Behavioural Interventions To Reduce The Risk Of Sexually Transmitted Infections In Genitourinary Medicine Clinic Patients: A Systematic Review

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West Midlands Health Technology Assessment Collaboration (WMHTAC)

The West Midlands Health Technology Assessment Collaboration (WMHTAC) produce rapid systematic reviews about the effectiveness of healthcare interventions and technologies, in response to requests from West Midlands Health Authorities or the HTA programme. Reviews usually take 3-6 months and aim to give a timely and accurate analysis of the quality, strength and direction of the available evidence, generating an economic analysis (where possible a cost-utility) of the intervention.

About InterTASC

West Midlands Health Technology Assessment Collaboration (WMHTAC) is a member of InterTASC which is a national collaboration with three other units who do rapid reviews: the Trent Working Group on Acute Purchasing; the Wessex Institute for Health Research and Development; York Centre for Reviews and Dissemination. The aim of InterTASC is to share the work on reviewing the effectiveness and cost-effectiveness of health care interventions in order to avoid unnecessary duplication and improve the peer reviewing and quality control of reports.

Conflicts of interest

The authors all declare that they have no conflicts of interest.

Contribution of the authors

This review was planned by DJW and RST with assistance from all authors. DJW developed the search strategy and together with BR undertook the searches, appraised the articles, and extracted the data. DJW analysed the data with the help of RST and HP. Writing up the report was principally done by DJW with input from all members of the review team. In particular, RST advised on systematic review methods and HP advised on behavioural interventions, their theoretical basis and application.

Acknowledgments

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West Midlands Regional Evaluation Panel Recommendation:

The recommendation for the use of behavioural interventions to reduce the risk of sexually transmitted infections in genitourinary medicine clinic patients was:

Not proven

The conclusions of the report were that certain behavioural interventions appeared to be effective in a US setting, and that the format and duration of the intervention was less important than study quality and careful development of the intervention through a process of formative research. These findings should be used to stimulate further research in a UK setting, which should also consider the acceptability and cost-effectiveness of any proposed intervention.

Anticipated expiry date: 2007

- This report was completed in August 2004
- The searches were completed in January 2004
- There appear to be no trials currently underway and we are not aware of any trials being planned in this area.

Contents

Summary

Background

The incidence of sexually transmitted infections (STIs) in the UK has doubled since 1991 reflecting changes in sexual behaviour, and pressures on genitourinary medicine (GUM) services have increased accordingly. Current best practice in GUM clinics includes brief education and advice about reducing risk and practising safer sex, yet many patients suffer repeat infections. Interventions that could modify behaviour among these individuals leading to a reduction in recurrent STIs could potentially be of great benefit.

Identified studies

Fourteen randomised controlled trials of behavioural interventions in various groups attending GUM type clinics were identified, of which twelve were conducted in the USA. The quality of studies was frequently poor and recruitment, adherence and follow-up rates were generally low. Interventions were varied in their number of sessions, format and theoretical basis. However, all sought to increase condom use, many incorporated behavioural skills training and most explored similar themes, often using role-play. Interventions offered to control subjects typically went beyond current UK practice, offering individualised counselling according to US guidelines[1, 2] as a minimum.

Evidence of effectiveness

This review did not find consistent evidence that behavioural interventions can reduce STI rates in the target population, though studies were generally effective at increasing the proportion of subjects reporting consistent condom use. Four studies reported a greater reduction in laboratory confirmed infection rates among their intervention groups, two of which were statistically significant ($p<0.05$). These studies included the two largest, recruiting adults of both sexes, and were generally of higher quality than others included in the review. Three were based on the theory of reasoned action or related social cognitive theory. Results were not apparently related to the number of intervention sessions or format. There was no consistent evidence that interventions reduced the number of new sexual partners or their risk characteristics.

Conclusions

Existing evidence does not support the immediate introduction of behavioural interventions into UK GUM clinics, though there was evidence to indicate that an appropriately tailored intervention could be effective in reducing STIs. In contrast, most interventions did increase the report of consistent condom use. The apparent contradiction between infection related and behavioural outcomes could be due to the inadequate power to detect changes to STI rates, or bias in the way these different outcomes were determined. Alternatively, condom use alone may relate poorly to overall STI risk, which is the sum of many complex aspects of behaviour. Additional research should aim to establish the effectiveness of interventions in a UK context while seeking to improve on the overall quality of studies. Research should also consider the feasibility and cost of introducing such interventions into routine practice.

1. Introduction

Sexually transmitted infections (STIs) are an important and increasing cause of morbidity in the UK, and may lead to long-term problems such as reduced fertility, pain, psychological distress and, particularly in the case of Human Immunodeficiency Virus (HIV), disability and death. The burden of infections is not distributed evenly within the population, and these inequalities are compounded by the stigma that accompanies STIs. Despite this, genitourinary medicine (GUM) clinics offering investigation and treatment for STIs are currently under increasing pressure and waiting times for appointments are rising.

This review follows a request by a local West Midlands GUM clinician who sought evidence on whether offering a behavioural intervention to clinic patients would reduce their likelihood of re-infection and re-attendance. The request was initially directed to the Aggressive Research Intelligence Facility (ARIF) based at the University of Birmingham. This group seeks to assist health care workers and commissioners access and interpret reviews of research evidence to address particular problems, but no systematic review of the topic was found.[3] Thus, the request was passed to the West Midlands Health Technology Assessment Collaboration where, in view of its public health and policy implications, the topic was selected for systematic review.

2. Background and problem identification

2.1 Sexually transmitted infections in the UK

STIs comprise a varied range of parasitic, bacterial and viral infections for which intimate sexual contact forms the major route of transmission.[4-6] These infections are clinically heterogeneous (appendix 1). Depending upon the organism, they may be acute or chronic, resulting in long-term effects on health, and they may also be asymptomatic (for instance genital chlamydia), increasing the potential for onward transmission.

The rate of known acquisition of STIs is rising in the UK and other developed countries[5-8] and the number of clinical episodes occurring annually in UK specialist services almost doubled during the period 1991-2001.[7] Using data compiled by the Health Protection Agency (and previously by the Public Health Laboratory Service)[7, 8] it is possible to estimate that over 46,000 diagnoses of new STIs (see Appendix 1) were made in GUM clinics from the West Midlands NHS Region during the year 2001. Of these 50 were infectious syphilis, over 2700 were cases of gonorrhoea, 6600 uncomplicated genital chlamydia, 1600 genital herpes simplex infection (first attack), and 5600 genital warts (first attack). Re-infection is thought to be common, but it is not possible to quantify this using routine data. However, in 1996 England-wide study of risk factors for gonorrhoeal infection[9] found that 22% of new cases had previously been diagnosed with an acute STI while 44% had previously attended a GUM clinic and presumably received existing standards of advice about safer sex and reducing risk.

Data from GUM clinics may underestimate the total burden of infection. Diagnoses made elsewhere in the NHS are not included, many infections are asymptomatic, and the figures are influenced by the accessibility of clinics and uptake of services.[7, 8] Prevalence surveys in other settings such as antenatal and gynaecological clinics, general practice, family planning and termination of pregnancy services also show high levels of genital chlamydia in young women, ranging from 4.5% to 16%.[6]

STI rates are not distributed evenly across the population. The highest burden of infection falls upon young people, particularly teenage women and men aged 20 to 24 years old,[7, 8] and young people may be at particular risk of re-infection.[8] Homosexual and bisexual men are also at increased risk of STIs. In the UK, the number of new HIV infections acquired through sex between men has increased since 1999, now making it the third most common diagnosis made in this group.[8] Higher rates are also seen among those affected by poverty and social exclusion (e.g. young offenders and prisoners, sex workers[6]), and those from black and ethnic minority communities.[4, 5, 7, 8] In some urban centres, this latter group suffers STI rates that are more than ten-times the rate among local white groups,[6] and gonorrhoea rates are particularly high in some UK black communities.[10]

2.2 Specialised services for STIs in the UK

In the UK, specialist STI screening, assessment, diagnosis, treatment and contact tracing services are available from GUM clinics (and some family planning clinics).[6] There are 22 such clinics in the West Midlands NHS Region based in both community and hospital settings that offer a confidential service to patients who self-refer or who are referred from other health services. Traditionally, clinics offered a direct open-access service to patients from anywhere in the country. However, pressures on the service and rising clinic workloads due to increasing numbers of infections, increased awareness of services, increasingly complex management of cases (especially HIV) and increased involvement in sexual health promotion have led to the widespread adoption of appointment systems with mean UK waiting times of almost two-weeks.[5, 6] Importantly, long-waiting times for treatment may increase the potential for disease transmission[5, 11] and increase the complexity of cases once they are seen.[6]

GUM clinics are consultant led, but work as multidisciplinary teams, typically employing a range of medical, nursing and other health professionals.[6] These include 'health advisors' who may be involved with pre and post HIV test counselling as well as partner notification. Typically, care for a patient with an STI will include brief educational advice about reducing risk and practising safe sex from the treating clinician [personal communications: D. Natin, Chair of the Regional GUM Services Committee, Warwick Hospital, 2002 and K. Radcliffe, Consultant in GUM, Birmingham Whittall Street Clinic, 2002]. This should be tailored to the individual's circumstances and may also include the provision of written materials and possibly referral to other (voluntary) initiatives seeking to promote safer sex in particular locations or risk groups.[12] Current services in the West Midlands and elsewhere do not include specific behavioural interventions that aim to reduce re-infection and re-attendance rates [personal communication: D. Natin, 2002].

In the USA, guidelines on the content and delivery of brief counselling for patients with STIs is available from the Centers for Disease Control and Prevention (CDC).[1, 2] These emphasise working with the patient to identify their personal risk factors for infection and then delivering specific messages about the actions that the patient can take to reduce their risk. These guidelines provide a more structured approach to risk-reduction advice that goes beyond what is currently offered in the UK.

2.3 Sexual health policy

The UK Government is currently implementing the 'National Strategy for Sexual Health and HIV'.[4, 8, 13] Amongst other aims, the strategy seeks to reduce transmission and undiagnosed infection by education and information, improving the evidence base for local prevention efforts, setting targets for the reduction of newly acquired cases of HIV and gonorrhoea (25% reduction in annual rates by 2007), and ensuring the needs of high-risk groups are met.[13] It is anticipated that local services will be arranged into networks offering services at different levels of care with increased primary care involvement over time in the assessment of those with STI symptoms. The capacity of GUM services and primary care to meet these challenges has been questioned[6, 13] and the demands on new resources is likely to be great.[13, 14] There is a need to systematically review the evidence base for prevention efforts prior to commissioning new services[15, 16] or further research.[17]

2.4 Sexual behaviour and risk

Increased transmission rates of all STIs are associated with similar specific sexual behaviours. These include age at first intercourse, the number of lifetime sexual partners, frequency of new partners, concurrent partners, and unsafe sex (unprotected by a barrier method of contraception, particularly the male condom).[5, 7, 8] Thus, at the individual level reducing the risk of all individual STIs (first or subsequent) requires similar health promotion messages.

Information from the National Survey of Sexual Attitudes and Lifestyle (NSSAL) shows condom use in the UK has increased since 1990. However, the average lifetime number of heterosexual partners and concurrent partnerships has also risen, more men report paying for sex, and the age at first intercourse has fallen.[5] Unsafe sexual practices among gay and bisexual men have also risen, as has the proportion of men reporting ever having a homosexual partner.[5] Overall, high-risk behaviour, defined in the NSSAL as "*two or more heterosexual and homosexual partners in the past year and inconsistent condom use in the past 4 weeks*",[6] rose from 13.6% in men and 7.1% in women to 15.4% and 10.1% respectively during the period 1990 to 2000.

The US CDC suggest five approaches to the prevention and control of STIs[2]: (i) education and counselling of those 'at-risk' to adopt safer sexual behaviour, (ii) identification of those with asymptomatic infections (or symptomatic but unlikely to seek diagnosis and treatment), (iii) effective diagnosis and treatment of those infected, (iv) evaluation, treatment and counselling of the sex-partners of those with STIs, and (v) pre-

exposure vaccination of those at-risk of vaccine preventable STIs. Individuals attending GUM clinics may be regarded as an at-risk group.

The most recent CDC guidelines[2] suggest that the following risk-reduction messages represent effective means of preventing STIs (in addition to vaccination where appropriate). The most reliable means of prevention is considered to be abstinence from sexual intercourse (oral, vaginal or anal) or a long-term mutually monogamous relationship with an uninfected partner (both partners should tested for STIs prior to sexual intercourse). If a person has sex with someone of unknown infection status, a new condom should be used for each act of intercourse. Those being treated for an STI, who have suggestive symptoms, or whose partners are being treated should not have sex. When used correctly, condoms (male and female) are effective in preventing STIs,[2, 18, 19] particularly those transmitted from bodily fluids to mucosal surfaces (e.g. gonorrhoea, chlamydia, trichomonas, HIV). They are less effective at preventing STIs transmitted from skin-to-skin contact (e.g. herpes simplex and human papilloma viruses, syphilis). Contraceptive sponges and diaphragms are probably not effective in preventing most STIs and are not recommended,[2] while spermicides containing nonoxynol-9 do not offer additional protection against STIs and may potentially increase HIV transmission, especially when used rectally.[2, 20, 21]

2.5 Effectiveness research and behavioural interventions

2.5.1 Behavioural influences and theory

In the context of preventing STIs, a behavioural intervention is one that seeks to alter aspects of an individual's behaviour(s) that lead to transmission of infection.[22] Sexual behaviour is influenced by a range of individual, social, economic and cultural factors.[10, 23] These modifying factors include a lack of self-esteem or skills in negotiating safer sex, perceived social norms and the views of peers, access to condoms or health services, and the use of alcohol or drugs.[15, 24] Interventions designed to influence sexual behaviour are therefore complex and need to be considered in the context of where, and to whom, they were delivered. Thus, as a minimum, the sexuality, gender, age, ethnicity and location of subjects, as well as the individual components and theoretical basis of an intervention should all be considered.

Complex interventions consist of many individual elements to which individual subjects may respond differently. Theory provides an "*explicit framework to enable a thorough consideration of what factors must be addressed to bring about the desired……change*"[23] by describing the determinants of individual or social behaviour, and the factors that promote or constrain behaviour change. Health promotion theories and models (section 5.1.5) also seek to categorise and prescribe approaches to different situations. Some authors suggest that interventions to prevent STI and HIV based on theory are more effective at changing behaviour than those that are not[24, 25] while others have found no such relationship.[15] In any case, no one model would be expected to fit all situations and not all its components may be required to construct an effective approach; in this context, theories and models are not mutually exclusive.[16, 24]

2.5.2 Study design

To determine whether an intervention is effective requires that a positive health outcome is associated with exposure to the intervention in question, while attempting to minimise the possibility that the association arose because of confounding (a factor that is associated with both the outcome and receipt of the intervention) or bias (baseline differences between those who received the intervention and those that did not, or differences in the care or assessment these groups subsequently receive). A control group receiving a different intervention from that being studied (ideally usual care) is extremely important in order to ascribe health outcomes to the experimental intervention.[25, 26] The acquisition of an STI itself may be an important modifier of behaviour, and changes to sexual behaviour and STI risk following this event may simply represent regression to the mean.[27]

Ideally, outcomes will relate to the incidence of infection,[25] but intermediate measures detailing behaviour change may be acceptable where there is a clear direct or indirect[26] pathway to STI rates, e.g. condom use or improved sexual negotiation skills (indeed behaviour change should be a precursor to health outcomes). Well-conducted experimental studies, specifically randomised-controlled trials (RCTs), represent the most rigorous approach to this task.[22, 23]

However, the use of RCTs to evaluate behavioural interventions is not without criticism. One objection relates to the idea of withholding a potentially effective intervention from the control group. Yet this presupposes that behavioural interventions can do no harm, an idea that has been refuted many times.[23, 26] Authors have also suggested that randomisation may be impractical where communities participate in planning and delivering an intervention,[23] control-group subjects may also be exposed to the intervention message,[23] it may be impossible to 'blind' participants and researchers to treatment allocation,[26] and the results of RCTs are unlikely to be useful or generalisable because of difficulties in standardising the content or social context of an intervention.[28] The difficulty in performing RCTs of complex behavioural interventions should not be underestimated,[26] but the inherent advantages of this trial design for determining the clinical effectiveness of an intervention, particularly for health service decision-makers, mean that this review focuses on RCTs.

2.6 Existing reviews of behavioural interventions to reduce STIs among GUM clinic patients

A scoping search[29] (appendix 2) was undertaken to identify existing systematic reviews of this topic (section 4.2). Ten reviews considering behavioural interventions in a range of clinical settings were found, but none focussed on studies of patients attending GUM (or equivalent) clinic settings. One review, published in 2000,[25] considered only RCTs with an outcome that included measurement of STI rates, though the search strategy was also not stated. Studies published up to 1999 were included (though the end date for searches was not stated) and the authors conclude that just two out of the seven included studies presented evidence that their interventions were effective in reducing STIs. Most studies were judged to be of poor quality, with inadequate methods of allocation and

blinding, low power, and poor rates of recruitment, intervention adherence and follow-up. The authors did not attempt to pool results because of a high degree of clinical heterogeneity.

Of the remaining nine,[30-38] two considered studies recruiting only men,[31, 34] one only women,[33] and four only heterosexuals.[30, 31, 34, 38] All included non-RCTs and observational studies, five considered a wider range of interventions including the provision of educational materials alone[31-33, 35-38] (and considered studies measuring change in knowledge or attitudes alone), and three[30-32] included only those conducted in North America. Additionally, one review[36] only considered studies demonstrating a favourable outcome! Most reviews reported that the majority of studies identified demonstrated favourable outcomes irrespective of the clinical setting. The effectiveness of interventions was related to their duration,[32, 33, 35] theoretical basis,[33, 35, 36] and the use of behavioural skills training,[34, 36] peer educators,[33, 36] personal goal setting,[36] and community or culturally appropriate strategies.[36, 38] However, most reviews considered effectiveness in terms behaviour change only, with few reporting effects on STI rates.[30, 31, 34] Authors also emphasised the poor quality of evidence available, with small sample sizes, non-equivalent control groups or failure to report baseline data, short follow-up and high loss to follow-up.[31, 33, 37, 38]

Reviews of related topics were also retrieved, including the use of video based education in STI clinics[39], HIV counselling and testing[40], population-based approaches for reducing STI and HIV infection[41], strategies to improve partner notification and contact tracing,[42] and sexual behaviour interventions to prevent cervical cancer.[43]

3. Question addressed by the review

This report aims to systematically review the available evidence regarding the following specific question:

What is the clinical effectiveness of behavioural interventions in reducing the risk of acquiring a sexually transmitted infection or re-infection among patients attending genitourinary medicine or sexual health clinics?

4. Methods for review of clinical effectiveness

The methods used are based on the guidelines set out by the NHS Centre for Reviews and Dissemination.[29] A review protocol was produced that was informed by the findings of a scoping search (appendix 2).

4.1 Criteria for included studies

Inclusion and exclusion criteria (Table 1) were defined with reference to the review question (section 3) and included questions of study design and quality. Only studies meeting all criteria were included.

A standard inclusion criteria form (appendix 3) was used by DJW to assess all potential studies selected for full review (section 4.2). All studies thought to meet the inclusion criteria and a 20% random sample of those that did not were also independently assessed by BR and disagreements identified, discussed and resolved. The degree of inter-observer agreement was assessed using a Kappa (κ) statistic.[44] There was no disagreement in the assessment of studies initially thought to meet the inclusion criteria, and overall the score was $\kappa=0.70$, indicating good agreement after allowing for the effects of chance. The review protocol allowed for referral of ongoing disagreements to a third reviewer (RST), but this was not necessary.

Table 1. Inclusion and exclusion criteria.

	Inclusion	Exclusion
Population	Any person attending a GUM or equivalent sexual health clinic[a] with an acute problem regardless of referral method	Studies primarily aimed at those with known HIV infection or AIDS
Interventions	Any behavioural intervention delivered to individuals or small groups that aims to reduce the future likelihood of acquiring an STI	Simple provision of educational materials, partner notification strategies or counselling only as a component of HIV testing
Comparators	Any	None
Outcomes	Subsequent rates of laboratory or clinically determined STIs. Where these are unavailable, self-reported STI rates or quantifiable changes in sexual behaviour[b]	Studies that consider only levels of knowledge, attitudes, intentions or beliefs only
Study design and quality	RCTs	Non-RCTs, RCTs that have not finished recruiting, publish only baseline characteristics, or results for a small proportion of participants

a. Public clinic offering free services and self-referral for the screening, investigation, diagnosis and treatment of STIs.

b. E.g. frequency and rate of condom use, number of sexual partners, etc.

4.2 Search strategy

An initial scoping search (appendix 2) involving four electronic databases (Table 2) was conducted to identify literature relevant to the background of the report, identify existing systematic and non-systematic reviews of the topic (section 2.6), estimate the size of the literature, and help develop the inclusion and exclusion criteria and data extraction forms.[29]

A comprehensive search involving 10 electronic databases (Table 2) was undertaken to identify primary completed and ongoing research. No language restrictions were set and the search used a published filter for identifying RCTs.[29] Full details of the search terms are presented in appendix 2. In addition, local specialist clinicians advised on published and ongoing trials and the citation lists of reviews identified in the scoping search and studies included in the review were inspected for further relevant studies.

Table 2. Bibliographic and other databases searched for this review.

Search and date conducted	Databases (full details in appendix 2)	Date and year(s) or issue searched
Scoping search (17/09/02 to 19/09/02)	MEDLINE (Ovid) Cochrane database of systematic reviews Database of Abstracts of reviews of effectiveness (DARE) Health technology assessment (HTA) database	1966 to September 2002 week 2 2002 Issue 3, no date restrictions No date restrictions No date restrictions (last update 12/09/02)
Primary completed and ongoing research (20/01/04 to 30/01/04)	MEDLINE (Ovid) CINAHL Embase PsychINFO Applied Social Sciences Index and Abstracts (ASSIA) Cochrane library controlled clinical trials register (CCTR)	1966 to week 3 January 2004 1982 to end December 2003 1980 to week 4 January 2004 1985 to 'current' (search date 30/01/04) 1987 to 'current' (search date 30/01/04) 2004 Issue 1, no date restrictions
Ongoing research only (30/01/04)	National Research Register	2004 Issue 1, no date restrictions

4.3 Quality assessment strategy

Included studies were quality assessed to identify potential problems with the validity of individual results (biases) and to permit comparisons between studies and sensitivity analyses. Poor quality controlled trials have been shown to overestimate positive treatment effects.[45] Factors considered important for internal study validity were based on the Jadad scoring system[46] and included the method of randomisation, concealment, blinding, completeness of follow-up and the use of intention to treat (ITT) analyses.

A standard form (appendix 4) was used by both DJW and BR independently to collect quality information on all included studies. As for study inclusion (section 4.1), disagreements were resolved by discussion. For each study, a total Jadad score was calculated. However, difficulties in blinding participants and investigators in behavioural trials were expected and total scores may therefore be low and insensitive to differences in quality. Thus, subcategories of the Jadad score were also considered separately.

In addition to the internal validity of each trial, factors related to the generalisability of study results and the potential implementation of study interventions were also collected and considered alongside study quality, namely the recruitment rate among those eligible for inclusion and the rate of adherence with the experimental programme. Trials identified by the initial scoping search had shown relatively poor recruitment rates, low intervention adherence and in some cases a high proportion of participants lost to follow up.

4.4 Data extraction strategy

A standard data extraction form was developed and piloted on a small number of trials identified during the scoping search (appendix 5). Data on all included studies were extracted by DJW and these were then checked by a second reviewer (BR) in a random 20% sample of studies.

4.5 Review analysis and data synthesis

Results were initially collated into tables and assessed qualitatively, taking into account any observed clinical heterogeneity between studies (i.e. population, intervention, comparator). Where outcomes reported by different trials were considered equivalent, results were displayed using forest plots and meta-analysis was conducted using 'Review Manager' software (version 4.2, The Cochrane Collaboration 2003). Random effects (RE) models were used throughout.

Where possible, measures of effect for each trial outcome were recalculated using data presented in the paper. Results for dichotomous outcomes were expressed as the relative risk (RR) and absolute risk difference (ARD). For continuous outcomes, the data were first expressed as the mean and standard error (SE) of the within-subject change from baseline for the intervention and control groups separately. The overall measure of effect for an individual study is then the difference between these two mean values (mean difference). Meta-analysis of study estimates presented as mean differences results in a weighted mean difference (WMD).

Typically the study data were not reported as within-individual differences, but as the mean value and standard deviation (SD) for each group at baseline and follow-up points. While the mean difference may still be calculated directly from these data, pooling of the SDs fails to take into account their lack of independence and may be overinflated.[47, 48] To correct for this, the pooled SD is adjusted by an amount related to the within-subject correlation coefficient (r). Where an estimate of r could not be obtained from the paper

or other literature, r=0.5 was assumed. Adjusted results were subjected to a sensitivity analysis, recognising that the degree of within-subject correlation is likely to vary by outcome and population (e.g. gender, age, location, ethnicity, sexuality and culture). For this purpose, plausible ranges of values were chosen (i.e. r=0.10 to 0.75).[49, 50]

5. Clinical effectiveness results

5.1 Studies identified by the review

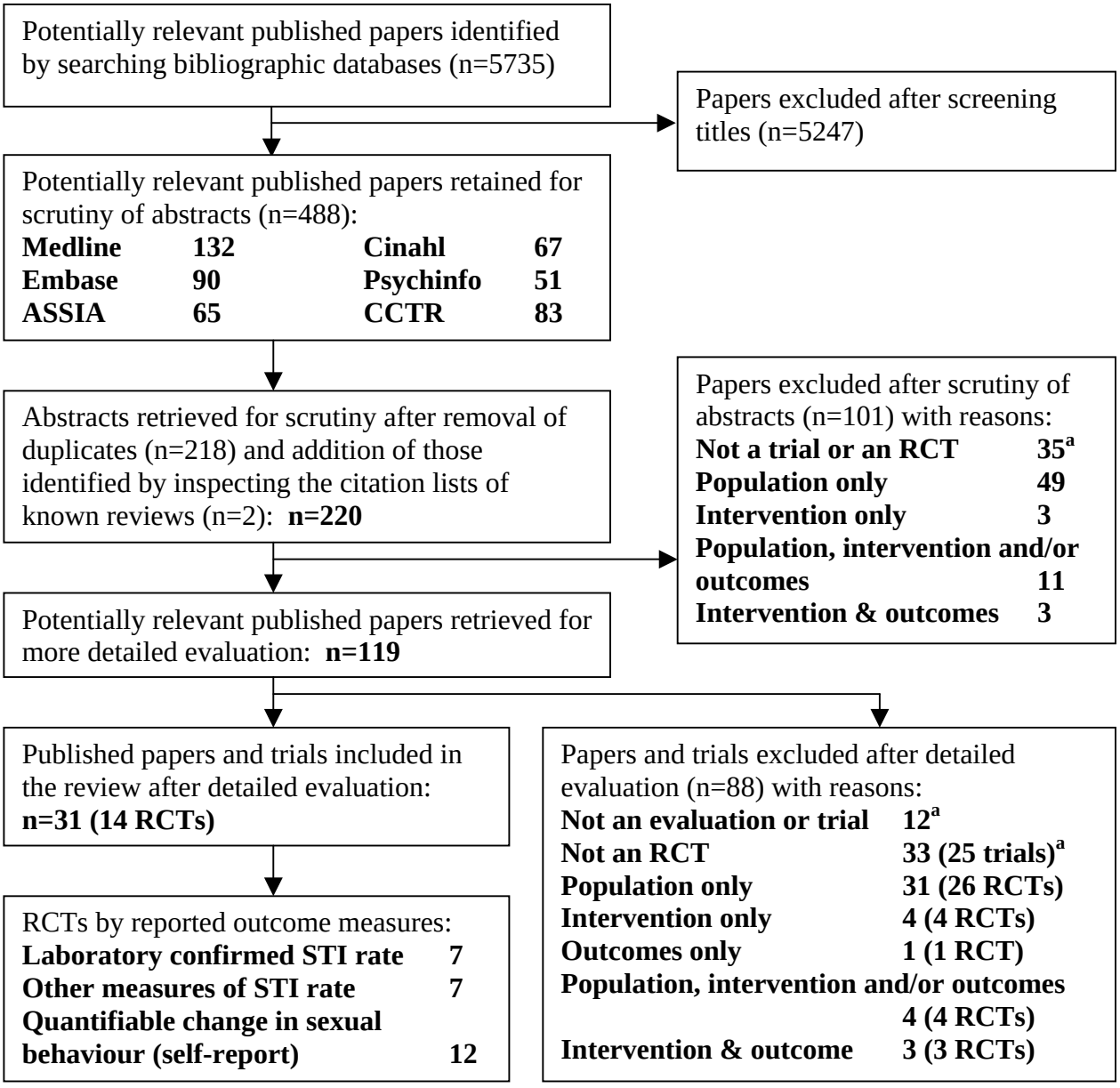
5.1.1 Quantity of identified studies

The search strategy (section 4.2) initially identified a very large number of papers for consideration (Figure 1), and the titles of these were screened by DJW before obtaining the abstracts of papers that did not clearly indicate a different topic of interest from that under investigation. This process reduced the potential number of papers to 488, of which 218 remained after removing duplicates. Finally, before detailed evaluation, almost half of these papers were rejected after reviewing their abstracts. The most common reason for exclusion was that the study population was not recruited from those attending GUM clinics or their equivalent (appendix 7).

Inspecting the citation lists of included studies and known reviews identified only two additional papers for consideration, neither of which were subsequently included. No ongoing relevant research was identified and clinicians did not suggest any trials in addition to those identified.

During detailed evaluation of the remaining 119 papers, extensive multiple publications from a smaller number of studies were identified (n=77, plus 12 papers which did not present information from a trial or other evaluation of an intervention). Of these, 14 RCTs were subsequently included in the review (appendix 6). The excluded trials (appendix 7) were mostly rejected as either not being an RCT or studying a population not recruited from the setting of interest.

Figure 1. Flowchart indicating the inclusion and exclusion of published papers and trials for review. Adapted from Moher *et al.* 1999.[62]



a. No further details reported on those papers or trials not reporting evaluations or RCTs.

5.1.2 General characteristics of studies included in the review

The general characteristics of studies included in this review are summarised in Table 3. In the case of multiple publications from a single trial, individual studies are identified by a principal citation only (appendix 6).

Almost all of the 14 included studies were conducted in North America. The two exceptions were conducted among men in London[12] and Kenya.[51] Three studies recruited participants from other settings in addition to a GUM or equivalent clinic. The National Institute of Mental Health (NIMH or Project LIGHT) trial included female patients from inner-city care health service organisations (HSOs) delivering primary care and community services,[52] female adolescents were recruited from family planning services in Indiana, USA,[53] and inpatients were included in the study of young women in Boston.[54] The earliest study identified began during 1986,[55] with the latest ending in 1998.[54] The mean follow-up period was less than 9 months, with a maximum period of one-year, and most studies reported using monetary and other incentives to improve retention rates.

The number and characteristics of participants recruited to the included studies varied widely (Table 4). In total, studies recruited over 14,000 participants of whom approximately two-thirds were enrolled in just two multi-centre studies.[52, 56] Seven studies recruited both males and females, of which two restricted entry to heterosexual men only[56, 57] and four did not specify the sexuality of their subjects. Of the remainder, four enrolled only males (one study, from London, recruited only homosexual men[12], one recruited only heterosexuals[58], and two, from Kenya and Miami, USA, did not state the men's sexuality[51, 59]) and three only females.[53, 54, 60]

Three studies were concerned only with adolescent[53, 61] and young (14-23 years)[54] subjects, two of which recruited only females. The remaining studies mostly restricted their recruitment to adults, with a lower age limit of between 16 and 20 years (where stated). The exception, a large multi-centre study reported by Kamb,[56] included participants as young as 14. Typically Black and African American subjects were the major ethnic group recruited by most studies, with Hispanic groups also prominent, reflecting the communities most represented in deprived inner-city and urban American centres (the Kamb study did not report ethnicity data). In contrast, a study of adolescents from Oregon, USA[61] and of homosexual men from London[12] recruited a group of subjects who predominantly labelled themselves as white.

Most studies reported a high rate of new or recently diagnosed STIs at enrolment. In nine cases, eligibility was based on those with newly diagnosed STIs and/or their partners,[12, 51, 53-55, 59, 60] or those with a recent history of STI.[57, 63] Three studies recruited only those reporting specific sexual behaviours seen as increasing the risk of STIs[12, 52, 61](principally recent unprotected sex), one of which, the large multi-centre NIMH study, noted that almost three-quarters of its subjects reported ever having suffered an STI. Two studies excluded those refusing an HIV test,[56, 63] including the study by Kamb. This large multi-centre study did not restrict entry by diagnosis or behaviour, yet reported a 32% STI rate at baseline.

Table 3. Summary of the general characteristics of included studies.

Study	Population and setting	Study dates	Cash incen -tive	Intervention and control conditions	Follow -up period
Kamb 1998[56] Project RESPECT	Heterosexual men & women from 5 public STI clinics in the USA	July 1993 to Sept 96	Yes	Enhanced (4 sessions) or brief (2 sessions) individual counselling vs. information session	12 months
NIMH 1998[52] Project LIGHT	Men & women from 37 inner-city public STI clinics and health service organisations (HSO) in the USA	Jan 1994 to Feb 96	Yes	Six single gender small group sessions vs. AIDS education session	12 months
Balmer 1998[51]	Men from a public STI clinic, Nairobi, Kenya	Not stated	Not stated	Twenty-six small group sessions vs. usual care	6 months
Boyer 1997[57]	Heterosexual men & women from a public STI clinic, San Francisco, USA	Jan 1992 to Jan 93	Yes	Individual counselling (4 sessions) vs. usual care	5 months
Branson 1998[63]	Men & women from a public STI clinic, Houston, USA	March 1992 to June 1993	Yes	Five small group sessions vs. usual care	12 months
Imrie 2001[12]	Homosexual men from a GUM clinic, London, UK	Sept 1995 to Nov 97	No	One day workshop vs. usual care	12 months
Kalichman 1999[58]	African American heterosexual men from a public STI clinic, Atlanta, USA	Not stated	Yes	Two group sessions vs. time matched information and discussion sessions	6 months
Maher 2003[59]	Black young men and male adolescents from 4 public STI clinics, Miami, USA	Sept 1994 to Dec 1995	Yes	Individual intensive counselling (3 sessions) vs. usual care	12 months
Metzler 2000[61]	Male & female adolescents from 3 public STI clinics, Oregon, USA	Not stated	Yes	Individual counselling (5 sessions) vs. usual care	6 months
O'Leary 1998[64]	Men & women from 7 public STI clinics in Maryland, Georgia & New Jersey, USA	Not stated	Yes	Seven small group sessions vs. usual care	3 months
Orr 1996[53]	Female adolescents from public STI and family planning clinics, Indiana, USA	Not stated	No	Individual counselling session vs. usual care	6 months
Shain 1999[60]	Hispanic and African American women from public STI clinics in San Antonio, Texas, USA	Jan 1993 to July 1994	Yes	Three small group sessions vs. usual care	12 months
Shrier 2001[54]	Young women with cervicitis or PID from a children's hospital clinic or inpatient facility, Boston, USA	July 1996 to July 98	Yes	Individual counselling session and subsequent reviews vs. usual care	12 months
Solomon 1989[55]	Men & women from a public STI clinic, Boston, USA	1986	Not stated	Videotape presentation in addition to usual care	Not stated

Table 4. Characteristics of the participants recruited to each study and subsequently randomised to intervention and control groups.

Major citation	Main inclusion criteria	Main exclusion criteria[a]	n	Female	Age (years)	Ethnicity	Baseline STI history	Comments
Kamb 1998[56]	Aged >14 years and HIV test negative	Men with male partner in last year	5758	43%	Not reported	Not reported	32%	Little demographic data presented
NIMH 1998[52]	Aged ≥20 years (STI clinic) or ≥18 years (HSO) reporting unprotected sex with new/high-risk partner in last 90 days	None reported	3706 (34.5% HSO)	42% of STI pop[n] 100% of HSO pop[n]	25% <25	African American 74%, Hispanic 25%	STI ever 73%	Groups demographically similar, 7% men report sex with male within 3 months
Balmer 1998[51]	Current STI (males only)	None reported	240	0%	Not reported	Kenyan	4% vs. 16% (control) HIV +ve	Groups said to be similar but no demographic data presented
Boyer 1997[57]	Heterosexuals aged 18-35 years with history of STI, current STI symptoms or partner of STI patient	None reported	399	49%	42% <25 35% >29	African American 46%, Hispanic 15%	STI ever 61%	Groups said to be similar but demographic data not presented separately
Branson 1998[63]	Attending with new problem and with history of STI in past 5 years	Refused HIV test or HIV +ve	964	43%	19% <20 28% 20-24 30% 25-34 23% >34	Black 90%	48%	Groups demographically similar
Imrie 2001[12]	Homosexual men with acute STI and/or history of unprotected anal intercourse/concerns about sexual practices	None reported	343	0%	Median 29, range 18-58	White 91%	See inclusion criteria	Groups demographically similar

Kalichman 1999[58]	African American heterosexual men waiting to see clinician	Male sex partner (last 3 months)	117	0%	Mean 33, range 18-50	African American 100%	Not reported	Groups said to be similar but demographic data not presented separately
Maher 2003[59]	Black men aged 16-29 attending clinic with a diagnosed (or clinically probable) STI	None reported	581	0	Mean 23.6 range 16-29	Black 100%	Inclusion criteria	Groups demographically similar
Metzler 2000[61]	Aged 15-19 with multiple partners, non-monogamous partners or no condom use (past 3 months)	None reported	339	68%	Mean: males 18, females 17 (32% <17)	White 68%, African American 12%	Not reported	Groups said to be similar but demographic data not presented separately
O'Leary 1998[64]	In clinic waiting area, aged 17-44 years and completing baseline interview	None reported	659	41%	Mean 30	Black 91%, Hispanic 3%	Not reported	Groups said to be similar but demographic data not presented separately
Orr 1996[53]	Females aged 15-19 years treated for confirmed *Chlamydia trachomatis* genital infection	None reported	209	100%	Mean 17.9, range 14-19	Black 55%	See inclusion criteria	Groups said to be similar but demographic data not presented separately
Shain 1999[60]	Heterosexual women attending clinic with nonviral STI	None reported	617	100%	Mean 21.6 36% <19	68% Mexican American, 31% African American	Inclusion criteria	Groups demographically similar
Shrier 2001[54]	Females aged <24 years presenting with gonococcal/ chlamydial cervicitis or admitted for confirmed PID	Pregnancy	123 (52% PID)	100%	Median 17.5, range 13.9-22.0	Black 49%, Hispanic 18%, White 14%	STI ever 44%	Groups demographically similar
Solomon 1989[55]	Clinic patient ≥18 years returning for test of cure or specialist follow up	No access to telephone	182	19.8%	Median 24, range 18-73 (83% <30)	Black 85%	Not reported	Groups said to be similar but demographic data not presented separately

a. Other than language proficiency or because of involvement in formative research or pilot study.

5.1.3 Stated aims of studies employed by the review

For each included study, the choice of intervention and its theoretical basis should be considered in the light of its study aims. Eight stated that their aim was to reduce the occurrence of new STIs in the study population,[12, 53, 54, 56, 57, 59, 60, 63] five of which stated that this was in the context of changing sexual behaviour.[53, 54, 56, 60, 63] Two of these studies,[53, 54] recruiting adolescent and young women, specified increased condom use as their desired behavioural change. One additional study,[55] aimed to increase the redemption of condom coupons.

The remaining studies aimed to reduce a range of so called high-risk sexual behaviours.[51, 52, 58, 61, 64] However, while these did not specifically concentrate on condom use, it would appear from the content of their interventions that this was seen as a key behaviour change desired by the investigators in order to reduce risk (section 5.1.4).

5.1.4 Interventions and control conditions employed by studies included in the review

The format, time course and composition of the study interventions were very varied (Table 5). Individual face-to-face sessions were used by six studies. In two cases this comprised a single short (≤30mins) session,[53, 54] while the others used between two ('brief' intervention[56]) and five[61] sessions (typically weekly) lasting a total of between 40 and 300 minutes. In addition, the Kamb multi-centre study offered a comparison between brief and longer lasting individual interventions.[56] The aims and content of this brief intervention were similar to that recommended by US CDC guidelines,[1] though it was divided into two 20-minute sessions.

Of the studies using group sessions, two involved a single contact only; a one-day workshop (homosexual males only[12]) and a shared viewing of a video (both sexes[55]). Other interventions lasted between three,[60] seven,[52, 64] and in one case 26 sessions,[51] lasting from approximately 5 to 26 hours in total. Single-sex groups received these interventions in all but two cases.[63, 64] Seven interventions (including two at the individual-level) included a video presentation. These were described as containing culturally specific content and actors, and illustrated living with HIV[52, 58] or condom use, portraying it as socially acceptable normative behaviour.[54, 55, 58]

The individual-level interventions explored many similar themes with their subjects. Typically, these focussed upon the perception of individual risks, barriers to safer sex and personal risky or trigger situations. The four studies employing multiple sessions also emphasised personal goal setting and planning,[56, 57, 59, 61] and three used role play and scenarios to rehearse and model skills such as communication and negotiation with partners and condom use.[57, 59, 61] The single session interventions emphasised an acceptance of condoms, promoting a positive attitude and negotiation of their use.[53, 54] Subjects were also encouraged to rehearse these skills through role-play and practised condom application using models.

Common themes were also evident within the group-level interventions. As for the individual-level interventions, the perception of individual risks and motivations, and the triggers or antecedents of unprotected sex were common throughout. In addition, exploring issues of self-esteem and relating these to shared community values and the expectations of others was included in some programmes,[12, 52, 63] while others focussed on improving subjects' self-efficacy.[52, 60, 64] Problem-solving and decision-making skills were seen as important elements of several interventions[58, 63] and these skills were practised during role-play scenarios. Similar exercises were part of all the study interventions considered, which typically emphasised condom use, negotiation and communication skills, with some studies asking participants to rehearse and model responses and behaviours.[52, 60, 64]

The choice of intervention for the control groups also varied. Many were described as 'usual-care' (Table 3) and typically consisted of one or two short individualised counselling sessions according to a standardised protocol (usually based on guidelines from the US Centres for Disease Control and Prevention[1]) with a clinic nurse, treating doctor or trained clinic adviser. These would consist of information giving and discussion, advice on 'risky' sexual behaviour and appropriate methods of reducing risk, contact tracing, and offering written material. This approach was supplemented by providing free condoms in three studies.[51, 54, 55] In contrast, a very short didactic information giving session was used as the control condition by Kamb.[56]

Two studies employed longer and more in-depth control interventions. The NIMH study used a single 60 minute education session that duplicated the first of seven intervention sessions,[52] while control subjects from a study in Atlanta, USA, participated in two 180 minute HIV information sessions, incorporating the same educational videos as the intervention.[58]

Table 5. Summary of intervention and control conditions for included studies.

Major citation and study population	Theoretical basis for intervention	Formative research	Number and length of sessions	Intervention format	Major elements of intervention	Skills taught and practised	Control condition
Kamb 1998[56] Heterosexual men & women from 5 public STI clinics in the USA	Theory of reasoned action, social cognitive theory[23]	Pilot studies and interviews described[65]	Weekly - enhanced: 1x 20min & 3x 60min, brief: 2x 20min	Individual	Enhanced sought to change key elements underlying condom use (self-efficacy, attitudes, perceived norms) Brief sought to assess actual vs. perceived risk, recognise barriers, negotiate acceptable/achievable plan, support patient initiated change Sessions included behavioural goal setting exercise		Didactic information giving: 2x 5min
NIMH 1998[52] Men & women from 37 inner-city public STI and clinics and HSOs in the USA	Theory of reasoned action, social cognitive theory,[23] current best practice	Pilot studies and interviews described[66]	Twice weekly - 1x 60min (as control) then 6x 90-120min	Group - 5-15 people of same sex. Includes video of HIV +ve community members	Aim to develop skills and self-efficacy through modelling effective behaviour & graded 'mastery through experience' (skills reinforced & repeated) Aim to influence factors critical for behaviour change (perceived risk of HIV associated with behaviours, perceived personal vulnerability, expectation of personal & social approval of adopting safer sex, acceptance of condoms) Sessions included behavioural goal setting and review	Condom use, sexual assertiveness, partner negotiation strategies, identify and manage antecedents to unsafe sex Used tailored role play (from self-reported situations & barriers)	Group education session, including video and questions: 1x 60min

Balmer 1998[51] Men from a public STI clinic in Nairobi, Kenya	Unified theory[51]	Not stated	Weekly - 26x 60min	Group - 10 men in each	Group discussion of motivators for high-risk behaviour, impediments to condom use. Solutions to problems highlighted then identified within group	Negotiation skills, condom use and other behavioural skills practised within group using role play	Information & advice (given as part of treatment). Condoms supplied (both groups)
Boyer 1997[57] Heterosexual men & women from a public STI clinic in San Francisco, USA	AIDS Risk Reduction Model[23]	Not stated	Weekly - 4x 60min	Individual (final session used telephone also). Includes written information & video material	Sessions included giving information, assessing personal risk, identifying personal triggers to unsafe sex and appropriate alternative approaches, self efficacy, partner choice, reasons for condom refusal, communication with partners, identifying sources of support Sessions also developed and reviewed a personal risk reduction plan	Condom use, communication & negotiation skills using scenarios and 'vignettes' (anatomical model for condoms also)	Standardised counselling in clinic (usual care): 1x 15min
Branson 1998[63] Men & women from a public STI clinic in Houston, USA	Information - Motivation - Behavioral Skills model[67]	Extensive use of interviews & focus groups, professional consultants and community advisory panel, pilot testing	4 sessions in 2 weeks plus a booster session at 2 months	'Enhanced group prevention program' - mixed gender groups. Includes video session with discussion	Sessions considered perception of personal risk, responsibility and self-esteem as related to community values, decision making skills, information about HIV and STIs and their prevention, review of previous sessions in a game format (booster)	Condom use, needle cleaning (where indicated by group), decision making skills & risk perception using role play	Standard client centred counselling (usual care): 2x 20min

Imrie 2001[12] Homosexual men from a GUM clinic in London, UK	Trans-theoretical model of behaviour change[68] plus elements of others (model of relapse prevention, social learning theory, motivational interviewing)[12]	Pilot study described	Single one-day session - 7 hours in addition to control condition	Group workshop	Included setting goals, assessing personal motivation, understanding and dealing with anxiety and stress, dealing with high-risk situations and the 'heat of the moment', body image and self-esteem, information about STIs, safer sex and condoms, lifestyle balance and 'moving forward'	Many exercises (in pairs) covering the major areas considered by the session	Standard individual counselling, contact tracing and referral to community service where appropriate (usual care): 20min plus
Kalichman 1999[58] African American men from a public STI clinic in Atlanta, USA	Information - Motivation - Behavioral Skills model[67]	Community research using interviews and focus groups to determine perceived threat of HIV, patterns of behaviour and gender/ cultural context of intervention	2x 180min sessions	Group sessions including use of culturally specific videos (information, living with AIDS, rap music & comedy, condom use)	Group discussions following: HIV and prevention and living with AIDS videos, pros and cons of condoms, decision making and problem solving, condom use skills training, applying problem solving skills to risk triggers and barriers to safer sex	Decision making and problem solving skills, condom application and use, sexual communication skills using scenarios from clips of popular films	Videos as for experimental intervention plus information about HIV testing and condoms, question and answer session

Maher 2003[59] Black men attending clinics in Miami, USA, with definite or probable STI	None described	Counsellors drawn from local community organisations – intervention developed with target group input	1x 60min plus 2x 40-50min sessions. Aim to complete within 30 days	Individual	Knowledge of STIs and risky behaviour, determine attitudes/beliefs and challenge 'invulnerability'. Encourage STI screening and condom use, identify barriers to safer sex, strategies to overcome these, alternatives to intercourse and supports to healthy behaviour (including reference to community norms). Determine educational/ employment plans and direct to appropriate resources to support these	Negotiation	Usual care (routine clinic counselling)
Metzler 2000[61] Male & female adolescents from 3 public STI clinics in Oregon, USA	Social cognitive theory,[23] Information - Motivation - Behavioral Skills model[67]	Said to follow pilot work	5x 60-90min sessions	Personalised individual sessions	Initially review current behaviour perceived consequences and assist in personal goal setting. Then work through individual list of situations and develop more effective ways of handling and reframe participant's avoidance of 'unpleasant feelings' accompanying efforts to change leading to acceptance	Behavioural training including assertion training, self-management, active listening skills, condom use. Social skills training including modelling or rehearsing behaviour	Usual care - brief interaction with nurse (advice on condoms and 'risky sex'), partner notification, written material
O'Leary 1998[64] Men & women from 7 public STI clinics in Maryland, Georgia, and New Jersey, USA	Social cognitive theory.[23] Specifically derived from 'successful' information & skills building intervention for adolescents	Past research only	7 sessions totalling 10 hours	Group - 3-10 of same or mixed sex	AIDS knowledge, misperceptions and personal risk, self-efficacy, antecedents to risk behaviour and how to manage them, condom use, partner negotiation, maintenance strategies Use upbeat messages throughout (acknowledging the positive side of sex), include fun elements and appropriate scenarios to illustrate message	Enhance self-efficacy through modelling and skills building, fun games used to develop negotiation skills, scenarios and role plays used throughout	Limited counselling, with or without information video, as part of usual care

Orr 1996[53] Female adolescents from public STI and family planning clinics in Indiana, USA	Health belief model[23, 68]	Not stated	Single session of 10-20min	Individual	Discuss chlamydia using written material to increase perception of personal vulnerability and seriousness, and reduce barriers to condom use by promoting positive attitudes and developing negotiation skills	Show and practice condom use, rehearse scenario of partner negotiation	Usual care - personalised discussion with nurse, partner notification, written information
Shain 1999[60]	AIDS Risk Reduction Model[23]	Extensive use of ethnographic research including interviews and focus groups. Iterations of intervention pre-tested in 13 groups	3x 3-4 hour sessions over 3 weeks	Small groups sessions	Recognise personal risk, commit to reducing risk and identify realistic strategies to achieve this (including the skills required). Requires knowledge of STIs, risk behaviours, personal vulnerabilities and sources of support. Perception of benefits (including enjoyment) and costs of making change	Self-efficacy and social skills increased through games, videos, behaviour modelling and role-play. Condom skills practised	Usual care (following CDC counselling guidelines). 1x 15min session
Shrier 2001[54] Young women with cervicitis or PID from a children's hospital clinic or inpatient unit in Boston, USA	Social cognitive theory,[23] trans-theoretical model of behaviour change[68]	Pilot study described	7 min video using popular entertainers and sports people then single 30min session	Personalised individual session	Video illustrates condoms - names, buying, negotiating use - as normative behaviour. Self assess stage of change - results used to tailor following: discuss video and pros and cons of condoms, information on STIs and transmission, written materials, discussion based on choice from a topic list	Negotiation skills using role play, demonstrate and practice condom use	Information on STI transmission and promote consistent condom use (usual care). Provision of condoms (both groups)

Solomon 1989[55] Men & women from a public STI clinic in Boston, USA	Not theory based ('social marketing')	Pilot study and previous research (characters share attitudes, beliefs, values identified in formative research)	Not stated	Group session viewing culturally specific video (featuring Black Americans) and coupons for condoms	Video portrays condoms as socially acceptable normative behaviour and seeks identification with target audience. Focuses on interpersonal/negotiation/ communication skills and attempts to make condoms more sexually appealing (advice for 'eroticizing' condoms)		Condom coupons as for experimental group

5.1.5 Theoretical basis for interventions in studies included in the review

The theoretical basis for each intervention was described in all but two cases,[55, 59] and several studies reported that more than one health promotion, social and cognitive psychology (relating behaviour to thoughts, attitudes or beliefs[23]) or sociological theory had informed their approach. The two large multi-centre studies based their interventions on the 'theory of reasoned action' and less specific 'social cognitive theory'.[52, 56] The theory of reasoned action asserts that a subject's attitude towards a protective behaviour, their perceived social support for the behaviour (social norms), and their self-efficacy (perceived ability to make the change) determine their intentions and subsequent action.[67] Cognitive models also address self-efficacy in the context of trying to modify a subject's thoughts, attitudes or beliefs ('cognitions').[23] An example is the 'Health Belief Model', cited as the basis for the trial among female adolescents in Boston.[53] This considers the individual's perceived susceptibility to an illness and its seriousness alongside their belief that the proposed behaviour change will prevent it occurring, and their personal perception of benefit and cost in adopting the new behaviour. The 'AIDS Risk Reduction Model' is a development of this model that seeks to encourage participants to label themselves as vulnerable, commit to changing behaviour, take action, and maintain the change,[23] and was cited by two studies[57, 60] as the theoretical basis for their interventions.

Three studies used the 'Information Motivation Behavioral Skills Model' (IMBS) to formulate their interventions[58, 61, 63] (this was combined with elements of social cognitive theory in one study of adolescents[61]). IMBS proposes that *"information that is directly relevant to the personal practice of preventive behaviour, motivation to practice prevention, and behavioural skills for practising prevention effectively, are the fundamental determinants of STI/HIV preventive behaviour"*.[67] The transtheoretical model of behaviour change (also called 'stages of change') was used (along with others) to develop the intervention in a study from London,[12] and combined with social cognitive theory in the study of young women from Boston.[54] This model suggests that change at the individual level may be seen as a series of ordered stages, from pre-contemplation and contemplation of change, to preparing, acting and maintaining change, and is generally conceived as a non-linear process allowing for relapse at any point.[68] This has implications for the delivery of interventions, which should seek to identify the stage an individual has reached and be tailored accordingly. Finally, social cognitive theory alone was stated as the main influence in developing the intervention for one study.[64]

The majority of studies reported that their interventions were developed with the results of formative research and/or pilot studies. However, detailed information on these, and/or qualitative research on the cultural and social context of sexual behaviour, condom use and perceived threats to health, and barriers to safer sex messages within the target communities is presented by only five studies.[52, 56, 58, 60, 63]

5.1.6 Quality assessment of studies included in the review

No study received a total Jadad score of greater than three out of a possible five (Table 6), and in seven cases it was not possible to address all the questions asked in the quality assessment form from the published papers (appendix 4). It was not possible to ascertain

from the published descriptions of five studies[51, 53, 55, 61, 64] whether the allocation of subjects to different treatment arms had been truly random, though all were described as RCTs. In one case, female subjects chose appointment times along with their peers, and these small groups were then randomised to either the experimental or control intervention.[60] This probably represents a cluster randomised design, as subjects may be more likely to share characteristics within than between groups.

All of the nine studies receiving a Jadad score of at least two described an acceptable process of randomisation, but in one case[58] it was not clear whether the allocation could be adequately concealed. While no study attempted to blind participants or their investigators, at least seven[12, 52, 56, 58-61] described their outcome assessors (who were required to obtain and review laboratory results, medical case notes and/or subject-completed questionnaires) as blinded to the group into which the subjects were allocated. Only six studies[12, 55, 56, 59, 60, 63] analysed and presented results for their principal outcome on an ITT basis, though for outcomes related to STI acquisition, this could be calculated from data presented in the paper for a further three[52, 54, 57] (section 5.2).

Overall, studies recruited fewer than half of those approached and eligible for inclusion (weighted mean 45%, median across studies 55%, n=12) though their reported rates of intervention adherence were generally higher (weighted mean 66%, median across studies 69.5%, n=10). Recruitment rates for group interventions were greater than for individual sessions (group median 65%, range 24-73 vs. individual median 43%, range 37-92), and inversely related to the total number of intervention contacts; those with just one or two sessions had a median rate of 71% (range 51-73) while those with more had a median rate of 40.5% (range 24-92). However, no data were available for the longest (Kenyan) study[51] or one of the single session individual studies.[53] Intervention adherence also varied by intervention frequency and format. Between 71 and 95% of subjects attended those with one or two sessions only (the studies by Orr and Solomon[53, 55] reported data only on those attending the intervention session), and this rate fell to between 46-82% (missed no more than one session) for other studies (again, no data are available for the longest study[51]). This time, where data were available, rates were similar for individual and group interventions (group median 71%, range 47-85 vs. individual median 68%, range 46-95).

The proportion of individuals for whom data were available at the end of follow-up was typically low, with a median across studies for the intervention group of 67.5% (range 50-93, n=12). Rates were not apparently affected by the number of intervention sessions (median 60% vs. 71.5% for studies with more than two sessions) or total length of follow-up (twelve months median 69.5% vs. less than twelve months median 67.5%). However, in five cases markedly different follow-up rates between intervention and control groups were observed (four studies[53, 56, 58, 63] do not report separate rates, rather they state no significant difference). Two[12, 64] report lower follow-up rates in the intervention group relative to control (84-87% control rate), while the remainder report follow-up rates in the intervention group between 1.4[57, 61] and 2.1[51] fold greater than the rate in the control group. One of these studies was rated highly for factors related to internal quality and validity,[12] but the remainder were not and received low Jadad scores.

Table 6. Quality assessment of included studies.

Major citation	Jadad total score	Selected factors related to internal validity of study (Jadad - sub-sections) - Y yes, N no & DK don't know (from paper)				Recruitment rate (% of those eligible)	Intervention adherence	Follow up rate (at endpoint)
		Allocation truly random	Allocation adequately concealed	Blinding of assessors	Intention to treat analysis[a]			
Kamb 1998[56]	2	Y	Y	Y	Y	43%	72% (control 85%)	66%[b] 51% all 4 visits
NIMH 1998[52]	3	Y	Y	Y	N	33%	63% attended ≥6 sessions	76% intervention 74% control (STI clinic patients[c])
Balmer 1998[51]	0	DK	DK	N	DK	Not stated	High drop-out rate reported	93% intervention 44% control
Boyer 1997[57]	3	Y	Y	N	N	38%	48% all 4 sessions	66% intervention 49% control
Branson 1998[63]	3	Y	Y	N	Y	59%	47% attended ≥4 sessions	73% any, and 22% complete follow up[2]
Imrie 2001[12]	3	Y	Y	Y	Y	72%	71%	66% intervention 76% control
Kalichman 1999[58]	2	Y	DK	Y	N	Approx. 70%	85% both sessions	69%[b]
Maher 2003[59]	2	Y	Y	Y	Y	92%	46% attended ≥2 sessions	N/A
Metzler 2000[61]	1	DK	DK	Y	N	42% agreed, of whom 89% eligible (37%)	68% attended ≥4 sessions	53% intervention 39% control
O'Leary 1998[64]	1	DK	DK	DK	N	24%	Not stated	70% intervention 83% control

Orr 1996[53]	0	DK	DK	DK	N	Not stated	N/A (100%)	54%[b]
Shain 1999[60]	2	Y (NB randomisation of self selected groups)	Y	Y	Y	65%	82% attended ≥2 sessions	91% intervention 87% control
Shrier 2001[54]	2	Y	DK	N	N	51%	95%	50% intervention 46% control
Solomon 1989[55]	1	DK	DK	DK	Y	73%	N/A (100%)	N/A

a. Intention to treat analysis in respect of primary outcome i.e. STI diagnosis except Kalichman 1999, Metzler 2000, O'Leary 1998, Shrier 2001 and Solomon 1989, where primary outcomes were behavioural.

b. Published paper states that there was no significant difference in follow up rates between the two groups.

c. Estimated from number randomised and number reporting data.

5.2 Primary outcomes - STI rates

5.2.1 Laboratory confirmed STIs

Eight studies considered this outcome at between 5 and 12 months (Table 7), and results were based on reviewing case and laboratory records from the study clinic, other locally accessible clinics, local reporting schemes, and in one case the results of screening for gonorrhoea and chlamydia.[60] The definition in each case was sufficiently similar (focussing on the principal bacterial causes of STI and HIV) to consider as equivalent, and thus the study RRs are illustrated together in Figure 2.

Four studies, which enrolled over 80% of the total participants for these studies, report lower STI rates at follow-up in their intervention groups relative to control,[52, 56, 60, 63] and in two of these the result is statistically significant ($p<0.05$). The effect of the intervention reported by Kamb[56] (the largest single study) suggests that one case of STI was prevented for every 32 individuals being allocated to the intervention (number needed to treat, NNT), while the NNT for the study reported by Shain[60] (the largest effect size reported) was just 13. The NIMH[52] paper also reports results for laboratory confirmed gonorrhoea in addition to all STIs. This result shows a greater impact of the group intervention on this diagnosis alone than for STIs as a whole (RR 0.61 versus 0.97, ARD -1.4% versus 0.2%). The remaining studies report non-significantly lower rates among their control groups and meta-analysis of these results using a RE approach did not show evidence of an overall effect (RR 1.03 {95% CI 0.82, 1.29}, ARD 0% {95% CI -2%, +3%}).

With the exception of the study by Orr,[53] for which it was not possible to calculate results on an ITT basis, the Jadad score for these studies was relatively high and the direction of effect was not apparently influenced by the overall score or relevant individual questions (section 5.1.5). Exclusion of the Orr study did not materially alter the pooled effect estimate (RR 0.96 {95% CI 0.76, 1.19}). There was no evidence that the recruitment rate was related to the size or direction of effect. However, the two studies reporting a statistically significant effect also reported two of the greatest adherence and follow-up rates.[56, 60] Two of the studies observing lower STI rates among their control groups, report differential follow-up rates. Boyer[57] found a greater loss to follow-up the control group, while Imrie[12] found the reverse.

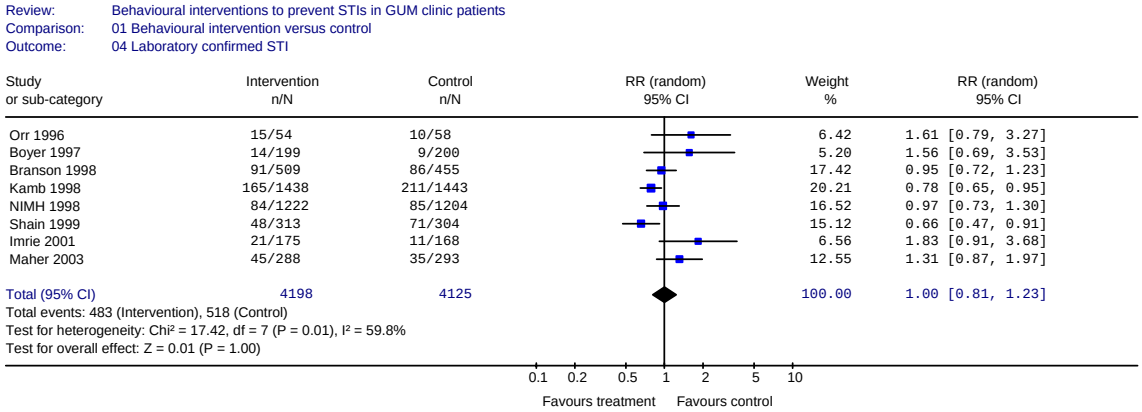
No clear pattern of intervention format or number of sessions and reported effects were noted. The NIMH,[52] Shain[60] and Branson[63] studies delivered group sessions over several weeks while the Kamb study[56] was individually based. Importantly, this latter study's result was essentially the same whether the enhanced or brief intervention (which was similar to the CDC Guidelines for counselling patients with STIs,[1] section 5.1.3) were considered versus didactic information giving control sessions (enhanced vs. control RR 0.78 {95% CI 0.65, 0.95}, brief vs. control RR 0.82 {95% CI 0.68, 0.99}). Substitution of the brief intervention result into the meta-analysis produces a very similar pooled effect estimate (RR 1.00 {95% CI 0.82, 1.23}).

Most studies recruited young adult populations of both sexes that were predominantly Black or African American. The exceptions were among those studies to show lower STI

rates among controls: Orr[53] investigated adolescent females and Imrie[12] predominantly white homosexual men from London. Two studies, both describing an intervention consisting of multiple group sessions, present separate results for men and women. One study[63] found a greater reduction in STI rates in women, though the results are widely spread. The other[52] found that men appeared to benefit far more than women, whose STI rates were actually higher in the intervention group.

Figure 2. Laboratory confirmed STI rates in intervention versus control groups.

Output from 'RevMan Analyses' (version 1.0, The Cochrane Collaboration 2003).



RR relative risk. Pooled effect estimate (total) from RE models.

5.2.2 Other diagnosed STIs

Four studies used a more broad-based STI definition that included both infections that may not be exclusively sexually transmitted and those that may become latent, so confusion as to first versus subsequent attacks can occur. In addition, clinical diagnoses were permitted as well as those confirmed in the laboratory (Table 7). Boyer[57] reported a small non-significant reduction of diagnoses other than those considered in section 5.2.1 in the intervention group of heterosexual adults, while Branson[63] found little evidence that a series of group sessions impacted on a range of specific STI diagnoses. In studies of homosexual men in London[12] and black men in Miami[59] a greater rate of STI diagnoses was seen in the intervention group than the control group, a result reported as statistically significant ($p<0.05$) in one case.[12]

One study from Kenya[51] presented results for individual STI outcomes but did not describe how these were ascertained. A statistically significant reduction in the acquisition of gonococcal urethritis and urethral discharge, but not genital ulcers or HIV, was reported in the intervention group, but the data are not presented.

Table 7. Summary of results - outcomes related to STI acquisition.

Data represent intention to treat analyses (ITT) unless indicated otherwise. Relative risk (RR), absolute risk difference (ARD) and their 95% confidence intervals (CI) recalculated from data presented in published paper unless indicated otherwise.

Major citation	Outcome	How results ascertained	Follow up period	Difference in event rates (intervention group relative to control)		Notes
				RR (95% CI)	ARD (95% CI)	
Kamb 1998[56]	Cumulative incidence of gonorrhoea, chlamydia or HIV	Laboratory confirmed diagnosis	12 months	Enhanced 0.78 (0.65, 0.95) Brief 0.82 (0.68, 0.99)	-3.1% (-5.6, -0.6) -2.6% (-5, 0)	Enhanced vs. brief RR 0.96 (0.79, 1.17) and ARD -0.5% (-3, 2)
NIMH 1998[52]	Cumulative incidence of gonorrhoea, chlamydia, non-gonococcal urethritis, syphilis, trichomonas	Laboratory confirmed diagnosis	12 months	Overall 0.97 (0.73, 1.30) *gonorrhoea 0.61 (0.39, 0.98)* men 0.81 (0.56, 1.17) women 1.33 (0.83, 2.14)	-0.2% (-2, 2) *-1.4% (-3, 0)* -1.4% (-4, 1) 2.1% (-1, 6)	Results presented for STI clinic patients only. Denominators for ITT analysis estimated from number randomised and lost to follow up - on treatment analyses: diagnosed STI - RR 0.83 men & 1.25 women, STI associated symptoms - RR 0.71 men & 0.86 women
	Cumulative incidence of STI associated symptoms	Self-report		Overall 0.78 (0.67, 0.90) men 0.70 (0.54, 0.90) women 0.86 (0.73, 1.00)	-5.9% (-9, -3) -4.8% (-8, -1) -6.5% (-13, 0)	
Balmer 1998[51]	*Cumulative incidence of:*					NB Not ITT analysis. Only published RR and ARD presented - data not shown and thus results could not be expressed as n/N or entered in pooled analyses
	Gonococcal urethritis Urethral discharge Genital ulcer HIV	Not stated	6 months	0.39[a] 0.36[a] 1.28 0.26	-2.4 -3.7 +0.3 -0.8	
				results expressed as rate per 100 person months		

Boyer 1997[57]	Cumulative incidence of gonorrhoea, chlamydia, syphilis, trichomonas, HIV	Laboratory confirmed diagnosis	5 months	1.56 (0.69, 3.53)	2.5% (-2, 7)	
	Cumulative incidence of other probable new STI	Clinical diagnosis		0.92 (0.42, 2.04)	-0.5% (-5, 4)	
				either confirmed or probable 1.20 (0.69, 2.07)	*+2.1% (-4, 8)*	
Branson 1998[63]	Cumulative incidence of gonorrhoea, chlamydia, syphilis, HIV	Laboratory confirmed diagnosis	12 to 15 months	Overall 0.95 (0.72, 1.23) men 0.99 (0.70, 1.40) women 0.89 (0.59, 1.35)	-1.0% (-6, 4) -0.3% (-7, 6) -2.0% (-9, 5)	Possible STI included non-gonococcal urethritis, pelvic inflammatory disease, scabies, trichomonas, first presentation of genital herpes or warts, HIV or hepatitis B (documented seroconversion)
	Cumulative incidence of any possible new STI (excluding those above)	Clinical diagnosis		No significant differences reported for any specific diagnosis considered		
Imrie 2001[12]	Cumulative incidence of gonorrhoea, chlamydia, syphilis	Laboratory confirmed diagnosis	12 months	1.83 (0.91, 3.68)	+5.5% (-1, 12)	Odds ratios adjusted for the diagnosis of a new STI at presentation - laboratory confirmed STI 1.66, any STI 1.84. Broad based STI category included non-gonococcal urethritis, hepatitis B, genital herpes or warts (first presentation)
	Cumulative incidence of any STI	Clinical diagnosis		1.45 (1.00, 2.11)	+9.5% (0, 19)	
Maher 2003[59]	Cumulative incidence of gonorrhoea, chlamydia, syphilis, chancroid, LGV, HIV	Laboratory confirmed diagnosis	12 months	1.31 (0.87, 1.97)	+3.7% (-3, 11)	Paper reports no difference in time to first infection. 3.8% of subjects were reported as suffering multiple STIs during study period RR 0.85 (ARD -0.6%)
	Cumulative incidence of above plus non gonococcal urethritis or treatment for presumptive gonorrhoea/ chlamydia	Clinical diagnosis		1.14 (0.89, 1.47)	+4.0% (-2, 9)	

Metzler 2000[61]	Cumulative incidence of any STI	Self reported diagnosis	6 months	Paper reports no significant differences - data not shown		NB not ITT analysis
Orr 1996[53]	Cumulative incidence of Chlamydia trachomatis re-infection	Laboratory confirmed diagnosis	6 months	1.61 (0.79, 3.27)	+10.5% (-5, 26)	NB not ITT analysis. Of those originally considered to be 'cured', RR 1.76 (ARD +13%)
Shain 1999[60]	Cumulative incidence of gonorrhoea, chlamydia	Laboratory confirmed diagnosis	12 months	0.66 (0.47, 0.91)	-8.0% (-14, -2)	Results suggest effect similar in 1st and 2nd 6-month follow-up period (RR 0.69 vs. 0.55). 5.8% of subjects were reported as suffering multiple STIs during study period RR 0.78 (ARD -1.5%)
Shrier 2001[54]	Cumulative incidence of any STI	Self reported diagnosis	12 months	0.48 (0.18, 1.29)	-9.2% (-21, 3)	On treatment analyses only presented in paper - RR 0.53 (ARD -15%)

a. Reported as statistically significant ($p<0.05$, only shown where 95% CI unavailable)

5.2.3 Self-report of STIs

A question on STI acquisition was included in the self-completed questionnaires used to collect behavioural data by three studies (section 5.2.3). The multi-centre NIMH study[52] reported a significant reduction in reported symptoms among the intervention group that was far greater than the reported impact on laboratory diagnoses (RR 0.78, ARD -5.9%, Table 7). Reported symptoms were also (non-significantly) reduced by an intervention among young women in Boston, USA.[54] However, Metzler[61] found no effect of a five session individual-based intervention in adolescents from Oregon, though the data are not shown.

5.3 Secondary outcomes - sexual behaviour change

Outcome data relating to sexual behaviour change were collected using either self-completed questionnaires (with assistance as required) or structured interviews. Reports of relevant behaviours relate to specified time periods, typically the previous one to three months (Table 8). As information was only available on those present at follow-up, in most cases the results do not refer to ITT analyses (the exception is largest study reported by Kamb[56]). While a range of relevant behaviours were examined, the majority relate to either the number of sexual partners or a measure of condom use (quantified as the proportion reporting consistent use, or the mean of individuals' reports of the proportion of sexual encounters protected by condoms).

5.3.1 Sexual partners

Eight studies consider either the number or characteristics of sexual partners (Table 8). Four report the number of new partners over the previous three to six months (in two cases[51, 61] the data were not presented so these results are not pooled to derive a summary measure of effect), but their results are inconsistent. Three studies, one in Kenyan men,[51] one in US adolescents,[61] and one in US adults,[64] show a lower rate among the intervention groups (significantly so in one case[61]), while a study of African American men[58] reported a lower rate in the control group.

Results from the studies of US adults[64] and African American men[58] are presented as the difference between groups in mean within-subject change, and assume a within-subject correlation coefficient of r=0.5 (section 4.5). If r is set to 0.75, the 95% CI for each study estimate is narrowed, making both results statistically significant ($p<0.05$). However, their effect estimates remain unchanged (mean difference -0.60 {95% CI -1.16, -0.04} and +2.00 {95% CI 0.54, 3.46} respectively).

Shain[60] noted a statistically significant decrease in the proportion of intervention group participants reporting multiple partners during the study period relative to the control group, while Branson[63] found a non-significantly higher proportion of intervention group subjects reporting more than one partner per month. Studies among adolescents[61] and heterosexual adults[57] found no apparent impact of interventions on rates of sexual contact

with strangers or on the number of different partners engaging in unprotected sex, respectively.

The characteristics of sexual partners were also reported by three studies. US adolescents significantly reduced their contacts with non-monogamous partners following a five session individual-level intervention,[61] while homosexual men who engaged in unprotected intercourse despite a behavioural intervention, were just as likely to not know their partner's HIV status as those who did not receive the intervention.[12] Finally, a significantly greater proportion of women avoided sex with a symptomatic or incompletely treated partner with an STI after receiving a series of three small group sessions in a study from Texas, USA.[60]

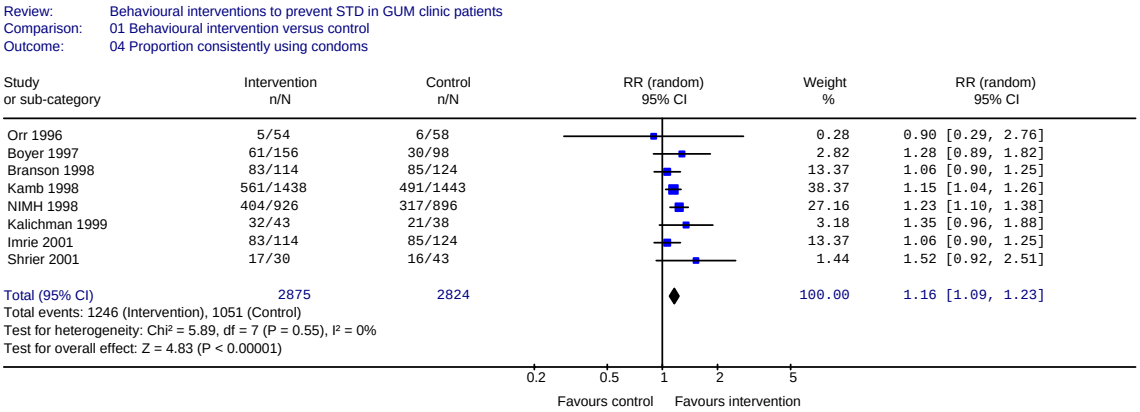
5.3.2 Condom use - consistent use

An outcome reporting condom use always or nearly always over the previous one to six months was presented by eight studies (Table 8, four of these phrased their outcome as the number reporting no acts of unprotected sex,[12, 54, 56, 57] and one[52] included abstinence). These outcomes were considered to be equivalent and the study RRs are presented together in Figure 3, which does not show evidence of statistical heterogeneity (p=0.55).

The results for all but one study are in the direction that favours increased consistent condom use among the intervention group; in two (the largest studies) this result is statistically significant ($p<0.05$)[52, 56] despite their very different formats and intensity (this is also true for the comparison of brief and enhanced interventions offered by Kamb). The exception is a study of a single individual session offered to female adolescents,[53] but that also found a statistically significantly lower proportion of the intervention group reporting never using a condom. However, there is little evidence for a relationship between number of sessions and effectiveness. The largest two effect estimates were reported from studies of a single individual session versus usual care among young women[54] and two group sessions versus time matched information sessions in African American men.[58] In general, there was also no relationship between the effect size and length of follow-up. However, after 12 months Imrie[12] found a greater effect when reports for the entire study period were considered rather than the previous month alone (RR 1.23 versus 1.06). Overall, the pooled estimate from a RE model was itself statistically significant, with a RR of 1.16 (95% CI 1.09, 1.23) and ARD of +6% (95% CI +4, +9).

Figure 3. Proportion of subjects reporting consistent condom use.

Output from 'RevMan Analyses' (version 1.0, The Cochrane Collaboration 2003).



RR relative risk. Pooled effect estimate (total) from RE models.

Table 8. Summary of results - outcomes related to sexual behaviour change.

Data **do not** represent intention to treat analyses (ITT) unless indicated otherwise. Relative risk (RR), absolute risk difference (ARD), difference in mean within-subject change, and where possible their 95% confidence intervals (CI) were recalculated from data presented in published paper unless indicated otherwise[2]. The CI for continuous outcomes reanalysed as inter-individual change from baseline, and were imputed using a within-subject correlation coefficient of r=0.5

Major citation	Outcome	How results ascertained	Follow up length	Difference in event rates or mean within-subject change (intervention group relative to control)	Notes
Kamb 1998[56]	Proportion not engaging in unprotected vaginal intercourse	Self report of sexual activity in last 3 months	12 months	Enhanced RR 1.15 (1.04, 1.26) ARD +5% (1, 8) Brief RR 1.12 (1.00, 1.25) ARD +5% (1, 8)	ITT analysis
NIMH 1998[52]	Mean number of unprotected acts of intercourse	Self report of sexual activity in last 3 months	12 months	Men -4.4[a,b] Women -6.8[a,b]	Results presented for STI clinic patients only
	Proportion of sex acts using condom - mean of individuals' results			Overall +11% (7.9, 14.2) Men +8%[a] Women +16%[a]	
	Proportion consistently using condoms or abstinent			RR 1.23 (1.10, 1.38) ARD +8.2% (4, 13)	
Balmer 1998[51]	Mean number of new sexual partners	Not stated	6 months	ARD -0.6 per 100 person months[b]	Original data not shown
	Condom use with high-risk sexual contact			7/24 vs. 0/9 occasions	

Boyer 1997[57]	Proportion not engaging in acts of unprotected intercourse Proportion of sex acts using condom - mean of individuals' results Mean number of partners engaging in unprotected sex	Self report of sexual activity during study period	5 months	RR 1.28 (0.89, 1.82) ARD +8.5% (-3, 20) Overall -4.00% (-15.7, 7.7) Men -6.7% Women -1.3% Men -0.3 Women +0.1	The proportion of reported sexual activity protected by condoms fell during the study follow up period and this was most marked in the intervention group At 5 months, little difference between groups reported in measures of knowledge, attitudes or intentions towards condoms
Branson 1998[63]	Proportion with more than one sexual partner per month Proportion using condom with most recent sexual partner	Self report of sexual activity in last 3 months	12 months	RR 1.15 (0.73, 1.83) ARD +3.4% (-8, 14) -1%[b]	Only data for men presented - results for women reported as being similar Baseline knowledge of STIs and condoms reportedly high
Imrie 2001[12]	Proportion **not** engaging in unprotected anal intercourse Of those engaging in unprotected intercourse, number with partner of different/ unknown HIV status	Self report of sexual activity in defined time period	12 months	In past year RR 1.23 (0.93, 1.62) ARD +9.4% (-3, 22) In past month RR 1.06 (0.90, 1.25) ARD +4.3% (-7, 16) RR 1.04[b] ARD +2.2%[b]	At 6 months, proportion reporting no unprotected anal intercourse in last month non-significantly increased in the intervention group (RR 1.12, p=0.07) At 12 months, measures of communication skills, safer sex efficacy and interpersonal skills increased in intervention group
Kalichman 1999[58]	Proportion using condoms almost always Proportion refusing unsafe sex Mean number of unprotected acts of intercourse Proportion of sex acts using condom - mean of individuals' results Mean number of sexual partners	Self report of sexual activity in last 3 months	6 months	RR 1.35 (0.96, 1.88) ARD +19% (-1, 40) RR 1.23 (0.90, 1.68) ARD +14% (-6, 34) -2.30 (-7.7, 12.3) +2.5% (-12.1, 17.1) +2.00 (-0.10, 4.10)	At 3 months, the intervention group reported significantly ($p<0.05$) higher proportion using condoms almost always (RR 1.47) and a significantly greater proportion of sex acts protected by a condom (mean of individual %, RR 1.32) Similar increases in measures of AIDS knowledge, condom attitudes and intentions reported in both groups

Metzler 2000[61]	Mean number of sexual partners Mean number of non-monogamous sexual partners Number of sexual contacts with strangers Frequency of sexual intercourse and condom use	Self reported sexual activity during study period	6 months	Significant decrease (especially in white males)[a,b] Significant decrease (especially in white males)[a,b] Significant decrease[a,b] No difference between groups[b]	Results reported as the outcome of statistical models only - original data not shown No reported differences between groups were reported in measures of knowledge, decision making skills or condom attitudes and intentions
O'Leary 1998[64]	Mean number of sexual partners Mean number of 'risky acts' Proportion of sex acts using condom - mean of individuals' results	Self report of sexual activity during study period	3 months	-0.60 (-1.39, 0.19) +0.7[b] -1.0% (-9.3, 7.3)	
Orr 1996[53]	Proportion never using condoms Proportion always using condoms	Self report of sexual activity during study period	6 months	RR 0.50 (0.31, 0.82) ARD -27% (-45, -10) RR 0.90 (0.29, 2.76) ARD-1% (-12, 10)	
Shain 1999[60]	Avoiding sex with partner incompletely or not treated for STI More than one sexual partner More than five unprotected sex acts	Self report of sexual activity in last 3 months	12 months	RR 1.18 (1.07, 1.30) ARD +12.8% (5, 20) RR 0.74 (0.59, 0.93) ARD -11.4% (-20, -3) RR 0.88 (0.79, 0.98) ARD -9.5% (-17, -2)	STI rates associated with sex with a partner incompletely or not treated for an STI, the number of sexual partners and the number of unprotected sex acts

Shrier 2001[54]	Proportion using condoms at last sexual encounter Mean frequency of condom use Proportion consistently using condoms (no unprotected episodes)	Self report of sexual activity during study period Self report of sexual activity in last 3 months	12 months	RR 1.13[b] ARD +7% With main partner +0.0 with new partners +0.2 Overall RR 1.52 (0.92, 2.51) ARD +19% (-3, 42) Main partner RR 1.47 (0.79, 2.72) ARD +17% (-10, 43) New partners RR 1.71 (0.76, 3.88) ARD +30% (-14, 73)	
Solomon 1989[55]	Mean number of condom coupons redeemed	Returns from clinic and shops	Not stated	+0.2 (0.0, 0.4)	

a. Reported as statistically significant ($p<0.05$, only shown where 95% CI unavailable).

b. Relative risk and absolute change in risk or mean values are as presented in the published paper and have not been recalculated.

5.3.3 Condom use - proportion of sexual encounters protected by condoms

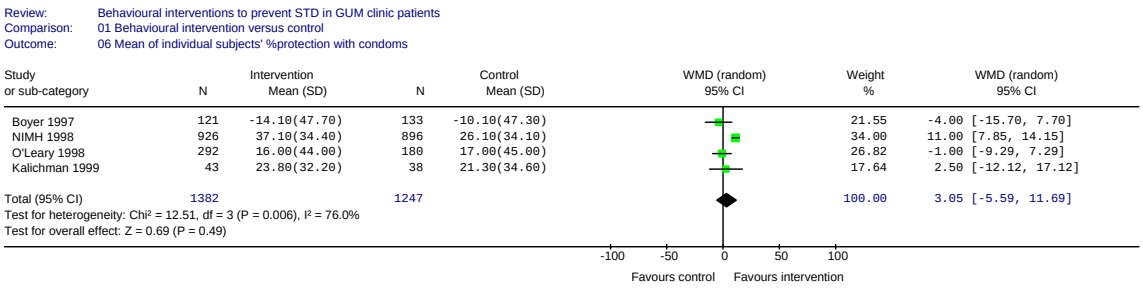
Additional information on condom use was collected by either asking subjects what proportion of their sexual encounters were protected by condoms, or indirectly by asking the number of encounters and then the number protected and calculating the relevant proportion. The mean of individual subjects' responses provides a continuous outcome measure that was available from four studies (
Figure 4), and these were reanalysed and presented as the differences between treatment groups in the mean within-subject change from baseline (section 4.5). In addition, one study asked women how many unprotected sex acts they had engaged in during the last 3 months, and reported a statistically significant decrease in the proportion reporting more than five.[60]

The large NIMH multi-centre study[52] was the only study to clearly indicate that receiving the intervention was associated with a greater increase in the proportion of sexual encounters protected by condoms, and was the only study in this group to follow-up participants for more than six months. Boyer[57] found a non-significantly greater fall in this proportion among the intervention group and was the only study to show a reduction in this outcome for either group during the study period, as well as being the only individually based intervention. Again, study intensity did not appear to be related to reported effect size, and the pooled estimate from a RE model suggested little overall effect (WMD +3.05% {95% CI -5.59, 11.69}).

The results and meta-analysis presented assume a within-subject correlation coefficient of r=0.5 (sections 4.5 and 5.3.1). Increasing this to 0.75 did not increase the number of studies whose results were regarded as statistically significant ($p<0.05$), and neither was the pooled result rendered significant (WMD +2.56 {95% CI -5.99, 11.10}). Reducing r to 0.10 increased the study estimates' SE and widened their 95% CI. However, the NIMH study result[52] remained statistically significant (mean difference +11.00 {95% CI 6.78, 15.22}).

Figure 4. Mean of all individual subjects' proportions of sexual encounters protected by condoms.

Output from 'RevMan Analyses' (version 1.0, The Cochrane Collaboration 2003).



NB data presented and analysed as mean within-subject change from baseline. WMD weighted mean difference. Pooled effect estimate (total) from RE models.

In four studies, the change in total number of sexual acts for a specified period was reported[56, 61] or could be calculated[52, 58], allowing changes in proportionate condom use to be put in the context of overall changes to sexual behaviour. Three studies reported either no difference[56] or a greater fall in the number of sex acts in the control groups[58, 61] (though the difference was small). Only one study, the multi-centre NIMH investigation of adults,[52] reported a greater reduction in total sex acts in the intervention group; the mean within-subject change across the study period was 174 per 3 month period in the intervention group (81% of the baseline value) and 154 in the control group (67% of baseline).

5.4 Stratified analysis

Considerable clinical heterogeneity is apparent between studies included in this review (section 5.1) and where outcomes have been considered equivalent and plotted together this has also been accompanied by statistical heterogeneity in all but one case (section 5.3.2). While the characteristics of included studies has already been discussed in terms of 'vote counting' (section 4.5), in order to further examine the role of differences in study population, study quality, and the format and theoretical basis for interventions, studies have been classified into subgroups and their results for the primary and one other behavioural outcome pooled (using RE models).

5.4.1 Laboratory confirmed STIs by subgroup

Of the eight studies reporting this outcome (section 5.2.1), four recruited both adult men and women (one from age 15[56] and two heterosexuals only[56, 57]) and were classified as one subgroup.[52, 56, 57, 63] Their results were pooled and compared to other studies recruiting either women (one recruiting only adolescents aged 15-19[53] and the other not restricting entry by age[60]), homosexual men[12] or young black men only[59] (the sexuality of the men recruited to this latter study are not described). The pooled effect estimates show that studies recruiting both sexes are more likely to show that the intervention group suffers fewer new STIs (Figure 5), but these results are not statistically significantly different from each other.

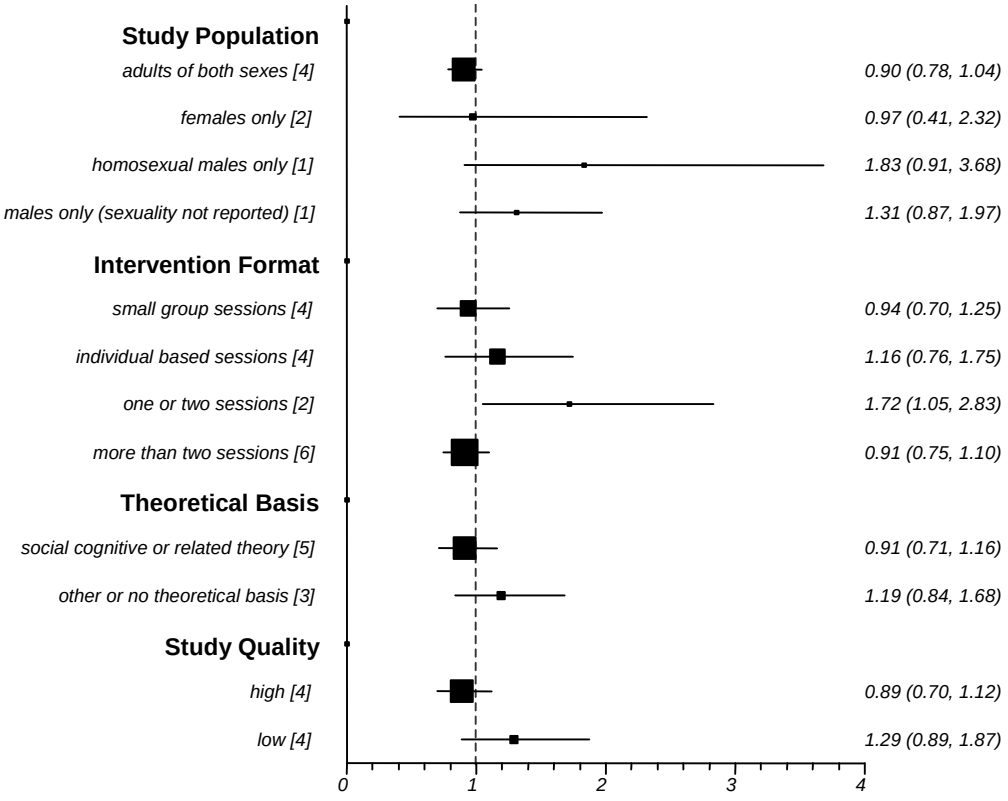
Four studies were group based,[12, 52, 60, 63] and their pooled results are not significantly different from studies using individual-based interventions.[53, 56, 57, 59] Pooled results for the two studies reporting interventions lasting a single session[12, 53] suggest these were less effective than studies reporting longer lasting interventions, though the difference is not statistically significant (t test, p=0.11). Five studies shared a similar theoretical basis,[52, 53, 56, 57, 60] drawing on social cognitive or related theories (section 5.1.5). Again, their pooled results do not appear to differ from those studies adopting other approaches.[12, 63]

Study quality was initially assessed as the total Jadad score (section 4.3), but this was found to be inadequate to classify this study set (section 5.2.1). Thus, in addition to a

Jadad score of 2 or 3, reported attempts to blind the outcome assessors and a non-differential rate of follow up (section 5.1.6) were used to classify four (including the two largest studies[52, 56]) as higher quality studies,[52, 56, 59, 60] reflecting a greater assurance that their results are valid. In this case the stratified analysis shows that the higher quality studies tended to show a greater benefit from their interventions. However, neither the pooled results nor the difference between the two (t test, p=0.21) is statistically significant.

Figure 5. Pooled results for subgroups of studies reporting laboratory confirmed STI rates in intervention versus control groups.

[n] Number of trials



5.4.2 Consistent condom use by subgroup

Four studies reporting consistent condom use recruited adults from both sexes,[52, 56, 57, 63] two recruited young women (aged either 15-19[53] or <24 years[54]), one homosexual men,[12] and one study recruited heterosexual men.[58] However, pooled results do not suggest that different effect estimates were reported by studies of different populations (Figure 6). Similarly, while four studies used a group format for their intervention[12, 52, 58, 63] and four

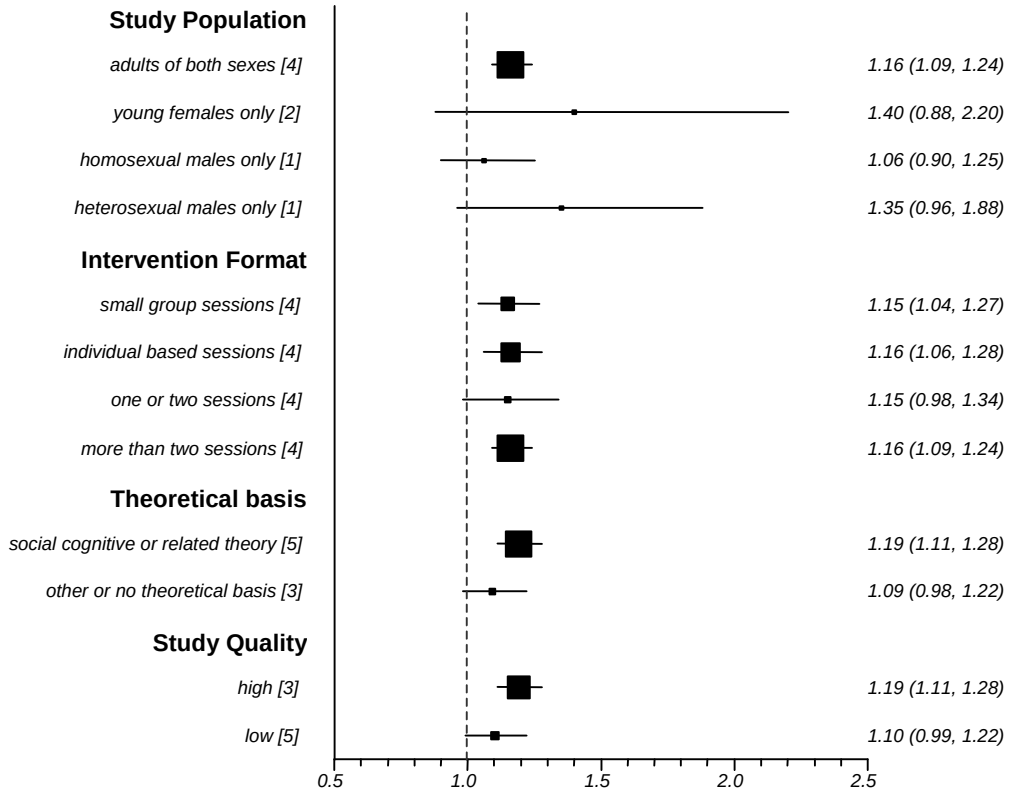
offered multiple sessions (>2, including the enhanced intervention used by Kamb),[52, 56, 57, 63] there was no evidence that their pooled effect estimates were different from those using an individual format[53, 54, 56, 57] or one to two sessions[12, 53, 54, 58] (Figure 6 and section 5.3.2).

The majority of interventions drew their theoretical basis from social cognitive or related theories (section 5.1.5). Of the three that did not, two reported that their interventions were based on Information Motivation Behavioral Skills model[58, 63] and one the transtheoretical model of behaviour change[12] (amongst other influences). Again, the pooled results for these two groups were not statistically significantly different (t test, p=0.22), but they do suggest that studies employing an intervention based on social cognitive theory may have been more successful in increasing the rate of consistent condom use.

Finally, three studies[52, 56, 58] were classified as higher quality on the same basis as that used for the laboratory confirmed STIs outcome (section 5.4.1). However, in contrast to that outcome, the pooled results were not significantly different from each other (t test, p=0.24, Figure 6), though the results for studies of higher quality did suggest a greater impact on condom use than those of lower quality.

Figure 6. Pooled results for subgroups of studies reporting the proportion of subjects reporting consistent condom use.

[n] Number of trials



6. Discussion and conclusions

6.1 Review findings

6.1.1 Impact on STI rates

This review did not find that behavioural interventions consistently reduce STI rates in patients attending GUM clinics (section 5.2). There was considerable heterogeneity between studies and pooling their results suggested no overall effect. Four studies (including the three largest and highest quality studies,[52, 56, 63] which investigated American adults of both sexes) did reported an effect in reducing rates of laboratory confirmed bacterial STIs and HIV, two of which were statistically significant.[56, 60] These two studies investigated different populations and used different formats for their interventions.

The study reported by Kamb[56] compared both a brief and enhanced intervention with a short didactic information giving session, and also presented a within-study comparison of its brief and enhanced interventions. The brief intervention consisted of two 20-minute individual sessions, and concentrated on issues of self-efficacy, yet this was as successful as the enhanced approach lasting over four-weeks in comparison. Similarly, the between-study stratified analysis (section 5.4.1) did not show a clear difference in reported effects according to intervention format or number of sessions, though three of the largest and most successful studies[52] used the theory of reasoned action and social cognitive models[56] or the related AIDS Risk Reduction Model[60] to formulate their interventions (section 5.1.5).

The results for more broad based definitions of STI were conflicting (section 5.2.2), and one study of homosexual men saw a statistically significantly higher rate of these diagnoses in the intervention group.[12] Similarly, there was no clear overall impact of interventions on self-reported STIs (section 5.2.3).

Disappointingly, this review does not appears to offer significant new information on reducing STI rates over and above the previously identified review,[25] though that made no attempt to combine results or conduct formal stratified analyses (section 2.6). Only one additional trial reporting infection related outcomes was identified.[59] The previous review did find that effectiveness may be related to a period of extensive formative research (or its reporting in the literature), which allows the intervention to be carefully tailored to the target population, as well as high attendance rates. Intervention adherence and follow-up rates also appeared to be related to the effectiveness of an intervention in our review (section 5.1.6), and three of the most successful interventions,[56, 60] including the two large multi-centre studies,[52] reported extensive formative research (Table 5).

6.1.2 Impact on sexual behaviour

This review did find evidence that behavioural interventions may alter certain aspects of sexual behaviour in the population of interest (section 5.2.3). The majority of studies who considered effects on behavioural outcomes found an increase in the proportion of subjects reporting consistent condom use, and this is reflected in the statistically significant pooled result. Stratified analyses did not indicate that this effect was related to the study population, intervention format or number of sessions (section 5.4.2). However, the use of social cognitive or related theory as the basis for interventions was (non-significantly) associated with a greater impact on this outcome. Results for the proportion of sexual encounters protected by condoms were more mixed (section 5.3.3). Only one study appeared to show an impact of the intervention on increasing this outcome,[52] consistent with this study's effect on increasing consistent condom use. However, one study saw the proportion of sexual encounters protected by a condom fall,[57] in contrast to its finding on consistent use. These results are similar to those reported in the previous review[25] (section 2.6), though that did not include studies where behavioural rather than biological outcomes alone were reported.

Interventions were less consistently successful in reducing the number of different sexual partners (section 5.3.1), their characteristics (e.g. strangers or unknown HIV status, section 5.3.1), or the total number of sex acts (section 5.3.3) over and above the effects seen in the control groups. However, it was not possible to pool the data for these outcomes or conduct formal stratified analyses to identify patterns in the individual study results.

6.1.3 Relating sexual behaviour change to STI rates

The difference in apparent effectiveness of interventions in reducing STIs and promoting condom use (their main immediate aim, section 5.1.3) may be explained in a number of ways. It could represent a chance event, related to the very different 'event rates'

between outcomes and the power of studies to detect a difference (section 6.2.4), or importantly it could represent bias, arising from the different methods of ascertainment (further discussion in section 6.2.3).

Alternatively, increased consistent condom use alone may not be a sensitive marker of STI risk. Overall, the proportion reporting consistent condom use rose by just 6%, while many studies found little difference in average condom use. Also, while condom use is an important predictor of risk in population surveys (section 2.3) and was the main behaviour change desired by investigators (section 5.1.3), at the individual level, specific aspects of sexual behaviour may not be predictors of STI risk when taken in isolation.[23, 25] STI risk is the sum of many complex individual aspects of behaviour, and it cannot be assumed that interventions can do no harm[25] if, for example, they result in increased confidence in an individual's perceived ability to control STI risk regardless of other sexual risks being taken. A further analysis of individual-level data from the NIMH study[69] found that reducing the number of sexual partners was an important determinant of reducing the risk of gonorrhoea in addition to condom use, while the risk of HIV (used as an example of an STI thought to be less infectious per act of intercourse), was sensitive only to condom use.

Finally, condoms may protect less well for certain STIs (section 2.3). Typically the identified studies defined their primary outcome in terms of laboratory confirmed STIs (these were predominantly bacterial with gonorrhoea and chlamydia being the most commonly reported diagnoses, Table 7). These are infections for which condoms are thought to offer good protection (section 2.3). However, in the NIMH study[52] the intervention appeared to be more effective in preventing gonorrhoea alone than a combined outcome including gonorrhoea, chlamydia, non-gonococcal urethritis, syphilis and trichomonas (Table 7).

6.2 Limitations of the review

6.2.1 Generalisability of evidence

Relatively few studies of behavioural interventions were identified and these did not add considerable new evidence to previous reviews of the topic. The generalisability and relevance of this review's result relates to the populations and settings studied.[15] The majority of evidence comes from US urban sexual health clinics, so that differences in cultural and ethnic influences on sexual behaviour (section 2.3) and differences in the way sexual health services are provided and perceived, make it difficult to simply apply the results of this review to UK GUM settings. Similarly, differences in the populations recruited preclude considering effects on groups based on gender, age, sexuality or ethnicity separately.

Estimates of the effectiveness of experimental interventions relate to the choice of control intervention for comparison. This has implications for the applicability and relative magnitude of study results if control groups received significantly more or less input than is typical in the UK. Most identified studies offered information and a brief personalised discussion of risk-reduction according to CDC guidelines[1, 2] as their control (though this

is also similar to the 'brief' intervention offered by Kamb[56], section 5.1.4). This structured approach goes beyond what is currently offered in routine UK practice (section 2.2). In addition, two of the most successful interventions (in terms of increasing condom use[52, 58]) offered considerably more input to their control subjects, in one case, matching the interventions for time.[58]

The applicability of study results to UK practice also relates to the feasibility of introducing the experimental interventions into a GUM clinic setting. Current services are over-stretched (section 2.2); frequently operating with inadequate buildings, demand exceeding appointment times and insufficient staff from some disciplines.[6] Introducing an extensive behavioural programme requiring skilled psychology professionals and facilities for lengthy sessions over many weeks that may be taken up by only a small proportion of clinic patients (Table 6) may be regarded as impractical. However, this review found little evidence that the format or length of interventions were related to their success. In particular, the Kamb study[56] demonstrated that two 20-minute individual sessions were effective in reducing STI rates, and found no additional benefit of a series of longer sessions conducted over four-weeks. Yet even this 'brief' intervention probably goes beyond what could currently be offered as part of routine care in UK clinics due to inadequate time, facilities, resources, and importantly, trained staff.

6.2.2 Study quality

The RCTs included in this review randomly allocated individuals from the same clinic (frequently the only one) to different treatment arms. As the intervention is behavioural, aiming to promote sexual health, there is the potential for contamination of control groups from social and other interactions with those allocated to the intervention group.[23] This could dilute the apparent effectiveness of an intervention, particularly as most studies did show a reduction in STI rates and uptake of safer sexual practices in their control groups (sections 5.2 and 5.2.3). In addition, one of the studies to show a significant effect on laboratory confirmed STI rates used a method that should probably be regarded as cluster randomisation[60] (section 5.1.6). This is not accounted for in the analysis, which could potentially over-estimate the effect of this intervention.

The quality of identified studies was frequently poor. In many cases it was not possible to judge the adequacy of the method or concealment of allocation (Table 6) and the results originally reported by the authors were frequently not analysed as ITT. Jadad scores were low, even for the highest quality studies. This partly reflects the importance attached to the blinding of participants, investigators and outcome assessors to the results of the allocation process, which is an important technique to minimise bias in experimental studies. In behavioural research it may only be feasible to blind the assessors. However, this is still a valuable action[26] and its importance was recognised in the assessment of study quality (section 4.3).

Importantly, there was also evidence of differential follow-up rates between study arms in five studies, and many reported a low rate of and intervention adherence. However, in this context quality relates to the likelihood of bias, but stratified analysis suggests that the higher quality studies were more likely to show an effect of the intervention than low

quality studies (section 5.4.1). Studies in this review also reported low recruitment rates. If this were repeated outside of the research setting it might limit the overall impact of even effective interventions.

6.2.3 Study outcomes

This review regards STI rates as the primary outcome, offering the best evidence for effectiveness in respect of the review question (section 3), while behavioural changes are secondary outcomes, potentially occurring in the absence of a change to overall STI risk[25, 70] (section 6.1.3). Behavioural outcomes offer an increased potential for bias as they are exclusively self-reported and information on those lost to follow-up cannot be obtained. This may be a key limitation, especially when making comparisons with laboratory or clinic data (which were frequently collected without the need for a subject to attend a specific study related follow-up session), and must be considered as a potential explanation whenever positive effects of an intervention are reported on behaviour.

For STI rates, laboratory based diagnoses were preferred over clinical diagnoses, and in turn these were preferred to self-reported symptoms. Five studies offered the opportunity to directly compare these measures (Table 7). The NIMH study[52] found that results based on self-reported symptoms were more strongly in the direction indicating reduced STI rates than were those for laboratory confirmed infections. However, while three studies reported a greater reduction in clinically diagnosed STIs than laboratory confirmed infections[12, 57, 59] (or at least a smaller increase), one other study reported the reverse.[63]

6.2.4 Study power

Inadequate power of the identified studies to detect change in certain outcomes could also contribute to the inconsistency between behavioural and STI related outcomes (section 6.1.3). To achieve 80% power to detect a 16% fall in STI rates from the overall reported event rate in the control groups (Figure 2, a RR of 0.84 reflects the pooled value for the four most successful studies) at a conventional level of statistical significance (95% two-tailed), would require almost 4,000 participants in each study arm. This is approximately the same as the total number of patients recruited to studies that considered this outcome.

6.3 Implications of the review

6.3.1 Potential impact on STIs in the West Midlands

This review suggests that behavioural interventions may be effective in increasing the proportion of GUM clinic patients reporting consistent condom use, though there were inconsistent effects on STI rates and other measures of sexual behaviour (e.g. number of partners). Crucially, the magnitude of such effects depends on the choice of study control, and it is not clear what level of input is currently provided to most patients in the UK. Overall, less than half of those approached agreed to enter a study, reducing the

impact that the introduction of such interventions would be expected to have, and only two-thirds completed all or most of the sessions.

Two studies did report a reduction in STI rates that was statistically significantly greater in their intervention groups.[56, 60] Using the effect estimate provided by the most successful study (RR=0.66[60]) it is possible to estimate the maximum impact likely to follow from the introduction of behavioural interventions into UK West Midlands GUM clinics. For this we also assumed that both average trial recruitment rates would reflect a real clinic's experience of uptake and UK survey data showing high rates of past contact with GUM clinics among gonorrhoea patients[9] could be applied more widely.

This model suggests that each year we could expect to prevent approximately 180 cases of gonorrhoea, 440 cases of chlamydia, and over 3000 diagnosed STIs overall, i.e. a 6.7% reduction in the total number of cases. Assuming a more modest level of intervention effectiveness in this model (RR=0.84, the pooled estimate for the four most successful studies) results in an estimated 90 fewer cases of gonorrhoea, 210 fewer cases of chlamydia and almost 1500 diagnosed STIs overall, a 3.2% reduction.

These estimates are very sensitive to assumptions regarding the likelihood of re-attendance. Overall, the identified studies reported a re-infection rate of 12.6% in their control arms. Using this figure and a RR of 0.84, reduces the anticipated impact to just 25 fewer cases of gonorrhoea, 60 fewer cases of chlamydia, and 400 fewer STI diagnoses overall, reductions of 0.9%.

6.3.2 Implications for future research

This review highlights a clear need for UK based research into this topic.[17] No ongoing studies were identified during our search of relevant bibliographic and research databases, which is disappointing given the importance of such work to current policy initiatives (section 2.3). Future studies should aim to include patients who are representative of a UK GUM clinic and include groups who are most affected by STIs and suffer inequality in their sexual health[15] (section 2.1). In addition, any proposed clinical trials should seek to address the principal methodological difficulties that we have identified with existing research (section 6.2). This includes using a control arm that simulates typical current UK practice, minimising bias by improving methods of blinding, and including laboratory based or biological diagnoses.[23, 25] Trials could also consider the merits of attempting to reduce contamination through cluster-randomisation by clinic or other natural unit,[23] though this would tend to reduce study power. This review did not consider costs, though the feasibility of introducing behavioural interventions is briefly discussed (section 6.3.3). Future research should seek to address both clinical and cost-effectiveness,[15] and consider the likely uptake of behavioural interventions in this setting.

However, it is unlikely that any single UK based trial could both address these concerns and adequately consider the effect of interventions on important sub-groups based on sexuality or ethnicity. The relationship between changes in individual aspects of sexual behaviour and subsequent STIs is not fully understood, and is likely to vary between

populations. Further research in this area could permit the use of behavioural outcomes as proxy measures for infection risk, increasing the power of trials to detect meaningful differences. In addition, while this review found that no particular format or intensity of behavioural intervention appeared to be related to effectiveness, there was a suggestion that its theoretical basis and the use of extensive formative research may well be important.[15, 25] Tailoring the content of interventions to the specific population may be crucial,[28] and additional work comparing cultural norms and sexual beliefs between groups attending GUM clinics will also be required to inform further prevention efforts.

6.3.3 Policy implications

Current UK policy aims to reduce the occurrence of STIs (section 2.3), and in GUM clinics this could be achieved through reducing the risk of re-infection among clients. However, this review identified only two studies in which a behavioural intervention clearly achieved this goal,[56, 60] and such interventions have not been shown to be effective in a UK context.

Behavioural interventions were effective in altering specific aspects of sexual behaviour in a US context. In addition, on the evidence available its seems likely that study interventions that were appropriately tailored to their population following extensive formative research were more likely to reduce subsequent bacterial STIs than those that were not. However, the potential benefit of behavioural interventions in a local (UK West Midlands) context, the most effective mode of intervention delivery for patients in UK GUM clinics, the ideal content of such interventions, and the target group(s) most likely to benefit must await further research.

Existing research, both between and within-study, suggests that the number of sessions and the total time required to complete an intervention may be less important to success than its theoretical basis and formative work, allowing tailoring of the intervention to population at-risk. One of the studies to show success in reducing STI rates found no advantage of an enhanced four-week intervention over and above two 20-minute individually based counselling sessions. However, even if such an approach was shown to be effective in a UK setting, currently it could not be delivered as part of routine clinic care without increased resources, clinic time, and trained staff. In addition, the potential impact of such an intervention on STIs rates is not clear. This will depend on the uptake of such an intervention were it offered, and crucially on the proportion of STIs thought to occur in those who have previously attended GUM clinics. It will be very important to carefully consider the cost-effectiveness of behavioural interventions in any future research.

7. Appendices

Appendix 1 Sexually transmitted infections

Classification from KC60 returns[7]:

A1-9	syphilis - all forms including epidemiological treatment of suspected syphilis
B1-5	gonorrhoea - all forms including gonococcal complications and epidemiological treatment of suspected gonorrhoea
C1-3	chancroid/LGV/Donovanosis
C4a-e	genital chlamydial infection - including complications and epidemiological treatment of suspected chlamydial infection
C4h-I, C5	non-gonococcal/non-specific infection (urethritis in males) - included complications and epidemiological treatment
C6a	trichomoniasis
C6b	anaerobic/bacterial vaginosis or male infection
C7a-b	genital candidosis and epidemiological treatment of C6 and C7
C8-9	Scabies/pediculosis pubis
C10a	genital herpes simplex - first attack
C11a	genital warts - first attack
C12	molluscum contagiosum
C13-14	viral hepatitis - all types
E1a, 2a, 3a	HIV infection or AIDS - first presentation

The following conditions/codes are not considered to represent the acquisition of a new STI:

C10b	genital herpes simplex - subsequent attack
C11b-c	genital warts - recurrence

E1b, 2b, 3b	HIV infection and AIDS - subsequent presentation
D2a	urinary tract infection
D2b	other conditions requiring treatment at GUM clinic
D3	other conditions not requiring treatment at GUM clinic
P1a-b	HIV antibody counselling and testing

Appendix 2 Search strategies

Scoping Search

- MEDLINE (Ovid), 1966 to present (17/09/02)

1 exp Sexually Transmitted Diseases/pc [Prevention & Control]
2 exp Sexually Transmitted Diseases/
3 (sexually transmitted or STD or STI$0 or venereal disease$ or VD).mp.
4 (syphili$ or gonococc$ or gonorrh$ or chlamydi$ or urethritis or vaginosis or (genital adj herpes) or (genital adj wart) or HIV or AIDS or inguinale or chancroid).mp.
5 or/2-4
6 exp Psychotherapy/
7 *risk-taking/ or exp sex behavior/ or exp social dominance/
8 exp Health Promotion/
9 exp Health Education/
10 exp Counseling/
11 or/6-10
12 5 and 11
13 1 or 12
14 (systematic adj review$).tw.
15 (data adj synthesis).tw.
16 (published adj studies).ab.
17 (data adj extraction).ab.
18 meta-analysis/
19 meta-analysis.ti.
20 comment.pt.
21 letter.pt.
22 editorial.pt.
23 animal/
24 human/
25 23 not (23 and 24)
26 13 not (20 or 21 or 22 or 25)
27 or/14-19
28 26 and 27

Main Searches

- MEDLINE (Ovid) search - 1966 to present (16/12/02)

1 randomized controlled trial.pt.
2 controlled clinical trial.pt.
3 randomized controlled trials.sh.
4 random allocation.sh.
5 double blind method.sh.
6 single blind method.sh.
7 or/1-6
8 (animal not human).sh.
9 7 not 8
10 clinical trial.pt.
11 exp clinical trials/
12 (clin$ adj25 trial$).ti,ab.
13 ((singl$ or doubl$ or treb$ or trip$) adj25 (blind$ or mask$)).ti,ab.
14 placebos.sh.
15 placebo$.ti,ab.
16 random$.ti,ab.
17 research design.sh.
18 or/10-17
19 18 not 8
20 19 not 9
21 comparative study.sh.
22 exp evaluation studies/
23 follow up studies.sh.
24 prospective studies.sh.
25 (control$ or prospectiv$ or volunteer$).ti,ab.
26 or 21-25
27 26 not 8
28 27 not (9 or 20)
29 9 or 20 or 28
30 exp sexually transmitted diseases/pc [prevention & control]
31 exp sexually transmitted diseases/
32 (sexually transmitted or STD or STI$0 or venereal disease$ or VD).mp.
33 (syphili$ or gonococc$ or gonorrh$ or chlamydi$ or urethritis or vaginosis or (genital adj herpes) or (genital adj wart) or HIV or AIDS or inguinale or chancroid).mp.
34 or/31-33
35 exp psychotherapy/
36 *risk-taking/ or exp sex behavior/ or exp social dominance/
37 exp health promotion/
38 exp health education/
39 exp counseling/
40 or 35-39

41 34 and 40
42 29 and 30
43 29 and 41
44 42 or 43

- Embase search - 1980 to present (16/12/02)

1 Randomized Controlled Trial/
2 exp clinical trial/
3 exp controlled study/
4 double Blind Procedure/
5 randomization/
6 single blind procedure/
7 (control$ adj (trial$ or stud$ or evaluation$ or experiment$)).mp.
8 ((singl$ or doubl$ or trebl$ or tripl$) adj5 (blind$ or mask$)).mp.
9 (placebo$ or matched communities or matched clinic$ or matched populations).mp.
10 placebo/
11 (comparison group$ or control group$).mp.
12 (clinical trial$ or random$).mp.
13 (quasiexperimental or quasi experimental or pseudo experimental).mp.
14 matched pairs.mp.
15 or/1-14
16 limit 15 to human
17 exp Sexually Transmitted Disease/pc [Prevention]
18 exp Sexually Transmitted Disease/
19 (sexually transmitted or STD$ or venereal disease or VD).mp.
20 (syphili$ or gonococc or gonorrh$ or chlamydi$ or urethritis or vaginosis or (genital adj (herpes or wart)) or HIV or AIDS or inguinale or chancroid).mp.
21 or/18-20
22 exp psychotherapy/ or behavior therapy/
23 exp Sexual Behavior/
24 exp sexual behavior/ or exp social behavior/
25 exp Health Promotion/
26 exp Health Promotion/ or exp Health Education/
27 exp Counseling/
28 16 and 17
29 21 and (or/22-27)
30 16 and 29
32 28 or 30

- CINAHL search - 1982 to present (04/12/02)

1 exp Clinical Trials/

2 randomi#ed control$ trial.mp. [mp=title, cinahl subject heading, abstract, instrumentation]
3 exp Random Assignment/ or exp Double-Blind Studies/
4 exp Placebos/
5 exp Single-Blind Studies/
6 (control$ adj (trial$ or stud$ or evaluation$ or experiment$)).mp.
7 ((singl$ or doubl$ or trebl$ or trip$) adj5 (blind$ or mask$)).mp.
8 (placebo$ or matched communities or matched clinic$ or matched populations).mp.
9 (comparison group$ or control group$).mp.
10 (clinical trial$ or random$).mp.
11 (quasiexperimental or quasi experimental or pseudo experimental).mp.
12 matched pairs.mp.
13 or/1-12
14 exp Sexually Transmitted Diseases/pc [Prevention and Control]
15 exp sexually transmitted diseases/
16 (sexually transmitted or STD or STI$0 or venereal disease$ or VD).mp.
17 (syphili$ or gonococc$ or gonorrh$ or chlamydi$ or urethritis or vaginosis or (genital adj herpes) or (genital adj wart) or HIV or AIDS or inguinale or chancroid).mp.
18 or/15-17
19 exp Psychotherapy/
20 exp behavioral changes/ or exp behavioral objectives/ or exp health behavior/ or exp help seeking behavior/ or exp information seeking behavior/ or exp power/ or exp risk taking behavior/ or exp self-injurious behavior/ or exp sexuality/ or safe sex/ or exp social behavior/ or exp social dominance/ or exp social skills/
21 exp Health Promotion/
22 exp Health Education/
23 exp Counseling/
24 or/19-23
25 18 and 24
26 14 or 25
27 13 and 26

- PsychINFO search - 1985 to present (16/12/02)

1 randomi#ed control$ trial$.mp. [mp=title, abstract, heading word, table of contents, key concepts]
2 clinical trial$.mp.
3 (control$ adj (trial$ or stud$)).mp.
4 placebo$.mp.
5 (randomization or randomisation or (random$ adj (assign$ or allocat$))).mp.
6 ((singl$ or doubl$ or tripl$ or treb$) adj5 (blind$ or mask$)).mp.
7 (matched communities or matched clinic$ or matched populations).mp.
8 (comparison group$ or control group$).mp.
9 random$.mp.

10 matched pairs.mp.
11 (quasi experimental or quasiexperimental or pseudo experimental).mp.
12 or/1-7
13 or/1-11
14 exp venereal diseases/
15 13 and 14
16 (sexually transmitted or STD$ or venereal disease$ or VD).mp.
17 13 and 16
18 exp cognitive therapy/
19 exp *Behavior Modification/ or exp *Health Care Psychology/ or exp *Behavior Therapy/
20 or/18-19
21 (14 or 16) and 20
22 15 or 17 or 21

- ASSIA search - 1987 to present (16/12/02)

Query: DE=((sexually transmitted disease)) AND DE=((prevention))

- CCTR - 2002 Issue 4 (17/12/02)

#1. SEXUALLY TRANSMITTED DISEASES explode all trees (MeSH)
#2. (sexually transmitted) or STD or venereal or VD or GUM or genitourinary or genito urinary
#3. syphili* or gonococc* or gonorrh* or chlamydi* or urethritis or vaginosis or genital or HIV or AIDS or inguinale or chancroid
#4. #1 or #2 or #3
#5. PSYCHOTHERAPY explode all trees (MeSH)
#6. SEX BEHAVIOR explode all trees (MeSH)
#7. HEALTH PROMOTION single term (MeSH)
#8. HEALTH EDUCATION explode all trees (MeSH)
#9. #5 or #6 or #7 or #8
#10. #4 and #9

Appendix 3 Inclusion criteria form

Trial reference

First author and year of publication

Date

Is the study a randomised controlled trial	Y	N	DK
Is the study population[a] recruited from those attending a genitourinary medicine clinic or equivalent (public clinic offering free services and self-referral for the screening, diagnosis and treatment of STDs)	Y	N	DK
Is the population primarily recruited from those with known HIV infection or AIDS	N	Y	DK
Is the intervention behavioural and aimed to reduce the future likelihood of acquiring an STD, but excluding the provision of HIV testing with or without counselling as the principle intervention (N.B. intervention should provide more than the passive availability of written educational material alone)	Y	N	DK
Are outcomes related to clinically or laboratory diagnosed STD rates, self-reported STD rates, or to self-report of quantifiable behavioural changes (e.g. condom use, number of partners, etc.), but not attitudinal or knowledge based measures alone, and not related to partner notification alone	Y	N	DK

If all answers are in the first column then include the study

a. *Or sub-group of study population, provided that full separate reported results are available for that sub-group*

Appendix 4 Quality assessment form

Trial reference

Date

a. Randomisation

1. Was the RCT described as randomised?	Y	N	DK
2. Was allocation truly random?	Y	N	DK

b. Concealment of allocation

Was concealment of treatment allocation truly adequate?	Y	N	DK

c. Masking

1. Was the trial described as double blind?	Y	N	DK
2. Was treatment allocation masked from participants?	Y	N	DK
3. Was treatment allocation masked from investigators	Y	N	DK
4. Was treatment allocation masked from outcome assessors?	Y	N	DK

d. Completeness of trial

1. Were the number of withdrawals in each group stated?	Y	N	DK
2. Was an intention to treat analysis done?	Y	N	DK
3. Were the drop out rates similar in both groups?	Y	N	DK

Scoring

If A1 = Y	add 1
if A2 = Y	add 1
if C1 = Y	add 1
if D1 = Y	add 1

If A1 = Y and either A2 = N or B = N	subtract 1
If C2 = Y and C4 = Y	add 1
if C1 = Y and either C2 = N or C4 = N	subtract 1

Total score (between 0 and 5):

Appendix 5 Data extraction form

Trial reference

First author and year of publication

Date

a. Setting for trial

1. Location (city and country)

2. Clinical setting of trial

3. Trial dates

b. Population

1. Specific characteristics of those recruited e.g. unselected clinic attenders, specific diagnosis, sexual orientation, sex workers, etc.

2. How were participants recruited to the trial

3. Total number of participants recruited to the trial

Characteristic	Intervention or comparator group			
4. Number randomised to group				
5. Gender				
6. Age mean and CI (or median and range)				
7. Expressed sexual orientation				
8. Ethnicity				
9. Drop outs prior to completing intervention				
10. Total number lost to follow up				

c. Intervention(s) *repeat and label A, B, C, etc if more than one*

1. Describe all the specific elements of the intervention

2. What was the duration of the intervention (or specific elements of the intervention)

3. What was the period of follow up for the intervention group

4. Did the intervention explicitly derive from a theoretical framework, and if so, what was the theoretical framework used

5. Did the intervention undergo a period of developmental or formative research, or if not, what justification is offered for the selection of elements that formed the intervention

d. Comparator(s) *repeat and label A, B, C, etc if more than one*

1. Describe all the specific elements of the comparator

2. What was the duration of the comparator (or specific elements of the comparator)

3. What was the period of follow up for the comparator group

4. What justification is offered for the selection of elements that formed the comparator

e. Dichotomous outcomes (e.g. acquisition of a further STD)
repeat for each outcome

1. Describe the specific outcome and how data were obtained e.g. self-report by questionnaire or interview, laboratory confirmed diagnosis

2. At what point(s) following the intervention was the outcome assessed

3. Was the analysis carried out on an intention to treat basis

	Intervention or comparator group			
4. Number allocated to group				
5. Events at baseline				
6. Number available at follow up 1				
7. Events at follow up 1				
8. Number available at follow up 2				
9. Event at follow up 2				

10. Stated measure of association (e.g. OR) and p-value for significance test (state which) and/or 95% confidence interval

f. Other outcomes (e.g. number of sexual partners) *repeat for each*

1. Describe the specific outcome and how data were obtained e.g. self-report by questionnaire or interview, laboratory confirmed diagnosis

2. At what point(s) following the intervention was the outcome assessed

3. Was the analysis carried out on an intention to treat basis

	Intervention or comparator group			
11. Number allocated to group				
12. Baseline value (and measure of spread)[1]				
13. Number available at follow up 1				
14. Mean (SD) at follow up 1				
15. Mean (SD) difference from baseline				
16. Number available at follow up 2				
17. Mean (SD) at follow up 2				
18. Mean (SD) difference from baseline				

1. state whether mean and SD, median and range or other

19. Stated p-value for significance test of difference (state which) and/or 95% confidence interval

g. Final comments

e.g. comments on drop-out rates, acceptability of intervention, other outcomes considered, etc

Appendix 6 Included studies

Principal citation and secondary citations:

1. M. L. Kamb, M. Fishbein, J. M. Jnr. Douglas, F. Rhodes, J. Rogers, G. Bolan, J. Zenilman, T. Hoxworth, C. K. Malotte, M. Iatesta, C. Kent, A. Lentz, S. Graziano, R. H. Byers, and T. A. Peterman. Efficacy of risk-reduction counseling to prevent human immunodeficiency virus and sexually transmitted diseases. A randomized controlled trial. *JAMA* 280 (13):1161-1167, 1998.

    Centers for Disease Control and Prevention. Distribution of STD clinic patients along a stages-of behavioral-change continuum - selected sites, 1993. *MMWR* 42 (45):880-883, 1993.

    Centers for Disease Control and Prevention. Contraceptive practices before and after an intervention promoting condom use to prevent HIV infection and other sexually transmitted diseases among women - selected U.S. sites, 1993-1995. *MMWR* 46 (17):373-377, 1997.

    D. Albarracín, R. M. Ho, P. S. McNatt, W. R. Williams, F. Rhodes, C. K. Malotte, T. Hoxworth, G. A. Bolan, J. Zenilman, and M. Iatesta. Structure of outcome beliefs in condom use. *Health Psychology* 19 (5):458-468, 2000.

    J. M. Douglas, T. Hoxworth, J. Rogers, M. Iatesta, F. Rhodes, C. K. Malotte, G. A. Bolan, C. Kent, J. Zenilman, and A. Lenz. Contraceptive practices before and after an intervention promoting condom use to prevent HIV infection and other sexually transmitted diseases among women - selected US sites, 1993-1995. *JAMA* 277 (22):1752-1753, 1997.

    R. A. Crosby, D. Newman, M. L. Kamb, J. Zenilman, J. M. Douglas, and M. Iatesta. Misconceptions about STD-protective behavior. *American Journal of Preventive Medicine* 19 (3):167-173, 2000.

    M. Fishbein, M. Hennessy, M. Kamb, G. A. Bolan, T. Hoxworth, M. Iatesta, F. Rhodes, and J. M. Zenilman. Using intervention theory to model factors influencing behavior change: Project RESPECT. *Evaluation and the Health Professions* 24 (4):363-384, 2001.

    M. L. Kamb, B. A. Dillon, M. Fishbein, and K. L. Willis. Quality assurance of HIV prevention counseling in a multi-center randomized controlled trial. *Public Health Reports* 111 (suppl. 1):99-107, 1996.

    M. L. Kamb, F. Rhodes, T. Hoxworth, J. Rogers, A. Lentz, C. Kent, R. MacGowan, and T. A. Peterman. What about money? Effect of small monetary incentives on enrolment, retention, and motivation to change behavior in an HIV/STD prevention counselling intervention. *Sexually Transmitted Infections* 74:253-255, 1998.

    C. K. Malotte, B. Jarvis, M. Fishbein, M. Kamb, M. Iatesta, T. Hoxworth, J. Zenilman, and G. Bolan. Stage of change versus an integrated psychosocial theory as a basis for developing effective behavioral change interventions. *AIDS Care* 12 (3):357-364, 2000.

    T. A. Peterman, L. S. Lin, D. R Newman, M. L. Kamb, G. Bolan, J. Zenilman, J. M. Jnr. Douglas, J. Rogers, and C. K. Malotte. Does measured behavior reflect STD risk? An analysis of data from a randomized controlled behavioral intervention study. *Sexually Transmitted Diseases* 27 (8):446-451, 2000.

2. The National Institute of Mental Health (NIMH) Multisite HIV Prevention Trial Group. The NIMH Multisite HIV Prevention Trial: Reducing HIV sexual risk behavior. *Science* 280 (5371):1889-1894, 1998.

anonymous. Methodological overview of a multisite HIV prevention trial for populations at risk for HIV. NIMH Multisite Prevention Trial. *AIDS* 11 (suppl. 2):S1-S11, 1997.

The National Institute of Mental Health Multisite HIV Prevention Trial Group. Social-cognitive theory mediators of behavior change in the National Institute of Mental Health Multisite HIV Prevention Trial. *Health Psychology* 20 (5):369-376, 2001.

The National Institute of Mental Health (NIMH) Multisite HIV Prevention Trial Group. Predictors of sexual behavior patterns over one year among persons at high risk for HIV. *Archives of Sexual Behavior* 31 (2):165-176, 2002.

G. S. Makulowich. HIV and STD prevention update. Multisite HIV prevention trial. *AIDS Patient Care and STDs* 12 (9):725-727, 1998.

D. A. Murphy, J. A. Stein, W. Schlenger, E. Maibach, and The National Institute of Mental Health Multisite HIV Prevention Trial Group. Conceptualizing the multidimensional nature of self-efficacy: assessment of situational context and level of behavioral change to maintain safe sex. *Health Psychology* 20 (4):281-290, 2001.

S. D. Pinkerton, P. M. Layde, W. DiFranceisco, H. W. Chesson, NIMH Multisite HIV Prevention Trial Group. All STDs are not created equal: an analysis of the differential effects of sexual behaviour changes on different STDs. *International Journal of STD and AIDS* 14 (5):320-328, 2003.

3. D. H. Balmer, E. Gikundi, and et al. A clinical trial of group counselling for changing high-risk sexual behavior in men. *Counselling Psychology Quarterly* 11 (1):33-43, 1998.

4. C. B. Boyer, D. C. Barrett, T. A. Peterman, and G. Bolan. Sexually transmitted disease (STD and HIV risk in heterosexual adults attending a public STD clinic: evaluation of a randomized controlled behavioral risk-reduction intervention trial. *AIDS* 11 (3):359-367, 1997.

5. B. M. Branson, T. A. Peterman, R. O. Cannon, R. Ransom, and A. A. Zaidi. Group counseling to prevent sexually transmitted disease and HIV: a randomized controlled trial. *Sexually Transmitted Diseases* 25 (10):553-560, 1998.

6. J. M. Imrie, J. M. Stephenson, F. M. Cowan, S. Wanigaratne, A. J. P. Billington, A. J. Copas, L. French, P. D. French, and A. M. Johnson. A cognitive behavioural intervention to reduce sexually transmitted infections among gay men: randomised trial. *Br Med J* 322:1451-1456, 2001.

7. S. C. Kalichman, C. Cherry, and F. Browne-Sperling. Effectiveness of a video-based motivational skills-building HIV risk-reduction intervention for inner-city African American men. *Journal of Consulting & Clinical Psychology* 67 (6):959-966, 1999.

8. J. E. Maher, T. A. Peterman, P. L. Osewe, S. Odusanya, and J. R. Scerba. Evaluation of a community-based organization's intervention to reduce the incidence of sexually transmitted diseases: a randomized controlled trial. *Sexually Transmitted Diseases* 96 (3):248-253, 2003.

9. C. W. Metzler, A. Biglan, J. Noell, D. V. Ary, and L. Ochs. A randomized controlled trial of a behavioral intervention to reduce high-risk sexual behavior among adolescents in STD clinics. *Behavior Therapy* 31:27-54, 2000.

10. A. O'Leary, T. K. Ambrose, M. Raffaelli, E. Maibach, L. S. Jemmot, J. B. III. Jemmott, E. Labouvie, and D. Celentano. Effects of an HIV risk reduction project in sexual risk behavior of low-income STD patients. *AIDS Education and Prevention* 10 (6):483-492, 1998.

    A. O'Leary, E. Maibach, T. K. Ambrose, J. B. III. Jemmott, and D. Celentano. Social cognitive predictors of sexual risk behavior change among STD clinic patients. *AIDS & Behavior* 4 (4):309-316, 2000.

11. D. P. Orr, C. D. Langefeld, B. P. Katz, and V. A. Caine. Behavioral intervention to increase condom use among high-risk female adolescents. *Journal of Pediatrics* 128 (2):288-295, 1996.

12. R. N. Shain, J. M. Piper, E. R. Newton, S. T. Perdue, R. Ramos, J. D. Champion, F. A. Guerra. A randomized controlled trial of an intervention to prevent sexually transmitted disease among minority women. *New England Journal of Medicine* 340 (2):93-100, 1999.

13. L. A. Shrier, R. Ancheta, E. Goodman, V. M. Chiou, M. R. Lyden, and S. J. Emans. Randomized controlled trial of a safer sex intervention for high-risk adolescent girls. *Archives of Pediatrics & Adolescent Medicine* 155 (1):73-79, 2001.

14. M. Z. Solomon and W. DeJong. Preventing AIDS and other STDs through condom promotion: a patient education intervention. *American Journal of Public Health* 79 (4):453-458, 1989.

Appendix 7 Excluded studies

Studies rejected after review of their published abstracts:

Citation	Reason(s) for rejection
D. Albarracín, P. S. McNatt, C. T. F. Klein, R. M. Ho, A. L. Mitchell, and G. T. Kumkale. Persuasive communication to change actions: an analysis of behavioral and cognitive impact on HIV prevention. *Health Psychology* 22 (2):166-177, 2003.	not an evaluation, trial or RCT[a]
Y. A. Amirkhanian, J. A. Kelly, E. Kabakchieva, T. L. McAuliffe, and S. Vassileva. Evaluation of a social network HIV prevention intervention program for young men who have sex with men in Russia and Bulgaria. *AIDS Education and Prevention* 15 (3):205-220, 2003.	not an evaluation, trial or RCT[a]
C. P. Archibald, R. K. Chan, M. L. Wong, A. Goh, and C. L. Goh. Evaluation of a safe sex intervention programme among sex workers in Singapore. *International Journal of STD & AIDS* 5 (4):268-272, 1994.	not an evaluation, trial or RCT[a]
C. S. Ashworth, R. H. DuRant, G. Gaillard, and J. Rountree. An experimental evaluation of an AIDS educational intervention for WIC mothers... Women, Infants and Children program. *AIDS Education and Prevention* 6 (2):154-162, 1994.	subjects not from GUM clinic study not reporting STI or appropriate behavioural outcome
K. Bellingham and P. Gillies. Evaluation of an AIDS education programme for young adults. *Journal of Epidemiology & Community Health* 47 (2):134-138, 1993.	subjects not from GUM clinic
G. Bhave, C. P. Lindan, E. S. Hudes, S. Desai, U. Wagle, S. P. Tripathi, and J. S. Mandel. Impact of an intervention on HIV, sexually transmitted diseases, and condom use among sex workers in Bombay, India. *AIDS* 9 (suppl. 1):s21-s30, 1995.	subjects not from GUM clinic
R. Blonna, P. Legos, and P. Burlack. The effects of an STD educational intervention on follow-up appointment keeping and medication-taking compliance. *Sexually Transmitted Diseases* 16 (4):198-200, 1989.	not studying a behavioural intervention aiming to change sexual behaviour study not reporting STI or appropriate behavioural outcome
B. O. Boekeloo, L. A. Schamus, S. J. Simmens, T. L. Cheng, K. O'Connor, and L. J. D'Angelo. A STD/HIV prevention trial among adolescents in managed care. *Pediatrics* 103 (1):107-115, 1999.	subjects not from GUM clinic
S. Booth-Kewley, A. M. Andrews, R. A. Shaffer, P. A. Gilman, R. Y. Minagawa, and S. K. Brodine. One-year follow-up evaluation of the sexually transmitted diseases/human immunodeficiency virus intervention program in a Marine Corps sample. *Military Medicine* 166 (11):987-995, 2001.	subjects not from GUM clinic
S. Booth-Kewley, R. Y. Minagawa, R. A. Shaffer, and S. K. Brodine. A behavioral intervention to prevent sexually transmitted diseases/human immunodeficiency virus in a marine corps sample. *Military Medicine* 167 (2):145-150, 2002.	subjects not from GUM clinic study not reporting STI or appropriate behavioural outcome

C. B. Boyer, M-A. B. Shafer, R. A. Shaffer, S. K. Brodine, S. I. Ito, D. L. Yniguez, D. M. Benas, and J. Schnachter. Prevention of sexually transmitted diseases and HIV in young military men: Evaluation of a cognitive-behavioral skills-building intervention. *Sexually Transmitted Diseases* 28 (6):349-355, 2001.	subjects not from GUM clinic
E. J. Brown and E. M. Simpson. Comprehensive STD/HIV prevention education targeting US adolescents: review of an ethical dilemma and proposed ethical framework. *Nursing Ethics* 7 (4):339-349, 2000.	not an evaluation, trial or RCT
A. D. Bryan, L. S. Aiken, and S. G. West. Increasing condom use: evaluation of a theory-based intervention to prevent sexually transmitted diseases in young women. *Health Psychology* 15 (5):371-382, 1996.	subjects not from GUM clinic
D. D. Celentano, K. C. Bond, C. M. Lyles, S. Eiumtrakul, V. F-l. Go, C. Beyrer, C. Na Chiangmai, K. E. Nelson, C. Khamboonruang, and C. Vaddhanaohuti. Preventive intervention to reduce sexually transmitted infections: A field trial in the Royal Thai Army. *Archives of Internal Medicine* 160 (4):535-540, 2000.	subjects not from GUM clinic
M. A. Chesney, B. A. Koblin, P. J. Barresi, M. J. Husnik, C. L. Celum, G. Colfax, K. Mayer, D. McKirnan, F. N. Judson, Y. Huang, and T. J. Coates. An individually tailored intervention for HIV prevention: baseline data from the EXPLORE study. *American Journal of Public Health* 93 (6):933-938, 2003.	not an evaluation, trial or RCT[a]
E. F. Clark. Women's self-reported experience and action in relation to protection against sexual transmission of HIV: A randomized case comparison study of three interventions. *Dissertation Abstracts International: Section B: the Sciences & Engineering* Vol 57(4-B), Oct 1996:2859, 1996.	subjects not from GUM clinic
L. R. Clark, C. Brasseux, D. Richmond, P. Getson, and L. J. D'Angelo. Effect of HIV counseling and testing on sexually transmitted diseases and condom use in an urban adolescent population. *Archives of Pediatrics & Adolescent Medicine* 152 (3):269-273, 1998.	not an evaluation, trial or RCT
A. L. Conboy Martiniuk, K. S. O'Connor, and W. D. King. A cluster randomized trial of a sex education programme in Belize, Central America. *International Journal of Epidemiology* 32 (1):131-136, 2003.	subjects not from GUM clinic study not reporting STI or appropriate behavioural outcome
K. Coyle, K. Basen-Engquist, D. Kirby, G. Parcel, S. Banspach, J. Collins, E. Baumler, S. Carvajal, and R. Harrist. Safer choices: Reducing teenage pregnancy, HIV, and STDs. *Public Health Reports* 116 (suppl. 1):82-93, 2001.	subjects not from GUM clinic
T. Coyne-Beasley, C. A. Ford, M. W. Waller, A. A. Adimora, and M. D. Resnik. Sexually active student's willingness to use school-based health centers for reproductive health care services in North Carolina. *Ambulatory Pediatrics* 3 (4):196-202, 2003.	not an evaluation, trial or RCT[a]
J. B. F. de Wit, N. Teunis, G. J. P. van Griensven, and T. G. M. Sandfort. Behavioral risk-reduction strategies to prevent HIV infection among homosexual men: a grounded theory approach. *AIDS Education and Prevention* 6 (6):493-505, 1994.	not an evaluation, trial or RCT

S. Deren, R. Stephens, W. R. Davis, T. E. Feucht, and S Tortu. The impact of providing incentives for attendance at AIDS prevention sessions. *Public Health Reports* 109 (4):548-554, 1994.	subjects not from GUM clinic not studying a behavioural intervention aiming to change sexual behaviour
S. Deren, W. R. Davis, M. Beardsley, S Tortu, and M. Clatts. Outcomes of a risk-reduction intervention with high-risk populations: the Harlem AIDS project. *AIDS Education and Prevention* 7 (5):379-390, 1995.	subjects not from GUM clinic
R. J. DiClemente and G. M. Wingwood. A randomized controlled trial of an HIV sexual risk-reduction intervention for young African-American women. *JAMA* 274 (16):1271-1276, 1995.	subjects not from GUM clinic
R. J. DiClemente, G. M. Wingwood, C. Sionean, R. Crosby, K. Harrington, S. Davies, E. W. III. Hook, and M. K. Oh. Association of adolescent's history of sexually transmitted disease (STD) and their current high-risk behavior and STD status: A case for intensifying clinic-based prevention efforts. *Sexually Transmitted Diseases* 29 (9):503-509, 2002.	not an evaluation, trial or RCT
S. M. Downs and J. D. Klein. Clinical preventive services efficacy and adolescents' risky behaviors. *Archives of Pediatrics & Adolescent Medicine* 149 (4):374-379, 1995.	subjects not from GUM clinic
M. Egger, J. Pauw, A. Lopatatzidis, D. Medrano, F. Paccaud, and G. D. Smith. Promotion of condom use in a high-risk setting in Nicaragua: a randomised controlled trial. *Lancet* 356 (9221):2101-2105, 2000.	subjects not from GUM clinic
N. El-Bassell, S. S. Witte, L. Gilbert, E. Wu, M. Chang, J. Hill, and P. Steinglass. The efficacy of a relationship based HIV/STD prevention program for heterosexual couples. *American Journal of Public Health* 93 (6):963-969, 2003.	subjects not from GUM clinic
J. Elford, L. Sherr, G. Bolding, F. Serle, and M. Maguire. Peer-led HIV prevention among gay men in London: process evaluation. *AIDS Care* 14 (3):351-360, 2002.	not an evaluation, trial or RCT
E. Faxelid, G. Tembo, J. Ndulo, and I. Krantz. Individual counseling of patients with sexually transmitted diseases. A way to improve partner notification in a Zambian setting? *Sexually Transmitted Diseases* 23 (4):289-292, 1996.	not studying a behavioural intervention aiming to change sexual behaviour study not reporting STI or appropriate behavioural outcome
P. J. Feldblum, M. Kuyoh, M. Omari, K. Aryan, J. J. Bwayo, and M. Welsh. Baseline STD prevalence in a community intervention trial of the female condom in Kenya. *Sexually Transmitted Infections* 76 (6):454-456, 2000.	subjects not from GUM clinic
A. M. Fitzgerald, B. F. Stanton, N. Terreri, H. Shipena, X. Li, J. Kahihuata, I. B. Richardo, J. S. Galbraith, and A. M. De Jaeger. Use of Western-based HIV risk-reduction interventions targeting adolescents in an African setting. *Journal of Adolescent Health* 25 (1):52-61, 1999.	subjects not from GUM clinic
P. P. French, M. Latka, E. L. Gollub, C. Rogers, D. R. Hoover, and Z. A. Stein. Use-effectiveness of the female versus male condom in preventing sexually transmitted disease in women. *Sexually Transmitted Diseases* 30 (5):433-439, 2003.	not studying a behavioural intervention aiming to change sexual behaviour

A. L. Fontanet, J. Saba, V. Chandelying, C. Sakondhavat, P. Bhiraleus, S. Rugpao, C. Chongsomchai, O. Kirwat, S. Tovanabutra, L. Dally, J. M. Lange, and W. Rojanapithayakorn. Protection against sexually transmitted diseases by granting sex workers in Thailand the choice of using the male or female condom: results from a randomized controlled trial. *AIDS* 12 (14):1851-1859, 1998.	subjects not from GUM clinic
K. Ford, D. N. Wirawan, P. Fajans, P. Meliawan, K. MacDonald, and L. Thorpe. Behavioral interventions for reduction of sexually transmitted disease/HIV transmission among female commercial sex workers and clients in Bali, Indonesia. *AIDS* 10 (2):213-222, 1996.	subjects not from GUM clinic
S. E. Hetherington, R. M. Harries, R. B. Bausell, K. H. Kavanagh, and D. E. Scott. AIDS prevention in high-risk African American women: behavioral, psychological, and gender issues. *Journal of Sex & Marital Therapy* 22 (1):9-21, 1996.	subjects not from GUM clinic
S. Hoffman, T. M. Exner, C-S. Leu, A. A. Ehrhardt, and Z. Stein. Female-condom use in a gender-specific family planning clinic trial. *American Journal of Public Health* 93 (11):1897-1903, 2003.	not studying a behavioural intervention aiming to change sexual behaviour
G. Hughes, M. Catchpole, P. A. Rogers, A. R. Brady, G. Kinghorn, D. Mercey, and N. Thin. Comparison of risk factors for four sexually transmitted infections: Results from a study of attenders at three genitourinary medicine clinics in England. *Sexually Transmitted Infections* 76 (4):262-267, 2000.	not an evaluation, trial or RCT
M. K. Hutchinson, J. B. 3rd. Jemmot, L. S. Jemmot, P. Braverman, and G. T. Fong. The role of mother-daughter sexual risk communication in reducing sexual risk behaviors among urban adolescent females: a prospective study. *Journal of Adolescent Health* 33 (2):98-107, 2003.	not an evaluation, trial or RCT[a]
J. B. 3rd. Jemmot, L. S. Jemmot, and G. T. Fong. Abstinence and safer sex HIV risk-reduction interventions for African American adolescents: a randomized controlled trial. *JAMA* 279 (19):1529-1536, 1998.	subjects not from GUM clinic
N. Job-Spira, L. Meyer, E. Bouvet, A. Janaud, and A. Spira. The prevention of sexually transmitted diseases which affect fertility: methodological problems and initial results. *European Journal of Obstetrics, Gynaecology, & Reproductive Biology* 27 (2):157-164, 1988.	subjects not from GUM clinic
W. D. Johnson, L. V. Hedges, and R. M. Diaz. Interventions to modify sexual risk behaviors for preventing HIV infection in men who have sex with men (Cochrane review). In: *The Cochrane Library*, Issue 4, 2003. Oxford: Update Software.	review article including non-RCTs[a]
S. C. Kalichman, J. A. Kelly, T. L. Hunter, D. A. Murphy, and R. Tyler. Culturally tailored HIV-AIDS risk-reduction mesages targeted to African-American urban women: impact on risk sensitization and risk reduction. *Journal of Consulting & Clinical Psychology* 61 (2):291-295, 1993.	subjects not from GUM clinic
S. C. Kalichman, D. Rompa, and B. Coley. Experimental component analysis of a behavioral HIV-AIDS prevention intervention for inner-city women. *Journal of Consulting & Clinical Psychology* 64 (4):687-693, 1996.	subjects not from GUM clinic
R. Kane, W. MacDowall, and K. Wellings. Providing information for young people in sexual health clinics: getting it right. *Journal of Family Planning & Reproductive Health Care* 29 (3):141-145, 2003.	not an evaluation, trial or RCT[a]

M. D. Kipke, C. Boyer, and K. Hein. An evaluation of an AIDS risk reduction education and skills training (ARREST) program. *Journal of Adolescent Health* 14 (7):533-539, 1993.	subjects not from GUM clinic
I. Kleinschmidt, B. N. Maggwa, J. Smit, M. E. Beksinska, and H. Rees. Dual protection in sexually active women. *South African Medical Journal* 93 (11):854-857, 2003.	not an evaluation, trial or RCT[a]
D. Koniak-Griffin, J. Lesser, A. Nyamathi, G. Uman, J. A. Stein, and W. G. Cumberland. Project CHARM: an HIV prevention program for adolescent mothers. *Family and Community Health* 26 (2):94-107, 2003.	subjects not from GUM clinic
Le Truong Giang, Nguyen Thanh Son, L. T. L. Thao, L. Vu, E. S. Hudes, and C. Lindan. Evaluation of STD/HIV prevention needs of low- and middle-income female sex workers in Ho Chi Minh City, Vietnam. *AIDS & Behavior* 4 (1):83-91, 2000.	not an evaluation, trial or RCT
R. M. Malow, J. A. West, S. A. Corrigan, J. M. Pena, and S. C. Cunningham. Outcome of psychoeducation for HIV risk reduction. *AIDS Education and Prevention* 6 (2):113-125, 1994.	subjects not from GUM clinic
L. Montesinos, B. F. Greene, L. E. Frisch, and M. Hamilton. An analysis of and intervention in the sexual transmission of disease. *Journal of Applied Behavior Analysis* 23 (Fall 90):275-284, 1990.	not studying a behavioural intervention aiming to change sexual behaviour
D. Morrison-Beedy, M. P. Carey, T. Aronowitz, L. Mkandawire, and J. Dyne. An HIV risk-reduction intervention in an adolescent correctional facility: lessons learned. *Applied Nursing Research* 15 (2):97-101, 2002.	not an evaluation, trial or RCT
T. Myers, F. G. Tudiver, R. G. Kurtz, E. A. Jackson, K. W. Orr, C. J. Rowe, and S. L. Bullock. The talking sex project: descriptions of the study population and correlates of sexual practices at baseline. *Canadian Journal of Public Health* 83 (1):47-52, 1992.	not an evaluation, trial or RCT
A. Nyamathi, J. Flaskerud, C. Keenan, and B. Leake. Effectiveness of a specialized vs. traditional AIDS education program attended by homeless and drug-addicted women alone or with supportive persons. *AIDS Education and Prevention* 10 (5):433-446, 1998.	subjects not from GUM clinic
A. M. Nyamathi, J. Flaskerud, C. Bennett, B. Leake, and C. Lewis. Evaluation of two AIDS education programs for impoverished Latina women. *AIDS Education and Prevention* 6 (4):296-309, 1994.	subjects not from GUM clinic
L. O'Donnell, A. San Doval, R. Vornfett, and C. R. O'Donnell. STD prevention and the challenge of gender and cultural diversity: Knowledge, attitudes, and risk behaviors among black and hispanic inner-city STD clinic patients. *Sexually Transmitted Diseases* 21 (3):137-148, 1994.	not an evaluation, trial or RCT
L. O'Donnell, A. San Doval, R. Duran, and C. R. O'Donnell. Predictors of condom acquisition after an STD clinic visit. *Family Planning Perspectives* 27 (1):29-33, 1995.	not an evaluation, trial or RCT
F. E. Okonofua, P. Coplan, S. Collins, F. Oronsaye, D. Ogunsakin, J. T. Ogonor, J. A. Kaufman, and K. Heggenhoyugan. Impact of an intervention to improve treatment-seeking behavior and prevent sexually transmitted diseases among Nigerian youths. *International Journal of Infectious Diseases* 7 (1):61-73, 2003.	subjects not from GUM clinic
A. O'Leary, L. S. Jemmot, F. Goodhart, and J. Gebelt. Effects of an institutional AIDS prevention intervention: moderation by gender. *AIDS Education and Prevention* 8 (6):516-528, 1996.	subjects not from GUM clinic

T. L. Patterson, W. S. Shaw, and S. J. Semple. Reducing the sexual risk behaviors of HIV+ individuals: outcome of a randomized controlled trial. *Ann Behav Med* 25 (2):137-145, 2003.	subjects not from GUM clinic recruiting from HIV positive population only
J. T. Parsons, P. N. Haltkitis, R. J. Wolitski, C. A. Gomez, D. Purcell, A. O'Leary, C. Hoff, R. Hays, and R. Remein. Correlates of sexual risk behaviors among HIV-positive men who have sex with men. *AIDS Education and Prevention* 15 (5):383-400, 2003.	not an evaluation, trial or RCT[a]
J. Pauw, J Ferrie, R. Rivera Villegas, J. Medrano Martinez, A. Gorter, and M. Egger. A controlled HIV/AIDS-related health education programme in Managua, Nicaragua. *AIDS* 10 (5):537-544, 1996.	subjects not from GUM clinic
F. Perez and F. Dabis. HIV prevention in Latin America: reaching youth in Colombia. *AIDS Care* 15 (1):77-87, 2003.	subjects not from GUM clinic not studying a behavioural intervention aiming to change sexual behaviour study not reporting STI or appropriate behavioural outcome
J. L. Peterson, T. J. Coates, J. Catania, W. W. Hauck, M. Acree, D. Daigle, B. Hillard, L. Middleton, and N. Hearst. Evaluation of an HIV risk reduction intervention among African-American homosexual and bisexual men. *AIDS* 10 (3):319-325, 1996.	subjects not from GUM clinic
P. Reddy, A. Meyer-Weitz, B. van den Borne, G. Kok, and W. Weijts. The learning curve: health education in STI clinics in South Africa. *Social Science and Medicine* 47 (10):1445-1453, 1998.	not an evaluation, trial or RCT
C. Renzi, S. R. Tabet, J. A. Stucky, N. Eaton, A. S. Coletti, C. M. Surawicz, S. N. Agoff, P. J. Heagerty, M. Gross, and C. L. Celum. Safety and acceptability of the Reality condom for anal sex among men who have sex with men. *AIDS* 17 (5):727-731, 2003.	not an evaluation, trial or RCT[a]
C. A. Richey, M. R. Gillmore, M. L. Balassone, L. Gutierrez, and J. Hartway. Developing and implementing a group skill training intervention to reduce HIV/AIDS risk among sexually active adolescents in detention. *Journal of HIV/AIDS Prevention & Education for Adolescents & Children* 1 (1):71-103, 1997.	subjects not from GUM clinic
V. I. Rickert, A. Gottlieb, and M. S. Jay. A comparison of three clinic-based AIDS education programs on female adolescents' knowledge, attitudes, and behavior. *Journal of Adolescent Health Care* 11 (4):298-303, 1990.	subjects not from GUM clinic
V. I. Rickert, A. A. Gottlieb, and M. S. Jay. Is AIDS education related to condom acquisition. *Clinical Pediatrics* 31 (4):205-210, 1992.	subjects not from GUM clinic
B. B. E. Robinson, G. Uhl, M. Miner, W. O. Bockting, K. E. Scheltema, B. R. S. Rosser, and B. Westover. Evaluation of a sexual health approach to prevent HIV among low income, urban, primarily African American women: Results of a randomized controlled trial. *AIDS Education and Prevention* 14 (3 suppl.):81-96, 2002.	subjects not from GUM clinic
J. D. C. Ross, A. Tariq, M. Ghanem, and G. Gilleran. Reducing the risk of gonorrhoea in black Caribbean men: can we identify risk factors? *Sexually Transmitted Infections* 79 (2):119-123, 2003.	not an evaluation, trial or RCT[a]

C. F. Roye and M. Hudson. Developing a culturally appropriate video to promote dual-method use by urban teens: rationale and methodology. *AIDS Education and Prevention* 15 (2):148-158, 2003.	not an evaluation, trial or RCT[a]
V. B. Sabherwal. Sexual behavioural patterns relating to HIV/AIDS and sexually transmitted diseases among college students of Dehli. *Health and Population - Perspectives & Issues* 26 (1):16-31, 2003.	not an evaluation, trial or RCT[a]
S. P. Schinke, A. N. Gordon, and R. E. Weston. Self-instruction to prevent HIV infection among African-American and Hispanic-American adolescents. *Journal of Consulting & Clinical Psychology* 58 (4):432-436, 1990.	subjects not from GUM clinic
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J. C. Shlay, B. Mayhugh, M. Foster, M. E. Maravi, A. E. Baron, and J. M. Jnr. Douglas. Initiating contraception in sexually transmitted disease clinic setting: a randomized controlled trial. *American Journal of Obstetrics and Gynecology* 189 (2):473-481, 2003.	not studying a behavioural intervention aiming to change sexual behaviour study not reporting STI or appropriate behavioural outcome
S. Singh. Study of the effect of information, motivation and behavioral skills (IMB) intervention in changing AIDS risk behavior in female university students. *AIDS Care* 15 (1):71-76, 2003.	subjects not from GUM clinic study not reporting STI or appropriate behavioural outcome
J. M. Jnr. Sizemore, W. M. Sanders, P. C. Lackey, D. M. Ennis, and E. W. III. Hook. Comparison of STD burden and risk among men with and without regular doctors attending a southern urban STD clinic. *Sexually Transmitted Diseases* 30 (6):512-515, 2003.	not an evaluation, trial or RCT[a]
J. E. Soet, C. DiIorio, W. N. Dudley, and T. M. Woodring. Gender differences in goal setting for HIV: prevention among college students. *Southern Online Journal of Nursing Research* 4 (1):18p, 2003.	not an evaluation, trial or RCT[a]
C. E. Sterk, K. P. Theall, and K. W. Elifson. Effectiveness of a risk reduction intervention among African American women who use crack cocaine. *AIDS Education and Prevention* 15 (1):15-32, 2003.	subjects not from GUM clinic
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B. F. Stanton, X. Li, I. Ricardo, J. Galbraith, S. Feigelman, and L. Kaljee. A randomized controlled effectiveness trial of an AIDS prevention program for low-income African-American youths. *Archives of Pediatrics & Adolescent Medicine* 150 (4):363-372, 1996.	subjects not from GUM clinic

H. C. Stevenson and G. Davies. Impact of culturally sensitive AIDS video education on the AIDS risk knowledge of African-American adolescents. *AIDS Education and Prevention* 6 (1):40-52, 1994.	subjects not from GUM clinic study not reporting STI or appropriate behavioural outcome
J. Todd, L. Carpenter, X. Li, J. Nakiyingi, R. Gray, and R. Hayes. The effects of alternative study designs on the power of community randomized trials: evidence from three studies of human immunodeficiency virus prevention in East Africa. *International Journal of Epidemiology* 32 (5):755-762, 2003.	not an evaluation, trial or RCT[a]
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M. J. Wawer, N. K. Sewankambo, D. Serwadda, T. C. Quinn, L. A. Paxton, N. Kiwanuka, F. Wabwire-Mangen, and C. Li. Control of sexually transmitted diseases for AIDS prevention in Uganda: a randomised controlled trial. *Lancet* (13 Feb):525-535, 1999.	subjects not from GUM clinic not studying a behavioural intervention aiming to change sexual behaviour
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L. C. W. Wiggers, J. B. F. de Wit, M. J. Gras, R. A. Coutinho, and A. Van Den Hoek. Risk behavior and social-cognitive determinants of condom use among ethnic minority communities in Amsterdam. *AIDS Education and Prevention* 15 (5):430-447, 2003.	not an evaluation, trial or RCT[a]
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B. D. M. Wilson and R. L. Miller. Examining strategies for culturally grounded HIV prevention: a review. *AIDS Education and Prevention* 15 (2):184-202, 2003.	not an evaluation, trial or RCT[a]
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T. E. Wilson, L. J. Koenig, E. Walter, I. Fernandez, and K. Ethier. Dual contraception method use for pregnancy and disease prevention among HIV infected and HIV uninfected women: the importance of an event-level focus for promoting safer sexual behaviors. *Sexually Transmitted Diseases* 30 (11):809-812, 2003.	not an evaluation, trial or RCT[a]

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M. L. Wong, K. W. Chan, and D. Koh. A sustainable behavioral intervention to increase condom use and reduce gonorrhea among sex workers in Singapore: 2-year follow-up. *Preventive Medicine* 27 (6):891-900, 1998.	subjects not from GUM clinic
M. L. Wong, R. K. W. Chan, and D. Koh. Promoting condoms for oral sex: impact on pharyngeal gonorrhea among female brothel-based sex workers. *Sexually Transmitted Diseases* 29 (6):311-318, 2002.	subjects not from GUM clinic
K. S. H. Yarnall, C. M. McBride, P. Lyna, L. J. Fish, D. Civic, L. Grothaus, and D. Scholes. Factors associated with condom use among at-risk women students and nonstudents seen in managed care. *Preventive Medicine* 37 (2):163-170, 2003.	not an evaluation, trial or RCT[a]
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A. Ziersch, J. Gaffney, and D. R. Tomlinson. STI prevention and the male sex industry in London: Evaluating a pilot peer education programme. *Sexually Transmitted Infections* 76 (6):447-453, 2000.	subjects not from GUM clinic

a. No further details are reported on those papers or trials not reporting evaluations or RCTs.

Studies rejected after full detailed review:

Citation	Reason(s) for rejection
S. Allen, A. Serufilira, J. Bogaerts, P. Van de Perre, F. Nsengumuremyi, C. Lindan, M. Carael, W. Wolf, T. Coates, and S. Hulley. Confidential HIV testing and condom promotion in Africa. *JAMA* 268 (23):3338-3343, 1992.	not an RCT[a]
H. Amaro, A. Raj, E. Reed, and K. Cranston. Implementation and long-term outcomes of two HIV intervention programs for Latinas. *Health Promotion Practice* 3 (2):245-254, 2002.	not an RCT
anonymous. Study prompts women to discuss condom use. *AIDS Alert* 15 (7):82-83, 2000	not an RCT
anonymous. Reduction of high-risk sexual behavior among heterosexuals undergoing HIV antibody testing: a randomized clinical trial. *Disease Markers* 9 (6):354-355, 1991.	not a trial or evaluation
L. Artz, M. Macaluso, I. Brill, J. Kelaghan, H. Austin, M. Fleenor, L. Robey, and E. W. III. Hook. Effectiveness of an intervention promoting the female condom to patients at sexually transmitted disease clinics. *American Journal of Public Health* 90 (2):237-243, 2000.	not an RCT
S. A. Baker, B. Beadnell, S. Stoner, D. M. Morrison, J. Gordon, C. Collier, K. Knox, L. Wickizer, and S. Stielstra. Skills training versus health education to prevent STDs/HIV in heterosexual women: a randomized controlled trial utilizing biological outcomes. *AIDS Education and Prevention* 15 (1):1-14, 2003.	subjects not from GUM clinic
S. A. Baker, D. M. Morrison, W. B. Carter, and M. S. Verdon. Using the theory of reasoned action (TRA) to understand the decision to use condoms in an STD clinic population. *Health Education Quarterly* 23 (4):528-542, 1996.	not an RCT
B. Beadnell, C. Collier, D. Morrison, and R. Ryan. Preventing sexually transmitted diseases (STD) and HIV in women: using multiple sources of data to inform intervention design. *Cognitive and Behavioral Practice* 4 (2):325-347, 1997.	not a trial or evaluation
L. Belcher, S. Kalichman, M. Topping, S. Smith, J. Emshoff, F. Norris, and J. Nurss. An randomized trial of a brief HIV risk reduction counseling intervention for women. *Journal of Consulting & Clinical Psychology* 66 (5):856-861, 1998.	subjects not from GUM clinic
J. M. Bellis, D. M. Grimley, and L. R. Alexander. Feasibility of a tailored intervention targeting STD-related behaviors. *American Journal of Health Behavior* 26 (5):378-385, 2002.	not an RCT
S. Bewley. Who defaults after treatment for gonorrhoea? Randomised controlled study of effect of an educational leaflet. *Genitourinary Medicine* 64:241-244, 1988.	not studying a behavioural intervention aiming to change sexual behaviour study not reporting STI or appropriate behavioural outcome
B. M. Branson, J. S. Moore, and R. Byers. HIV sexual risk-reduction interventions for African-American women [letter]. *JAMA* 275 (8):593-594, 1996.	not a trial or evaluation

M. P. Carey, S. A. Maisto, S. Kalichman, A. D. Forsyth, E. M. Wright, and B. T. Johnson. Enhancing motivation to reduce the risk of HIV infection for economically disadvantaged urban women. *Journal of Consulting & Clinical Psychology* 65 (4):531-541, 1997.	subjects not from GUM clinic
M. P. Carey, L. S. Braatan, S. A. Maisto, J. R. Gleason, A. D. Forsyth, L. E. Durant, and B. C. Jaworski. Using information, motivational enhancement, and skills training to reduce the risk of HIV infection for low-income urban women: a second randomized clinical trial. *Health Psychology* 19 (1):3-11, 2000.	subjects not from GUM clinic
K-H. Choi, S. Lew, E. Vittinghoff, J. A. Catania, D. C. Barrett, and T. J. Coates. The efficacy of brief group counseling in HIV risk reduction among homosexual Asian and Pacific Islander men. *AIDS* 10 (1):81-87, 1996.	subjects not from GUM clinic
D. A. Cohen, C. Dent, D. MacKinnon, and G. Hahn. Condoms for men, not women. Results of brief promotion programs. *Sexually Transmitted Diseases* 19 (5):245-251, 1992.	not an RCT
D. A. Cohen, D. P. MacKinnon, C. Dent, H. R. C. Mason, and E. Sullivan. Group counseling at STD clinics to promote use of condoms. *Public Health Reports* 107 (6):727-731, 1992.	not an RCT
P. A. Coury-Doniger, J. C. Levenkron, P. L. McGrath, K. L. Knox, and M. A. Urban. From theory to practice: use of stage of change to develop an STD/HIV behavioral intervention: phase 2: stage-based behavioral counseling strategies for sexual risk reduction. *Cognitive and Behavioral Practice* 7 (4):395-406, 2000.	not an RCT
B. L. Dancy, R. Marcantonio, and K. Norr. The long-term effectiveness of an HIV prevention intervention for low-income African American women. *AIDS Education and Prevention* 12 (2):113-125, 2000.	not an RCT
W. DiFranceisco, J. A. Kelly, K. J. Sikkema, A. M. Somlai, D. A. Murphy, and L. Y. Stevenson. Differences between completers and early dropouts from 2 HIV intervention trials: a health belief approach to understanding prevention program attrition. *American Journal of Public Health* 88 (7):1068-1073, 1998.	not an RCT
J. W. Dilley, W. J. Woods, J. Sabatino, T. Lihatsh, B. Adler, S. Casey, J. Rinaldi, R. Brand, and W. McFarland. Changing sexual behavior among gay male repeat testers for HIV: a randomized, controlled trial of a single-session intervention. *Journal of Acquired Immune Deficiency Syndromes* 30 (2):177-186, 2002.	subjects not from GUM clinic
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T. M. Exner, S. Hoffman, K. Parikh, C-S. Leu, and A. A. Ehrhardt. HIV counseling and testing: women's experiences and the perceived role of testing as a preventive strategy. *Perspectives on Sexual and Reproductive Health* 34 (2):76-83, 2002.	subjects not from GUM clinic
L. A. Fogarty, C. M. Heilig, K. Armstrong, R. Cabral, C. Galavotti, A. C. Gielen, and B. M. Green. Long-term effectiveness of a peer-based intervention to promote condom and contraceptive use among HIV-positive and at-risk women. *Public Health Reports* 116 (supplement 1):103-119, 2001.	not an RCT

N. Ford and S. Koetsawang. A pragmatic intervention to promote condom use by female sex workers in Thailand. *Bulletin of the World Health Organization* 77 (11):888-894, 1999.	not an RCT
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A. C. Gielen, L. A. Fogarty, K. Armstrong, B. M. Green, R. Cabral, B. Milstein, C. Galavotti, and C. M. Heilig. Promoting condom use with main partners: a behavioral intervention for women. *AIDS & Behavior* 5 (3):193-204, 2001.	not an RCT
M. R. Gillmore, D. M. Morrison, C. A. Richey, M. L. Balassone, L. Gutierrez, and M. Farris. Effects of a skill-based intervention to encourage condom use among high risk heterosexually active adolescents. *AIDS Education and Prevention* 9 (suppl. A):22-43, 1997.	not an RCT
E. L. Gollub, P. French, A. Loundou, M. Latka, C. Rogers, and Z. Stein. A randomized trial of hierarchical counseling in a short, clinic-based intervention to reduce the risk of sexually transmitted diseases in women. *AIDS* 14 (9):1249-1255, 2000.	not an RCT
E. L. Gollub, P. French, M. Latka, C. Rogers, and Z. Stein. Achieving safer sex with choice: studying a women's sexual risk reduction hierarchy in an STD clinic. *Journal of Women's Health & Gender-Based Medicine* 10 (8):771-783, 2001.	not an RCT
J. Greenberg, J. Lifshay, N. Van Devanter, V. Gonzales, and D. Celentano. Preventing HIV infection: the effects of community linkages, time, and money on recruiting and retaining women in intervention groups. *Journal of Women's Health* 7 (5):587-596, 1998.	subjects not from GUM clinic
J. Greenberg, M. Henessy, R. MacGowan, D. Celentano, V. Gonzales, N. Van Devanter, and J. Lifshay. Modeling intervention efficacy for high-risk women. The WINGS project. *Evaluation and the Health Professions* 23 (2):123-148, 2000.	subjects not from GUM clinic
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K. F. Harrington, R. J. DiClemente, G. M. Wingwood, R. A. Crosby, S. Person, M. K. Oh, and E. W. III. Hook. Validity of self-reported sexually transmitted diseases among African American female adolescents participating in an HIV/STD prevention intervention trial. *Sexually Transmitted Diseases* 28 (8):468-471, 2001.	subjects not from GUM clinic not studying a behavioural intervention aiming to change sexual behaviour study not reporting STI or appropriate behavioural outcome
S. E. Hobfoll, A. P. Jackson, J. Lavin, R. J. Johnson, and K. E. E. Schröder. Effects and generalizability of communally oriented HIV-AIDS prevention versus general health promotion groups for single, inner-city women in urban clinics. *Journal of Consulting & Clinical Psychology* 70 (4):950-960, 2002.	subjects not from GUM clinic
D. R. Holtgrave and J. A. Kelly. Preventing HIV/AIDS among high-risk urban women: the cost-effectiveness of a behavioral group intervention. *American Journal of Public Health* 86 (10):1442-1445, 1996.	not a trial or evaluation
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J. B. III. Jemmott, L. S. Jemmot, and G. T. Fong. Reductions in HIV risk-associated sexual behaviors among Balck male adolescents: effects of an AIDS prevention intervention. *American Journal of Public Health* 82 (3):372-377, 1992.	subjects not from GUM clinic
J. B. III. Jemmott, L. S. Jemmot, G. T. Fong, and K. McCaffree. Reducing HIV risk-associated sexual behavior among African American adolescents: testing the generality of intervention effects. *American Journal of Community Psychology* 27 (2):161-187, 1999.	subjects not from GUM clinic
P. R. Jenkins, R. A. Jenkins, E. D. Nannis, K. T. McKee, and L. R. Temoshok. Reducing risk of sexually transmitted disease (STD) and human immunodeficiency virus infection in a military STD clinic: evaluation of a randomized preventive intervention trial. *Clinical Infectious Diseases* 30:730-735, 2000.	study not reporting STI or appropriate behavioural outcome
S. C. Kalichman, D. Rompa, and B. Coley. Lack of positive outcomes from a cognitive-behavioral HIV and AIDS prevention intervention for inner-city men: lessons from a controlled pilot study. *AIDS Education and Prevention* 9 (4):299-313, 1997.	subjects not from GUM clinic
S. C. Kalichman, E. Williams, and D. Nachimson. Brief behavioural skills building intervention for female controlled methods of STD-HIV prevention: outcomes of a randomized controlled clinical field trial. *International Journal of STD & AIDS* 10 (3):174-181, 1999.	not studying a behavioural intervention aiming to change sexual behaviour
S. C. Kalichman and C. Cherry. Male polyurethane condoms do not enhance brief HIV-STD risk reduction interventions for heterosexually active men: results from a randomized test of concept. *International Journal of STD & AIDS* 10:548-553, 1999.	not studying a behavioural intervention aiming to change sexual behaviour

R. Kaul, J. Kimani, N. J. Nagelkerke, K. Fonck, F. Keli, K. S. MacDonald, A. R. Ronald, F. A. Plummer, J. J. Bwayo, E. N. Ngugi, M. Temmerman, and S. Moses. Reduced HIV risk-taking and low HIV incidence after enrollment and risk-reduction counseling in a sexually transmitted disease prevention trial in Nairobi, Kenya. *Journal of Acquired Immune Deficiency Syndromes* 30 (1):69-72, 2002.	subjects not from GUM clinic not studying a behavioural intervention aiming to change sexual behaviour
J. A. Kelly, J. S. St Lawrence, H. V. Hood, and T. L. Brasfield. Behavioral intervention to reduce AIDS risk activities. *Journal of Consulting & Clinical Psychology* 57 (1):60-67, 1989.	subjects not from GUM clinic
J. A. Kelly, D. A. Murphy, C. D. Washington, T. S. Wilson, J. J. Koob, D. R. Davis, G. Ledezma, and B. Davantes. The effects of HIV/AIDS intervention groups for high-risk women in urban clinics. *American Journal of Public Health* 84 (12):1918-1922, 1994.	subjects not from GUM clinic
M. Laga, M. Alary, N. Nzila, A. T. Manoka, M. Tuliza, F. Behets, J. Goeman, M. St Louis, and P. Piot. Condom promotion, sexually transmitted disease treatment and declining incidence of HIV-1 infection in female Zairian sex workers. *Lancet* 344 (July 24th):246-248, 1994.	not an RCT
M. Latka, E. Gollub, P. French, and Z. Stein. Male-condom and female-condom use among women after counseling in a risk-reduction hierarchy for STD prevention. *Sexually Transmitted Diseases* 27 (8):431-437, 2000.	not an RCT
M. Leslie, R. W. St Pierre, and P. A. Schuster. The Ohio AIDS prevention survey: a study of psychometric properties. *AIDS Education and Prevention* 4 (4):345-349, 1992.	not an RCT
L. C. Leviton, R. O. Valdiserri, D. W. Lyter, C. M. Callahan, L. A. Kingsley, J. Huggins, and C. R. Rinaldo. Preventing HIV infection in gay and bisexual men: experimental evaluation of attitude change from two risk reduction interventions. *AIDS Education and Prevention* 2 (2):95-108, 1990.	subjects not from GUM clinic
E. A. Lichter. Voluntary counseling and testing reduced unprotected intercourse among adults in 3 developing countries. *ACP Journal Club* 134 (1):22, 2001.	subjects not from GUM clinic
C. S. Lindenberg, R. M. Solorzano, D. Bear, O. Strickland, C. Galvis, and K. Pittman. Reducing substance use and risky sexual behavior among young, low-income, Mexican-American women: comparison of two interventions. *Applied Nursing Research* 16 (2):137-148, 2002.	subjects not from GUM clinic
M. Macaluso, L. Artz, J. Kelaghan, H. Austin, M. Fleenor, and E. W. III. Hook. Prospective study of barrier contraception for the prevention of sexually transmitted diseases. *Sexually Transmitted Diseases* 26 (3):127-136, 1999.	not an RCT
C. J. Mansfield, M. E. Conroy, S. J. Emans, and E. R. Woods. A pilot study of AIDS education and counseling of high-risk adolescents in an office setting. *Journal of Adolescent Health* 14 (2):115-119, 1993.	subjects not from GUM clinic
H. S. Margolis, H. H. Handsfield, R. J. Jacobs, and J. E. Gangi. Evaluation of an office-based intervention to improve prevention and counseling for patients at risk for sexually acquired hepatitis B virus infection. *American Journal of Obstetrics and Gynecology* 182 (1):1-6, 2000.	subjects not from GUM clinic

L. McIntyre and J. Jagosh. Challenges in implementing innovative and sucessful sexually transmitted disease control programs: theory and practice. *The Canadian Journal of Human Sexuality* 7 (4):321-329, 1998.	not a trial or evaluation
A. M. Nyamathi, B. Leake, J. Flaskerud, C. Lewis, and C. Bennett. Outcomes of specialized and traditional AIDS counseling programs for impoverished women of color. *Research in Nursing and Health* 16:11-21, 1993.	subjects not from GUM clinic
A. M. Nyamathi and J. A. Stein. Assessing the impact of HIV risk reduction counseling in impoverished African American women: a structural equations approach. *AIDS Education and Prevention* 9 (3):253-273, 1997.	subjects not from GUM clinic
P. O'Campo, L. Fogarty, A. C. Gielen, K. Armstrong, L. Bond, C. Galavotti, and B. M. Green. Distribution along a stages-of-behavioral-change continuum for condom and contraceptive use among women accessed in different settings. *Journal of Community Health* 24 (1):61-72, 1999.	not an RCT
C. R. O'Donnell, L. O'Donnell, A. San Doval, R. Duran, and K. Labes. Reductions in STD infections subsequent to an STD clinic visit. *Sexually Transmitted Diseases* 25 (3):161-168, 1998.	not an RCT
L. O'Donnell, A. San Doval, R. Duran, and C. R. O'Donnell. The effectiveness of video-based interventions in promoting condom acquisition among STD clinic patients. *Sexually Transmitted Diseases* 22 (2):97-103, 1995.	not an RCT
L. N. O'Donnell, A. San Doval, R. Duran, and C. O'Donnell. Video-based sexually transmitted disease in patient education: its impact on condom acquisition. *American Journal of Public Health* 85 (6):817-822, 1995.	not an RCT
B. O. Ogunbanjo, M. C. Asuzu, E. E. Edet, and A. O. Osoba. Reinforcement of health education and counseling by doctors in treatment and control of sexually transmitted disease. *Genitourinary Medicine* 62:53-55, 1986.	not studying a behavioural intervention aiming to change sexual behaviour study not reporting STI or appropriate behavioural outcome
J. F. Picciano, R. A. Roffman, S. C. Kalichman, S. E. Rutledge, and J. P. Berghuis. A telephone based brief intervention using motivational enhancement to facilitate HIV risk reduction among MSM: a pilot study. *AIDS & Behavior* 5 (3):251-262, 2001.	subjects not from GUM clinic
S. D. Pinkerton, D. R. Holtgrave, and R. O. Valdiserri. Cost-effectiveness of HIV-prevention skills training for men who have sex with men. *AIDS* 11 (3):347-357, 1997.	not a trial or evaluation
S. D. Pinkerton, D. R. Holtgrave, and J. B. III. Jemmott. Economic evaluation of HIV risk reduction interventions in African-American male adolescents. *Journal of Acquired Immune Deficiency Syndromes* 25 (2):164-172, 2000.	not a trial or evaluation
R. A. Roffman, J. F. Picciano, M. Bolan, and S. C. Kalichman. Factors associated with attrition from an HIV-prevention program for gay and bisexual males. *AIDS & Behavior* 1 (2):125-135, 1997.	subjects not from GUM clinic

R. A. Roffman, J. F. Picciano, R. Ryan, B. Beadnell, D. Fisher, L. Downey, and S. C. Kalichman. HIV-prevention group counseling delivered by telephone: an efficacy trial with gay and bisexual men. *AIDS & Behavior* 1 (2):137-154, 1997.	subjects not from GUM clinic
R. N. Shain, J. M. Piper, E. R. Newton, S. T. Perdue, R. Ramos, J. D. Champion, and F. A. Guerra. A randomized, controlled trial of a behavioral intervention to prevent sexually transmitted disease among minority women. *New England Journal of Medicine* 340 (2):93-100, 1999.	not an RCT
P. B. Smith, M. L. Weinman, and J. Parrilli. The role of condom motivation education in the reduction of new and reinfection rates of sexually transmitted diseases among inner-city female adolescents. *Patient Education and Counseling* 31:77-81, 1997.	not an RCT
M. Z. Solomon and W. DeJong. The impact of a clinic-based educational videotape on knowledge and treatment behavior of men with gonorrhea. *Sexually Transmitted Diseases* 15 (3):127-132, 1988.	not studying a behavioural intervention aiming to change sexual behaviour study not reporting STI or appropriate behavioural outcome
M. J. Steiner, L. H. Glover, I. Bou-Saada, and C. Piedrahita. Increasing barrier method use among oral contraceptive users at risk of STDs. *Sexually Transmitted Diseases* 25 (3):139-143, 1998.	subjects not from GUM clinic
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