers to condom use (Xia 2005). For men who have sex with men (MSM), negative community attitudes towards homosexuality combined with legal restrictions on their sexual behavior and official relationships contribute to the marginalization and stigmatization of this community and drive their relationships underground, hindering an easy acquisition of condoms and resulting in risky sexual behavior (Adimora 2010).

It is also important to mention that depending on the local context, prevalence of condom use tends to differ between different sex-risk-behavior groups. Several studies have described a tendency of high-risk groups such as individuals with multiple sexual partners and frequent casual sexual encounters (Maticka-Tyndale 2012), MSM (Adam 2009; Lau 2008; Reece 2010) and FSWs (Maticka-Tyndale 2012; Rojanapithayakorn 1996; Suleman 2012) to report higher condom use figures than non-high-risk groups (Abdullah 2002; Jones 2012; Reece 2010). The general population tends to present a lower condom use prevalence for reasons such as use of other contraceptive methods (Abdullah 2002; Jones 2012) and a negative perception of condoms, which symbolize promiscuity and unfaithfulness (Maticka-Tyndale 2012). Consequently, condom promotion interventions may also have a different impact on each of these populations.

Description of the intervention

It is widely understood in the field of public health that social determinants of health, or the circumstances in which individuals are born, live, work and age, play an important role in their health (WHO 2012). Those contexts are shaped by structural determinants such as physical, social, cultural, legal, and organizational factors, and several other aspects of the environment that hinder or promote HIV prevention (Gupta 2008; Sumartojo 2000).

A structural intervention is defined as any public health intervention that aims to improve society's health status by modifying the context in which health-related risk behavior takes place (Blankenship 2000). When addressing condom use through structural interventions, there are three key concepts to consider (Blankenship 2000). The first one is availability, which focuses on the attitudes, materials, or settings that are essential to reduce exposure to a specific health problem (Blankenship 2000). For example, community campaigns may install condom machines in public places, or implement a policy of 100% condom use in brothels (Blankenship 2000; Charania 2011). The second factor is acceptability, which sets out to modify the preconceptions in a society, allowing people to consider and accept new ideas (Blankenship 2000) mainly through social learning theory (Bandura 1986). Programs to prevent the stigmatization of prostitution, sexual education, and marketing of condoms are examples (Blankenship 2000; Charania 2011). The last factor is accessibility, which aims to improve access to interventions, services and goods in health for those who face unfavourable social or economic

conditions (Blankenship 2000). Examples of this concept include distribution of free or low-cost condoms and the creation of female controlled prevention strategies, such as female condom use (Blankenship 2000; Charania 2011). Therefore, structural interventions usually include changes to policies, environment, or social beliefs, and in many cases also involve the empowerment of minorities and other disenfranchised groups (Adimora 2010).

Structural interventions can be implemented at three levels: individual, group, and community (Charania 2011). Individual and group level interventions target knowledge, attitudes, and behaviors associated with the condom use of the participant in one-on-one settings and in existing (e.g. a couple) or recently created groups, respectively (Charania 2011). Community-level interventions have typically been conceptualized as geographic units (e.g. cities, counties, villages), although alternative conceptualizations of smaller units also exist (e.g. workplaces and schools) (Atienza 2002); the present review was developed based on the former concept. Interventions at a community level directly and indirectly concentrate on knowledge, attitudes and behaviors in relation to the entire community and strongly address the alteration of social norms (Charania 2011). This strategy might have the capacity to modify social determinants of health at all levels in which it is implemented (Swerissen 2004).

How the intervention might work

Previous research on HIV and STI prevention strategies shows that structural interventions have the capacity to initiate significant change in behaviors and attitudes.

For example, Thailand's renowned 100% Condom Program modified availability and accessibility of condoms by empowering sex workers to consistently engage in safe sexual practices via government policies that enforced mandatory condom use (Rojanapithayakorn 1996). Likewise, in the Dominican Republic two non-governmental organizations (NGOs) investigated in 1995 the adoption of Thailand's initiative into the Dominican setting (Kerrigan 2006). This intervention addressed the three different components of structural interventions at a group and community level. Assessment of this program revealed that condom use did increase after the introduction of this intervention (Kerrigan 2006). Another program, the Sonagachi project in India, focused on community mobilization, aiming to reduce discrimination and stigma against FSWs (Basu 2004).

Dealing with inequitable gender norms, especially those that define masculinity, was an important component of HIV prevention strategies in Brazil (Pulerwitz 2006). In this intervention, the aim was to modify acceptability at a community level. In South Africa an HIV prevention strategy was implemented to modify both accessibility through a local micro-finance program addressed at women and acceptability by initiating community activism in opposition to women mistreatment (Gupta 2008). Such interventions aim to empower women, decrease domestic violence and enable women to negotiate safe sex (Gupta 2008).

Finally, media campaigns promoting condom use also have the potential to influence norms and change values, expectations, and behaviors by modifying acceptability at a community level (Cohen 2006).

In spite of the cost, financial analyses demonstrate that structural interventions may have the most impact in HIV prevention, and may also generate other social advantages, such as stimulating the economy and making gains in human rights (Hecht 2009). Given the large amount of resources required for individual-based interventions to be successfully implemented on a broader scale, it has been hypothesized that structural interventions might be an adequate solution since they are more ample in their scope (Cohen 2006).

Why it is important to do this review

Despite the implementation of extensive HIV prevention programs over the past decades, the number of people newly infected with HIV continues to rise in some regions across the globe (UNAIDS 2013). Some studies argue that one of the reasons for this phenomenon is the excessive attention to individual behaviors at the expense of changes to the context in which those behaviors occur (Barnett 2006).

The consensus in recent years that social factors affect HIV transmission as well as risky sexual behaviors has prompted an increasing attention on structural interventions for HIV and other STIs (Gupta 2008). However, few strategies to prevent HIV transmission have implemented structural interventions, mainly due to a lack of clear definition, a poor understanding of technical implementation, and insufficient data to support the effectiveness of such interventions in the context of people living with HIV (Gupta 2008).

Behavioral interventions that aim to encourage a change in individual attitudes toward safer sexual practices such as condom use or reduction of sexual partners play an important role in overall HIV prevention efforts. However, these interventions alone may be inadequate to produce substantial and long-term reductions in HIV transmission (Coates 2008). As a result, taking into account the limitations of these strategies, structural interventions offer a potentially powerful shift in the manner HIV prevention is implemented (Blankenship 2010).

Despite a growing interest in the topic, there is little evidence on structural interventions at a community level that aim to increase condom use to prevent HIV and other STIs. Policy makers require high quality quantitative information in order to develop and implement prevention programmes, as well as to set priorities in research and funding (Johnson 2008). Determining if structural interventions for promoting condom use are effective in halting HIV transmission at a community level is central to the current strategies against HIV, given the number of people whose lives may be improved by this policy. In addition, deciding what the most effective approaches to reducing HIV transmission are will allow wise investment in public health resources.

OBJECTIVES

The objective of this review is to assess the effects of structural and community-level interventions for increasing condom use in both general and high-risk populations to reduce the incidence of HIV and STI transmission 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

We included randomized controlled trials (RCTs) including cluster-RCTs that compared either two or more alternative condom promotion strategies, or one condom promotion strategy with a control (i.e. no condom promotion strategy). We decided to search only for RCTs since they are the gold standard in scientific experimentation, reducing the likelihood of bias and misleading causality, thus providing the highest quality of primary data.

We only included studies conducted at a community level in this review. We defined community as a geographical area with delimited boundaries such as a village, city or county ([Atienza 2002](#)).

Types of participants

We assessed studies that included the following types of participants and satisfied this review's definition of 'community'.

1. General population (adolescents and adults).
2. Patients with STIs, including those living with HIV, or serodiscordant couples, or both.
3. Drug users, including injecting drug users (IDUs) as well as other drug-using populations.
4. Sex workers (male and female).
5. Men who have sex with men (MSM).

Types of interventions

A. Experimental group

We attempted to include all the following types of interventions at a community level.

1. Interventions focusing on increasing the acceptability of condom use behaviors by altering social norms, such as the social-cognitive theory ([Bandura 1986](#)), mass media campaigns, use of public opinion, and social marketing strategies.
2. Interventions which improve condom accessibility, or change or improve distribution, whether through the public sector, the private sector, or NGOs via condom subsidization (either total or partial), as well as strategies focusing on altering economic situations which impact condom use, such as condom taxes or tariffs removal. Female empowerment was also included as an intervention to improve their access to condoms.
3. Interventions aimed to extend the availability of condoms such as condom machines in clubs, brothels, or other public spaces.
4. Combinations of the above.

B. Control group

1. Standard intervention or standard care. These terms refer to the usual HIV and STIs knowledge to which communities are exposed in daily life, such as regular STIs/HIV education programs in school, television advertisements, medical advice, and the like.
2. Delayed intervention.
3. Partial or shortened version of the intervention.

Types of outcome measures

Primary outcomes

1. HIV incidence/prevalence.
2. STI incidence/prevalence.

Secondary outcomes

1. Self reported condom use (male or female condoms).
2. Self reported number of sexual partners in the last year.
3. Knowledge about HIV.
4. Knowledge about STIs.
5. Knowledge about condom use (both self reported and tested).
6. Self efficacy (assessing self confidence related to condom use and sexual practices after receiving the intervention through standard questionnaires).

Since the primary objective of our revision was to measure the impact of condom promotion on the transmission of HIV and other STIs, it was decided to set up as inclusion criteria the reporting of any of the primary outcomes proposed for this review (i.e. HIV and/or other STIs), as long as they were confirmed through laboratory markers.

Search methods for identification of studies

Electronic searches

We used the Cochrane search strategy for RCTs with the assistance of the Cochrane HIV/AIDS Review Group to identify appropriate studies within electronic databases ([Higgins 2011](#)). We did not impose any restrictions on language or publication status. We searched the Cochrane Central Register of Controlled Trials (CENTRAL) from 2007 (issue 1) to April 2014, as well as MEDLINE, EMBASE, Psychological Abstracts and Sociological Abstracts using a strategy similar to MEDLINE, from January 1980 to April 2014 (see [Appendix 1](#)). The sensitivity of the search strategies was improved when 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 this sensitivity, searches were performed both with and without keywords related to the study design.

Searching other resources

We handsearched the following sources.

1. Proceedings of the International AIDS Conferences.
2. Proceedings of the International Society of STD Research (ISSTD).
3. Other proceedings, including those of major behavioral studies conferences focusing on people living with HIV/AIDS, STIs, or other reproductive health issues.

We examined bibliographies of studies and previous reviews to find other relevant evaluation studies. We contacted professionals in the field (e.g. authors of previous reviews or investigators of previous primary research) (via email) to identify continuing studies. We also contacted relevant organizations possibly involved in condom promotion interventions, including international agencies (e.g. UNAIDS, WHO, United Nations Population Fund (UNFPA), national public health agencies with projects in developing countries, major NGOs and major academic centers).

Data collection and analysis

Selection of studies

The search for trials was performed with the assistance of the Cochrane HIV/AIDS Group. Two authors (HN and RM) critically appraised all identified citations independently, in order to establish their relevance for inclusion into the review. Studies were reviewed for relevance based on study design, types of participants, interventions and outcome measures. Any disagreement was resolved by discussion or by contacting a third author (EO). We provided reasons for excluding potentially relevant trials in the [Characteristics of excluded studies](#) table.

Data extraction and management

We used a standardized form for data extraction. Two reviewers (HN and RM) independently extracted study characteristics and outcomes including information on:

1. contexts of study setting;
2. study populations (including sociocultural 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;
4. type of intervention;
5. outcome measures; and
6. findings.

Assessment of risk of bias in included studies

Two review authors (HN and RM) independently assessed the quality of all selected studies using the Cochrane 'Risk of bias' assessment tool ([Higgins 2011](#)).

1. Random sequence generation (selection bias)

- Low risk: the process of randomization was properly described
- Unclear risk: the information provided is not enough to judge if the sequence generation was at random or not
- High risk: a non-random approach was used

2. Allocation concealment (selection bias)

- Low risk: participants and researchers were unaware of participants' future allocation to the condition until after decisions about eligibility were made and informed consent was obtained
- Unclear risk: allocation concealment measures were not described in detail
- High risk: allocation was not concealed from either participants before informed consent or from researchers before decisions about inclusion were made

3. Blinding of participants, assessors and providers of care (performance bias)

- Low risk: assessor blind to condition
- Unclear risk: blinding of assessor not reported and information not available from researchers
- High risk: assessor not blind to condition

4. Blinding of outcome assessment (detection bias)

- Low risk: blinding of outcome assessment was ensured, or the outcome measurement is unlikely to be biased by lack of blinding
- Unclear risk: Outcome assessment was not described
- High risk: no blinding of outcome assessment and the results are likely to be biased if blinding did not take place

5. Incomplete outcome data (attrition bias)

- Low risk: losses to follow up were equally distributed between treatment and comparison groups
- Unclear risk: information about losses to follow up unavailable
- High risk: losses to follow up in excess of 30% or unevenly distributed between treatment and comparison groups. It was decided to set up the threshold for attrition bias above the usual 20% since all studies were community based, thus large loss to follow-up was expected due to migration and death

6. Selective reporting (reporting bias)

- Low risk: the outcomes of interest are the same in the protocol and in the published paper
- High risk: the outcomes pre-specified in the protocol are not the same than those presented in the paper

7. Other bias

- Low risk: other bias such as different individual recruitment, cluster imbalance, loss of cluster and secular trend are unlikely to have taken place
- Unclear risk: it is not possible to judge if the abovementioned bias took place
- High risk: it is likely that any of the abovementioned bias took place

For each trial, two reviewers (HN and RM, see [Contributions of authors](#)) categorised the risk of bias as 'high', 'unclear', or 'low'. When there was any disagreement between them regarding the quality of a particular study, a third reviewer (EO) reconciled the disagreement.

Measures of treatment effect

We measured the size of the intervention effect using risk ratio (RR), with either the number of participants as the denominator for estimated prevalence or person-years for estimated incidence. We adjusted event rates and sample sizes using methods outlined under [Sensitivity analysis](#).

Unit of analysis issues

Studies with similar units of analysis (e.g. incidence, prevalence, type of outcome) were grouped together for the purposes of analysis, while studies with different units of analysis were not. In case of multiple-arms trials, we combined groups to generate a single-pair wise comparison.

Dealing with missing data

In cases of missing or inadequate data, we made three attempts to obtain the data by contacting authors via email.

Assessment of heterogeneity

We anticipated substantial heterogeneity across studies, and thus we undertook meta-analysis of these studies with caution. For studies that were homogenous with respect to types of study populations, interventions and outcome measures, overall risk ratios were calculated and translated into risk ratio reductions. When there was no statistically significant heterogeneity ($P < 0.10$) in the results, we used a fixed-effect model (Mantel-Haenszel). When there was statistically significant heterogeneity we identified possible explanations and used a random-effects model (DerSimonian and Laird method); this was compared with the corresponding results of the fixed-effect model. The following factors were considered as possible explanations for significant heterogeneity: study quality, patient gender or age, or both, study setting (low- and middle-income or high-income countries), and type of intervention. To test for robustness of results, we performed sensitivity analyses.

Given the likelihood of substantial heterogeneity across studies, and the subsequent insufficient data for meta-analysis, we included in this review a qualitative overview of the studies and their findings. The main aim of this analysis was to identify interventions that have been shown to be effective, the circumstances under which they have been shown to be effective, and the specific effects that have been measured. We also identified patterns of intervention strategies that appeared ineffective, as well as important gaps in existing knowledge.

Assessment of reporting biases

We evaluated possible reporting bias through asymmetry in funnel plots. We screened meta-analyses containing five or more studies with this technique.

Data synthesis

Two authors (HN and RM) extracted the data and entered all eligible studies into RevMan. All the entries were rechecked by both authors. Disagreements were resolved by discussion. When no consensus was reached, the HIV/AIDS mentor for this review (EO) was contacted.

Subgroup analysis and investigation of heterogeneity

When possible, we performed stratified analysis among subgroups of participants to assess the origin of heterogeneity. Subgroups included age of target population (e.g. adolescent versus

adult), gender, motivation for condom use (contraception and prophylaxis versus prophylaxis only), and combinations of different interventions. We performed additional stratified analyses by methodological quality, when possible. Only those analyses in which a particular subgroup explained heterogeneity were shown in this review.

Sensitivity analysis

Correction for cluster effect in RCTs: intra-cluster correlation coefficient (ICC)

As community-level interventions were the objective of the present analysis, we only included cluster-RCTs in this review. Therefore, calculation of design effects (DEs) was necessary to estimate effective sample sizes. In order to calculate these figures (DE), intra-cluster correlation coefficients (ICCs) were required (Donner 2000). Since the majority of studies did not report on ICCs, we attempted to contact the authors (via email) to obtain those figures. Unfortunately, we often failed to receive any response, or the answer did not provide the information we needed (e.g. the study was conducted a long time ago, and those data were not available). We therefore decided to screen other trials with similar populations in order to infer the ICCs. It proved difficult to obtain studies in which the cluster size matched studies in this review. Furthermore, when correcting for ICCs it is preferable to assign an individual ICC value to each outcome instead of using one single ICC for all outcomes in one trial (Taljaard 2008). Given these obstacles, we decided to employ a regression model to generate an estimated ICC value for every single outcome in each trial. We ran a model with natural logarithm of ICC as the dependent variable, and both average cluster size and outcome prevalence as the independent variables. We hypothesized that this specific set of variables would predict the value of any given ICC. The required data to build the model was obtained from studies that reported both the covariates and an individual ICC value for each outcome. Five studies were included in the final model (D'Amico 2012; Feldblum 2001; Garcia 2012; Majoko 2007; Taljaard 2008). After running the linear regression model, we found that the hypothesized independent variables (average cluster size and outcome prevalence) were significant and in agreement with other studies (Killip 2004; Taljaard 2008). The model explained 45% of variation in ICCs (Figure 1). Residuals were calculated and displayed no evident pattern, indicating ordinary least squares regression was appropriate for this data. Finally, the model was used to estimate the ICC for a given prevalence and average cluster size for each outcome.

Figure 1. ICC Linear Regression Model.

				R-squared: 0.45
Independent variable	Coefficient	Standard error	p-value	95% confidence interval
Prevalence	0.06	0.01	<0.01	0.02 to 0.09
Cluster size	0.02	0.01	0.02	0.01 to 0.03
Constant	-6.11	0.54	<0.01	-7.24 to -4.97

Then the DE was calculated using the standard formula: $1 + ((\text{average cluster size} - 1) * \text{ICC})$ (Higgins 2011, Section 16.3.4). Once the DE was estimated, effective sample sizes for each individual outcome were calculated by dividing the original sample size by the DE. Finally, these effective sample sizes were the figures used in the meta-analysis. We set an upper limit of 40 to the design effect, which corresponds to ICCs higher than 0.1 for the cluster sizes in the selected studies. This limit was chosen based on the trend reported by Taljaard and Donner (Taljaard 2008) in which design effects rarely surpass this value.

Since outcomes may vary based on ICC fluctuation, sensitivity analysis was carried out with an ICC of 0 (i.e. original sample size with no correction), 0.001, 0.005, 0.01, 0.05 and 0.1 for every outcome in which a meta-analysis was possible.

RESULTS

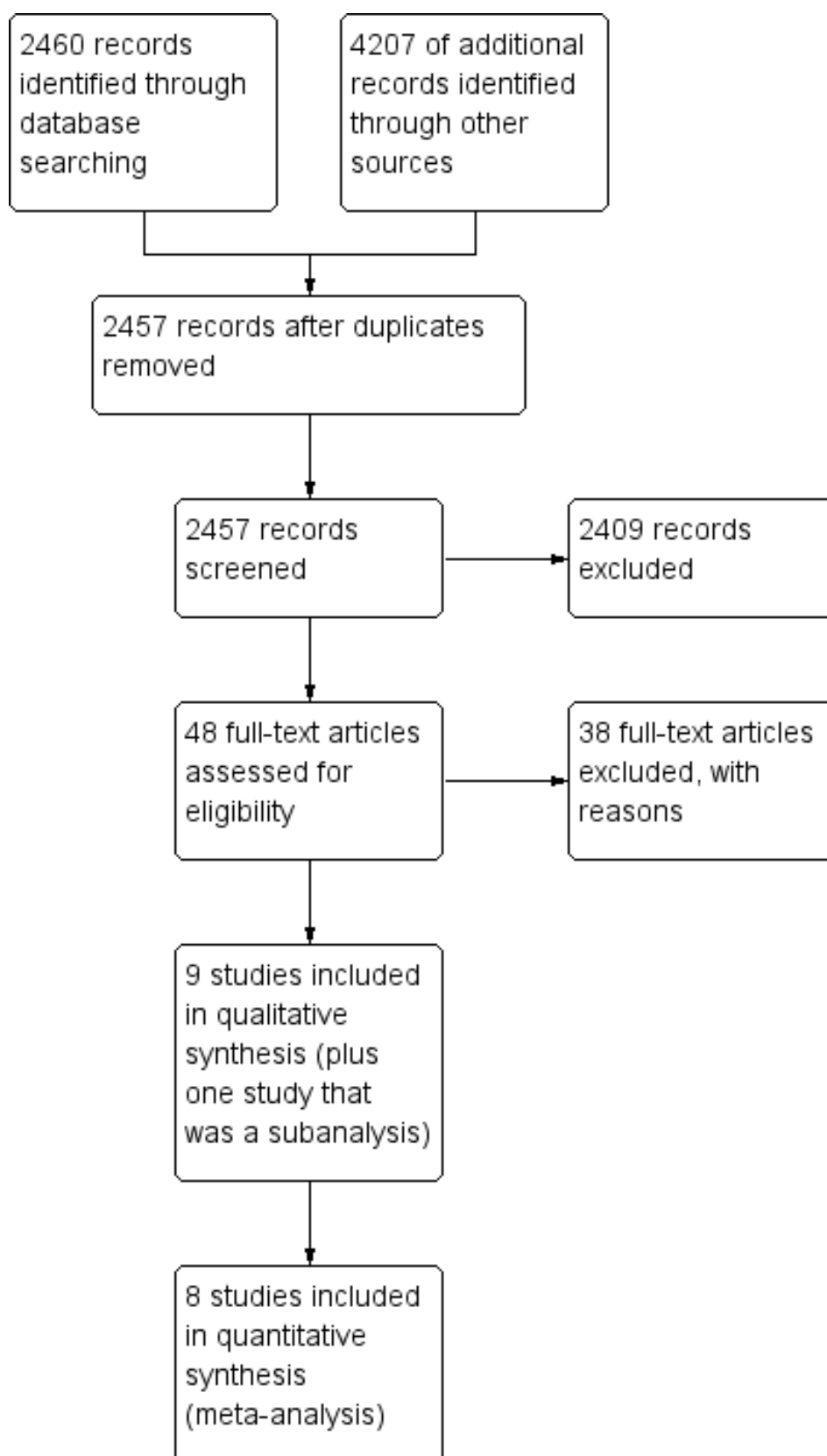
Description of studies

Results of the search

See [Characteristics of included studies](#); [Characteristics of excluded studies](#).

We retrieved a total of 6,667 citations, ranging from those published between January 1980 to April 2014. After thorough screening, we selected 48 full-text studies and assessed for eligibility, with an inter-rater agreement (kappa) score of 0.34. In the subsequent analysis, we excluded 38 studies for different reasons ([Characteristics of excluded studies](#)), leaving nine studies for risk of bias assessment (Cowan 2010; Doyle 2010; Feldblum 2001; Garcia 2012; Gregson 2007; Jewkes 2008; Kamali 2003; NIMH 2010; Ross 2007), and one study that was a subanalysis from Feldblum 2001, in which condom use was reported (see Welsh 2001, under included studies, Feldblum 2001). The kappa score for this second screening process was 0.46. Out of these trials, we selected eight for meta-analysis, excluding NIMH 2010 since it only reported one pooled result (see [Figure 2](#)). The nine studies included 75,891 participants.

Figure 2. Study flow diagram.



Included studies

Seven studies were conducted in Sub-Saharan Africa: Zimbabwe (Cowan 2010; Gregson 2007), South Africa (Jewkes 2008), Uganda (Kamali 2003), Kenya (Feldblum 2001) and Tanzania (Doyle 2010; Ross 2007); one study was conducted in Peru (Garcia 2012), and one was a multi-country study conducted in China, India, Peru, Russia and Zimbabwe (NIMH 2010). The multi-country study only provided a composite biological result, including HIV, Herpes simplex virus 2 (HSV-2), syphilis, gonorrhea, chlamydia, and trichomoniasis in women, which was not comparable to other studies. Therefore, it was not possible to include it in the meta-analysis; nonetheless, risk of bias assessment was carried out. Ross 2007 and Doyle 2010 are studies that developed the same intervention but with differences in methodology (Ross 2007 was a cohort study and Doyle 2010 was a cross-sectional study) and follow-up times (three and nine years after the initial intervention, respectively).

Given the definition of 'community' we used in this review, all studies were conducted in the general population, rather than in high-risk groups. All studies were obtained through database searching.

All nine studies were cluster-RCTs. Eight trials were originally designed as cohort studies (Cowan 2010; Doyle 2010; Feldblum 2001; Gregson 2007; Jewkes 2008; Kamali 2003; NIMH 2010; Ross 2007), and one as a repeated cross-sectional study (Garcia 2012); however, due to methodological issues such as attrition bias during the trials' development, Cowan 2010 and Doyle 2010 switched to a repeated cross-sectional approach. Incomplete outcome data ranged from 18% in NIMH 2010, to 60% in Doyle 2010.

All studies included primary outcomes (Cowan 2010; Doyle 2010; Feldblum 2001; Garcia 2012; Gregson 2007; Jewkes 2008; Kamali 2003; NIMH 2010; Ross 2007), but NIMH 2010 only reported a unique biological-composite score. Four studies included HIV incidence (Gregson 2007; Jewkes 2008; Kamali 2003; Ross 2007), and three included HIV prevalence (Cowan 2010; Doyle 2010; Garcia 2012). Two studies included incidence of HSV-2 (Jewkes 2008; Kamali 2003), and six studies included prevalence of HSV-2, or any other STI, or both (Cowan 2010; Doyle 2010; Feldblum 2001; Garcia 2012; Gregson 2007; Ross 2007). Three studies included composite biological scores (Feldblum 2001; Garcia 2012; NIMH 2010).

Secondary outcomes were identified in all included studies; however, for the purpose of comparison and in order to carry out meta-analyses, only those primary and secondary results that were both common across studies and reported in at least two trials were included in the quantitative analysis.

The follow-up period varied substantially between trials: one year in Feldblum 2001 (although an interim assessment was conducted at six months), two years in Jewkes 2008 and NIMH 2010, three years in Garcia 2012, Gregson 2007 and Ross 2007, four years in Cowan 2010 and Kamali 2003, and nine years in Doyle 2010.

All trials in this review were sponsored by local or foreign governments, education institutions or international NGOs. Thus, all studies declared no conflict of interest. The included studies did not report any adverse effects after the interventions were implemented.

Interventions performed in the included studies

The structural and community-level interventions that aimed to promote condom use were acceptability and accessibility.

Acceptability, through specific programs such as:

- sexual health education in schools and communities, provided by teachers and professional peer educators (Cowan 2010; Doyle 2010; Garcia 2012; Kamali 2003; Ross 2007);
- improving reproductive knowledge in the community (Feldblum 2001), promoting communication between parents and teenagers and enhancing community support for the reproductive health of adolescents (Cowan 2010);
- participatory learning approaches such as dramas and role playing (Jewkes 2008; Kamali 2003);
- training of medical staff with the purpose of creating a clinical environment suitable to the care of adolescents' reproductive health (Cowan 2010; Doyle 2010; Ross 2007);
- social marketing of condoms (Doyle 2010; Garcia 2012; Gregson 2007; Ross 2007); and
- task-shifting through community popular opinion leaders (C-POLs), who are identified as natural leaders among their communities. These people then imparted educational messages about HIV and other STIs (NIMH 2010).

Accessibility, through specific programs such as:

- distribution of free condoms (Doyle 2010; Feldblum 2001; Gregson 2007; Ross 2007); and
- income-generating projects (Gregson 2007).

All the selected interventions incorporated or promoted condoms as an important mechanism to prevent HIV and STI transmission.

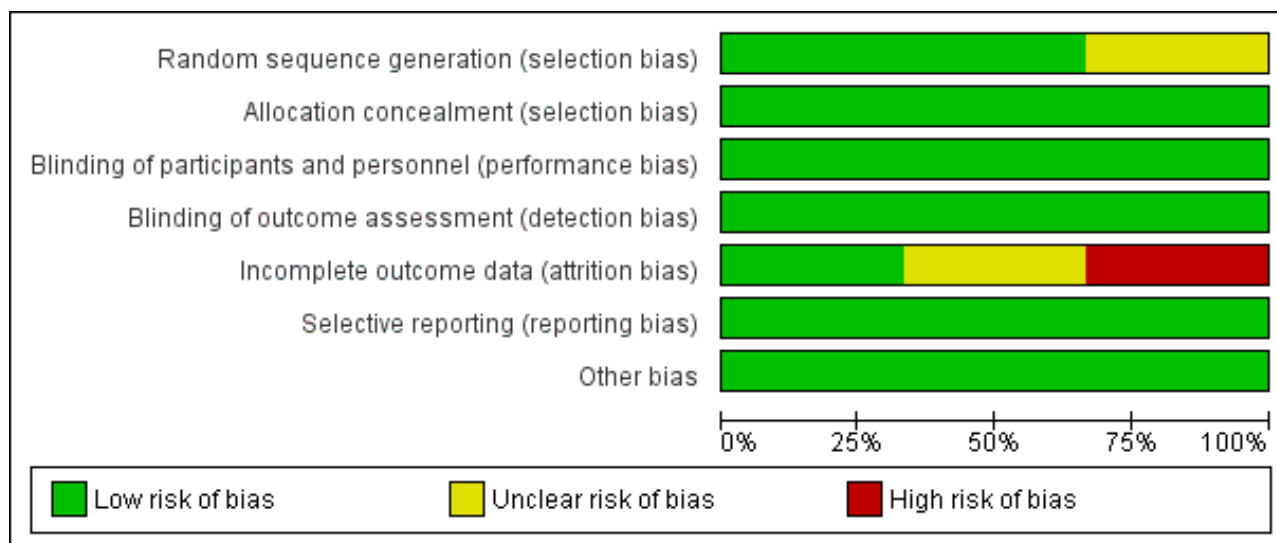
Risk of bias in included studies

Risk of bias assessment is illustrated in Figure 3 and Figure 4.

Figure 3. 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 of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Cowan 2010	?	+	+	+	-	+	+
Doyle 2010	?	+	+	+	-	+	+
Feldblum 2001	+	+	+	+	?	+	+
Garcia 2012	+	+	+	+	?	+	+
Gregson 2007	+	+	+	+	-	+	+
Jewkes 2008	+	+	+	+	+	+	+
Kamali 2003	+	+	+	+	+	+	+
NIMH 2010	?	+	+	+	?	+	+
Ross 2007	+	+	+	+	+	+	+

Figure 4. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.



Allocation

Random sequence generation

Random sequence generation: six studies were considered to be at low risk of bias (Feldblum 2001; Garcia 2012; Gregson 2007; Jewkes 2008; Kamali 2003; Ross 2007). The other three studies were deemed to be at unclear risk of bias; although all three implemented random sequence generation, the method was not specified (Cowan 2010; Doyle 2010; NIMH 2010).

Allocation concealment

All studies were deemed to be at low risk of bias, since allocation concealment does not influence the results in cluster-RCTs (Higgins 2011).

Blinding

Due to the nature of the intervention, blinding was not feasible. Since the primary outcomes were biological, it is unlikely that lack of blinding influenced those results. Therefore, all studies were considered to be at low risk of bias for the primary outcomes. It is also unlikely that lack of blinding biased the measurement of knowledge since this outcome was measured through standardized questionnaires. On the other hand, results including self reported behaviors may be prone to bias when individuals know they have taken part in an intervention. Thus, significant changes for this type of outcome (i.e. condom use during last sexual intercourse and two or more sexual partners in the last year) should be interpreted with caution.

Incomplete outcome data

Three studies were considered to be at low risk of attrition bias (Jewkes 2008; Kamali 2003; Ross 2007). Three studies were considered to be at unclear risk of bias: Garcia 2012 was cross-sectional, therefore there was no mention of attrition bias; Feldblum 2001 and NIMH 2010 had attrition bias below 30% (the threshold point chosen for this systematic review), but the specific reasons for loss to follow-up were not clearly stated. Three studies were deemed to be at high risk of bias (Cowan 2010; Doyle 2010;

Gregson 2007): although all three trials stated that the loss to follow-up was balanced between the intervention and control groups, and clearly stated the reasons for attrition (i.e. migration, death and absence), the loss to follow-up was higher than 30%. Two of these studies (Cowan 2010; Doyle 2010) tried to compensate for this deficiency by changing the methodological approach from cohort to cross-sectional.

Selective reporting

All trials were judged to be at low risk of selective reporting bias since they reported the outcomes originally proposed in each individual study's protocol.

Other potential sources of bias

Different individual recruitment, loss of clusters, early trial termination and inadequate statistical analysis were not detected. Although only four studies conducted pair-matched randomisation/block randomisation (Feldblum 2001; Garcia 2012; Jewkes 2008; Ross 2007), no study was found to present baseline characteristic imbalance. Thus, all nine studies were deemed as at low risk of bias from these other sources.

Since all studies were community trials, control groups might have been exposed to external sources of information (i.e. national media advertisement, sex education programs in schools) related to condom use and HIV prevention, thus decreasing the relative effect of educational programs in the experimental group. This is known as secular trend, and it is considered as a possible source of bias in any trial conducted at community level (Atienza 2002). In this review, this possible source of bias was judged as unclear since it was not feasible to either confirm it or rule it out.

Funnel plots were possible for three outcomes: gonorrhea prevalence, chlamydia prevalence and two or more sexual partners in last year. Publication bias was not detected for gonorrhea prevalence (Figure 5). Although the results for chlamydia prevalence suggested possible publication bias, this is unlikely since the direction of the effect indicates a higher risk of infection in the treatment group (i.e. four out of five studies reported a risk ratio

above one; [Figure 6](#)). The same trend was displayed by the outcome two or more sexual partners in the last year, in which four out of

five trials reported a higher risk ratio in the treatment group when compared to controls ([Figure 7](#)).

Figure 5. Funnel plot of comparison: Interventions to increase condom use versus standard care. Outcome: 1.7 Gonorrhoea prevalence.

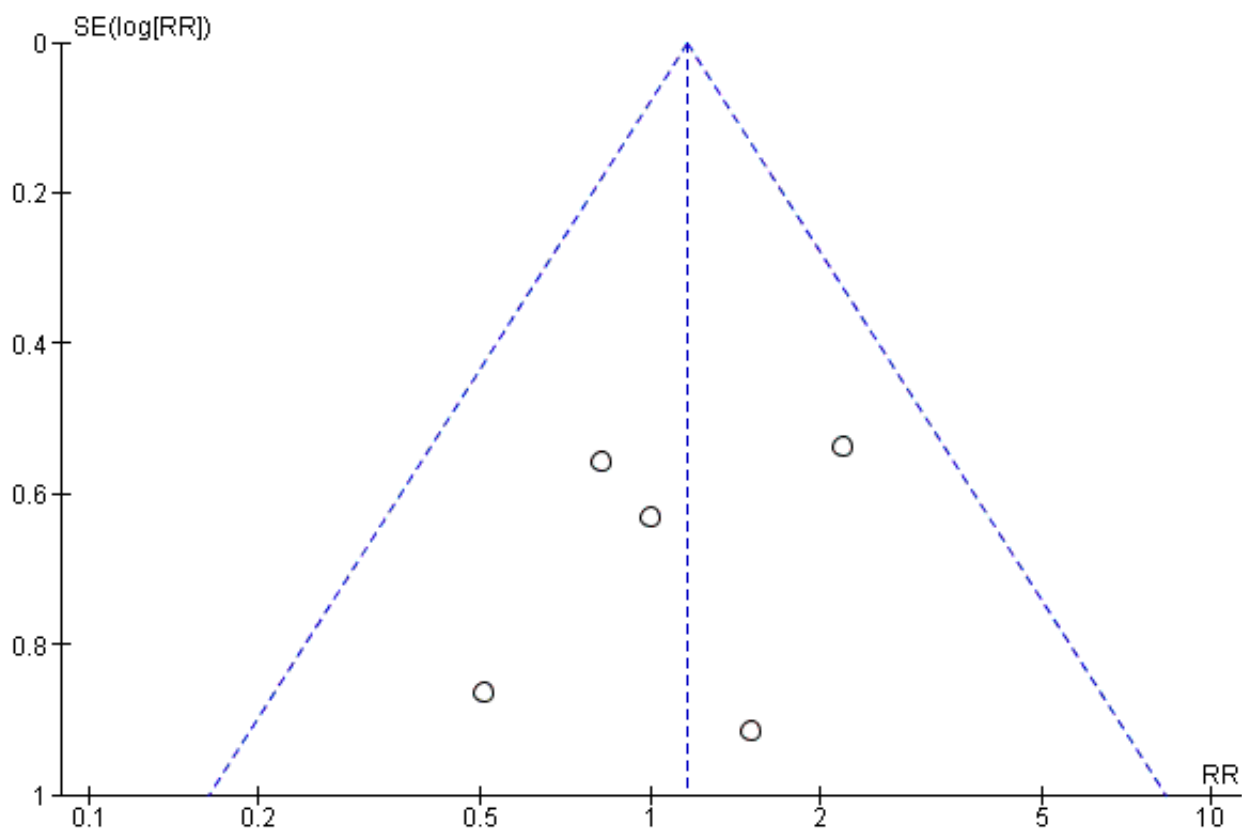


Figure 6. Funnel plot of comparison: Interventions to increase condom use versus standard care. Outcome: 1.8 Chlamydia prevalence.

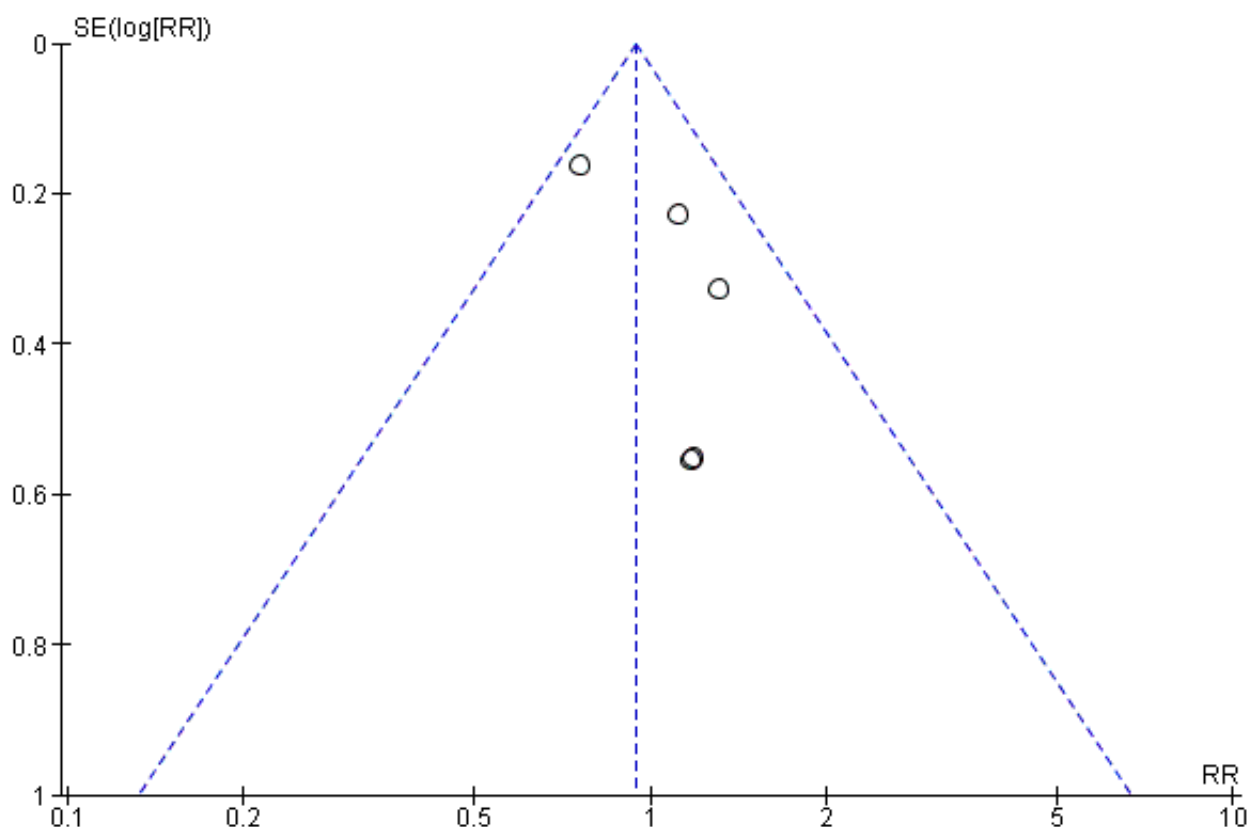
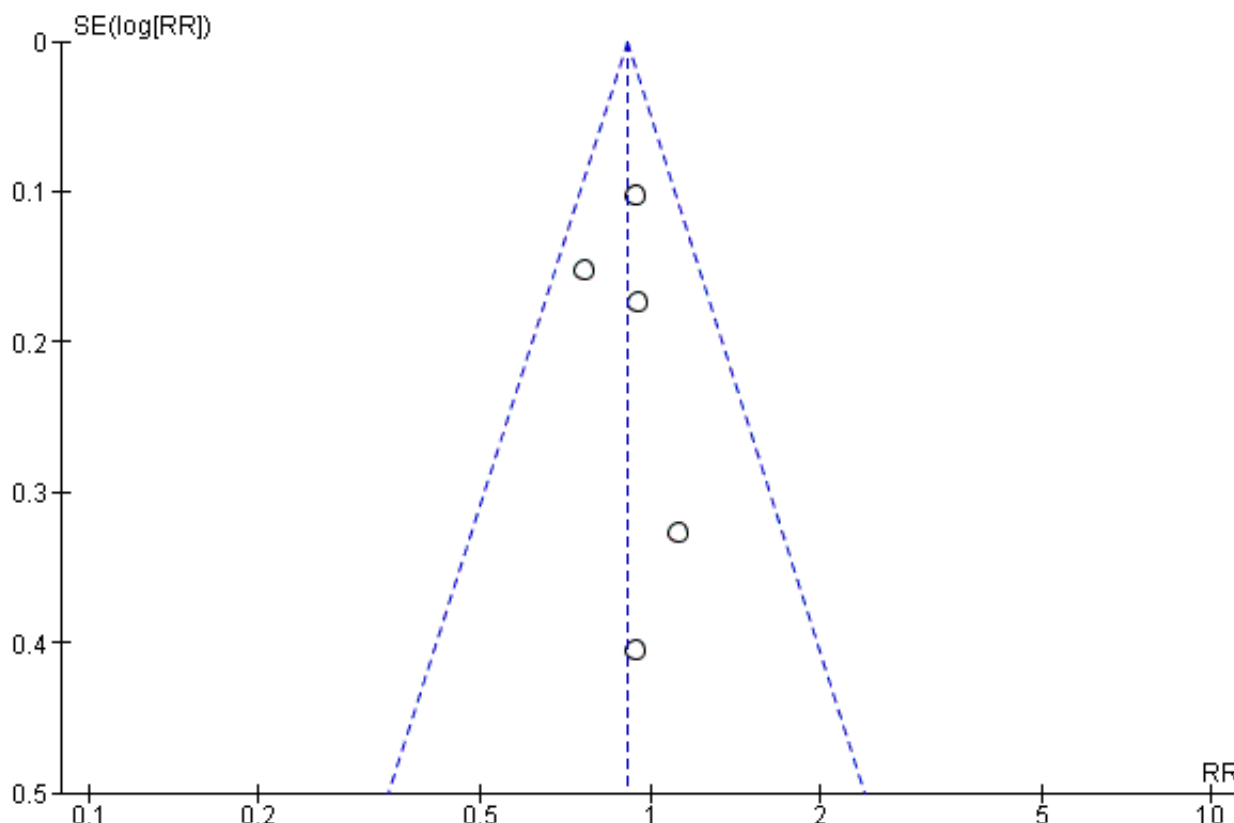


Figure 7. Funnel plot of comparison: Interventions to increase condom use versus standard care. Outcome: 1.14 Two or more sexual partners in last year.



Effects of interventions

See: [Summary of findings for the main comparison Structural and community-level interventions for increasing condom use versus standard care to prevent the transmission of HIV and other sexually transmitted infections](#)

Primary outcomes

1. HIV incidence / prevalence
2. Other STI's incidence / prevalence

Four studies reported HIV incidence ([Gregson 2007](#); [Jewkes 2008](#); [Kamali 2003](#); [Ross 2007](#)), and all showed no statistical difference between intervention and control groups (RR 0.90, 95% CI 0.69 to 1.19; [Analysis 1.1](#))

Three studies reported HIV prevalence ([Cowan 2010](#); [Doyle 2010](#); [Garcia 2012](#)), demonstrating non-significant effect after the intervention (RR 1.02, 95% CI 0.79 to 1.32; [Analysis 1.2](#))

Other individual STIs were also reported in seven ([Cowan 2010](#); [Doyle 2010](#); [Feldblum 2001](#); [Garcia 2012](#); [Jewkes 2008](#); [Kamali 2003](#); [Ross 2007](#)) out of the eight studies included in the quantitative analysis ([Gregson 2007](#) only reported HIV incidence).

Two studies ([Jewkes 2008](#); [Kamali 2003](#)) yielded no difference in incidence of HSV-2 (RR 0.76, 95% CI 0.55 to 1.04; [Analysis 1.3](#)); two

studies ([Cowan 2010](#); [Doyle 2010](#)) found no difference in prevalence of HSV-2 (RR 1.01, 95% CI 0.85 to 1.20; [Analysis 1.4](#)).

Only one study reported syphilis incidence ([Kamali 2003](#)), finding no change in this result (RR 0.59, 95% CI 0.18 to 1.95; [Analysis 1.5](#)). Three trials ([Doyle 2010](#); [Garcia 2012](#); [Ross 2007](#)) addressed syphilis prevalence, finding no change after the intervention (RR 0.91, 95% CI 0.71 to 1.17; [Analysis 1.6](#)).

Gonorrhea prevalence was reported in five studies ([Doyle 2010](#); [Feldblum 2001](#); [Garcia 2012](#); [Kamali 2003](#); [Ross 2007](#)), finding no change after the intervention (RR 1.16, 95% CI 0.67 to 2.02); [Analysis 1.7](#)).

Five trials ([Doyle 2010](#); [Feldblum 2001](#); [Garcia 2012](#); [Kamali 2003](#); [Ross 2007](#)) reported chlamydia prevalence, finding the intervention non-effective (RR 0.94, 95% CI 0.75 to 1.18; [Analysis 1.8](#)).

Trichomoniasis' prevalence was measured in different types of populations (i.e. both genders and only in women), thus differential analysis was conducted. Two trials ([Feldblum 2001](#); [Ross 2007](#)) assessed this outcome in women, finding no difference between the intervention and control group (RR 1.00, 95% CI 0.77 to 1.30; [Analysis 1.9](#)). One trial ([Garcia 2012](#)) found a significant reduction in trichomoniasis in both genders after intervention (RR 0.07, 95% CI 0.02 to 0.18; [Analysis 1.10](#)).

Three studies reported composite biological scores, ([Feldblum 2001](#); [Garcia 2012](#); [NIMH 2010](#)). Since the STIs included in each

study were different, we decided not to conduct a meta-analysis, but instead report individual results. We found the three studies to have non-significant results (RR 0.94, 95% CI 0.84 to 1.06 ([Analysis 1.11](#)), RR 0.78, 95% CI 0.59 to 1.04 ([Analysis 1.12](#)) and RR 0.99, 95% CI 0.72 to 1.36 ([Analysis 1.13](#)), respectively).

Secondary outcomes

1. Self reported condom use (male or female condoms).
2. Self reported number of sexual partners in the last year.
3. Knowledge about HIV.
4. Knowledge about STIs.
5. Knowledge about condom use (both self reported and tested).
6. Self efficacy (assessing self confidence related to condom use and sexual practices after receiving the intervention through standard questionnaires).

Behaviors

Five trials ([Cowan 2010](#); [Doyle 2010](#); [Gregson 2007](#); [Kamali 2003](#); [Ross 2007](#)) reported prevalence of two or more sexual partners during the last year, finding no differences between intervention and control groups (RR 0.90, 95% CI 0.78 to 1.04; [Analysis 1.14](#)).

Three studies reported on the use of condom during last sexual intercourse without specifying whether sex was with a casual or regular partner ([Cowan 2010](#); [Doyle 2010](#); [Ross 2007](#)), finding a statistically significant change after intervention (RR 1.20, 95% CI 1.03 to 1.40; [Analysis 1.15](#)).

[Doyle 2010](#) reported use of condom at last sexual intercourse with a non-regular partner, yielding a non-significant result (RR 1.16, 95% CI 0.78 to 1.72; [Analysis 1.16](#)).

[Gregson 2007](#) reported unprotected sex with a regular partner during the last three years, finding no significant results (RR 1.03, 95% CI 0.91 to 1.16; [Analysis 1.17](#)).

One cohort study reported correct condom use at last sexual intercourse ([Jewkes 2008](#)) at 12 and 24 months; the results showed

no significant change (RR 0.98, 95% CI 0.85 to 1.12 ([Analysis 1.18](#)), and RR 0.97, 95% CI 0.84 to 1.12 ([Analysis 1.19](#)), respectively).

One study ([Feldblum 2001](#)) assessed consistent condom use at 6 and 12 months; both results showed non-significant difference between treatment and control groups (RR 0.63, 95% CI 0.38 to 1.05 ([Analysis 1.20](#)) and RR 0.92, 95% CI 0.53 to 1.60 ([Analysis 1.21](#)), respectively).

Knowledge

Four trials ([Cowan 2010](#); [Doyle 2010](#); [Gregson 2007](#); [Ross 2007](#)) reported improvement in knowledge about HIV, finding a statistically significant change after intervention (RR 1.16, 95% CI 1.03 to 1.29; [Analysis 1.22](#)).

Three trials ([Cowan 2010](#); [Doyle 2010](#); [Ross 2007](#)) reported improvement in knowledge about other STIs, finding the intervention to be effective (RR 1.23, 95% CI 1.07 to 1.41; [Analysis 1.23](#)).

Self efficacy

Since all results under this classification assessed different and non-comparable outcomes, a meta-analysis was not feasible; instead, individual results are described below.

[Cowan 2010](#) reported condom self efficacy and HIV self efficacy, yielding no significant results in both cases (RR 1.16, 95% CI 0.94 to 1.41 ([Analysis 1.24](#)), and RR 0.99, 95% CI 0.68 to 1.46 ([Analysis 1.25](#)) respectively).

[Gregson 2007](#) reported non-specified self efficacy, finding no changes after intervention (RR 1.02, 95% CI 0.90 to 1.17; [Analysis 1.26](#)).

Sensitivity analysis

Primary outcomes

There was no significant change in any of the biological results at any of the six different ICC values (all results remained non-significant: [Figure 8](#), [Figure 9](#), [Figure 10](#), [Figure 11](#), [Figure 12](#), [Figure 13](#), [Figure 14](#), [Figure 15](#)).

Figure 8. Sensitivity analysis ICCs; outcome: HIV incidence.

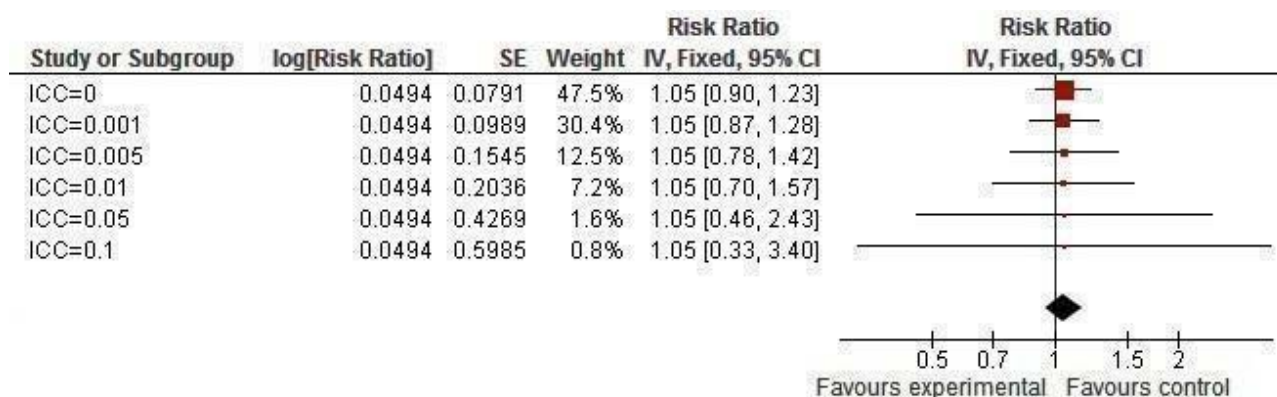


Figure 9. Sensitivity analysis ICCs; outcome: HIV prevalence.

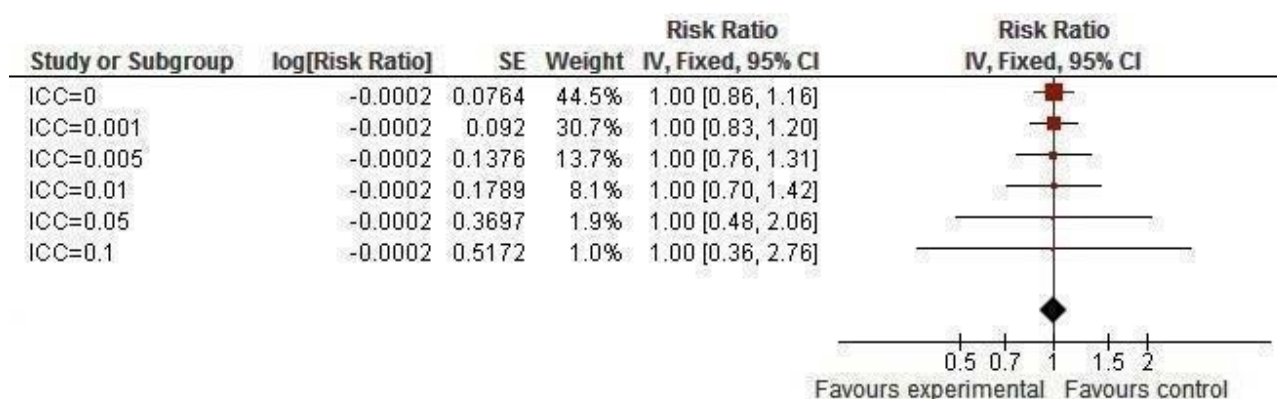


Figure 10. Sensitivity analysis ICCs; outcome: HSV-2 incidence.

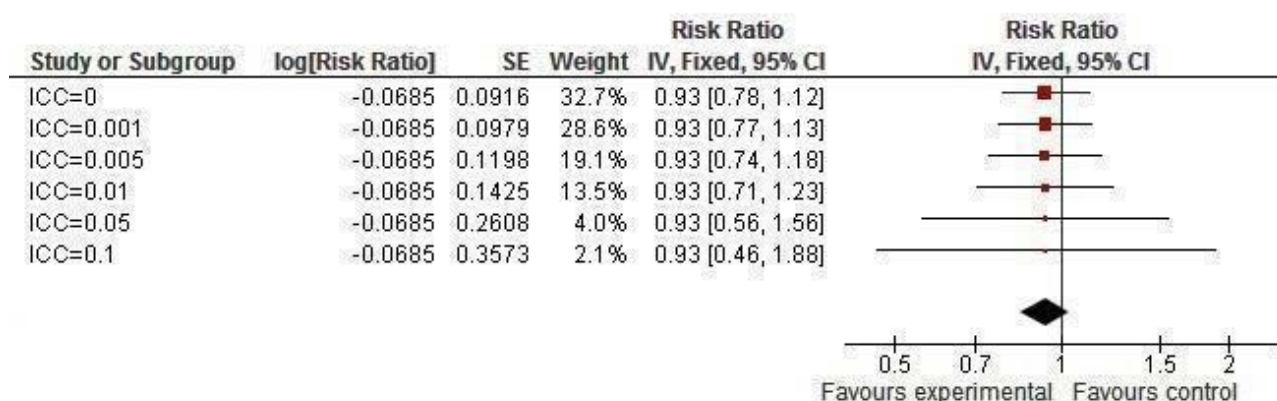


Figure 11. Sensitivity analysis ICCs; outcome: HSV-2 prevalence.

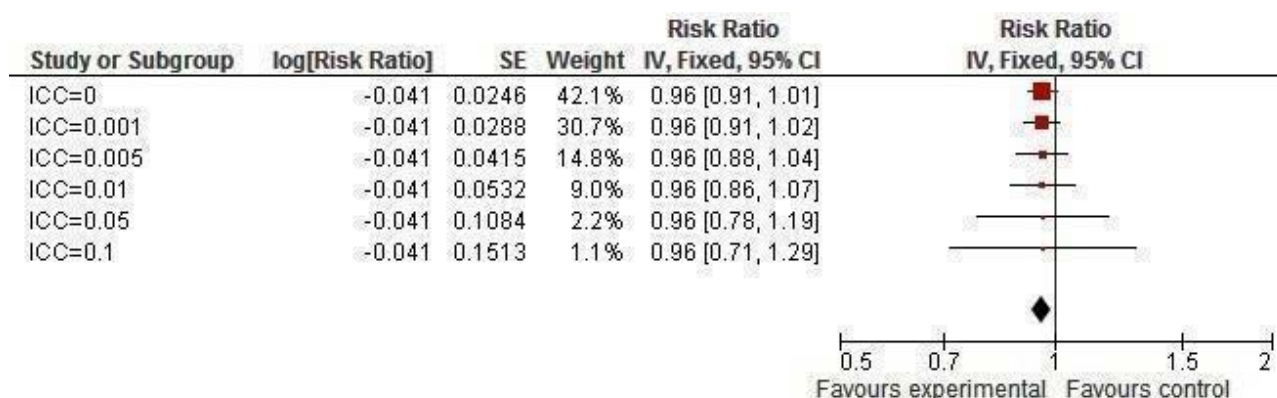


Figure 12. Sensitivity analysis ICCs; outcome: Syphilis prevalence.

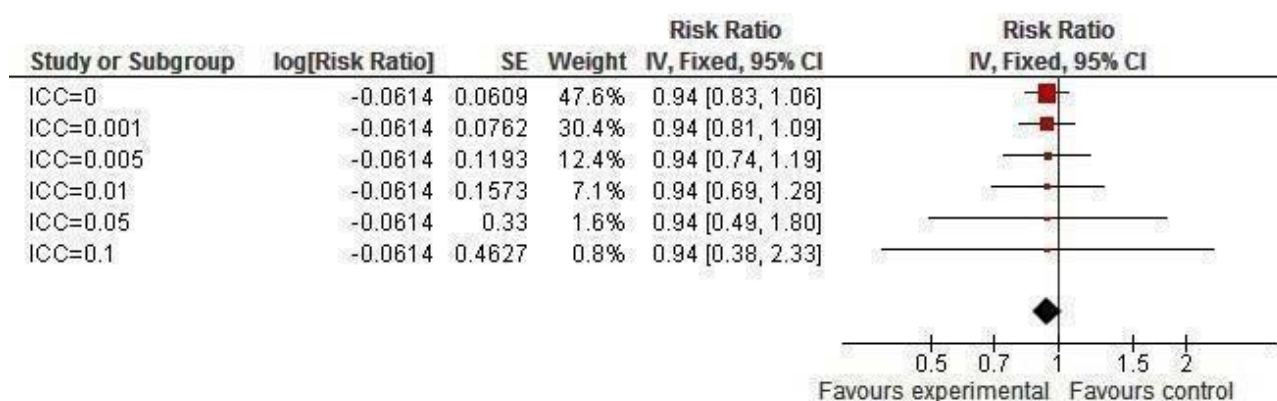


Figure 13. Sensitivity analysis ICCs; outcome: Gonorrhea prevalence.



Figure 14. Sensitivity analysis ICCs; outcome: Chlamydia prevalence.

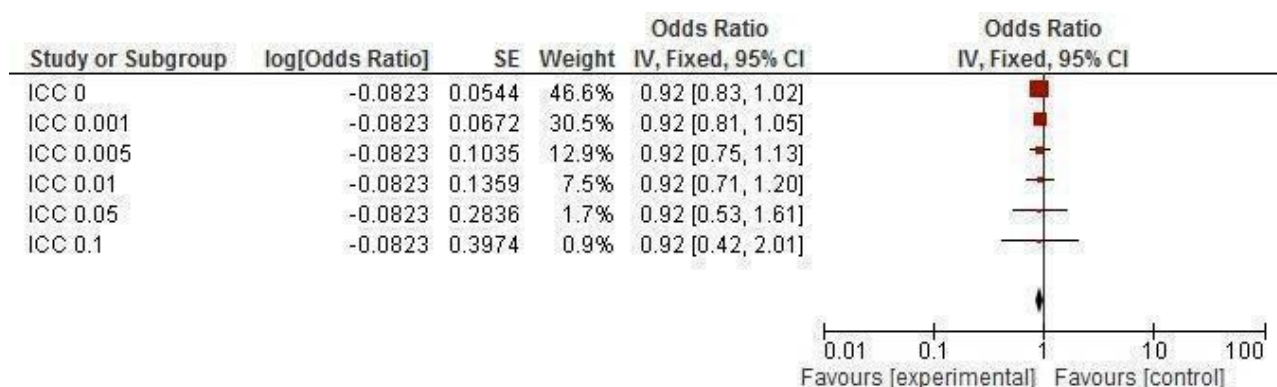
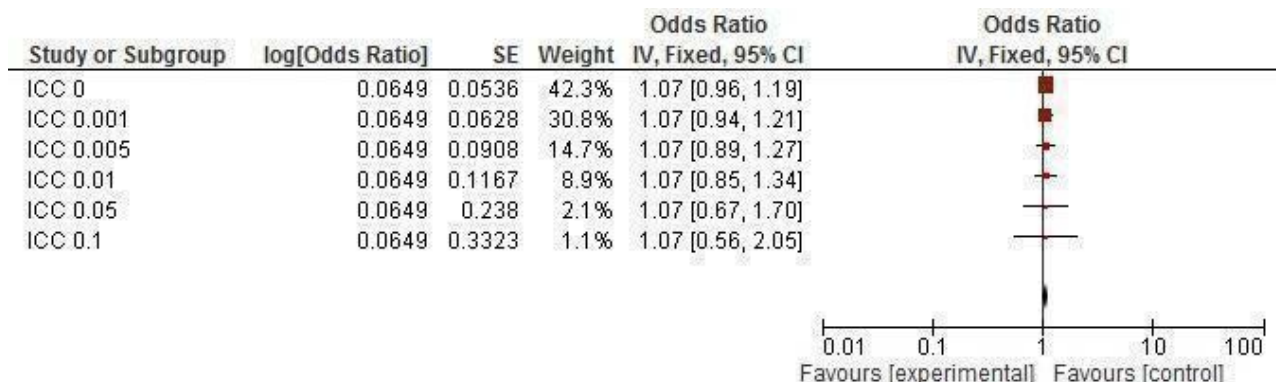


Figure 15. Sensitivity analysis ICCs; outcome: Trichomonas prevalence.



Secondary outcomes

It was found that prevalence of two or more sexual partners became significant with an ICC value of 0.005 or less (Figure 16). Condom use

at last sexual intercourse became non-significant at an ICC value of 0.05 and above (Figure 17). Knowledge about HIV and other STIs remained significant, irrespective of the ICC value (Figure 18, Figure 19).

Figure 16. Sensitivity analysis ICCs; outcome: Two or more sexual partners in last year.

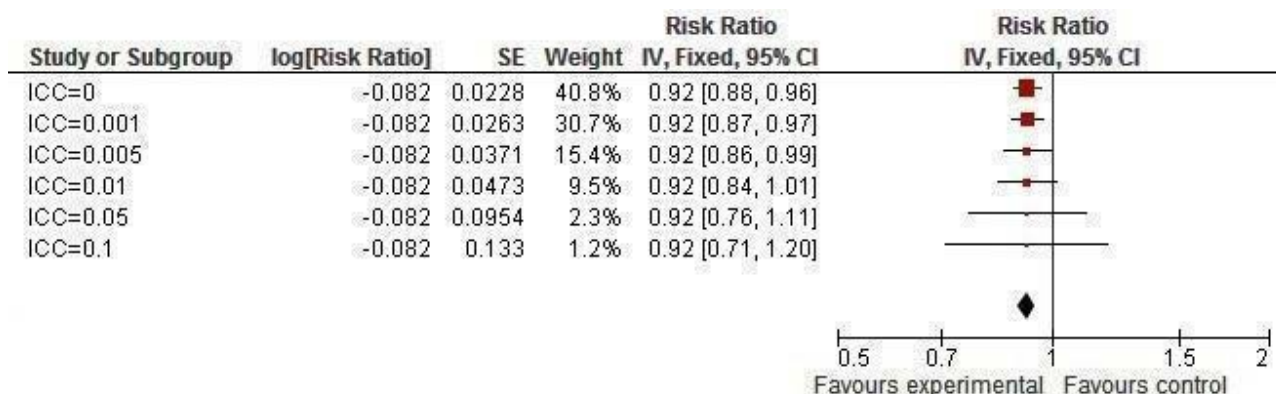


Figure 17. Sensitivity analysis ICCs; outcome: Condom use at last sexual intercourse.

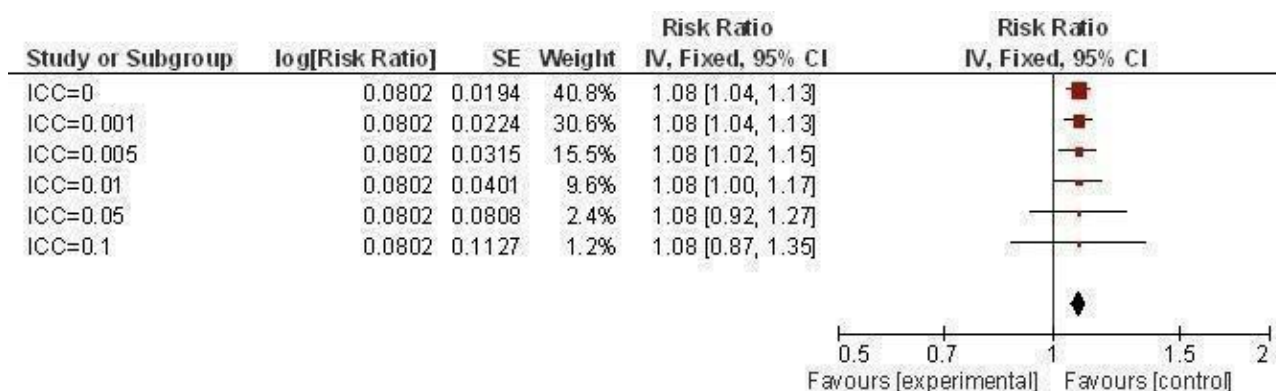


Figure 18. Sensitivity analysis ICCs; outcome: Knowledge, condoms can prevent HIV.

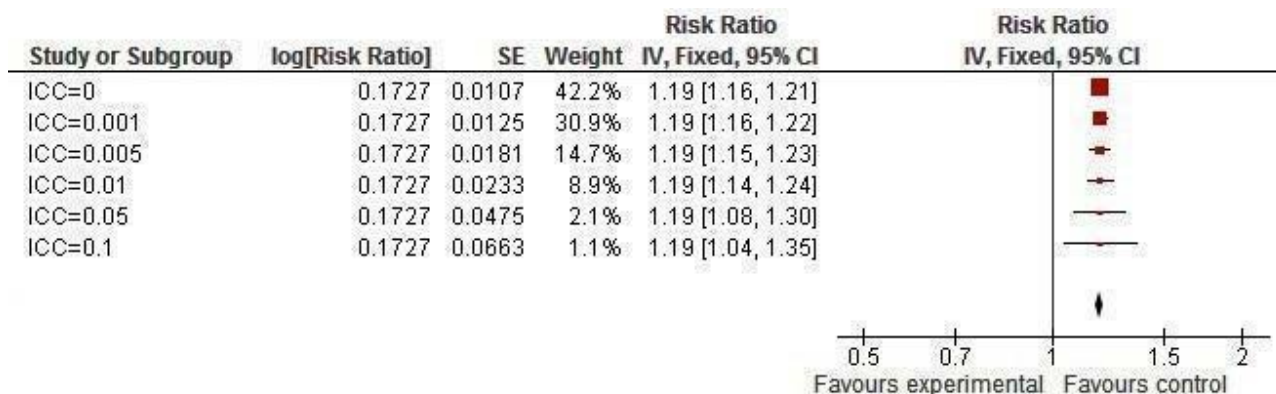
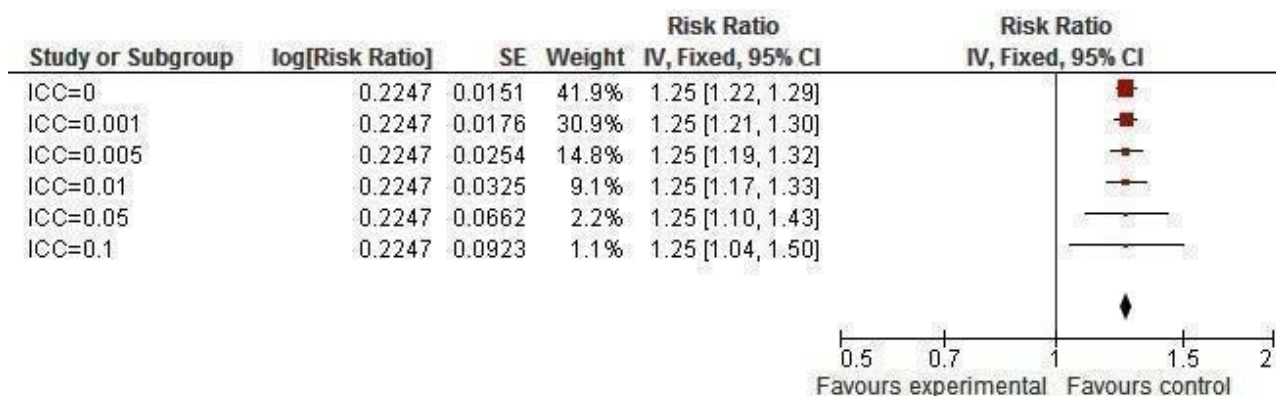


Figure 19. Sensitivity analysis ICCs; outcome: Knowledge, condoms can prevent STIs.



DISCUSSION

Summary of main results

This review addressed the question of whether structural interventions to promote condom use at the community level reduced the incidence or prevalence of HIV and other STIs, assessed through laboratory test, as well as other secondary outcomes such as knowledge, self efficacy and sexual behaviors.

Nine studies meeting all inclusion criteria were obtained. Loss to follow-up in three studies was the only relevant source of bias. The studies featured condom acceptability by imparting sexual education and promoting social marketing of condoms; accessibility was addressed through provision of free condoms and implementation of micro-credits. After adjusting for clustering effects, the meta-analysis demonstrated the intervention(s) to have a non-significant effect in reducing incidence or prevalence of HIV, nor did they reduce prevalence or incidence of HSV-2, syphilis, gonorrhea, chlamydia or trichomonas. One individual study (Garcia 2012) proved to be effective in reducing the prevalence of trichomoniasis in the general population when addressing both genders.

In each trial authors reported the possible reasons for the intervention(s) to have not had a significant effect on biological outcomes, including: a 'diluted' intervention in which the results

were assessed in some people who were not directly exposed to the intervention (Cowan 2010); social ambivalence toward condoms, thus hindering their use (Cowan 2010; Doyle 2010; Feldblum 2001); attrition bias since some people who received the intervention then left the study, consequently reducing the effect of the intervention (Cowan 2010; Doyle 2010; Garcia 2012); 'secular trend', defined as the exposure of the control groups to other sources of HIV and condom awareness such as media condom campaigns or sex education programs, thus reducing the relative impact of the intervention(s) in the experimental group (Doyle 2010; Gregson 2007; Kamali 2003; NIMH 2010); difficulty in changing behaviors (Doyle 2010); insufficient statistical power (Gregson 2007; Jewkes 2008; Kamali 2003); insufficient follow-up (Gregson 2007); and self reporting bias related to sexual behaviors (Jewkes 2008; Kamali 2003; Ross 2007).

The results varied substantially regarding secondary outcomes. There was no significant change in the prevalence of respondents with two or more sexual partners in the last year. Although individual trials did not demonstrate any statistically significant change in unprotected sex, the meta-analysis proved the intervention(s) to be effective; individual trials exploring consistent condom use showed non-significant results. All meta-analyses regarding change in knowledge yielded statistically significant results in favor of the intervention(s). Meta-analysis addressing self efficacy was not feasible, but all three individual studies reported no significant results.

After conducting sensitivity analysis with different ICC values, we found that biological and knowledge-related outcomes were robust, whereas behavioral outcomes such as condom use and number of sexual partners tended to fluctuate between significant and non-significant depending on the magnitude of the ICC.

Possible reasons for non-significant results

One plausible explanation for the non-significant results regarding biological outcomes is that not all studies widely distributed free or low-cost condoms, limiting the effect of social acceptability and education regarding HIV and STIs due to financial barriers. However, this possible explanation was ruled out after conducting a stratified analysis which included studies featuring both education and free condom distribution, obtaining non-significant results (Analysis 2.1, Analysis 2.2, Analysis 2.3, Analysis 2.4, Analysis 2.5, Analysis 2.6).

There is a gap between improvement in knowledge, behaviors and biological outcomes. This review showed that people in intervention groups indeed acquired more knowledge about HIV prevention, but HIV and other STIs' prevalence and incidence did not decrease. Results involving knowledge and biological markers were robust, presenting no heterogeneity and similar outcomes when sensitivity analysis was conducted. In contrast, the intermediate results for behaviors showed a more diverse pattern; condom use showed a statistically significant change, whereas number of sexual partners in the last year did not. However, both of these outcomes showed volatility when sensitivity analysis was conducted. To explain this, several authors have pointed out that modifying sexual behaviors is a difficult task, irrespective of the approach used (Foss 2007; Michielsen 2010; Ojo 2011; Ota 2011). Another study showed that levels of consistent condom use have been far from optimum in many communities, despite continuous and intensive promotion campaigns (Potts 2008). This in turn may be accounted for the fact that sex occurs in private settings, making these behaviors more difficult to change (Coates 2008), and because of the entrenched influence of cultural norms and religion (Lefkowitz 2004; Thomsen 2004).

It is also extremely difficult to confirm the validity of self reported behaviors (Coates 2008) given the tendency of people to over-report practices that are perceived as positive, and similarly, to under-report behaviors that have social negative connotations. This is called social desirability bias, and it is considered an undermining factor in self reported studies (Randall 1991). Likewise, lack of blinding could have introduced some bias in self reported condom use. Thus, the validity of the significant findings for these results is questionable, and may explain to some extent the poor impact on biological outcomes.

This review found no change in HIV/STI incidence and prevalence despite an apparent increase in condom use. This may be explained by inconsistent condom use (Hearst 2004). People may increase condom use as a result of campaigns, social acceptability and condom availability, but if condom use is not constant and concurrency takes place, particularly with multiple regular partners where condom use is more likely to be irregular (Foss 2007; Mah 2010), the probability of acquiring an HIV and other STI remains (Foss 2007; Mah 2010; Senn 2009; Subramanian 2008). Although this review did not present results regarding concurrency, and only included number of sexual partners, it is likely that both circumstances have played a role in the non-significant biological

results (Gorbach 2005). Most of the retrieved studies were obtained from Sub-Saharan Africa, a region in which concurrency has been frequently reported (Mah 2010).

In addition, a methodological issue involving the nature of control groups may explain to some degree the non-significant outcomes. Since constant campaigns on HIV prevention have been implemented in Sub-Saharan Africa (Painter 2001), some communities (e.g. South Africa, Senegal and Uganda) already had some awareness about HIV (Shisana 2001; UNAIDS 1999; USAID 2002). As a consequence, control groups are likely to have been exposed to some type of 'intervention' by the time the reviewed strategies were implemented, partially offsetting the overall effect in the experimental group. This is a phenomenon known as a 'secular trend', and it has been regarded as a potential threat in any community trial (Atienza 2002).

Finally, this review attempted to be comprehensive by including all possible rigorous studies in which structural and community level interventions promoted condom use. However, there could be other structural and community-level strategies that may yield positive results, but have not been conducted/published under rigorous methodologies to date. For example, media advertisements or placement of public condom machines using a RCT design coupled with biological outcomes. Thus, future studies may change the conclusions we are presenting in this revision.

Overall completeness and applicability of evidence

A potential limitation to the external validity of this review is that seven out of the nine trials were carried out in Sub-Saharan Africa, a region that in turn is widely diverse. For example, male circumcision is practiced in most of West Africa, rather infrequent in several southern African countries, and variable in central and eastern Africa (UNAIDS 2007); Islam is the predominant religion in the countries located in the Sahel and the African horn, whereas Christianity is widely extended in central and southern Africa (Britannica 2003); also, concurrency has been reported as more prevalent in western and central Africa when compared to eastern and southern Africa (Reniers 2010). In addition, the multi-country trial (NIMH 2010) did not provide individual figures for each disease, leaving only one study (Garcia 2012) with specific results conducted outside Sub-Saharan Africa. Although the results from this review may not be applicable in other settings, most of the global HIV burden is concentrated in Sub-Saharan Africa, which underlines the relevance of the results to the current global HIV prevention context.

Furthermore, given both our definition of community and the population to which the interventions were addressed, the participants included in each trial were mainly drawn from the general population rather than high-risk populations such as men who have sex with men (MSM), injecting drug users (IDUs) or female sex workers (FSWs). Had the trials included and identified large segments of high-risk populations, our meta-analysis may have yielded different results.

Each individual trial proposed a specific set of STIs to be measured, thus making it unfeasible to assess the same STIs in all studies. This was also the case with the proposed secondary outcomes.

It is important to mention that although most studies reported on condom use, their type of assessment was not always comparable

across trials; thus preventing a larger pooling of studies in the meta-analysis.

Quality of the evidence

Although only nine trials were retrieved, the number of total participants was large at 75,891. To the best of our knowledge, this meta-analysis covers the largest total sample size related to this topic. Moreover, all meta-analyses were consistent and had low heterogeneity.

An important finding of this review is that none of the studies implemented promotion of condoms as a unique intervention. In fact, all trials promoted it through education, distribution, or both, in combination with one or several of the following: training of medical staff, providing accessible and open health services to adolescents, educating parents on sexuality and encouraging dialogue about sex with teenagers, task-shifting through community members, income generation and strengthened treatment of STIs. Therefore, these results reflect the synergy of promoting condom use along with other strategies as opposed to an outcome derived solely from condom promotion. Nevertheless, conclusions can still be inferred based on these outcomes. Incidence or prevalence of HIV and most biological results did not change after the interventions, implying that condom use combined with other strategies enacted at a community level may not work effectively.

Potential biases in the review process

This review only included biological outcomes confirmed by laboratory tests as primary results and thus excluded the possibility of self reporting bias. Moreover, all studies were RCTs, reducing the likelihood of imbalance of known and unknown baseline characteristics and confounders.

In order to conduct meta-analysis, each set of results should be comparable. Due to the limited number of studies that were retrieved and a large variation in methodology, performing meta-analysis was not always possible. When meta-analyses were feasible, only a few studies were included with an average of three trials per analysis.

Most studies reported blinding as unfeasible, or did not mention it at all, leading to possible bias in self reported outcomes. This may be the case with measures of condom use, in which a significant result was obtained. Bias arising from lack of blinding is unlikely in the other self reported outcome (two or more sexual partners in the last year) since it did not yield a significant result.

Attrition bias was an important finding in this review. Since the present study focused only on community interventions, entire populations were the subject of research. Under these circumstances, it was frequent that large numbers of participants left the study due to either migration or death, leading to incomplete data. This situation may have undermined to some extent the validity of our findings (Higgins 2011).

In addition, the secular trend phenomenon that tends to take place in community trials may have biased to some extent the results in this review by diminishing the apparent effect that education could have on HIV/STIs prevention.

Moreover, It is possible that HIV/STIs prevention programs have different levels of impact depending on the actor leading the initiative. For example, the success of the 100% condom use program in Thailand's brothels is likely to have worked since there was government enforcement at a national level (Rojanapithayakorn 1996). In Uganda, the early commitment of the government coupled with intersectoral collaboration (i.e. civil organizations, NGOs, private sector) is thought to have hampered the HIV epidemic (USAID 2002). In most of the included studies for this revision, the interventions were led by an international organization/NGO, and some through a partnership between these institutions and local governments. Unfortunately, it was not possible to obtain studies in which a policy change led primarily by the local government took place under the experimental conditions proposed in this review.

Finally, the primary purpose of this review was to explore the effect of condom promotion on the transmission of HIV and other STIs; thus, only studies reporting biological outcomes were included. This approach, in consequence, may have limited the validity of the secondary outcomes reported in this revision. Depending on the scope and purpose of further updates of this document, the inclusion of studies might not be restricted by the type of outcomes so that all results are free of bias.

Agreements and disagreements with other studies or reviews

This review found that the intervention(s) had a significant impact in increasing both condom use at last sex and knowledge that condoms can prevent the transmission of HIV and other STIs. However, the incidence and prevalence for HIV and HSV-2 as well as the prevalence of gonorrhea, chlamydia, syphilis and trichomonas did not yield a significant change after the interventions were implemented. Similarly, number of sexual partners did not show a significant decrease.

The present findings are in agreement with other systematic reviews that found the continued transmission of HIV despite increased condom use (Ng 2011; Ota 2011; Shahmanesh 2008). One systematic review featuring behavioral interventions (i.e. acceptability) at group and community level in FSWs (Wariki 2012) found that HIV transmission declined when results were assessed within six months immediately after the intervention was conducted; however, a non-significant effect was found at 12 months' follow-up. Sangani 2004 found that population-based interventions implementing education for preventing STIs did not reduce HIV transmission. It should be also noted that few publications have directly assessed HIV sero-prevalence as an outcome, so many reviews could not be compared.

Systematic reviews have found contradictory results regarding condom use along with behavioral interventions and their impact in transmission of other STIs. We found that the intervention(s) described in this paper do not reduce transmission of most STIs. Thus, our results were consistent with other systematic reviews on this topic: Medley 2009 and Ota 2011 found a non-significant effect in STI reduction, Underhill 2008 did not find any statistical effect on self reported STIs, and Michielsen 2010 found only one study reporting a decrease in HSV-2. In contrast, studies with pooled results of several STIs such as Charania 2011; Herbst 2007a; Lyles 2007; Shahmanesh 2008, and with individual STI outcomes such as Ng 2011 and Wariki 2012 found statistical differences

between intervention and control groups after the interventions were conducted. [Sangani 2004](#) found mixed results (individual STI results). It is, however, difficult to establish a direct comparison with several of those analyses, since many of them did not provide independent figures for each disease, but aggregated all STIs into a unique composite score.

This review yielded a non-significant effect in changing the number of sexual partners. This was consistent with previous studies by [Ojo 2011](#), [Michielsen 2010](#) (who found heterogeneous results, highlighting an overall non-significant result), and partially by [Townsend 2013](#) who found mixed or little effect. The opposite result was reported by [Paul-Ebhohimhen 2008](#), [Lyles 2007](#), [Herbst 2007a](#), and [Noar 2008](#). However, in the majority of systematic reviews we found, the number of sexual partners is usually either aggregated into a composite score (risky behaviors) or not assessed at all.

This review found that condom use increased after intervention. This was also reported by [Charania 2011](#), [Medley 2009](#), [Herbst 2007a](#), [Herbst 2007b](#), [Lyles 2007](#), [Shahmanesh 2008](#), [Johnson 2008](#), [Underhill 2008](#) and [Wariki 2012](#); studies in which the target was mainly high risk populations (i.e. FSWs, MSM, IDUs). [Wang 2011](#), [Bertrand 2006](#) and [Sangani 2004](#) found a small increase in condom use; with the exception of [Wang 2011](#), they were conducted in the general population. Conversely, [Michielsen 2010](#), [Paul-Ebhohimhen 2008](#) and [Ota 2011](#) found no significant change; apart from [Ota 2011](#) which targeted FSWs, these trials were carried out in general populations. [Foss 2007](#) reported that interventions were not effective in increasing condom use in steady couples and evidence for casual partners was scarce, whereas the intervention worked for FSWs and their clients.

Findings in this review demonstrated increased knowledge about HIV and STIs. The same result was reported by [Medley 2009](#), [Paul-Ebhohimhen 2008](#), [Underhill 2008](#), [Ota 2011](#) and [Bertrand 2006](#). No systematic review was found stating that knowledge did not increase after intervention.

Among the previous reviews [Charania 2011](#), [Herbst 2007a](#), [Johnson 2008](#), [Underhill 2008](#), [Wariki 2012](#), [Ng 2011](#), [Sangani 2004](#) and [Bertrand 2006](#) included studies that were conducted at the community level.

Although several of these systematic reviews have directly or indirectly assessed the impact of condom promotion, this is the first review reporting on individual biological outcomes and including only community-based interventions. For example, [Charania 2011](#) focused on reported condom use and only provided a unique pooled figure for STIs incidence in which all three levels of interventions (i.e. individual, groups and community) were combined; moreover, it did not mention what particular STIs were included in the analysis. [Herbst 2007a](#) did not include the general population, and [Ng 2011](#) focused on STI control and did not use structural approaches. Moreover, despite the different methodologies used in the trials included in this review, a quantitative estimate of the intervention's effect (i.e. meta-analysis) was possible.

AUTHORS' CONCLUSIONS

Implications for practice

We did not find clear evidence that condom promotion, when implemented at community and structural levels, reduces the transmission of HIV or other STIs. The quality of evidence for HIV transmission was moderate when analysed as incidence data due to imprecision, and low when analysed as prevalence data due to imprecision and risk of bias. Moreover, caution is advised regarding to what extent this conclusion reflects the full spectrum of structural interventions, as well as the population in which it is applicable. The selected studies were conducted primarily in Eastern and Southern Africa, and to a lesser extent, in other developing nations (i.e. Peru, China, India, Russia). Therefore, our conclusions are mainly applicable to these settings and inferences may not be adequate in other contexts. Despite these limitations, it is important to note that the largest proportion of the global HIV burden takes place in these countries, with Sub-Saharan Africa the most affected region worldwide; therefore, our conclusions are pertinent to the current context of the HIV epidemic.

Other considerations

Since the intervention assessed in this review did not have a clear impact in preventing the transmission of HIV and other STIs, efforts to scale up programs that have already proven useful in doing so, such as, but not limited to, circumcision for heterosexual men ([Arora 2012](#); [Siegfried 2009](#); [Weiss 2000](#)) and provision of antiretroviral treatment for people living with HIV (in general and high-risk populations) should be evaluated ([Anglemeyer 2011](#); [Cohen 2011](#)). Consequently, governments, private sector stakeholders, NGOs and policy makers may need to consider reallocation of some resources from broad-based condom use campaigns in the general population to, for example, HIV screening and treatment programs and male circumcision projects in those developing regions in which the latter interventions have been overlooked. This is of special relevance in those contexts wherein HIV is prevalent. These interventions could be enhanced with community engagement, awareness building and innovative ideas to promote condoms. Also, efforts from the scientific community and financial sponsors should be devoted to search and develop more effective and cost-effective strategies to decrease HIV transmission, such as vaccination or identification of what kinds of voluntary testing and counseling programs are feasible and cost-effective in specific settings. We suggest that these initiatives should be tested within community and structural frameworks to determine their effectiveness under such conditions.

Implications for research

To evaluate the full extent of the role that structural interventions play in condom promotion, we recommend applying strategies that engage different mechanisms to those described in this review. Such interventions should be methodologically strict (i.e. RCTs, providing biological data) and may include changes to policies, installing condom machines, use of public health media campaigns and women empowerment. It is possible that these strategies may have the potential to prevent the transmission of HIV and other STIs.

A significant finding in our review is the inconsistent reporting of ICCs in the literature, suggesting that most cluster trials do not provide ICCs when presenting their results. When conducting

systematic reviews that include cluster-RCTs, it is essential to take into account and report design effects and ICCs in order to adjust for the heterogeneity within and between groups. Therefore, we call on researchers to report individual ICCs for each included outcome when conducting cluster trials. In the case of systematic reviews that include cluster studies where ICCs were not reported, it is important to implement a standard procedure to estimate those figures accurately.

Future research that explores structural interventions should both state which of its three main components - acceptability, accessibility or availability - was conducted and identify the underlying factors influencing these components. If more than one of these interventions were carried out, the review should implement stratified analysis, since each subintervention tackles different obstacles. For example, if a community changes its perception about certain technology (e.g. condoms) but faces economic barriers to purchase it, it is unlikely the intervention produces the expected changes. Using this approach would allow authors to pinpoint which substrategy or combination of substrategies yielded results and which did not.

Finally, since the present review treated the term 'community' as a whole geographical area (i.e. towns, cities), the participants were mainly general and not high-risk populations. Thus, those definitions in which a community implies a smaller group of people were excluded. These 'smaller communities' include brothels, MSM groups, and STI clinics. Therefore, further research should be undertaken to evaluate if high-risk community interventions, at a structural level, and promoting condom use yield better results than those obtained in this review.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Cowan 2010

Methods	Cluster randomized controlled trial
Participants	6791 young Zimbabweans who were attending Form 2 at secondary school (intervention 3381, control 3410)
Interventions	The intervention aims to change societal behaviors through social learning theory. It has three components: 1. A program addressed to young people, with the objective of increasing their knowledge about HIV prevention 2. A program addressed to parents and the community, with the objective of enhancing their knowledge on reproductive health, improving communication between parents and children, and developing community support to reproductive health in adolescents 3. A program which aimed to train nurses and other medical staff, in order to provide better health care access to young people Control: Same intervention delayed for a period of 4 years
Outcomes	Primary outcomes: Prevalence of HIV and of HSV-2 Secondary outcomes: 1. Pregnancy prevalence 2. Reported sexual knowledge, behavior and attitudes
Notes	Assessment: Baseline survey, interim and representative population-based survey (3 years after baseline survey), and final survey (4 years after baseline survey) Funding: The trial was funded by the National Institute of Mental Health, additional funding was received from DFID Zimbabwe

Risk of bias

Cowan 2010 (Continued)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Although it states that the venues were selected randomly, the study does not provide the specific technique of randomization that was used
Allocation concealment (selection bias)	Low risk	Lack of concealment would not affect the outcome
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Blinding was not feasible. However, since the outcome was biological, it was unlikely that the outcome would have been influenced by the lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not stated, but it was unlikely that the outcome was influenced by lack of blinding
Incomplete outcome data (attrition bias) All outcomes	High risk	It provides detailed information of attrition causes (death, migration, not reached, away long-term) and the causes of attrition between arms were relatively symmetric. Attrition after 4 years of follow-up was 31% in the control group and 31% in the intervention group. Due to attrition, the author decided to treat the study as cross-sectional
Selective reporting (reporting bias)	Low risk	All outcomes were reported
Other bias	Low risk	a. Different individual recruitment: No b. Cluster imbalance: No Baseline characteristics were comparable across groups c. Loss of cluster: No d. Statistical analysis: Performed correctly e. Secular trend: Unclear Statistical methods that allow for clustering of events within the community was used for the analysis

Doyle 2010

Methods	Community randomized trial
Participants	9645 Tanzanian adolescents, aged 14 years or more who were in Years 4–6 of all 121 government primary schools within the 20 trial communities (intervention 4870, comparison 4775)
Interventions	Intervention: MEMA kwa Vijana interventions: 1. Activities addressed to the community 2. Sexual health education to students in Years 5-7 at primary school, provided by teachers, supported by peers 3. Training and supervision in 'youth-friendly' services to health workers

Doyle 2010 (Continued)

4. Social marketing of condoms, supported by peers

Comparison:

Standard activities

Outcomes	Primary outcomes: 1. HIV seroincidence during follow-up 2. HSV-2 seroprevalence at final survey Secondary outcomes: 1. Six biological outcomes: syphilis prevalence, chlamydia prevalence, gonorrhoea prevalence, trichomoniasis prevalence, pregnancy test prevalence, reported pregnancy during follow-up 2. Five behavioral outcomes: sexual debut during follow-up, more than 1 partner in the past 12 months, first used a condom during follow-up, used a condom during last sexual intercourse, visited a health facility for most recent STI symptoms within the past 12 months 3. Reported attitude to sex 4. Three knowledge outcomes: HIV acquisition, STI acquisition, pregnancy prevention
Notes	Assessment: Baseline assessment, interim follow-up survey (2 years after recruitment), final follow-up (approximately 3 years after recruitment), long-term assessment (> 8 years post-intervention)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The specific technique of randomization was not specified
Allocation concealment (selection bias)	Low risk	Lack of concealment would not affect the outcome
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Since the outcome was biological, it was unlikely that the outcome would have been influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not stated. However, it was unlikely that the outcome measurement was influenced by lack of blinding
Incomplete outcome data (attrition bias) All outcomes	High risk	Attrition was balanced among the two groups. The reasons were the same in each group: death, absence or migration However, after 9 years of follow-up attrition was 60% in the control group and 61% in the intervention group
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	a. Different individual recruitment: No b. Cluster imbalance: No Baseline characteristics were balanced across groups

Doyle 2010 (Continued)

c. Loss of cluster: No

d. Statistical analysis: Performed correctly

e. Secular trend: Unclear

The data were analysed as described for stratified cluster randomized trials

Feldblum 2001

Methods	Cluster randomized controlled trial
Participants	1929 women employees, spanning from 18 to 50 years old (intervention 969, control 960)
Interventions	Intervention: Education program (using Information Education Communication concept, social learning theory, and cultural adaptation) on prevention and management of STI. Provision of male and female condoms Control: Education program (without mentioning female condoms), and male condoms only
Outcomes	Trichomonas, chlamydia and gonorrhoea
Notes	Baseline assessment, first follow-up (6 months after baseline assessment), and second follow-up (12 months after baseline assessment)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	A computerized random number algorithm was used
Allocation concealment (selection bias)	Low risk	Although it was not performed, it is unlikely that lack of concealment affects the outcome
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Blinding was not feasible. However, it is unlikely that this feature had an important impact on the outcomes since these are biological-based
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not stated, but since the outcomes were biological, it was unlikely they were influenced by the lack of blinding
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	First follow-up (6 month after baseline assessment): Numbers of loss to follow-up were balance and less than 20% (intervention 9.08%, control 10.83%), but the reasons were not stated Second follow-up (14 months after baseline assessment): Numbers of loss to follow-up were balance and less than 30% (intervention 17.75%, control 16.87%), but the reasons were not stated

Feldblum 2001 (Continued)

Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	a. Different individual recruitment: No Permanent female employees were recruited using randomly sorted employee rosters b. Cluster imbalance: No Baseline characteristics were comparable across groups c. Loss of cluster: No There was no loss of cluster d. Statistical analysis: Adequate

Garcia 2012

Methods	Community randomized controlled trial	
Participants	15,261 young adults aged 18-29 years old in 24 Peruvian cities who have lived in the city for 6 months (intervention 7626, control 8021), and female sexual workers (FSWs)	
Interventions	Intervention: Internet courses for health workers, social marketing of cheap condoms and STIs treatment strategies, healthcare staff training on management of STIs, regular visits of 'prevention salespersons', educational campaigns to the entire community, and recognition of STIs by pharmacy employees. All these activities were developed in order to improve the syndromic management of STIs Control: Standard care	
Outcomes	Prevalence at a community level (mainly in young adults, but also in FSW) of the following STIs: gonorrhoea, syphilis, chlamydia and vaginal trichomoniasis	
Notes	Assessment: Baseline surveys in 2002, and subsequent outcome surveys in 2005 and 2006	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Statistical software was used to randomly allocate cities either to the intervention or control group
Allocation concealment (selection bias)	Low risk	Allocation concealment was not applied, but lack of concealment would not affect the outcome
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Investigators were blinded regarding what cities were receiving the intervention until the surveys and laboratory tests were completed

Garcia 2012 (Continued)

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Members analyzing laboratory data were blinded
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not stated (cross-sectional)
Selective reporting (reporting bias)	Low risk	All outcomes were reported
Other bias	Low risk	a. Different individual recruitment: No b. Cluster imbalance: No Baseline characteristics were comparable across groups, even though some imbalances existed c. Loss of cluster: No d. Statistical analysis: Performed correctly e. Secular trend: Unclear

Gregson 2007

Methods	Cluster randomized controlled trial
Participants	9454 Zimbabweans, males aged 17-54 years old and females aged 15-44 years old from the included communities (intervention 4792, control 4662)
Interventions	Intervention: The program included three interventions: strengthening of the syndromic management of STIs, distribution and use of condoms among sex workers and their clients and also among the general population –all supported by income-generating projects – and finally, activities in healthcare facilities in order to boost STI treatment and safer sexual behaviors Control: Both intervention and control communities received standard services provided by the government such as condoms from private and public institutions, frequent activities to promote awareness regarding HIV/AIDS in the communities (e.g leaflets), and syndromic STI management. Social marketing of condoms (male and female) was also developed
Outcomes	Primary outcome: Outcomes: community-level HIV incidence Secondary outcomes (measured at the community and individual level): 1. Urethral discharge and/or genital ulcers (self report) 2. Change in health-seeking habits and sexual behavior 3. Knowledge related to HIV and other STIs
Notes	Interventions were conducted in two rounds Assessment:

Gregson 2007 (Continued)

Baseline assessment, assessment of first round (three years after baseline assessment), final assessment (assessment of second round)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Communities were randomly assigned to either intervention or control groups by tossing a coin
Allocation concealment (selection bias)	Low risk	Not performed, but lack of concealment would not affect the outcome
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Since the outcome was biological, It was unlikely that the outcome was influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Most research staff were blind to the individuals' HIV status
Incomplete outcome data (attrition bias) All outcomes	High risk	Follow-up (3 years after baseline assessment) Numbers of loss to follow-up were balanced but were higher than 30% (intervention and control 45%). Similar reasons across groups
Selective reporting (reporting bias)	Low risk	All outcomes were reported
Other bias	Low risk	a. Different individual recruitment: No b. Cluster imbalance: No There were some differences across groups, but their magnitude was small enough to be considered not significant c. Loss of cluster: No d. Statistical analysis: Performed correctly e. Secular trend: Unclear

Jewkes 2008

Methods	Cluster randomised trial
Participants	2776 men and women volunteers from South Africa, aged 16-23 years old, normally resident in the villages (Intervention 1409, control 1367)
Interventions	Intervention: The Stepping Stones Program based its interventions on participatory learning approaches such as role plays, dramas, critical reflection and participants' personal experiences. It also included concepts related to relationships, contraception, pregnancy, STIs and HIV, taking risks and its consequences, condom use, safer sex, gender violence, communication skills, and motivations for sexual behavior

Jewkes 2008 (Continued)

Comparison:

A three-hour session on HIV, safer sex, and condoms

Outcomes	Primary outcome: Incidence of HIV Other outcomes: 1. Incidence of HSV-2 2. Unwanted pregnancy 3. Reported sexual practices 4. Depression 5. Substance misuse
Notes	Assessment: Baseline assessment, first follow-up (12 months after baseline assessment), second follow-up (24 months after baseline assessment)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Each village was numbered and listed, and the study arm allocation was determined using computer-generated randomization with equal numbers of villages allocated to each arm in each stratum
Allocation concealment (selection bias)	Low risk	Not performed, but lack of concealment would not affect the outcome (the project manager and field work coordinators in Mthatha identified and randomized the clusters and then enrolled participants)
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Blinding was not feasible. However, since the outcome was biological, it was unlikely that the outcome would have been influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	All blood tests were conducted blind to the treatment arm
Incomplete outcome data (attrition bias) All outcomes	Low risk	First follow-up (12 months after baseline assessment): Numbers of loss to follow-up were balanced and less than 30% (intervention: women 24.2%, men 24.9%; control: women 24.7%, men 28.2%), similar reasons across groups Second follow-up (24 months after baseline assessment): Numbers of loss to follow-up were balanced and less than 30% (intervention: women 26.9%, men 30.5%; total: 28.7%; control: women 24%, men 30.8%; total: 27.4%), similar reasons across groups
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	a. Different individual recruitment: No

Jewkes 2008 (Continued)

b. Cluster imbalance: No

Baseline characteristics were balanced across groups

c. Loss of cluster: No

d. Statistical analysis: Performed correctly

e. Secular trend: Unclear

Kamali 2003

Methods	Community randomized trial
Participants	Total: 14554 Ugandans Intervention (behavioural; group A): 4931 Intervention (behavioural + STD treatment; group B): 4787 Control (group C): 4836
Interventions	Intervention The program was based on the behavioural change for an intervention model that includes motivation, knowledge, skills and attitudes development. The community was targeted through a variety of approaches, including communal and one-to-one activities, role plays, leaflets, and others Healthcare staff received training along with the provision of medication. These activities were supported by community health education. Group B: Same as the intervention for Group A, plus improved management of STIs Group C (control): The activities developed in this group were chosen by the community, and were related to general health topics. The activities in this group included taking care of elderly people, profit-making and self support groups, seminars about general health issues, in addition to general health programs provided by the government Social marketing of female and male condoms along with voluntary HIV counselling were provided to three groups (for ethical considerations)
Outcomes	Primary outcome: Incidence of HIV-1 Secondary outcomes: 1. Incidence of HSV-2 and active syphilis 2. Prevalence of gonorrhoea, chlamydia, reported genital ulcers, reported genital discharge 3. Behavioral change
Notes	Interventions were undertaken over three rounds: Round 1 (April 1994 to November 1996): Initial cohort members Round 2 (December 1996 to December 1998): New individuals were enrolled (either missed at baseline, new immigrants, children at 13 years of age, or those who initially refused)

Kamali 2003 (Continued)

Round 3 (January 1999 to June 2000): Only those who previously provided a blood sample at either of the first two rounds were eligible for participation

Assessment:

Effects of the interventions were assessed through three laboratory tests and baseline surveys during Rounds 1, 2 and 3 covering knowledge, attitudes, behavior, and practices

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	The names of communities within each group of three were written on individual cards, mixed and selected randomly: the first from each group was assigned to arm A (IEC alone), the second to arm B (IEC and STI management) and the third to arm C
Allocation concealment (selection bias)	Low risk	Lack of concealment would not affect the outcome
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Blinding was not feasible, but since the outcome is biological, it is unlikely that it is influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The trial research team remained blind to the data until the end of the study
Incomplete outcome data (attrition bias) All outcomes	Low risk	Round 1 to Round 2 (after 2 years): Numbers of loss to follow-up were balanced and less than 30% (Group A: 27%, Group B: 25%, Group C: 25%), similar reason across groups Round 2 to Round 3 (after 2 years): Numbers of loss to follow-up were balanced and less than 30% (Group A: 18%, Group B: 19%, Group C: 20%), similar reason across groups Round 1 to Round 3 (after 5 years) Numbers of loss to follow-up were balanced but more than 30% (Group A: 68%, Group B: 67%, Group C: 68%), similar reason across groups
Selective reporting (reporting bias)	Low risk	All outcomes were reported
Other bias	Low risk	a. Different individual recruitment: Unclear, possibly no b. Cluster imbalance: No Baseline characteristics were balanced across groups c. Loss of cluster: No d. Statistical analysis: Performed correctly e. Secular trend: Unclear

NIMH 2010

Methods	Group randomized trial
Participants	18,147 people (intervention 9044, control 9103) from China, India, Peru, Russia, and Zimbabwe
Interventions	Intervention: The intervention was based on community popular opinion leaders, people defined as natural leaders of the communities - who conveyed an educational message about HIV/AIDS, including condom use and in general safer sex practices. These community popular opinion leaders reached the community in public venues where people tend to gather. The objective was to change people's behaviours by using the innovation diffusion theory which posits that innovations and changes often originate within a subset of the population, made up of its opinion leaders whose views are then adopted by others in the community. Because the intervention was carried out in different cultural settings, the content of the program was tailored to fit each local community Control: General information and education about HIV/AIDS was communicated through brochures and educational materials, along with HIV/STI counselling, testing, and - if positive - treatment. This group was also given free or inexpensive condoms
Outcomes	Primary outcomes: Behavioral: change between the 24-month follow-up assessment and baseline in the proportion of participants reporting unprotected acts with non-spousal/non live-in partners in the past 3 months Biological: the incidence of any new STIs, including chlamydia, gonorrhoea, HIV, HSV-2, syphilis, and - for women - trichomoniasis observed across the 12-month and 24-month follow-up points
Notes	Assessment: Baseline, 2-month follow up, and 24-month follow-up

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The randomization method was not described
Allocation concealment (selection bias)	Low risk	Unclear, but lack of concealment would not affect the outcome
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Since the outcome is biological, it is unlikely that the outcome is influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome assessment was blinded to site investigators
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	First follow-up (12 months after baseline assessment): Numbers of loss to follow-up were balanced and less than 30% (intervention 15.7%, control 15.6%), reasons were not stated. Second follow-up (24 months after baseline assessment):

NIMH 2010 (Continued)

Numbers of loss to follow-up were balanced and less than 30% (intervention: 18.4%, control 17.6%), but the specific reasons were not stated

Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	a. Different individual recruitment: Unclear, possibly no b. Cluster imbalance: No Baseline characteristics were balanced across groups c. Loss of cluster: No. However, after initial randomization, 10 venues in China and 4 venues in India were replaced due to the closure of food markets in China and the 2004 tsunami that destroyed 4 venues in India d. Statistical analysis: Performed correctly e. Secular trend: Unclear

Ross 2007

Methods	Community randomized trial
Participants	9645 adolescents from Tanzania, aged 14 years or more who were in Years 4–6 of all 121 government primary schools within the 20 trial communities (intervention 4870, comparison 4775)
Interventions	Intervention: MEMA kwa Vijana interventions: - Community activities - Teacher-led, peer-assisted sexual health education in Years 5–7 of primary school - Training and supervision of health workers to provide a 'youth-friendly' sexual health service - Condom social marketing Comparison: Standard activities
Outcomes	Primary outcomes: 1. HIV seroincidence during follow-up. 2. HSV2 seroprevalence at final survey. Secondary outcomes: 1. Six biological outcomes: syphilis prevalence, chlamydia prevalence, gonorrhoea prevalence, trichomoniasis prevalence, pregnancy test prevalence, reported pregnancy during follow-up 2. Five behavioral outcomes: sexual debut during follow-up, more than 1 partner in the past 12 months, first used a condom during follow-up, used a condom during last sexual intercourse, visited a health facility for most recent STI symptoms within the past 12 months 3. Reported attitude to sex 4. Three knowledge outcomes: HIV acquisition, STD acquisition, pregnancy prevention

Ross 2007 (Continued)

Notes

Assessment:

Baseline assessment, interim follow-up survey (2 years after recruitment), and final follow-up (approximately 3 years after recruitment)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	A system of constrained randomization was used to allocate communities to the two study arms, ensuring adequate balance of important factors. There were 28,000 ways of allocating half the communities in each stratum to the intervention arm. A computer program tested whether each of these allocations satisfied balance criteria, and one was randomly chosen at a meeting attended by senior government officials
Allocation concealment (selection bias)	Low risk	Lack of concealment would not affect the outcome
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Blinding was not feasible. However, since the outcome was biological it was unlikely that the outcome was influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not stated, but it is unlikely that it is influenced by lack of blinding
Incomplete outcome data (attrition bias) All outcomes	Low risk	Final follow-up (after 3 years) Numbers of loss to follow-up were balanced and less than 30% (intervention 28%, comparison 26%); reasons were similar across groups
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	a. Different individual recruitment: No All those aged 14 years or more (mean 15.7 years) in late 1998, who were in years 4–6 of all 121 government primary schools within the 20 trial communities (and about to enter years 5–7) were eligible for enrolment b. Cluster imbalance: No Baseline characteristics were balance across groups c. Loss of cluster: No d. Statistical analysis: Performed correctly e. Secular trend: Unclear

AIDS: Acquired immunodeficiency syndrome

DFID: Department for International Development

FSW: Female sex workers

HIV: Human immunodeficiency virus

HSV-2: Herpes simplex virus 2

IEC: Information, education and communication

MEMA kwa vijana: It translates from the local language “good things for young people”

STI: Sexually transmitted infection

STD: Sexually transmitted disease

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

Study	Reason for exclusion
Arnold 2012	No biological outcomes. The units of randomisation were schools instead of entire communities
Bassett 1998	Lacked key information to properly assess inclusion criteria, risk of bias and risk ratio. The author could not be reached
Basu 2004	No biological outcomes
Beattie 2010	Not randomized controlled trial
Bolu 2004	Clinical setting, not community based
Boyer 2005	Military setting with platoons as the unit for randomisation; not a community study; military population -(military women) not representative of general population
Campos 2013	No HIV outcomes. Study is a subanalysis of Garcia 2012
Celentano 1998	Not randomized controlled trial; Observational, cohort study. The units of randomisation were military bases
DiClemente 2009	Clinical setting; not community based
Doyle 2011	Subanalysis from Doyle 2010
Duan 2013	No biological outcomes
El-Bassel 2010	Conducted in health facilities, focusing on couples and groups; not a community study
Fontanet 1998	Randomization process took place in brothels, instead of an entire geographical community
Grosskurth 1995	The objective of the study was not to distribute or promote condoms (the study aimed to improve the management of STIs and encourage people to seek medical attention)
Kalichman 2013	No biological outcomes
Kamb 1998	Face-to-face counselling in a clinical setting; not community based
Kennedy 2012	No biological outcomes
Kerrigan 2006	Not randomized controlled trial
Kim 2007	No assessment of biological outcome; substudy from “Effect of a structural intervention for the prevention of intimate-partner violence and HIV in rural South Africa: a cluster randomised trial”.
Kim 2009	Biological data not provided
Koblin 2004	Clinical based with one-to-one counselling; not community based
Labbe 2012	The main intervention was provision of antibiotics. The units of randomisation were brothels instead of entire communities

Study	Reason for exclusion
Larke 2010	Self reported outcome and sub-study from "Biological and behavioural impact of an adolescent sexual health intervention in Tanzania: a community-randomized trial"
Mathews 2012	No biological outcomes; The units of randomisation were schools instead of entire communities
Maticka-Tyndale, E. 2011	No biological outcomes
Metcalf 2005	One-to-one counselling; not community based
Okonofua 2003	Self reported STI symptoms: no biological markers used
Padian 2007	Clinical study (clinical setting); not community based
Pronyk 2006	Lack of information in the study and protocol about the extent of condom promotion; no response from author
Pronyk 2008	Biological outcomes not assessed; promotion of condom use unclear; secondary analysis from "Effect of a structural intervention for the prevention of intimate-partner violence and HIV in rural South Africa: a cluster randomised trial"
Quigley 2004	It is a secondary study from "Syndromic management of sexually transmitted infections and behaviour change interventions on transmission of HIV-1 in rural Uganda: a community randomised trial"
Rotheram-Borus 2011	Substudy from China included in "The NIMH Collaborative HIV/STD Prevention Trial Group, 2010"
Sawaya 2008	Clinical setting; not community based
Shain 2004	Personal counselling; not community intervention
Spielberg 2013	No biological outcomes
Strathdee 2013	Not a community-level study. Randomization conducted on female sex workers
Van der Straten 2009	Clinical trial, not community based; no biological outcome
Wawer 1999	Condom promotion was not one of the goals of the study. Instead, its objective was to determine if HIV transmission could be reduced through the control of sexually transmitted diseases, using home-based mass antibiotic treatment

FSW: Female sex worker

HIV: Human immunodeficiency virus

STD: Sexually transmitted disease

Characteristics of studies awaiting assessment *[ordered by study ID]*

Wagman ongoing

Methods	Cluster randomized controlled trial, "The SHARE Project"
Participants	Not clear
Interventions	Intimate partner violence prevention program along with routine HIV services

Wagman ongoing (Continued)

Outcomes	Physical violence, HIV incidence
Notes	The available text in the ClinicalTrials.gov's webpage with the name "Assessing the Impact of an Intervention to Prevent Intimate Partner Violence and HIV in Uganda" (ID: NCT02050763) does not provide proper information about the study's design or its results. The only full-text study related to this clinical trial and that is available in other databases is "A Public Health Approach to Intimate Partner Violence Prevention in Uganda" by Wagman JA, published in 2012. However, this document only describes a theoretical framework, the implementation and design of the project and the challenges faced by the research team. It is a descriptive document without quantitative results. Thus, no proper classification of the study was feasible (it is unclear if the study was implemented at a community level, the specific type of interventions implemented, if condoms were delivered and if the study collected HIV samples after the intervention(s) took place)

Characteristics of ongoing studies [ordered by study ID]

Vermund ongoing

Trial name or title	Can combination prevention strategies reduce HIV transmission in generalized epidemic settings in Africa? The HPTN 071 (PopART) study plan in South Africa and Zambia
Methods	Community-RCT
Participants	1.2 million individuals
Interventions	ART therapy, male circumcision, treatment of STIs, behavioral interventions and condom distribution
Outcomes	HIV incidence
Starting date	2013
Contact information	Nulda Beyers, nb@sun.ac.za
Notes	Ongoing study in which several proven interventions to reduce HIV transmission will be assessed at a community-structural level. The study is also awaiting for classification given the broad spectrum of interventions implemented.

HIV: Human immunodeficiency virus

IDU: Intravenous drug user

MSM: Men who have sex with men

RCT: Randomized controlled trial

STI: Sexually transmitted infections

DATA AND ANALYSES

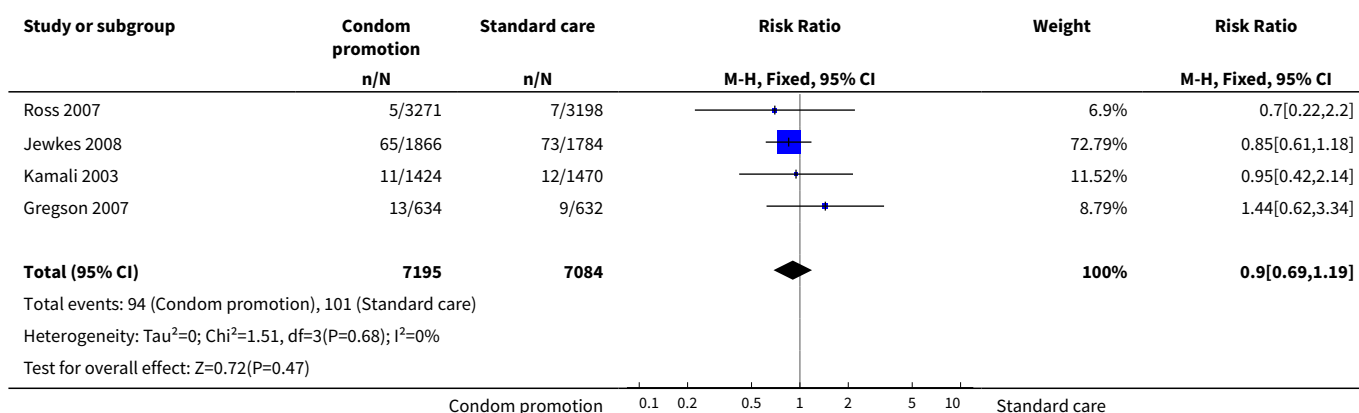
Comparison 1. Interventions to increase condom use versus standard care

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 HIV incidence (person/years)	4	14279	Risk Ratio (M-H, Fixed, 95% CI)	0.90 [0.69, 1.19]

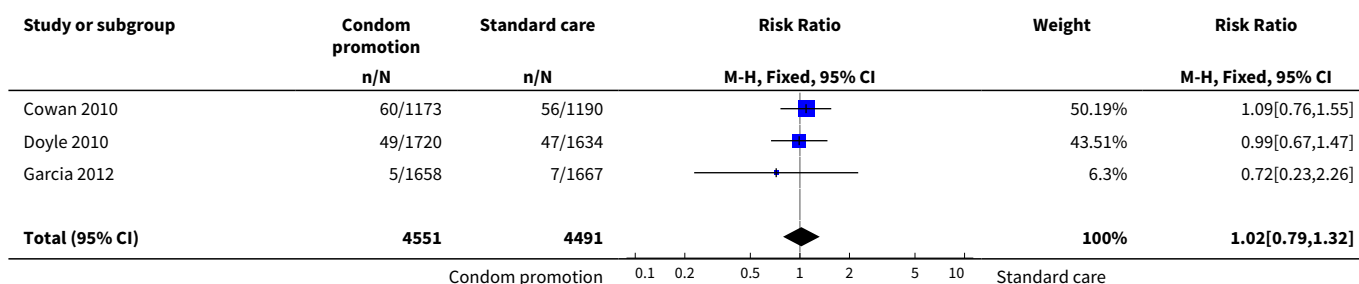
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2 HIV prevalence	3	9042	Risk Ratio (M-H, Fixed, 95% CI)	1.02 [0.79, 1.32]
3 HSV-2 incidence (person/years)	2	3877	Risk Ratio (M-H, Fixed, 95% CI)	0.76 [0.55, 1.04]
4 HSV-2 prevalence	2	2974	Risk Ratio (M-H, Fixed, 95% CI)	1.01 [0.85, 1.20]
5 Syphilis incidence, 1:8 dilutions (person/years)	1	255	Risk Ratio (M-H, Fixed, 95% CI)	0.59 [0.18, 1.95]
6 Syphilis prevalence (1:8 dilutions)	3	7982	Risk Ratio (M-H, Fixed, 95% CI)	0.91 [0.71, 1.17]
7 Gonorrhoea prevalence	5	10746	Risk Ratio (M-H, Fixed, 95% CI)	1.16 [0.67, 2.02]
8 Chlamydia prevalence	5	9623	Risk Ratio (M-H, Fixed, 95% CI)	0.94 [0.75, 1.18]
9 Trichomona prevalence (only in women)	2	916	Risk Ratio (M-H, Fixed, 95% CI)	1.00 [0.77, 1.30]
10 Trichomona prevalence (both sexes)	1	2894	Risk Ratio (M-H, Fixed, 95% CI)	0.07 [0.02, 0.18]
11 Composite score 1: HIV, HSV-2, syphilis, gonorrhea, chlamydia, trichomonas (in women)	1	8377	Risk Ratio (M-H, Fixed, 95% CI)	0.94 [0.84, 1.06]
12 Composite score 2: HIV, syphilis, gonorrhea, chlamydia, trichomonas	1	2441	Risk Ratio (M-H, Fixed, 95% CI)	0.78 [0.59, 1.04]
13 Composite score 3: gonorrhea, chlamydia and trichomonas (all results assessed in women)	1	669	Risk Ratio (M-H, Fixed, 95% CI)	0.99 [0.72, 1.36]
14 Two or more sexual partners in last year	5	4008	Risk Ratio (M-H, Fixed, 95% CI)	0.90 [0.78, 1.04]
15 Use of condom during last sexual intercourse	3	1898	Risk Ratio (M-H, Fixed, 95% CI)	1.20 [1.03, 1.40]
16 Use of condom during last sexual intercourse with non-regular partner	1	122	Risk Ratio (M-H, Fixed, 95% CI)	1.16 [0.78, 1.72]
17 Unprotected sex with regular partner in past three years	1	103	Risk Ratio (M-H, Fixed, 95% CI)	1.03 [0.91, 1.16]
18 Correct condom use at last sexual intercourse at 12 months	1	489	Risk Ratio (M-H, Fixed, 95% CI)	0.98 [0.85, 1.12]
19 Correct condom use at last sexual intercourse 24 months	1	386	Risk Ratio (M-H, Fixed, 95% CI)	0.97 [0.84, 1.12]

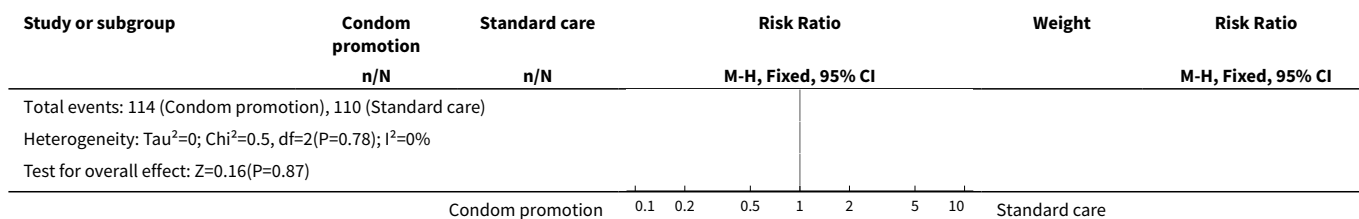
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
20 Consistent condom use at 6 months	1	726	Risk Ratio (M-H, Fixed, 95% CI)	0.63 [0.38, 1.05]
21 Consistent condom use at 12 months	1	566	Risk Ratio (M-H, Fixed, 95% CI)	0.92 [0.53, 1.60]
22 Knowledge: Condom can prevent HIV	4	2004	Risk Ratio (M-H, Fixed, 95% CI)	1.16 [1.03, 1.29]
23 Knowledge: Condom can prevent STIs	3	1231	Risk Ratio (M-H, Fixed, 95% CI)	1.23 [1.07, 1.41]
24 Condom self efficacy	1	699	Risk Ratio (M-H, Fixed, 95% CI)	1.16 [0.94, 1.41]
25 HIV self efficacy	1	329	Risk Ratio (M-H, Fixed, 95% CI)	0.99 [0.68, 1.46]
26 Self efficacy	1	132	Risk Ratio (M-H, Fixed, 95% CI)	1.02 [0.90, 1.17]

Analysis 1.1. Comparison 1 Interventions to increase condom use versus standard care, Outcome 1 HIV incidence (person/years).

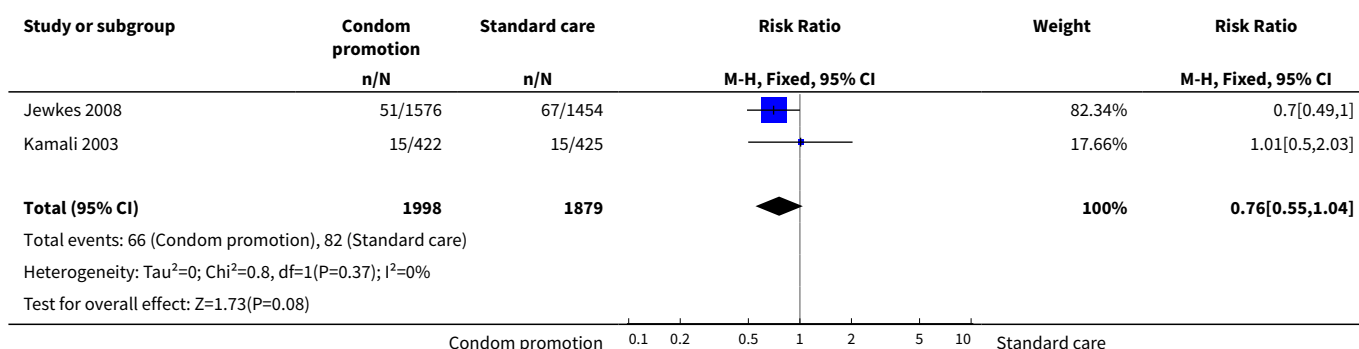


Analysis 1.2. Comparison 1 Interventions to increase condom use versus standard care, Outcome 2 HIV prevalence.

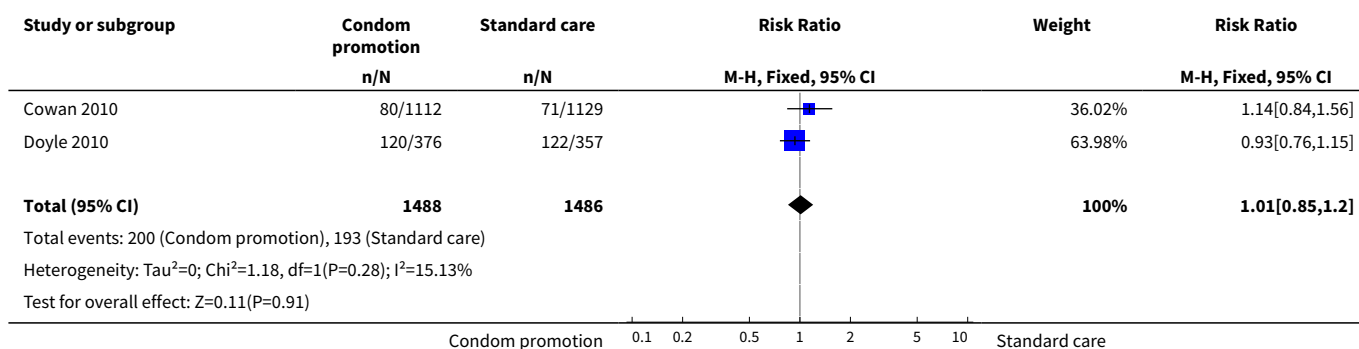




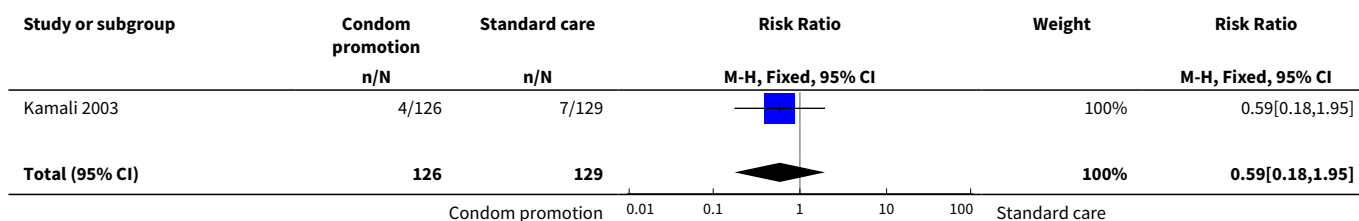
Analysis 1.3. Comparison 1 Interventions to increase condom use versus standard care, Outcome 3 HSV-2 incidence (person/years).

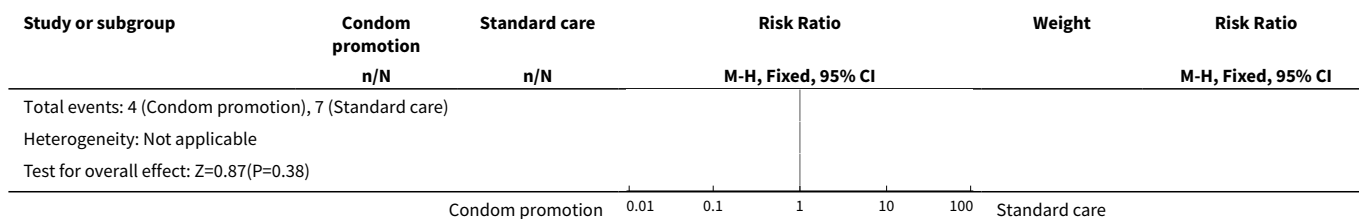


Analysis 1.4. Comparison 1 Interventions to increase condom use versus standard care, Outcome 4 HSV-2 prevalence.

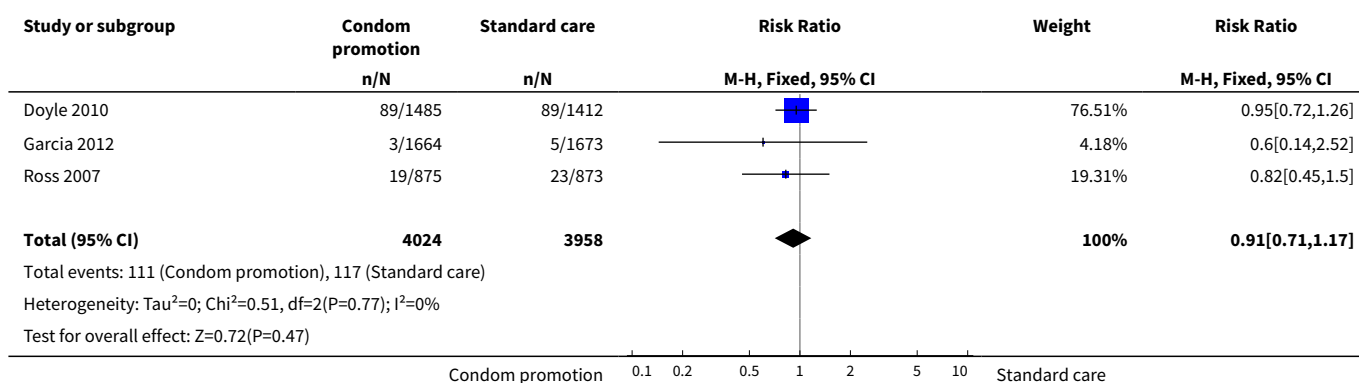


Analysis 1.5. Comparison 1 Interventions to increase condom use versus standard care, Outcome 5 Syphilis incidence, 1:8 dilutions (person/years).

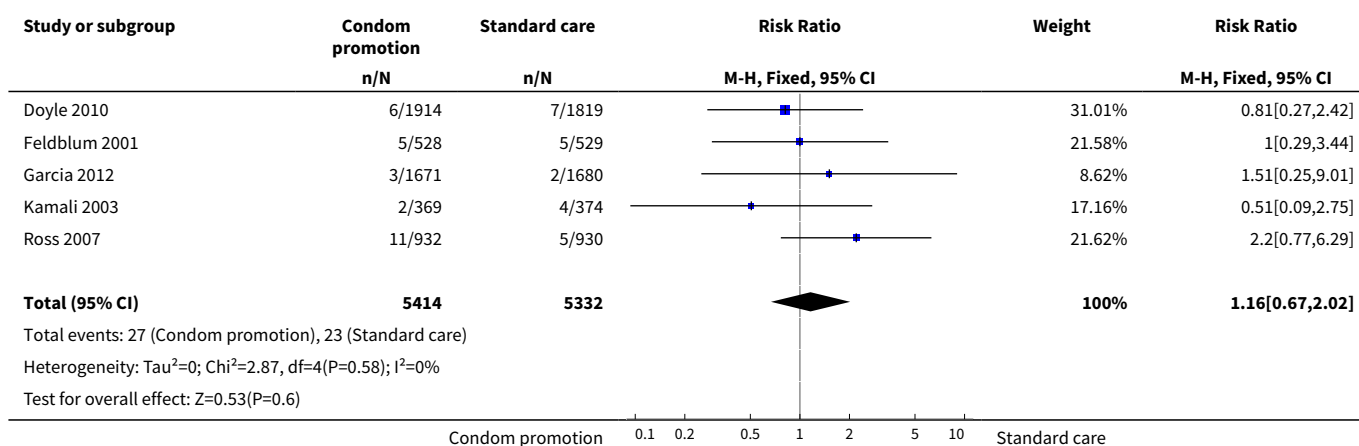




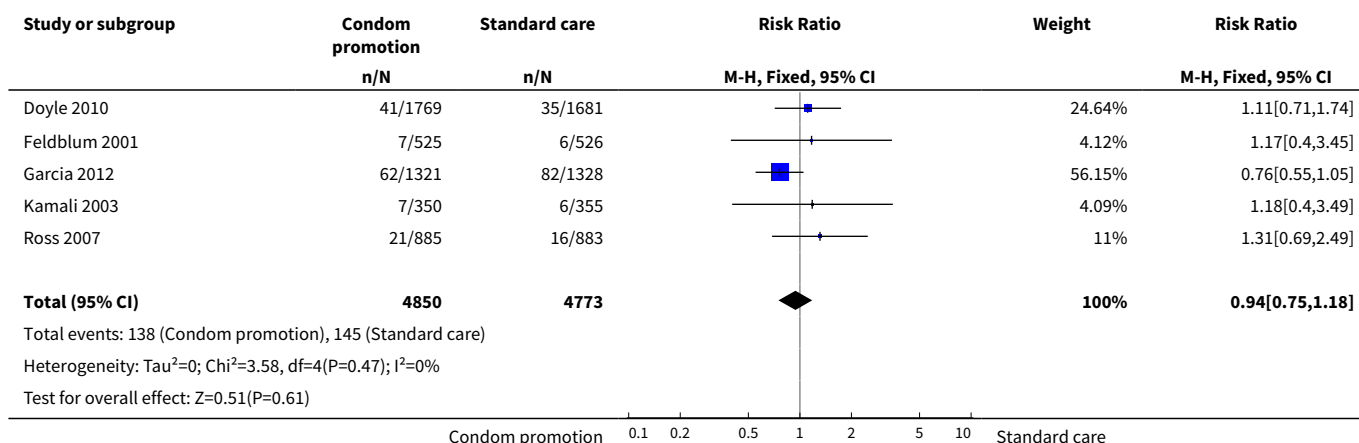
Analysis 1.6. Comparison 1 Interventions to increase condom use versus standard care, Outcome 6 Syphilis prevalence (1:8 dilutions).



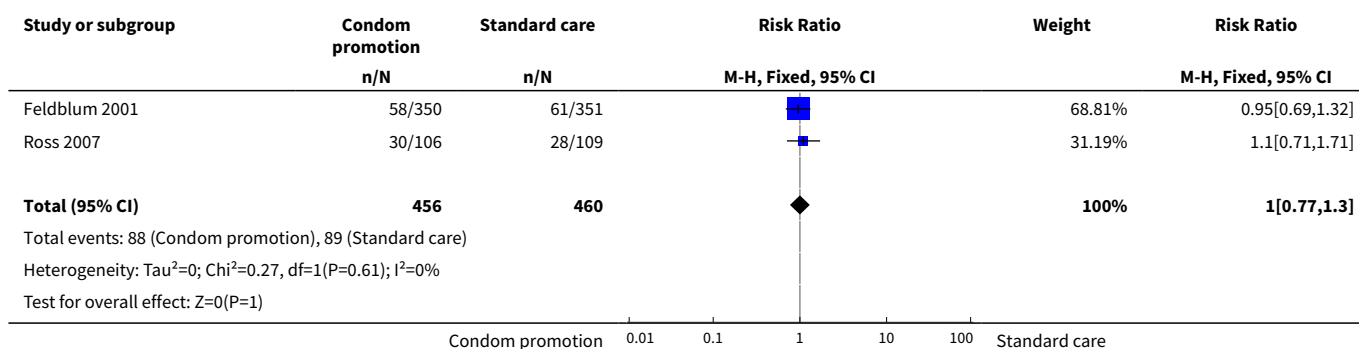
Analysis 1.7. Comparison 1 Interventions to increase condom use versus standard care, Outcome 7 Gonorrhoea prevalence.



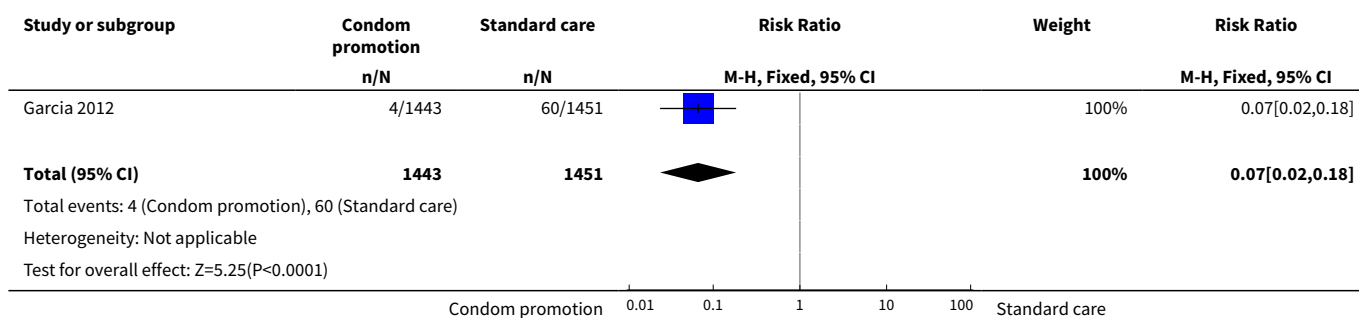
Analysis 1.8. Comparison 1 Interventions to increase condom use versus standard care, Outcome 8 Chlamydia prevalence.



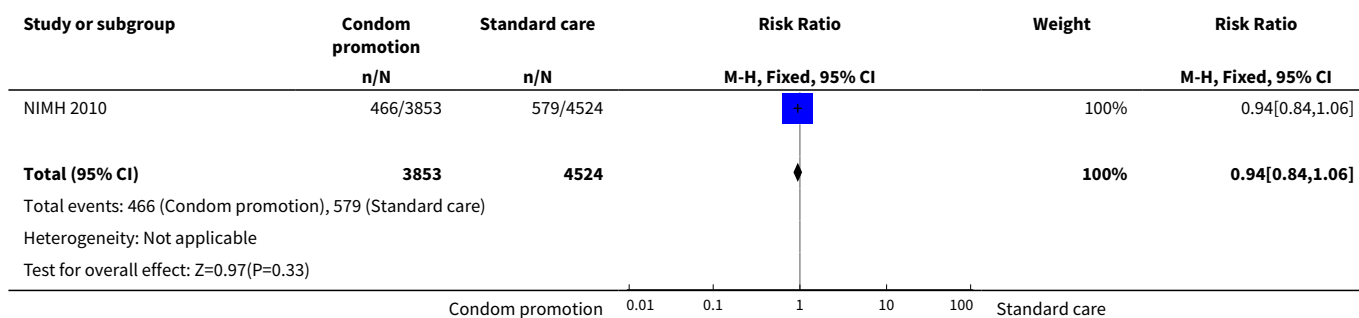
Analysis 1.9. Comparison 1 Interventions to increase condom use versus standard care, Outcome 9 Trichomona prevalence (only in women).



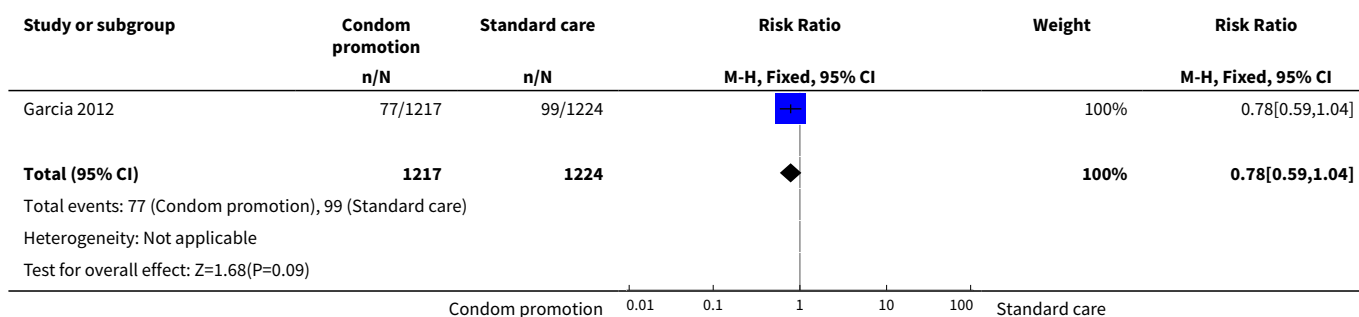
Analysis 1.10. Comparison 1 Interventions to increase condom use versus standard care, Outcome 10 Trichomona prevalence (both sexes).



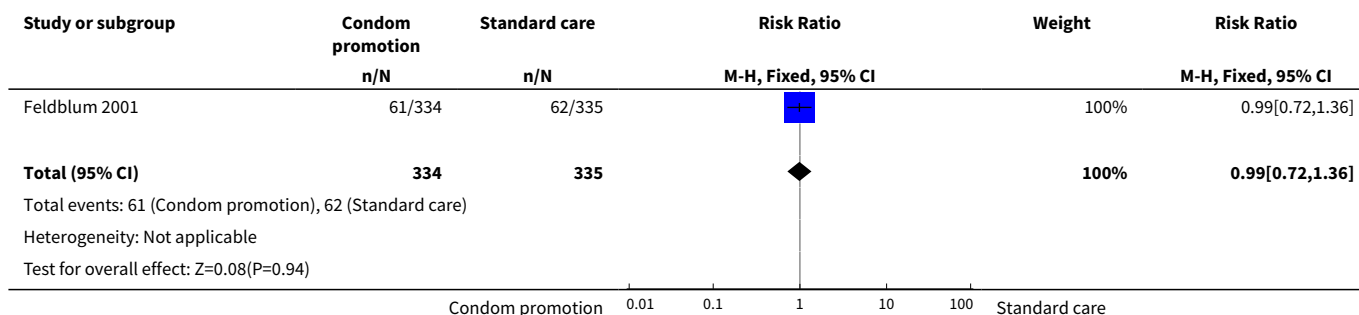
Analysis 1.11. Comparison 1 Interventions to increase condom use versus standard care, Outcome 11 Composite score 1: HIV, HSV-2, syphilis, gonorrhea, chlamydia, trichomonas (in women).



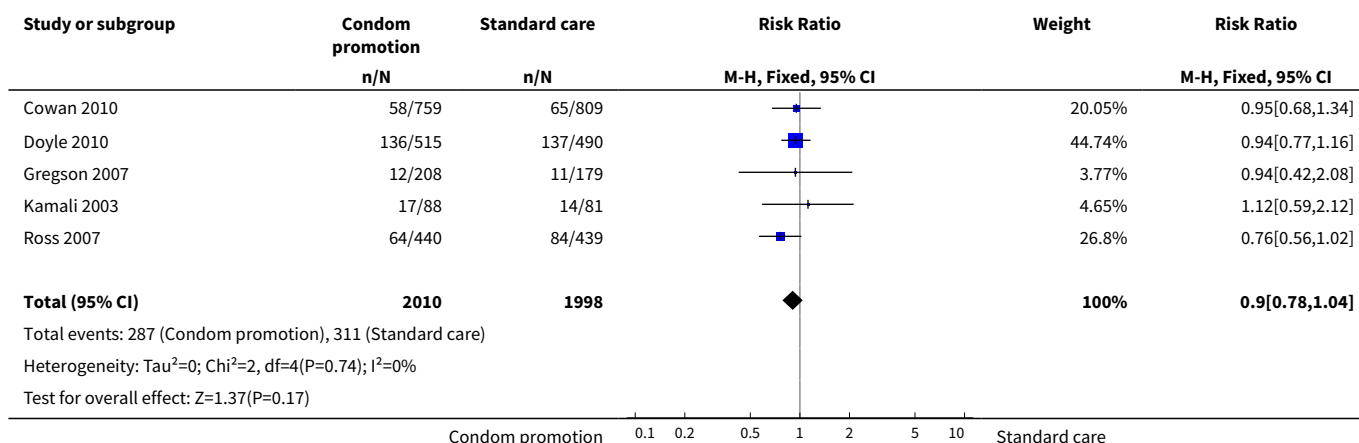
Analysis 1.12. Comparison 1 Interventions to increase condom use versus standard care, Outcome 12 Composite score 2: HIV, syphilis, gonorrhea, chlamydia, trichomonas.



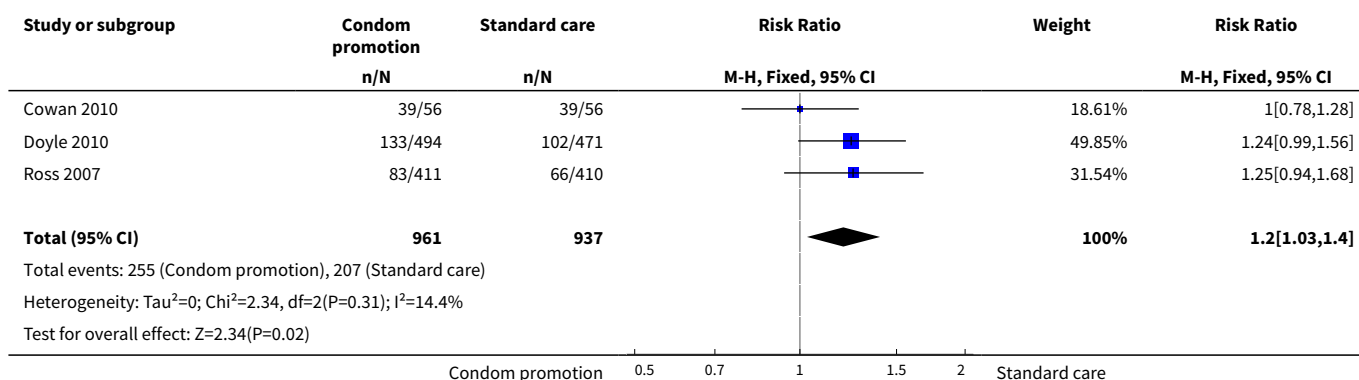
Analysis 1.13. Comparison 1 Interventions to increase condom use versus standard care, Outcome 13 Composite score 3: gonorrhea, chlamydia and trichomonas (all results assessed in women).



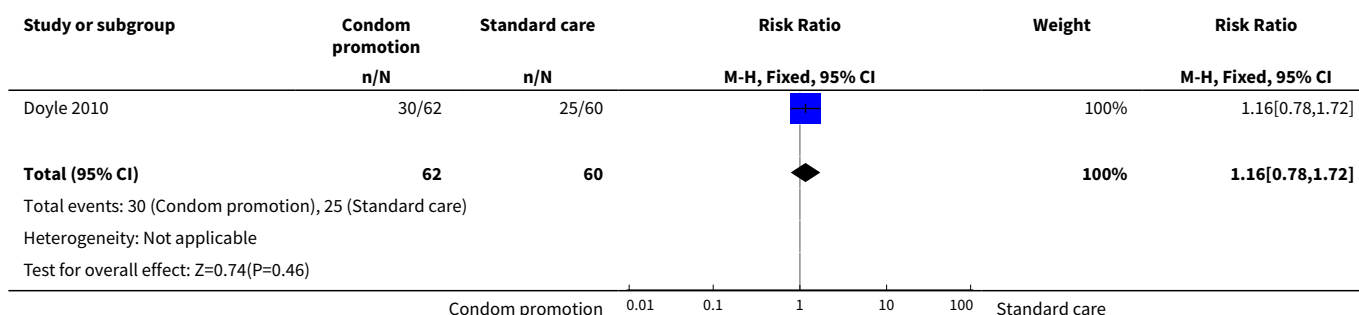
Analysis 1.14. Comparison 1 Interventions to increase condom use versus standard care, Outcome 14 Two or more sexual partners in last year.



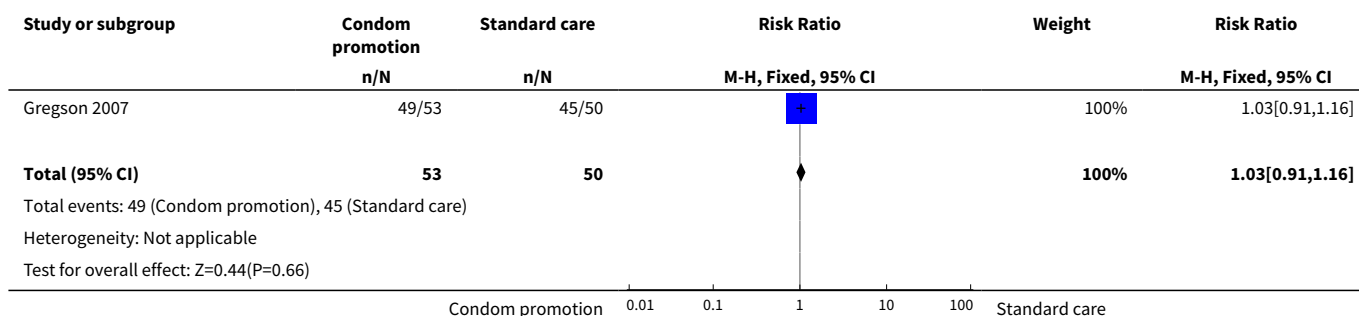
Analysis 1.15. Comparison 1 Interventions to increase condom use versus standard care, Outcome 15 Use of condom during last sexual intercourse.



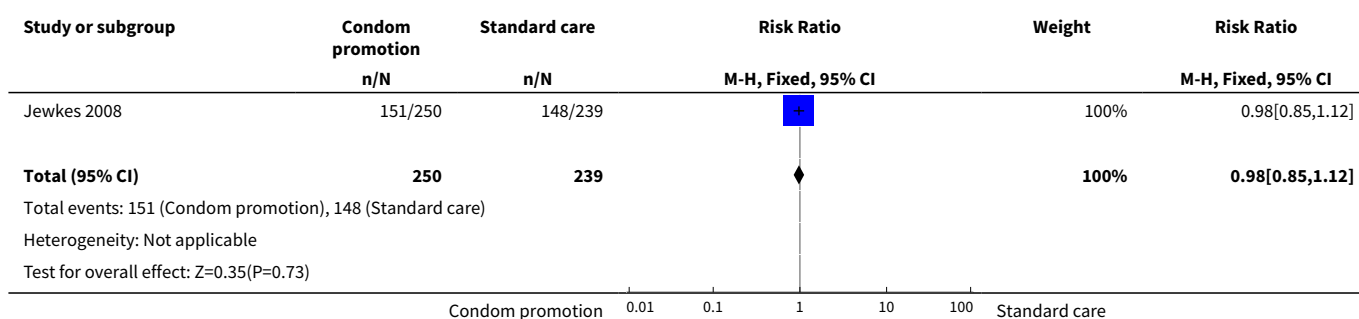
Analysis 1.16. Comparison 1 Interventions to increase condom use versus standard care, Outcome 16 Use of condom during last sexual intercourse with non-regular partner.



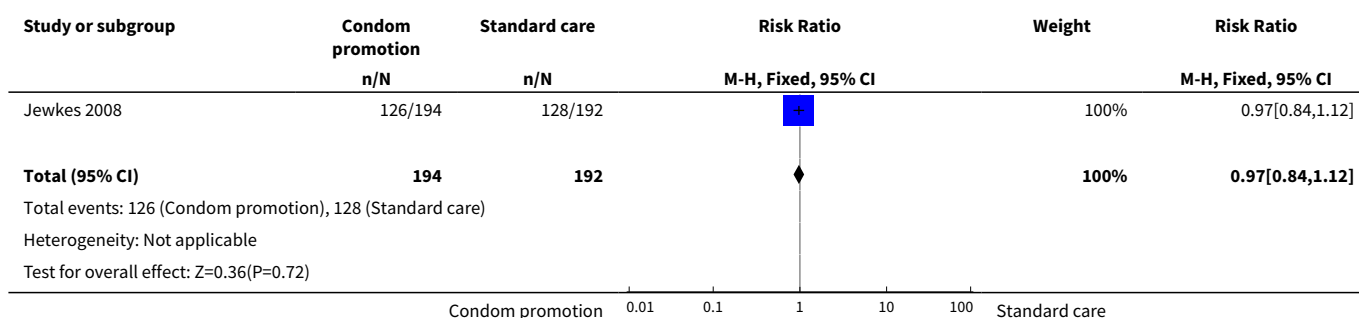
Analysis 1.17. Comparison 1 Interventions to increase condom use versus standard care, Outcome 17 Unprotected sex with regular partner in past three years.



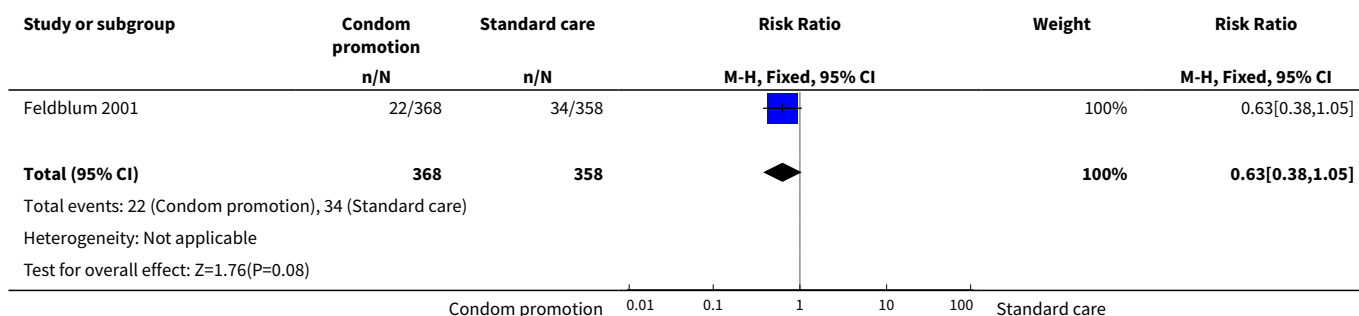
Analysis 1.18. Comparison 1 Interventions to increase condom use versus standard care, Outcome 18 Correct condom use at last sexual intercourse at 12 months.



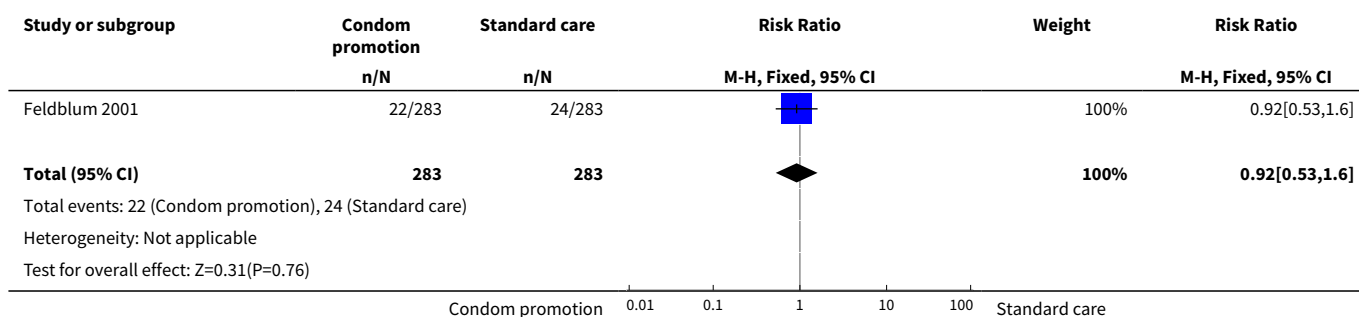
Analysis 1.19. Comparison 1 Interventions to increase condom use versus standard care, Outcome 19 Correct condom use at last sexual intercourse 24 months.



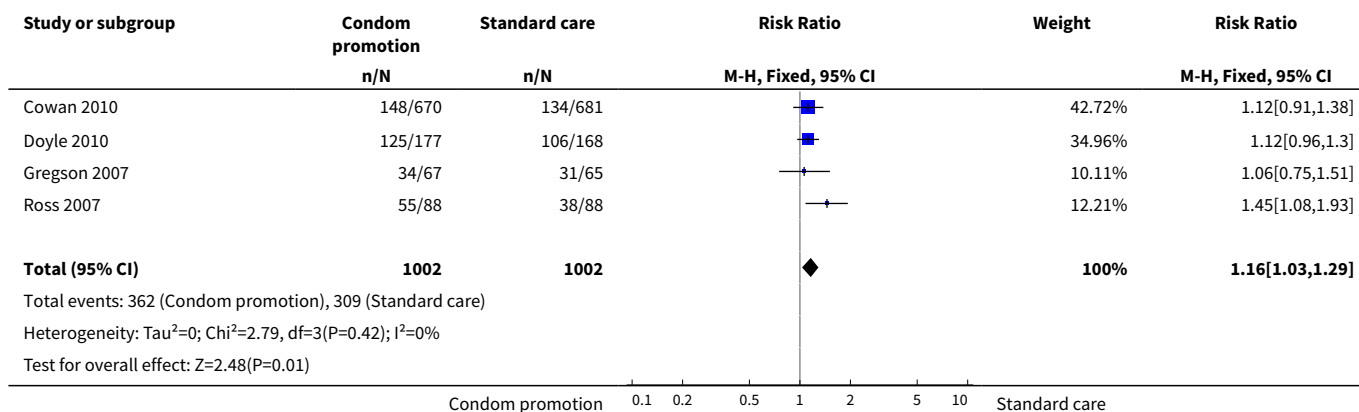
Analysis 1.20. Comparison 1 Interventions to increase condom use versus standard care, Outcome 20 Consistent condom use at 6 months.



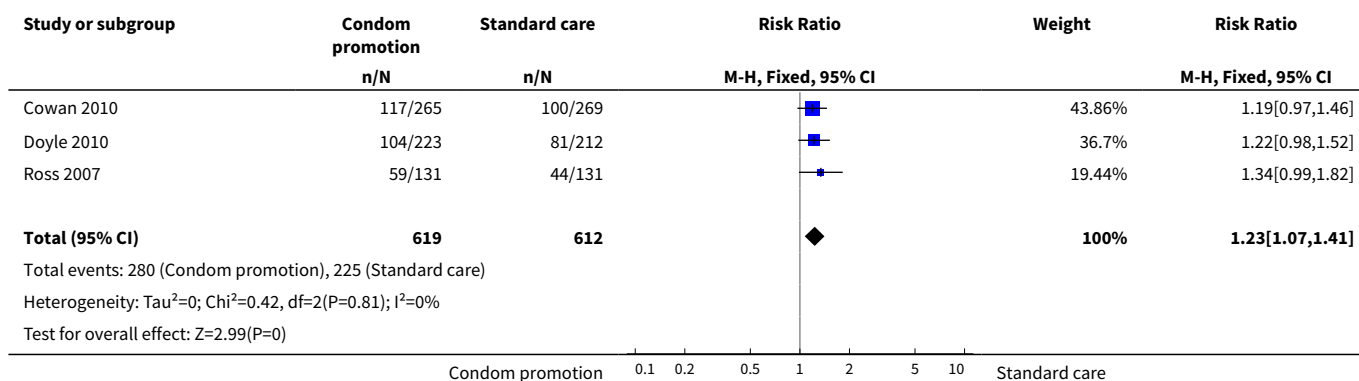
Analysis 1.21. Comparison 1 Interventions to increase condom use versus standard care, Outcome 21 Consistent condom use at 12 months.



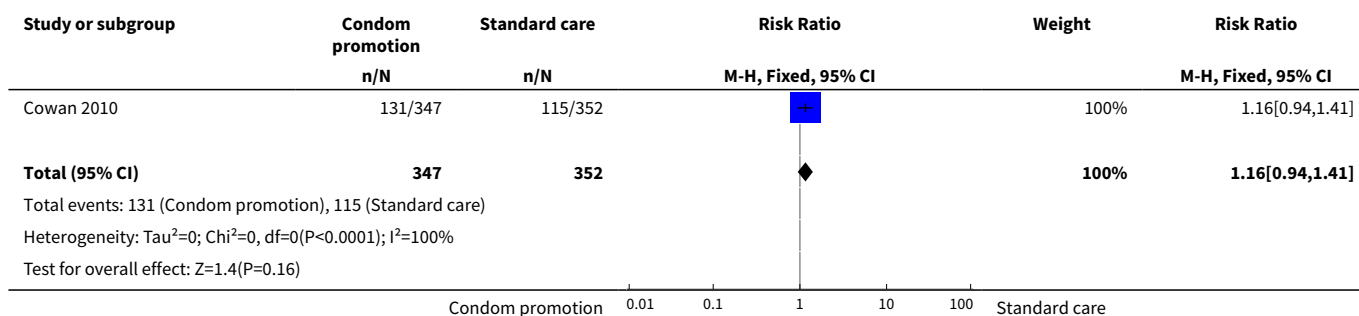
Analysis 1.22. Comparison 1 Interventions to increase condom use versus standard care, Outcome 22 Knowledge: Condom can prevent HIV.



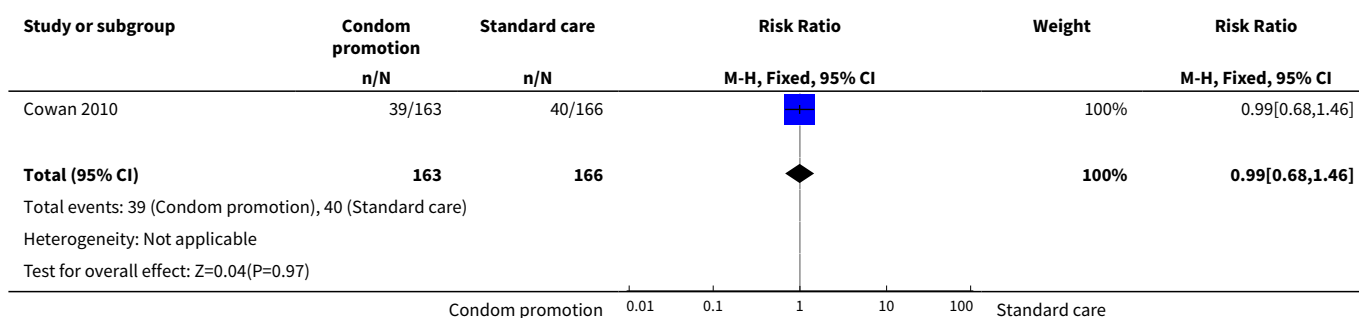
Analysis 1.23. Comparison 1 Interventions to increase condom use versus standard care, Outcome 23 Knowledge: Condom can prevent STIs.



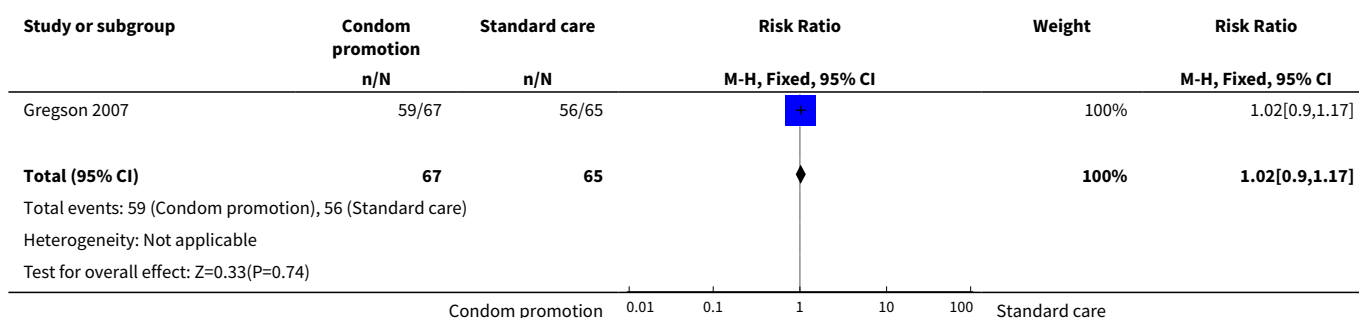
Analysis 1.24. Comparison 1 Interventions to increase condom use versus standard care, Outcome 24 Condom self efficacy.



Analysis 1.25. Comparison 1 Interventions to increase condom use versus standard care, Outcome 25 HIV self efficacy.



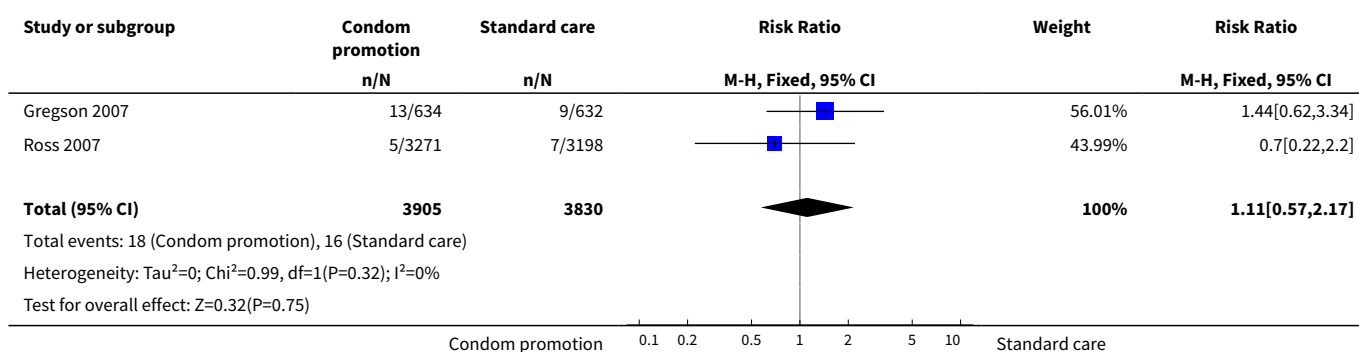
Analysis 1.26. Comparison 1 Interventions to increase condom use versus standard care, Outcome 26 Self efficacy.



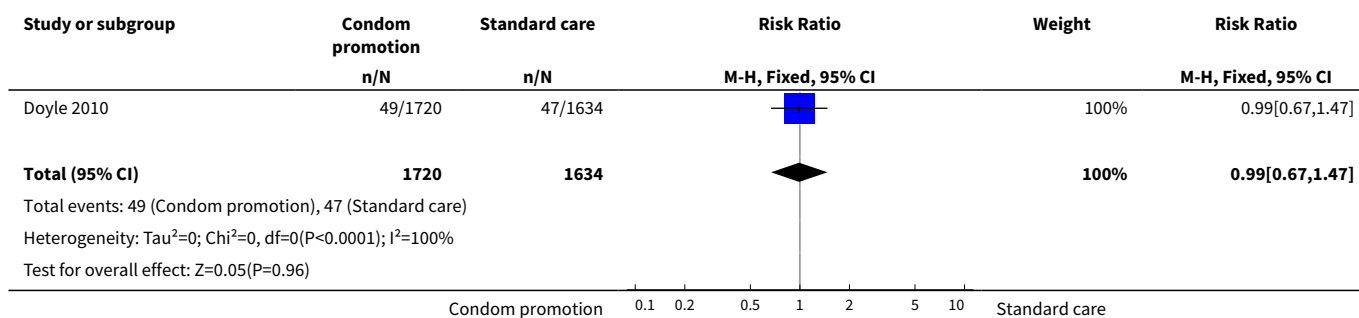
Comparison 2. Stratified analysis: Condom promotion along with free massive condom distribution

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 HIV incidence (per-son/years)	2	7735	Risk Ratio (M-H, Fixed, 95% CI)	1.11 [0.57, 2.17]
2 HIV prevalence	1	3354	Risk Ratio (M-H, Fixed, 95% CI)	0.99 [0.67, 1.47]
3 HSV-2 prevalence	1	733	Risk Ratio (M-H, Fixed, 95% CI)	0.93 [0.76, 1.15]
4 Syphilis prevalence (1:8 dilutions)	2	4645	Risk Ratio (M-H, Fixed, 95% CI)	0.93 [0.72, 1.20]
5 Gonorrhoea prevalence	3	6652	Risk Ratio (M-H, Random, 95% CI)	1.25 [0.66, 2.38]
6 Chlamydia prevalence	3	6269	Risk Ratio (M-H, Fixed, 95% CI)	1.17 [0.83, 1.66]

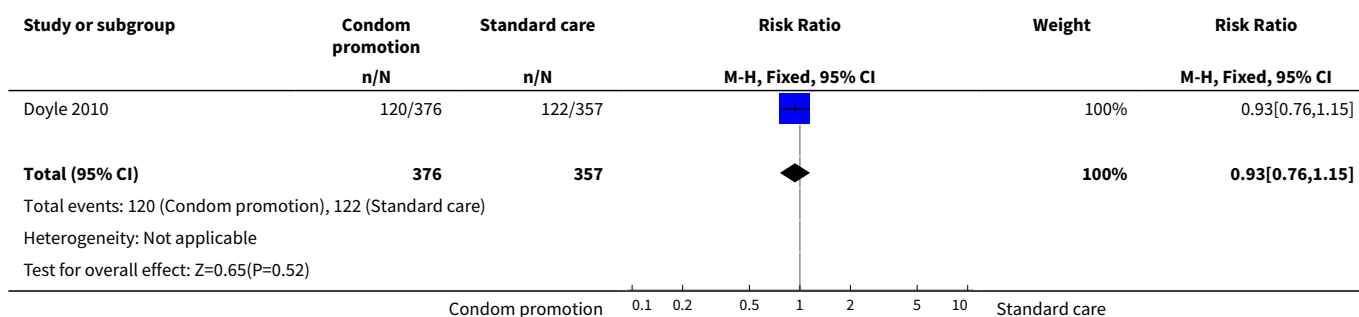
Analysis 2.1. Comparison 2 Stratified analysis: Condom promotion along with free massive condom distribution, Outcome 1 HIV incidence (person/years).



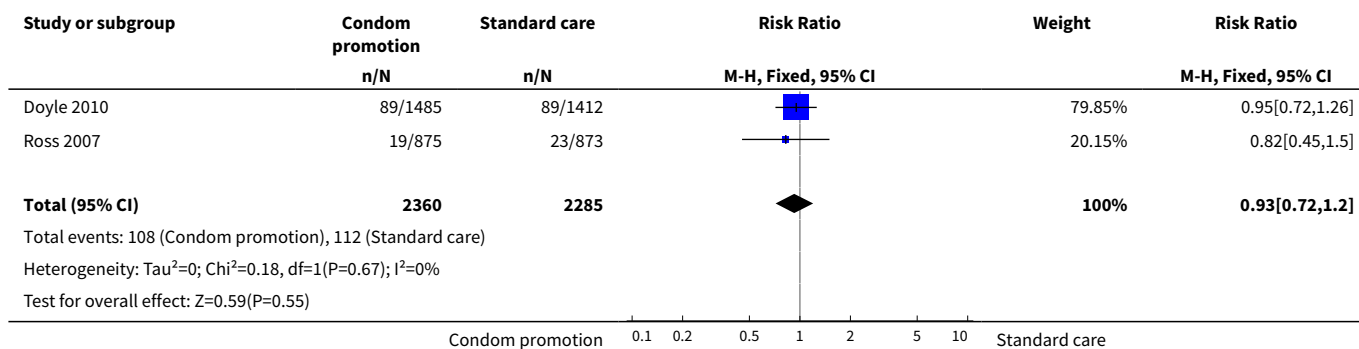
Analysis 2.2. Comparison 2 Stratified analysis: Condom promotion along with free massive condom distribution, Outcome 2 HIV prevalence.



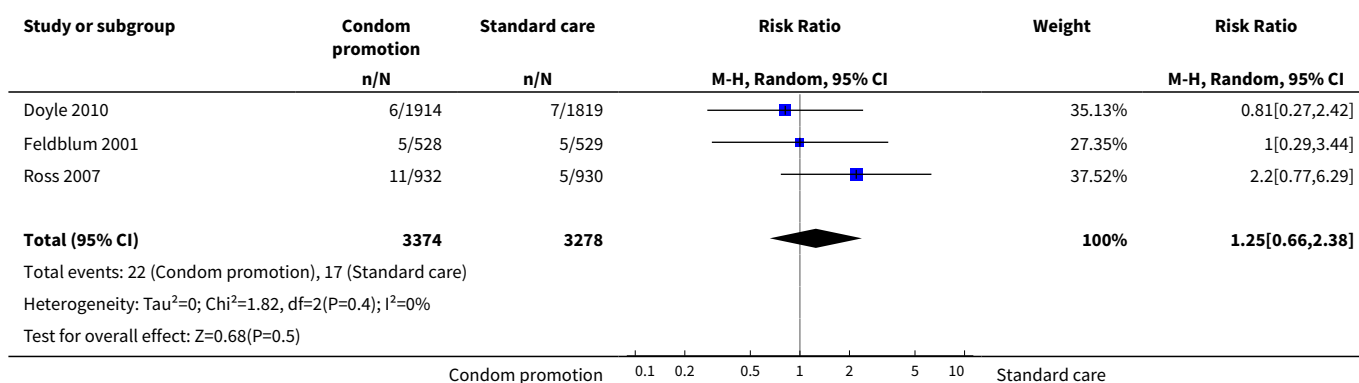
Analysis 2.3. Comparison 2 Stratified analysis: Condom promotion along with free massive condom distribution, Outcome 3 HSV-2 prevalence.



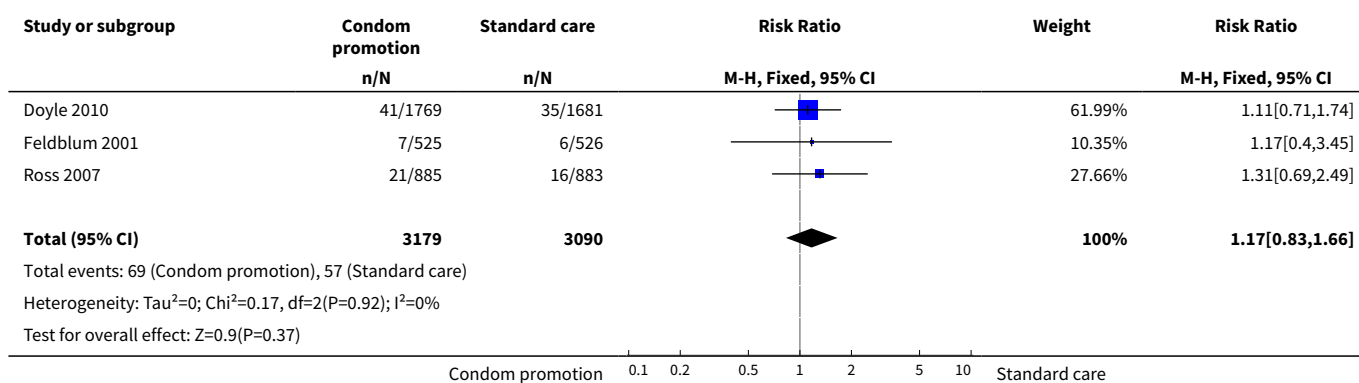
Analysis 2.4. Comparison 2 Stratified analysis: Condom promotion along with free massive condom distribution, Outcome 4 Syphilis prevalence (1:8 dilutions).



Analysis 2.5. Comparison 2 Stratified analysis: Condom promotion along with free massive condom distribution, Outcome 5 Gonorrhoea prevalence.



Analysis 2.6. Comparison 2 Stratified analysis: Condom promotion along with free massive condom distribution, Outcome 6 Chlamydia prevalence.



APPENDICES

Appendix 1. Search strategy

Title: Structural and community level intervention for increasing condom use to prevent the transmission of HIV and others STI

Database: WHO International Clinical Trials Registry Platform

Date: 1 April 2014

Search terms: HIV AND condom

Number of records retrieved: 29 records for 27 trials

Database: Clinicaltrials.gov

Date: 1 April 2014

Search strategy: HIV and CONDOM | Interventional studies | received from 01/01/1980 to 01/04/2014

Number of studies retrieved: 164 studies

Database: CLIB 2014, Issue 4 of 4 (1980 – 2014)

ID Search

Date: 1 April 2014

#1 MeSH descriptor HIV Infections explode all trees

#2 MeSH descriptor HIV explode all trees

#3 hiv OR hiv-1* OR hiv-2* OR hiv1 OR hiv2 OR HIV INFECT* OR HUMAN

IMMUNODEFICIENCY VIRUS OR HUMAN IMMUNODEFICIENCY VIRUS OR HUMAN

IMMUNE-DEFICIENCY VIRUS OR HUMAN IMMUNO-DEFICIENCY VIRUS OR

HUMAN IMMUN* DEFICIENCY VIRUS OR ACQUIRED IMMUNODEFICIENCY

SYNDROME OR ACQUIRED IMMUNODEFICIENCY SYNDROME OR ACQUIRED

IMMUNO-DEFICIENCY SYNDROME OR ACQUIRED IMMUNE-DEFICIENCY

SYNDROME OR ACQUIRED IMMUN* DEFICIENCY SYNDROME

#4 MeSH descriptor Lymphoma, AIDS-Related, this term only

#5 MeSH descriptor Sexually Transmitted Diseases, Viral, this term only

#6 (#1 OR #2 OR #3 OR #4 OR #5)

#7sexually transmitted disease*:ti,ab,kw OR sexually transmissible disease*:ti,ab,kw OR

sexually transmitted infection*:ti,ab,kw OR sexually transmissible infection*:ti,ab,kw OR

sexually transmitted infectious disease*:ti,ab,kw OR sexually transmissible infectious

disease*:ti,ab,kw OR sexually transmitted disorder*:ti,ab,kw OR sexually transmissible

disorder*:ti,ab,kw OR STI:ti,ab,kw OR STIs:ti,ab,kw OR STD:ti,ab,kw OR STDs:ti,ab,kw

#8 MeSH descriptor Sexually Transmitted Diseases explode all trees

#9 (#7 OR #8)

#10 (#6 OR #9)

#11 MeSH descriptor Community Networks, this term only

#12 (structural OR community OR communities OR school OR schools):ti,ab,kw

#13 (#11 OR #12)

#14 (#13 AND (intervention OR interventions))

#15 MeSH descriptor Health Knowledge, Attitudes, Practice, this term only

#16 MeSH descriptor Risk Reduction Behavior explode all trees

#17 (risk reduction OR risk reducing):ti,ab,kw

#18 (#15 OR #16 OR #17)

#19 MeSH descriptor Socioeconomic Factors explode all trees

#20 (socioeconomic OR socio economic OR social or economic*):ti,ab,kw

#21 MeSH descriptor Social Marketing explode all trees

#22 (#19 OR #20 OR #21)

#23 MeSH descriptor Public Opinion, this term only

Structural and community-level interventions for increasing condom use to prevent the transmission of HIV and other sexually transmitted infections (Review)

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#24 MeSH descriptor Women's Rights, this term only

#25 public opinion OR ((woman OR female OR women*) AND empower*)

#26 (#23 OR #24 OR #25)

#27 MeSH descriptor Mass Media explode all trees

#28 (media OR mass communication OR mass communications OR campaign OR campaigns):ti,ab,kw

#29 (#27 OR #28)

#30 MeSH descriptor Health Policy, this term only

#31 (legislation OR political OR policy OR legal OR subsidy OR subsidisation OR subsidization OR subsidies OR environment OR environmental OR access OR accessibility OR availability OR distribution):ti,ab,kw

#32 (#30 OR #31)

#33 (#14 OR #18 OR #22 OR #26 OR #29)

#34 (condom OR condoms):ti,ab,kw

#35 (#10 AND #33 AND #34)

#36 (#10 AND #33 AND #34), from 1980 to 2011

Database: PubMed (1980 – 2014)

Date: 1 April 2014

Search Most Recent Queries Time

#15 Search #11 AND #12 AND #13 Limits: Publication Date from 1980/01/01 to 2011/12/05

03:27:20

#14 Search #11 AND #12 AND #13 03:25:38

#13 Search (randomized controlled trial [pt] OR controlled clinical trial [pt] OR randomized [tiab] OR placebo [tiab] OR "clinical trials as topic"[mesh: noexp] OR randomly [tiab] OR trial [ti]) NOT (animals [mh] NOT humans [mh])

03:25:25

#12 Search Condoms[MH] OR condom*[tiab] 03:25:03

#11 Search #3 AND #10 03:24:49

#10 Search #4 OR #5 OR #6 OR #7 OR #8 OR #9 03:24:34

#9 Search legislation[tiab] OR health policy[mh] OR political[tiab] OR policy[tiab] OR legal[tiab] OR subsidy[tiab] OR subsidies[tiab] OR environment[tiab] OR environmental[tiab] OR subsidization[tiab] OR subsidisation[tiab] OR access[tiab] OR accessibility[tiab] OR

availability[tiab] OR distribution[tiab]

03:23:49

#8 Search mass media[mh] OR media[tiab] OR mass

communication[tiab] OR mass communications[tiab] OR

campaign[tiab] OR campaigns[tiab]

03:23:34

#7 Search public opinion[mh:noexp] OR public opinion[tiab] OR

women's rights[mh] OR ((woman[tiab] OR female[tiab] OR

women*[tiab]) AND empower*[tiab])

03:23:22

#6 Search socioeconomic factors[mh] OR socioeconomic[tiab] OR

socio economic[tiab] OR social marketing[mh] OR social[tiab] OR

economic*[tiab]

03:22:59

#5 Search health knowledge, attitudes, practice[mh] OR risk reduction

behavior[mh] OR risk reduction[tiab] OR risk reducing[tiab]

03:22:45

#4 Search (structural[tiab] OR community[tiab] OR communities[tiab]

OR school[tiab] OR schools[tiab] OR community networks[mh]) AND

(intervention[tiab] OR interventions[tiab])

03:22:38

#3 Search #1 OR #2 03:22:13

#2 Search sexually transmitted diseases[mh] OR sexually transmitted

disease*[tiab] OR sexually transmissible disease*[tiab] OR sexually

transmitted infection*[tiab] OR sexually transmissible infection*[tiab]

OR sexually transmitted infectious disease*[tiab] OR sexually

transmissible infectious disease*[tiab] OR sexually transmitted

disorder*[tiab] OR sexually transmissible disorder*[tiab] OR STI[tiab]

OR STIs[tiab] OR STD[tiab] OR STDs[tiab]

03:21:55

#1 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 immuno-deficiency virus[tw] OR human

03:21:36

Structural and community-level interventions for increasing condom use to prevent the transmission of HIV and other sexually transmitted infections (Review)

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immune-deficiency virus[tw] OR ((human immun*) AND (deficiency
virus[tw])) OR acquired immunodeficiency syndrome[tw] OR
acquired immunodeficiency syndrome[tw] OR acquired immunodeficiency
syndrome[tw] OR acquired immune-deficiency
syndrome[tw] OR ((acquired immun*) AND (deficiency
syndrome[tw]))

Database: EMBASE (1980 – 2014)

Date: 1 April 2014

No. Query

#16 #12 AND #13 AND #14 AND [humans]/lim AND [embase]/lim AND [1980-2011]/py

#15 #12 AND #13 AND #14

#14 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 volunteer*:ti OR
volunteer*:ab OR 'crossover procedure'/de OR 'crossover procedure' OR 'doubleblind
procedure'/de OR 'double-blind procedure' OR 'single-blind procedure'/de OR
'single-blind procedure' OR 'randomized controlled trial'/de OR 'randomized
controlled trial' OR allocat*:ti OR allocat*:ab

#13 'condom'/exp OR condom*:ab,ti

#12 #3 AND #11

#11 #4 OR #5 OR #6 OR #7 OR #9 OR #10

#10 'health care policy'/de OR legislation:ab,ti OR political:ab,ti OR policy:ab,ti OR
legal:ab,ti OR subsidy:ab,ti OR subsidies:ab,ti OR subsidisation:ab,ti OR
subsidization:ab,ti OR environment:ab,ti OR environmental:ab,ti OR access:ab,ti OR
accessibility:ab,ti OR availability:ab,ti OR distribution:ab,ti

#9 'mass media'/de OR media:ab,ti OR 'mass communication':ab,ti OR 'mass
communications':ab,ti OR campaign:ab,ti OR campaigns:ab,ti

#8 'public opinion'/de OR 'public opinion':ab,ti OR 'womens rights'/de

#7 empower* NEAR/3 (women OR female OR women*)

#6 'socioeconomics'/de OR socioeconomic*:ab,ti OR 'social marketing'/de OR
social:ab,ti OR economic*:ab,ti

#5 'attitude to health'/de OR 'risk reduction'/de OR 'risk reduction':ab,ti OR 'risk
reducing':ab,ti

#4 structural:ab,ti OR community:ab,ti OR communities:ab,ti OR school:ab,ti OR

schools:ab,ti OR 'community program'/de AND (intervention:ab,ti OR

interventions:ab,ti)

#3 #1 OR #2

#2 'sexually transmitted diseases'/exp OR 'sexually transmitted diseases' OR 'sexually

transmitted diseases, bacterial'/exp OR 'sexually transmitted diseases, bacterial'

OR 'sexually transmitted diseases, viral'/exp OR 'sexually transmitted diseases,

viral' OR (sexually AND transmitted AND disease*:ti OR sexually AND transmitted

AND disease*:ab) OR (sexually AND transmissible AND disease*:ti OR sexually AND

transmissible AND disease*:ab) OR (sexually AND transmitted AND infection*:ti OR

sexually AND transmitted AND infection*:ab) OR (sexually AND transmissible AND

infection*:ti OR sexually AND transmissible AND infection*:ab) OR (sexually AND

transmitted AND infectious AND disease*:ti OR sexually AND transmitted AND

infectious AND disease*:ab) OR (sexually AND transmissible AND infectious AND

disease*:ti OR sexually AND transmissible AND infectious AND disease*:ab) OR

(sexually AND transmitted AND disorder*:ti OR sexually AND transmitted AND

disorder*:ab) OR (sexually AND transmissible AND disorder*:ti OR sexually AND

transmissible AND disorder*:ab) OR sti:ti OR sti:ab OR std:ti OR std:ab

#1 'human immunodeficiency virus infection'/exp OR 'human immunodeficiency virus

infection' OR 'human immunodeficiency virus'/exp OR 'human immunodeficiency

virus' OR 'b cell lymphoma'/de OR 'b cell lymphoma' 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 immune-deficiency virus':ti OR

'human immune-deficiency virus':ab OR 'human immuno-deficiency virus':ti OR

'human immuno-deficiency virus':ab OR 'acquired immunodeficiency syndrome':ti

OR 'acquired immunodeficiency syndrome':ab OR 'acquired immuno-deficiency

syndrome':ti OR 'acquired immuno-deficiency syndrome':ab OR 'acquired immunodeficiency

syndrome':ti OR 'acquired immune-deficiency syndrome':ab OR

'acquired immunodeficiency syndrome':ti OR 'acquired immunodeficiency

syndrome':ab

HISTORY

Protocol first published: Issue 4, 2001

Review first published: Issue 7, 2014

Date	Event	Description
5 October 2011	New citation required but conclusions have not changed	New author team, and complete revision of protocol
6 January 2011	Amended	"Clean slate" for new author team
12 November 2008	Amended	Converted to RevMan 5 and re-published without new citation

CONTRIBUTIONS OF AUTHORS

Herfina Nababan (HN), Erika Ota (EO) and Windy Wariki (WW) designed, set up, and drafted the protocol. HN and Ralfh Moreno (RM) conducted both the selection of the articles and the risk of bias assessment. Any disagreement between HN and RM was resolved by EO. RM developed the protocol, and wrote the document. Stuart Gilmour (SG), Satoshi Ezoe (SE), and Jenji Shibuya (KS) commented upon and revised the article. All authors have approved the final review.

DECLARATIONS OF INTEREST

Ralfh Moreno declared not having any conflict of interest.

Herfina Nababan declared not having any conflict of interest.

Erika Ota declared not having any conflict of interest.

Windy Wariki declared not having any conflict of interest.

Satoshi Ezoe declared not having any conflict of interest.

Stuart Gilmour declared not having any conflict of interest.

Kenji Shibuya declared not having any conflict of interest.

SOURCES OF SUPPORT

Internal sources

- Department of Global Health Policy, Graduate School of Medicine, The University of Tokyo, Tokyo, Japan.

External sources

- Ministry of Health, Labour and Welfare, Health Labour Sciences Research Grant (No.13800128), Japan.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Title in the Review

The title slightly changed since the Protocol was published, from "Structural and community-level interventions for increasing condom use to prevent HIV and other sexually transmitted infections" to "Structural and community-level interventions for increasing condom use to prevent the transmission of HIV and other sexually transmitted infections."

Authors

The authors changed from "Nababan H, Ota E, Wariki WMV, Koyanagi A, Ezoe S, Shibuya K, Tobe-Gai R" in the last published protocol, to "Moreno R, Nababan HY, Ota E, Wariki WMV, Ezoe S, Gilmour S, Shibuya K" in this document.

Type of interventions

When a trial did not explicitly mention condom promotion but the intervention suggested it, authors were contacted (via email) in order to clarify whether condom promotion occurred or not.

Population

The protocol mentioned examples of 'communities', but without specifying the definition used during study selection. Nonetheless, this concept was crucial during the selection of trials as each study defined the term 'community' in a different manner. Therefore, the

selection criterion was based on the most accepted and common concept of community: “a geographic unit, such as counties, cities or villages” (Atienza 2002). Thus, trials conducted exclusively in 'smaller communities' such as schools, workplaces, brothels or others alike were ruled out.

Outcomes

The original primary outcomes were: reported condom use, HIV incidence or prevalence and STI incidence or prevalence. However, during the review process it was decided that in order to give strength to the review, intermediate outcomes (i.e. reported condom use) should be avoided as primary outcomes and as selection criteria. Instead, only those studies reporting biological data were included. Studies that solely contained self reported STIs without laboratory confirmation were excluded as well.

The initial secondary outcomes for this review were: knowledge about condom use (both self reported and tested), attitudes towards condom use (both self reported and tested), condom acquisition/procurement, stated intention to use condoms, negotiation skills around condom use (both self reported and tested), changes of other STI risk-related practices, including number of partners, 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), reported harms related to condom use, such as domestic violence, abuse or allergic reactions to latex, and comparative costs of interventions. However, for several reasons not all these outcomes were included in this review: first, most of these results were not reported in the original papers; second, if they were reported, it was difficult to include these results in a meta-analysis given the different presentation of the data; third, in this review 26 different results were already presented, so the addition of extra outcomes would have made the document difficult to follow given its extension.

Subgroup analysis and investigation of heterogeneity

The protocol stated that when possible, stratified analysis would be undertaken among participant subgroups. Subgroups included age, gender, and primary motivation for condom use (contraception and prophylaxis versus prophylaxis only). Additional stratified analyses divided studies according to methodological quality, when sufficient numbers were available. However, since outcomes were homogeneous for all results, subanalysis was deemed unnecessary.

Correction for cluster effect

In the original protocol it was stated that different statistical methods would be used when needed, without mentioning a specific strategy to calculate cluster effect and ICCs. Since it was not possible to find ICCs from authors, and a unique ICC value applied to all results taken from a trial with the same total population is inaccurate, we decided to use a linear regression model to find the missing ICCs.

INDEX TERMS

Medical Subject Headings (MeSH)

Adult; Chlamydia Infections [epidemiology] [prevention & control]; Condoms [*statistics & numerical data]; Gonorrhea [epidemiology] [prevention & control]; Health Promotion [*organization & administration]; Herpes Genitalis [epidemiology] [prevention & control]; Herpesvirus 2, Human; HIV Infections [epidemiology] [prevention & control]; Humans; Incidence; Prevalence; Randomized Controlled Trials as Topic; Sexually Transmitted Diseases [epidemiology] [*prevention & control]; Syphilis [epidemiology] [prevention & control]; Trichomonas Infections [epidemiology] [prevention & control]