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Interventions for encouraging sexual behaviours intended to prevent cervical cancer

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Abstract

Background—Human papillomavirus (HPV) is the key risk factor for cervical cancer. Continuing high rates of HPV and other sexually transmitted infections (STIs) in young people demonstrate the need for effective behavioural interventions.

Objectives—To assess the effectiveness of behavioural interventions for young women to encourage safer sexual behaviours to prevent transmission of STIs (including HPV) and cervical cancer.

Search methods—Systematic literature searches were performed on the following databases: Cochrane Central Register of Controlled Trials (CENTRAL Issue 4, 2009) Cochrane Gynaecological Cancer Review Group (CGCRG) Specialised Register, MEDLINE, EMBASE, CINAHL, PsychINFO, Social Science Citation Index and Trials Register of Promoting Health Interventions (TRoPHI) up to the end of 2009. All references were screened for inclusion against selection criteria.

Selection criteria—Randomised controlled trials (RCTs) of behavioural interventions for young women up to the age of 25 years that included, amongst other things, information provision about the transmission and prevention of STIs. Trials had to measure behavioural outcomes (e.g. condom use) and/or biological outcomes (e.g. incidence of STIs, cervical cancer).

Data collection and analysis—A narrative synthesis was conducted. Meta-analysis was not considered appropriate due to heterogeneity between the interventions and trial populations.

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Main results—A total of 5271 references were screened and of these 23 RCTs met the inclusion criteria. Most were conducted in the USA and in health-care clinics (e.g. family planning).

The majority of interventions provided information about STIs and taught safer sex skills (e.g. communication), occasionally supplemented with provision of resources (e.g. free sexual health services). They were heterogeneous in duration, contact time, provider, behavioural aims and outcomes. A variety of STIs were addressed including HIV and chlamydia. None of the trials explicitly mentioned HPV or cervical cancer prevention.

Statistically significant effects for behavioural outcomes (e.g. increasing condom use) were common, though not universal and varied according to the type of outcome. There were no statistically significant effects of abstaining from or reducing sexual activity. There were few statistically significant effects on biological (STI) outcomes. Considerable uncertainty exists in the risk of bias due to incomplete or ambiguous reporting.

Authors' conclusions—Behavioural interventions for young women which aim to promote sexual behaviours protective of STI transmission can be effective, primarily at encouraging condom use. Future evaluations should include a greater focus on HPV and its link to cervical cancer, with long-term follow-up to assess impact on behaviour change, rates of HPV infection and progression to cervical cancer. Studies should use an RCT design where possible with integral process evaluation and cost-effectiveness analysis where appropriate. Given the predominance of USA studies in this systematic review evaluations conducted in other countries would be particularly useful.

Medical Subject Headings (MeSH)

*Safe Sex; Condoms [utilization]; Randomized Controlled Trials as Topic; Sexual Behavior; Sexually Transmitted Diseases [*prevention & control]; Uterine Cervical Neoplasms [*prevention & control]

MeSH check words

Adolescent; Female; Humans; Young Adult

BACKGROUND

Description of the condition

Incidence of cervical cancer—Cervical cancer is the second most commonly diagnosed cancer in women worldwide, with more than 500,000 new cases diagnosed each year and an age-standardised incidence rate of 15.3 per 100,000 women. Incidence of cervical cancer varies sevenfold between the different regions of the world; it is the most commonly diagnosed cancer among women in Southern Africa and Central America (GLOBOCAN 2008; Stewart 2003). Cervical cancer incidence rates have declined substantially in Western countries with screening programmes. Incidence rates tend to be highest in women aged under 40, with a peak incidence occurring in the group aged 25 to 29 years (CRUK 2010). The stage breakdown varies across the age groups, with older women being diagnosed with progressively later stage disease (CRUK 2010).

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Many studies have shown that the incidence of cervical cancer, as well as survival and mortality, vary with ethnic group and socioeconomic status (SES). For example, studies have demonstrated higher incidence of cervical cancer in Hispanic and black women than in white women (CDC 2010; Clegg 2008; Patel 2009) and that incidence of cervical cancer is highest in women with the lowest SES (Clegg 2008; Franceschi 2009; Pukkala 2010). Reasons for ethnic and socio-economic differences in the incidence of cervical cancer can be difficult to determine because definitions of ethnic groups and SES are not always consistent and because ethnicity may be confounded with SES and other variables, which may or may not be controlled for in analyses (Pruitt 2009). Possible reasons for social disparities in the incidence of cervical cancer include: increased likelihood of smoking, poor diet, physical inactivity and HPV infection in women with lower SES (see section on risk factors below) (Clegg 2008); differences between ethnic groups in their likelihood of receiving cervical screening (Patnick 2007); and differences between ethnic groups in their awareness of cervical cancer risk (NHS 2009).

Worldwide, cervical cancer causes more than 273,000 deaths each year (2.1% of all deaths; Yang 2004) and it accounts for 9% of female cancer deaths. The survival rate is higher in younger women as the disease tends to be diagnosed at an earlier stage. Survival rates in developed countries have improved over recent decades, as a consequence of screening and more effective treatment.

Aetiology in relation to risk of cervical cancer—HPV belongs to the family of papillomaviruses. Clinical manifestations of genital HPV can include genital warts (condylomata acuminata), dysplasia and cancer of the cervix, anus, vulva, vagina and penis and recurrent respiratory papillomatosis. Transmission of HPV is by skin-to-skin contact, requiring access to basal cells through micro abrasions or tears in squamous or mucosal epithelium that often result from sexual activity. Although the majority of HPV transmission is by sexual contact, it can also occur by fingers or sex toys (Moscicki 2005; Winer 2003).

Development of the cervix has an important bearing on the development of cervical cancer. With the occurrence of puberty, columnar epithelium of the cervix gradually transforms into squamous epithelium, a process known as squamous metaplasia. In this transformation, large areas of transitional cells are formed, all of which support HPV replication and are potentially prone to virus-induced genetic alterations. Persistence of HPV infection during squamous metaplasia can lead to cervical intra-epithelial neoplasia (CIN) 2 or CIN3 lesions and, eventually, development of invasive cervical cancer. Early sexual activity appears to influence squamous metaplasia, as adolescents with multiple partners have been found to exhibit greater cervical maturity than nonsexually active adolescents (Moscicki 2005).

Modern classification, based on DNA nucleotide sequence differences, has identified over 130 different types of HPV. Types 16 and 18 contain potent viral oncogenes that are associated with the development of cervical carcinoma and at least 13 other HPV types are also considered to confer high risk of cervical cancer (Bosch 2005). Results of a meta-analysis of published data indicated that HPV types 16, 18 and 45 are most likely to lead to infections which progress to cervical cancer (Clifford 2003). HPV type 16 accounts for close to 50% of the types identified in cervical cancer and together types 16 and 18 are implicated

in 70% of cervical cancers worldwide. A second group of at least 11 HPV types that is rarely found in cervical cancer cases has been classified as low risk. The predominant low-risk HPV types are 6 and 11; these are the most common HPV types overall and are responsible for most cases of genital warts (Weaver 2006). Presence of multiple highrisk HPV types does not appear to increase the risk of cervical cancer over having one high risk type. In extremely rare cases, lowrisk HPV may be the only type associated with invasive cervical cancer; this might indicate that a minute fraction of the population has a special susceptibility to these types (Bosch 2005).

Exposure to genital HPV among women can happen soon after sexual debut, followed by a one to eight month period during which there may be no symptoms or signs of infection. After this incubation period, a lesion (e.g. cervical cancer or genital wart) may develop and trigger a sustained immune response over three to six months, followed either by sustained clinical remission or persistent or recurrent disease (Weaver 2006). Unlike CIN1, the development of CIN2 and CIN3 requires persistent high-risk type HPV infection (Moscicki 2005). Overall, the incubation period from initial HPV infection to carcinoma in situ is estimated to be 7 to 12 years (Moscicki 2005).

The causal association between HPV and cervical cancer is one of the strongest observed for any human cancer. Case-control studies, case series and prevalence surveys have unequivocally shown that HPV-DNA can be detected in 95 to 100% of adequate specimens of cervical cancer compared with 5 to 20% of cervical specimens from control subjects. However, the majority (around 90%) of HPV infections are spontaneously cleared by the immune system and do not progress to CIN 2, CIN3 or invasive cancer (Bosch 2005).

Risk factors—HPV infection is so prevalent that approximately 75 to 85% of sexually active individuals will become infected in their lifetime (Weaver 2006) and having just one sexual partner is often sufficient for a woman to acquire infection with HPV (Moscicki 2005). The National Health and Nutrition Examination Survey (NHANES) in the US reported an overall HPV prevalence of 26.8% among females aged 14 to 59 years (Dunne 2007). Prevalence was 24.5% among females aged 14 to 19 years and 44.8% among women aged 20 to 24 years. There was a statistically significant trend for increasing HPV prevalence with each year of age from 14 to 24 years, followed by a gradual decline in prevalence through 59 years, confirming the predominance of HPV infection in younger women. The NHANES study also reported a prevalence of 15.6% for HPV type 16 and 6.5% for type 18 (Markowitz 2009).

Given the high prevalence of HPV being sexually active is therefore a key determinant in the incidence of cervical cancer. Several prospective studies have demonstrated that risk of cervical cancer increases as the number of male sex partners increases (Bosch 2005; Weaver 2006). Non-sexually transmitted HPV infections are rare among adolescent girls. Other important risk factors are the age at first sexual intercourse of the woman and also of her male partner (in both cases younger age is associated with higher risk), recent partner change and the likelihood that at least one of the male partners is an HPV carrier. Studies have shown that subsequent wives of husbands whose previous wife developed cervical cancer had an increased risk of cervical neoplasia; and wives of men with cancer of the

penis had a high incidence and mortality rate of cervical cancer (Bosch 2005). Male circumcision reduces the risk of both HPV-DNA prevalence and cervical cancer in the female partner (Bosch 2005; Castellsagué 2002; Weaver 2006). Other factors that are associated with an increase in the risk of cervical cancer among HPV-DNA positive women include: use of oral contraceptives for five or more years; smoking; high parity (five or more full term pregnancies); and previous exposure to other sexually transmitted infections (STIs), notably chlamydia trachomatis, some herpes viruses and HIV (Bosch 2005). The effect of exposure to these infections underlines the importance of STI prevention for reducing the risk of cervical cancer. Risk of cervical cancer may be influenced by genetic factors, but the evidence is not strong at present (CRUK 2010).

Prevention of cervical cancer—Prevention of cervical cancer can be classified as primary, or secondary. Primary prevention of cervical cancer involves safer sexual practices, such correct and consistent condom use to prevent HPV infection of the cervix. Primary prevention of cervical cancer can also potentially be achieved through the recently launched HPV vaccines, Cervarix (GlaxoSmithKline) and Gardasil (Merck). These have been shown to be safe and effective at preventing transmission of HPV and low grade CIN (Dillner 2010; FUTURE II Study Group 2007; Paavonen 2007), though long-term follow-up over a number of years will be needed to assess all possible benefits (particularly duration of protection against HPV and effectiveness in preventing invasive cervical cancer) and adverse effects. The vaccine is most effective when given prior to first HPV acquisition, underlining the importance of vaccinating girls before they become sexually active. Ceravix is a bivalent vaccine and protects against HPV types 16 and 18, whilst Gardasil is a quadrivalent vaccine and also protects against two non-oncogenic types that cause genital warts (types 6 and 11).

The World Health Organisation's (WHO) position paper on HPV vaccines recommends that it should be introduced in countries where cervical cancer is a public health priority, where it is likely to be programmatically feasible and economically sustainable and where cost-effectiveness aspects have been considered (WHO 2009a). The WHO also recommend that vaccination programmes be part of a co-ordinated strategy including education about risk behaviours for HPV infection. It should be acknowledged that the vaccines do not necessarily afford protection against the other high risk HPV types that are associated with around 30% of cervical cancer cases. This therefore underlines the importance of promoting protective behaviours as a key primary prevention strategy.

Secondary prevention of cervical cancer involves periodic cervical screening of eligible women to detect changes in cervical cytology, which may necessitate treatment to prevent or manage invasive cervical cancer. Cervical screening programmes are established in most developed countries and in the UK screening is offered to women between the ages of 25 and 60 years (the age range varies between different Nations within the UK), every three to five years. Cervical screening is widely credited with reducing the incidence of cervical cancer (Peto 2004), with an estimated saving of 5,000 lives each year in the UK alone. Following the introduction of cervical screening in the 1960s, age-standardised mortality rates due to cervical cancer in the UK have declined from 7.1 per 100,000 females in 1979 to 2.4 per 100,000 females in 2008 (CRUK 2010). In contrast, declines in mortality rates

have not occurred in developing countries which lack routine cervical screening (Sankaranarayanan 2009). Data from the World Health Organisation (WHO 2009b) show that mortality rates due to cervical cancer are particularly high in China and India. It has been estimated that, worldwide, over 2.7 million years of life are lost annually among women between the ages of 25 and 64, of which 2.4 million years of life are lost in developing countries (Yang 2004).

Description of the intervention

This review is focused on the primary prevention of cervical cancer, through the promotion of sexual behaviours which afford protection against acquisition of high risk HPV types associated with cervical cancer. The term behavioural interventions is used because their primary aim is to promote protective sexual behaviours which can include (and are not restricted to) any of the following: use of condoms for vaginal intercourse, abstinence from sexual activity, delaying becoming sexually active, reducing the number of sexual partners and mutual monogamy.

Darbes 2002 classifies three types of behavioural interventions: (i) individually focused interventions without explicit or direct attempts to change the norms of the community or the target population as a whole (e.g. peer education, referrals, skills training); (ii) social interventions that aim to change not only individual behaviours but also social norms or peer norms (e.g. community mobilization); and (iii) policy interventions that aim to change individual behavior or peer/social norms or structures through administrative or legal decisions (e.g. condom availability in public settings). This is a relatively broad classification of behavioural interventions and allows for changes to wider, structural, determinants of health to influence health-related behaviour. Interventions which address social, demographic, economic and political influences on health are recognised as having greater potential to reduce health inequalities than those which are solely aimed at the individual (Marmot 2010). This review adopts a similar classification to that of Darbes 2002. At its most basic a behavioural intervention can provide information about the transmission and prevention of STIs and the promotion of sexual health in general. However, this may also be accompanied by additional components such as skills development for safer sexual practices (e.g. effective communication with partners), counselling and provision of resources (e.g. free condoms) and services (e.g. STI testing, immunisation), or even changes in policy and legislation. Interventions may be provided in a variety of locations, including schools and colleges, health care settings (e.g. primary care, family planning clinics, sexual health clinics), in a variety of formats (e.g. group discussion sessions, mass media, computer programmes) and be of variable length (e.g. one-off initiatives, or sustained activities over weeks or months).

How the intervention might work

Behavioural interventions can potentially influence health-related behaviour (and, in turn, health outcomes) via effecting changes in mediators of behaviour change such as knowledge, attitudes, community/peer norms, beliefs and self-efficacy. A number of conceptual models, drawn from disciplines such as sociology, psychology and education, predict and explain mechanisms of behaviour change and have been used to guide the

development of interventions. Such models include Social Learning Theory (Bandura 1971), Social Cognitive Theory (Bandura 1986; Bandura 1990), The Theory of Reasoned Action/ Planned Behaviour (Ajzen 1980; Ajzen 1985), the Health Belief Model (Becker 1984) and the Transtheoretical Model (Prochaska 1994; Prochaska 1997).

As mentioned, behavioural interventions can promote a range of protective sexual behaviours such as use of condoms for vaginal intercourse. There is evidence for the effectiveness of condoms for vaginal intercourse as a method of preventing HIV (Weller 2002). There is relatively less evidence available for the effectiveness of condoms to prevent other STIs (e.g. chlamydia, gonorrhoea). As HPV can be transmitted through skin-to-skin contact, condoms may not necessarily prevent infection of other anogenital epithelial sites not covered by the condom. A meta-analysis of observational studies found no consistent evidence of a protective effect of condom use on infection with HPV (Manhart 2002). However, there was some evidence to suggest a protective effect against CIN 2 or CIN 3 and also against invasive cervical cancer. It was suggested that condoms may not necessarily prevent HPV infection, but may inhibit progression to cervical lesions. This may be due to a reduction in the total amount of virus transmitted through condom use which may lessen the likelihood of developing a clinical lesion (Manhart 2002).

More recent studies provide stronger evidence on the effectiveness of condoms to prevent HPV and cervical cancer. A randomised controlled trial (RCT) found that condom use was associated with regression of CIN lesions and the clearance of HPV in women with an abnormal cervical smear test and/or with CIN, the majority of whom were HPV positive and none of whom were regularly using condoms prior to the study (Hogewoning 2003). It is thought that reducing the continuity of HPV transmission improves the chances of HPV clearance. Winer 2006 studied 82 newly sexually active female university students (aged 18 to 22 years) over a median period of 40 months. The incidence of genital HPV infection was 37.8 per 100 person years at risk for women whose partners used condoms for all instances of vaginal intercourse during the eight months before testing, compared with 89.3 per 100 person years at risk in women whose partners used condoms less than five per cent of the time. The results of this study provide greater support for the use of condoms as a method of protection against HPV in newly sexually active young women, though they may not necessarily be generalisable to young women of low socio-economic status and/or those with multiple partners.

Aside from condom use, other protective strategies have been advocated such as reducing the number of sexual partners, mutual monogamy or abstaining from any sexual contact/ delaying becoming sexually active. The latter is particularly salient given the trend for lower age of first sexual intercourse in some countries (commonly around 16 years) (Hawes 2010; Rotermann 2005; Wellings 2001). However, the promotion of abstinence is a contentious issue (Stammers 2007; Tanne 2006; Underhill 2007). Some commentators suggest that promoting anything other than abstinence to young people is incompatible with particular social, culturaland religious values. Others argue that abstinence promotion is unlikely to be acceptable to many young people and therefore an unrealistic intervention. Specifically, it denies them the chance to make choices about their own health and relationships and does not equip them with the information and safer sex skills they may need when they do

become sexually active. The most pragmatic approach, therefore, might be interventions that advocate a broad range of protective strategies enabling young women to exercise choices relevant to their stage of sexual development, whether it be delaying having sex until married or in a committed relationship, monogamy, limiting the number of sexual partners, or using condoms consistently with all partners.

Why it is important to do this review

Invasive cervical cancer is one of the most common cancers worldwide and is associated with considerable morbidity and mortality. Transmission of HPV, the most significant risk factor for cervical cancer, remains common. High rates of STIs in young people continue to be reported in many countries, as well as sexual risk behaviour and in some countries a reduction in the age of first sexual intercourse. Effective primary prevention to promote protective sexual behaviours therefore remains crucial.

The first version of this review was published in 2000 (see Other published versions of this review). This is an active research field necessitating an update to capture all relevant recent evidence.

OBJECTIVES

To assess the effectiveness of behavioural interventions in young women (aged 25 years or less) at encouraging sexual behaviours to prevent STIs (e.g. HPV) and cervical cancer.

METHODS

Criteria for considering studies for this review

Types of studies—Only randomised controlled trials (RCTs) were eligible (Note that in the original version of this review both RCTs and non-randomised controlled trials were eligible - see Differences between protocol and review and Other published versions of this review). We only included conference abstracts reporting RCTs if they were published within the last three years (i.e. 2007 to 2010) and if they contained sufficient detail to enable an appraisal of the methodology and results. We assumed that studies reported in conference abstracts prior to 2007 would have been fully published since then.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW:
This systematic review was originally published under the title ‘Interventions for encouraging sexual lifestyles and behaviours intended to prevent cervical cancer’ (see Other published versions of this review). The inclusion criteria of this update have been changed, as follows.

Restriction to RCTs
The first published edition of this review permitted inclusion of both random and non-random controlled trials, however, for this update it was decided to restrict inclusion to RCTs. This was because a number of RCTs potentially within the scope of the review were available and given the general agreement that they provide the lowest risk of bias (Kleijnen 1997; Schulz 2002; Stephenson 1998) it was felt that inclusion of non-randomised evidence would only increase the uncertainty regarding study effects.

Restriction to young women up to the age of 25 years
In the original version of this review the eligible age range was 13 - 64 years. In this update the eligible age was 25 years and under. This threshold was chosen because incidence of HPV is highest in this age group. An accompanying lower threshold (e.g. from 15 to 25 years) was not chosen given the falling age at first sexual intercourse in some countries and the fact that cell changes in the cervix during puberty can support HPV replication, which is associated with later progression to cervical cancer.

Types of participants—Females aged 25 years or less. This threshold was chosen because incidence of HPV is highest in this age group. An accompanying lower threshold (e.g. from 15 to 25 years) was not chosen because of the falling age at first sexual intercourse in some countries and the fact that cell changes in the cervix during puberty can support HPV replication, which is associated with later progression to cervical cancer (see Description of the condition). Hence, it was important to assess the effectiveness of interventions targeted at younger females (Note that in the original version of this review the eligible age range was 13 to 64 years - see Differences between protocol and review and Other published versions of this review). To be included a trial had to meet one of the following criteria:

1. The trial's own eligibility criteria specified young women aged 25 years or less; or.
2. 70% of the young women randomised were aged 25 years or less; or
3. From the mean/median/mode age given (and standard deviation) it was likely that the 70% of young women were aged 25 years or less.

The intervention had to be targeted at females only. Interventions which were provided to young women along with their male partners or to young women and family members (e.g. mother and daughter dyads) were not included.

Types of interventions—Behavioural interventions which provide factual information about sexual risk factors for cervical cancer (e.g. HPV) and/or about the transmission and prevention of STIs in general. At its most basic the intervention should be described as including provision of factual information, education, instruction and/or knowledge. This can be accompanied by other activities such as motivation building, practical skill development or provision of incentives (see Description of the intervention).

The following interventions were not included unless they reported inclusion of an educational component to encourage protective sexual behaviours: cervical cancer screening, HPV vaccination, STI testing or changes to policy or service provision. Promotion of safer sexual behaviours has the potential to prevent transmission of HPV even if preventing HPV/cervical cancer was not the main focus of the trial. Therefore, trials in which the focus was on preventing HIV/AIDS, chlamydia or other STIs were eligible.

There was no restriction on the setting, provider or media used.

Types of outcome measures—Relevant outcomes were classified as behavioural (i.e. sexual behaviour) or biological (i.e. incidence of STIs and/or changes in cervical cytology). To be included a trial had to report at least one behavioural and/or at least one biological outcome.

Relevant behavioural outcomes could include (amongst others): condom use for vaginal intercourse, sexual partner reduction, reduction in sexual intercourse episodes, delayed first intercourse and abstinence from sexual activity. Behavioural measures are a stronger indicator of the potential of interventions to prevent health problems than measures such as knowledge or attitudes, which, as is well-established, may not on their own lead to a change

in behaviour (Prochaska 1994). The trials included in this review measured a variety of non-behavioural outcomes including knowledge, attitudes and intentions (see Characteristics of included studies). However, it was beyond the scope of this review to extract and analyse them.

In terms of biological outcomes, trials reporting changes in incidence of any STI were eligible. Incidence of HPV (particularly high risk types 16 and 18) is most relevant to this review, though where this was not measured occurrence of other STIs were used as a proxy. This was a pragmatic decision given the likely predominance of chlamydia and gonorrhoea as outcome measures, though notwithstanding the greater infectiousness of HPV relative to other STIs. Changes in cervical cytology (e.g. CIN 1 to 3) and progression to cervical cancer were also relevant outcome measures. Rates of pregnancy were not included as outcome measures.

Search methods for identification of studies

Trials included in this review were derived from two main sources: electronic database searching and hand-searching.

The searches for the original version of this review (published in 2000, see Other published versions of this review)) were performed in December 1997. Updated searches were carried out in January 1999 and December 2001, though those review updates were never fully completed and published. A further update search was performed in December 2009 to January 2010. Collectively these searches support this current version of the review.

Only trials that were published in the English language were eligible.

Electronic searches—The original search strategies for electronic bibliographic databases were devised by the EPPI-Centre, Institute of Education, University of London. Some of these strategies were revised in December 2009 by the Cochrane Gynaecological Cancer Review Group (CGCRG) Trials Search Co-ordinator (namely MEDLINE, EMBASE and the Cochrane Central Register of Controlled Trials (CENTRAL) to reflect the change in the scope and inclusion criteria of the review for this update. The CINAHL, PsychINFO, ERIC and the Social Science Citation Index (SSCI) strategies were revised by the review team (GKF and JS) also to take into account the change in scope and inclusion criteria, as well as to accommodate changes to the database platforms available to us at that time. These revised search strategies are located in the Appendices). Electronic database searching was performed on the following databases:

- CENTRAL (Issue 4, 2009) (Appendix 1)
- CGCRG Specialised Register (to December 2009)
- MEDLINE (WinSPIRS/Ovid) (1992 to December 2009) (Appendix 2)
- MEDLINE In-Process (Ovid) (to December 2009) (Appendix 2)
- EMBASE (WinSPIRS/Ovid) (1993 to December 2009) (Appendix 3)
- CINAHL (WinSPIRS/EBSCO) (1982 to January 2010) (Appendix 4)

- PsychINFO (WinSPIRS/EBSCO) (to January 2010) (Appendix 5)
- ERIC (WinSPIRS/CSA) (1994 to December 2009) (Appendix 6)
- SSCI (Web of Science) (1994 to November 2009) (Appendix 7)
- Trials Register of Promoting Health Interventions (TRoPHI) (Eppi-Centre) (to November 2009) (Appendix 8)
- Bibliomap (Eppi-Centre) (1998 to December 2001)
- National Library of Medicine (NLM) Gateway (restricted to AIDS Meeting Abstracts) (to December 2001)

(NB. Some databases are listed as being searched via more than one platform, as the platforms available to the review team changed over time with the various search updates).

The reason why some of the databases were not searched prior to 1992 is because the review utilised the extensive searching that was conducted for the review of sexual health interventions for young people conducted by the EPPI-Centre (Peersman 1996). The EPPI-Centre supplied the relevant references from their bibliographic database in December 1997.

All references were downloaded into a Reference Manager software database (except for the results of the 1997 search which were downloaded into a ProCite database).

Searching other resources

Hand-searching: Hand-searching was conducted for the original published version of this review, but not for this update.

Issues of the following journals were hand-searched, building on EPPI-Centre hand-searching of earlier issues:

- AIDS (September 1995 to April 1998)
- The American Journal of Public Health (September 1995 to January 1998)
- Health Education Journal (October 1995 to December 1997)
- Health Education Research (October 1995 to December 1997)
- Family Planning Perspectives (September 1995 to January 1998)*

* N.B. There were some missing volumes in the 1995 to 1998 search.

In addition, the following journals were also hand-searched:

- Public Health (January 1994 to January 1998)
- Public Health Reports (January 1994 to December 1996)
- Health Psychology (January 1994 to January 1998)
- Journal of the American Medical Association (January 1994 to December 1997)
- Journal of Epidemiology and Community Health (January 1994 to March 1998)

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- AIDS Care (January 1993 to December 1996)

As mentioned above, the reason why hand-searching did not include years prior to 1994 to 95 is because this review utilised the extensive searching that was conducted for the review of sexual health interventions for young people conducted by the EPPI-Centre team (Peersman 1996).

Checking reference lists: The reference lists of publications included in the review were checked to identify further potentially relevant references. Systematic reviews were not eligible for inclusion in the review, though those meeting this review's inclusion criteria (in terms of participants, interventions and outcome measures) were retrieved and, in turn, their list of included studies inspected to identify any relevant studies we had not already found.

Data collection and analysis

Selection of studies—Inclusion criteria were applied to all titles and, where available, abstracts identified from the 2009 to 2010 update literature search by two review authors and independently (GKF, JS or PH). Potentially relevant references were then retrieved for further screening by one review author and checked by a second. Any disagreements were resolved through discussion with recourse to a third review author when necessary.

In addition to our 2009 to 2010 update search, we re-screened, using our revised inclusion criteria, our bibliographic reference databases containing references identified from searches performed in 1997, 1999 and 2001 (the 1997 search supporting the original published version of this review - see Search methods for identification of studies). Since the inclusion criteria for this update are narrower than our original inclusion criteria, it was only necessary to re-screen full papers identified from our previous searches which had been screened and classified as included and to determine which were still relevant (i.e. excluding those which were not RCTs and/or which did not feature young women aged under 25 years).

All references excluded after screening on full paper and the reason for exclusion, are listed in Characteristics of excluded studies. We have only listed the first criterion in our inclusion worksheet that the trial failed to meet. The order of the criteria in the worksheet was: trial population, trial design, intervention and outcome measures. References may have failed to meet criteria other than just the one listed.

Data extraction and management—For included studies, the following data were extracted:

- Author, year of publication and journal citation
- Country
- Setting
- Trial design, methodology
- Total number of intervention groups
- Data analysis method

- Attrition
- Unit of data analysis
- Sample size calculation
- Process evaluation
- Duration of follow-up
- Trial population
    - total number enrolled
    - participant characteristics
    - age
    - ethnicity
    - socio-economic status
    - location
    - sexual behaviour and previous STI history
- Intervention details
    - type of intervention
    - description of intervention
    - frequency and duration of intervention
    - type of intervention provider
    - theoretical basis
    - comparator group(s) details
- Outcomes measures (primary, secondary)
- Cost data

The time points at which outcomes were collected and reported was noted.

Data were extracted directly into Cochrane Review Manager (Version 5.0.25) software by one review author and checked by a second (see Characteristics of included studies and Table 1 to Table 2).

Some evaluations of STI/cervical cancer prevention reported outcomes for particular sub-groups of participants, such as by race/ethnicity or those categorised as being at particular ‘risk’ for STIs. We only extracted outcome data for the randomised trial groups, rather than for sub-groups.

Assessment of risk of bias in included studies—The risk of bias in the included RCTs was assessed using the Cochrane Collaboration’s tool and the criteria specified in Chapter 8 of the Cochrane Handbook 2008 (Higgins 2009). This included an assessment of:

- Sequence generation
- Allocation concealment
- Blinding (of outcome assessors only)
- Incomplete outcome data
- Selective reporting of outcomes
- Other possible sources of bias

In many health promotion experimental evaluations it is not feasible to blind participants or intervention providers to which trial group they have been allocated. It is possible, however, to conceal trial group assignment to some outcome assessors (Stephenson 1998), particularly for biological outcomes where assessors analysing laboratory specimens may have no or minimal contact with the intervention recipients (Boutron 2007; Flay 1986). For this reason we only assessed the risk of detection bias associated with outcome assessor blinding, rather than participant or intervention provider blinding.

The risk of bias assessment was applied to each trial independently by two review authors (either JS, GKF or PH) and any differences were resolved by discussion or by appeal to a third review author. Risk of bias judgments are described in the Risk of bias in included studies section and summarised graphically in Figure 1 and Figure 2. In addition, the risk of bias judgements for each individual trial are provided in the Characteristics of included studies.

Data synthesis—Meta-analysis was considered to be inappropriate due to the heterogeneity of interventions, trial populations and outcome measures. A narrative synthesis was conducted (see Effects of interventions), with the effects split into the four categories of intervention comparison described below (see ‘Type of comparator’ in Description of studies). Trials with more than two randomised groups may appear in more than one category depending on the comparisons made. All behavioural outcomes are presented, as well as biological outcomes (STIs, but excluding pregnancy). As mentioned, non-behavioural and non-biological outcomes such as knowledge, attitudes, behavioural intentions are not reported as they were beyond the scope of this review update.

The effects are generally presented in terms of whether or not there were statistically significant differences between randomised groups at the last time point at which outcomes were assessed by the studies. Effects observed at interim and final assessment points are reported in Table 3 (condom use), Table 4 (incidence of STIs),Table 5 (sexual partners), Table 6 (casual sexual partners) and Table 2 (engagement in sex).

All studies are included in the narrative synthesis, irrespective of their risk of bias. Where necessary, comments are made in the text to advise caution for serious methodological shortcomings, but readers are also encouraged to refer back to the Risk of bias in included studies section and Figure 1 and Figure 2, as well as the Characteristics of included studies tables for more detailed comments on bias and methodological quality (e.g. equivalence of trial groups at baseline; statistical power). In some studies not all of the randomised

population were sexually active during the trial period and therefore outcomes are reported for smaller sample sizes rather than the randomised population. This is noted where relevant.

Process evaluation data, where reported by studies, was not data extracted and synthesised as this was beyond the scope of this review. However, the Characteristics of included studies table does report which trials conducted process evaluation and a brief overview is given in Included studies.

RESULTS

Description of studies

Results of the search—Literature searching of electronic bibliographic databases for this update review identified a total of 7355 references. Following deduplication, a total of 5129 references remained. A further 20 references were identified from checking of reference lists of systematic reviews and included studies. The total number of references screened was therefore 5149, of which 4991 references were excluded on title and (where available) abstract. The full reports of the remaining 158 references were obtained for further screening, of which 134 were excluded (see Characteristics of excluded studies) and five are awaiting classification (see Studies awaiting classification). The remaining 19 references describe a total of 15 studies which are included in this review (Boyer 2005; Bull 2008; Choi 2008; Dancy 2009; DiClemente 2004; DiClemente 2009; Downs 2004; Jaworski 2001; Jemmott 2005; Kershaw 2009; Koniak-Griffin 2003; Morrison-Beedy 2005; Peipert 2008; Roye 2007; Scholes 2003).

In addition to our 2009 to 2010 update search, we re-screened, using our revised inclusion criteria, our bibliographic reference databases containing references identified from searches performed in 1997, 1999 and 2001 (see Search methods for identification of studies and Selection of studies). A total of 64 studies (described in a total of 122 full papers) were re-screened, of which 56 did not meet the revised criteria. The remaining eight studies (each described by a single full paper) met the inclusion criteria for this update (Bryan 1996; Ferguson 1998; Maynard 1994; Orr 1996; Ploem 1997; Shain 1999; Shrier 2001; Smith 1993).

In summary then, 5721 full papers were screened and a total of 23 trials reported in a total of 27 publications were included in this review.

Included studies

Further detail of each intervention can be found in the Characteristics of included studies table.

Design—In 17 of the 23 trials the individual participants were randomly allocated to intervention arms. The remaining six studies were cluster designs in which groups rather than individuals were allocated to the interventions. The units of randomisation in these cluster trials were neighbourhoods (Bull 2008; Ferguson 1998), urban localities (Dancy 2009), schools (Koniak-Griffin 2003), family planning clinics (Orr 1996) or floors within a university student dormitory (Smith 1993). In cluster trials, observations on individuals

within the same intervention group may be correlated, which would reduce the statistical power of the trial and the precision of estimates of effect. Correlation of observations increases the sample size required and should be taken into account when planning a trial. Only two of the six cluster trials considered intra-group correlation: Bull 2008 assumed an intra-class correlation coefficient of 0.02 for the calculation of sample size, based on a pilot study; and Dancy 2009 used multi-level analyses to evaluate the possibility that individuals in the same group may have been similar on characteristics that were not measured in the trial. Total sample sizes were reported either as the number of individuals or the number of clusters randomised. The total number of individuals randomised ranged from 62 (Morrison-Beedy 2005) to 5297 (Maynard 1994), with an overall mean of 848 and a median of 522. One of the cluster trials (Koniak-Griffin 2003) did not report how many clusters were randomised. In the five remaining cluster trials the number of clusters randomised ranged from 2 (Orr 1996) to 12 (Bull 2008).

Sample sizes per trial arm were not reported in two of the individually randomised studies (Downs 2004; Jaworski 2001) and one of the cluster randomised trials (Koniak-Griffin 2003). The reported number of individuals randomised per arm ranged from 19 (Ploem 1997) to 1691 (Maynard 1994). The reported number of clusters randomised per arm ranged from one urban locality (Dancy 2009) or one family planning clinic (Orr 1996) to four neighbourhoods (Bull 2008) or four student dormitory floors (Smith 1993).

Sample size calculations were reported in eight of the 23 trials. Six trials gave a sample size calculation for the primary outcome (Boyer 2005; Bull 2008; DiClemente 2004; DiClemente 2009; Jemmott 2005; Peipert 2008) whilst in two trials it was not stated which outcome(s) the sample size calculation was for (Ferguson 1998; Jaworski 2001). The sample size calculations were based on estimates of statistical power, apart from two trials (Boyer 2005; Bull 2008) which based their sample size calculations on correlations of observations within trial groups.

Process evaluations, which are important for understanding the mechanisms of (or barriers to) action of complex interventions were conducted and reported in nine of the 23 trials. The most frequently reported aspects of process evaluation were participant exposure to interventions (reported in six trials: Bryan 1996; Bull 2008; DiClemente 2004; DiClemente 2009; Maynard 1994; Scholes 2003) and participant perception of the content, delivery and/or relevance of interventions (also reported in six trials: DiClemente 2004; DiClemente 2009; Jaworski 2001; Jemmott 2005; Koniak-Griffin 2003; Scholes 2003). The fidelity of intervention implementation was reported in four trials (Bryan 1996; DiClemente 2004; DiClemente 2009; Maynard 1994), whilst one trial mentioned briefly, without providing details, that a quality assessment of the intervention was conducted (Koniak-Griffin 2003). The most comprehensive process evaluations, which assessed all three components (exposure, intervention fidelity and participant perception) were reported in two trials by DiClemente 2004 and DiClemente 2009.

Settings—The majority of the trials evaluated interventions which were delivered in health-care settings (14 of the 23 trials). The types of health care-settings varied and included family planning clinics (Choi 2008; Jemmott 2005; Morrison-Beedy 2005; Orr

1996; Roye 2007), STI clinics (Orr 1996), a sexual health clinic (DiClemente 2009), a family medicine clinic (DiClemente 2004), a primary care site (unspecified) (Downs 2004), a University health centre (Jaworski 2001), obstetric clinics (Kershaw 2009), a hospital for women and infants (Peipert 2008), managed care networks (of practices, clinics and hospitals) (Scholes 2003), a public health clinic (Shain 1999) and a children's hospital adolescent clinic and inpatient service (Shrier 2001).

Three of the 23 trials evaluated interventions in community/city settings, comprising urban neighbourhood community venues (Bull 2008) and urban public housing developments Ferguson 1998. Precise details of the setting of the third were not reported (Maynard 1994).

Three of the 23 included trials were conducted in university/college settings (Bryan 1996; Ploem 1997; Smith 1993) and one in schools with programmes for pregnant minor or young parents (Koniak-Griffin 2003). In the remaining two trials the setting was not stated (Boyer 2005; Dancy 2009).

In terms of location all but two of the 23 trials were undertaken in the USA and all of these appeared to be in urban areas. Within the USA the locations varied and included Texas, California, New York, Chicago, Pennsylvania, Virginia and others. Both of the remaining two trials were conducted in Canada (Ploem 1997; Smith 1993).

Participants

Demographic characteristics: As specified in the Methods section, to be included in this review a trial had to include women predominantly under the age of 25 years. In two trials the mean age was below 15 years (12.29 years in the trial by Dancy 2009 and 13 years in the trial by Ferguson 1998). In 12 trials the mean, median or modal age was between 15 and 19 years (Bryan 1996; DiClemente 2004; DiClemente 2009; Jemmott 2005; Koniak-Griffin 2003; Maynard 1994; Morrison-Beedy 2005; Orr 1996; Ploem 1997; Roye 2007; Shrier 2001; Smith 1993). In five trials the mean age was between 20 and 25 years (Choi 2008; Jaworski 2001; Kershaw 2009; Scholes 2003; Shain 1999). In the remaining four of the 23 included trials a mean or median age was not specified but 70% or over were aged under 25 years (Boyer 2005; Bull 2008; Peipert 2008), including Downs 2004 where a trial eligibility criterion was age 11 to 14 years.

The ethnic and racial composition of the trials (of which, as reported earlier, all but two were conducted in the USA) could be summarised as diverse. In 10 of the 23 trials there was no predominant racial or ethnic category (Boyer 2005; Bull 2008; Choi 2008; Jemmott 2005; Morrison-Beedy 2005; Orr 1996; Peipert 2008; Roye 2007; Scholes 2003; Shrier 2001).These trials tended to comprise varying proportions of African-Americans, Caucasians, Hispanics, Asians and others. In a further seven trials the predominant (i.e. greater than 70%) race/ethnicity was African-American (Dancy 2009; DiClemente 2004; DiClemente 2009; Downs 2004; Ferguson 1998; Kershaw 2009; Maynard 1994) and in four of these seven the eligibility criteria permitted only African-American women (Dancy 2009; DiClemente 2004; DiClemente 2009; Ferguson 1998). In three trials the predominant race/ethnicity was Caucasian (Bryan 1996; Jaworski 2001; Ploem 1997) and in two trials it was Hispanic (Koniak-Griffin 2003; Shain 1999). In the remaining trial, conducted at the

University of Ontario in Canada, the race/ethnicity of the young women was not stated (Smith 1993).

Socio-economic status: Data on markers of SES were reported in numerous ways and in varying detail (see the Characteristics of included studies). Across the trials the SES profile of the young women varied. Commonly reported markers of SES included level of education (e.g. whether completed high school or above), years of education and qualifications achieved. Employment and income was another commonly reported characteristic, including employment status, personal and household income, classifications of poverty status, receipt of benefits and welfare (e.g. family aid, food stamps) and medical insurance coverage. Also mentioned were general family/household details such as whether or not the young women had children (and whether they were single mothers) and whether they themselves lived with both parents or with a single parent (and whether employed/unemployed). A further marker of SES was the locality in which the young women lived and indicators of its health status, with inner-city locations sometimes considered synonymously with poor health and low income. Some of the trials were designed specifically to benefit those considered to have low SES. For example, Dancy 2009 recruited young women from areas high in low-income/single-mother-headed homes and Jemmott 2005 recruited low-income inner-city women. Eight trials did not provide any detail on markers of SES (Bryan 1996; Bull 2008; Downs 2004; Jaworski 2001; Ploem 1997; Roye 2007; Shrier 2001; Smith 1993), though two of these were trials of young women in Universtiy which may indicate a relatively higher SES (Ploem 1997; Smith 1993).

Sexual experience and risk status: All of the included trials included (varying proportions of) young women reported to be sexually experienced (i.e. they had reported at least one episode of vaginal intercourse). Of these, 13 trials restricted inclusion to women who were currently or who had recently been sexually active (e.g. in the past six months or a year) Choi 2008; DiClemente 2004; DiClemente 2009; Downs 2004; Jaworski 2001; Jemmott 2005; Morrison-Beedy 2005; Orr 1996; Peipert 2008; Roye 2007; Scholes 2003; Shain 1999; Shrier 2001) and in three trials women were pregnant or young mothers and therefore by default were sexually experienced (Kershaw 2009; Koniak-Griffin 2003; Maynard 1994). In seven trials (Bryan 1996; Boyer 2005; Bull 2008; Dancy 2009; Ferguson 1998; Ploem 1997; Smith 1993) the proportion of women who were sexually experienced varied, from around 10% (Dancy 2009) to 85% (Boyer 2005).

Seventeen of the 23 trials gave the proportion of young women who had self-reported ever having had an STI (Boyer 2005; Bryan 1996; Choi 2008; DiClemente 2004; DiClemente 2009; Downs 2004; Jaworski 2001; Jemmott 2005; Kershaw 2009; Morrison-Beedy 2005; Orr 1996; Peipert 2008; Ploem 1997; Roye 2007; Scholes 2003; Shain 1999; Shrier 2001). The proportions varied from 7% (Bryan 1996) to 49% (DiClemente 2009) with the exception of the trial by Shain 1999 in which diagnosis with a (non-viral) STI was a trial eligibility criterion and the trial by Orr 1996 in which diagnosis with chlamydia was necessary for entry into the trial. Jaworski 2001 reported only that a ‘small’ proportion of women had declared a recent STI. Two of the 23 trials reported the proportion of young women who had an STI at entry to the trial (DiClemente 2009; Jemmott 2005). The

remaining six of the 23 trials did not report whether or not the young women studied had ever had an STI (Bull 2008; Dancy 2009; Ferguson 1998; Koniak-Griffin 2003; Maynard 1994; Smith 1993). However, in the trial by Bull 2008 neighbourhoods were selected that had the highest rates of chlamydia, gonorrhoea and teen births for 15 to 25 year old women in the campaign area and similarly Dancy 2009 reported that the sample sites had poor indicators related to teen birth rates and STIs including HIV/AIDS.

The trials reported a wide range of measures of baseline sexual risk behaviour for STIs. Data for these measures were reported in numerous different ways and have not been summarised here (see the Characteristics of included studies). Commonly reported measures included the number of lifetime sexual partners, the number with multiple partners over a given time period, the number with a regular partner, use of condoms with casual and regular partners, consistency of condom use, age at first intercourse and number of unprotected sex acts over a given time period. Less commonly reported measures included the number who had ever been pregnant, use of drugs and alcohol with sex, condom use skills and use of general (non-condom) forms of contraception. The data reported suggest varying levels of behavioural risk for STIs. For example, relatively low proportions of women reported consistent condom use, varying from around 25% in the trial by DiClemente 2009 to 41% in the trial by Scholes 2003. As is evident from the data on sexual experience and history of STIs reported above, some of the trials appeared to be specifically aimed at women they considered to be at ‘high risk’. For example, Jaworski 2001 excluded women if they used condoms at every episode of vaginal, oral or anal sex, whilst Peipert 2008 only included young women who were sexually active with a male partner in the past six months and at high risk for unintended pregnancy or STI. In contrast, in the trial by Ferguson 1998, the majority of women reported not ever being sexually active at the start of the trial and most of those who were active were judged to be using effective contraceptives. However, it should be noted that the girls in this trial were comparatively younger than many of the other trials included in this review (mean age 13 years).

Interventions

Types of intervention: An overview of the characteristics of the interventions (type, length, setting) can be found in Table 1. Given the diversity in the types of behavioural intervention meeting our inclusion criteria, we categorised the experimental interventions into four types, based on their key components:

1. Information provision plus skills development (n = 17 trials) (Boyer 2005; Bryan 1996; Choi 2008; Dancy 2009; DiClemente 2004; Downs 2004; Ferguson 1998; Jaworski 2001; Jemmott 2005; Kershaw 2009; Maynard 1994; Morrison-Beedy 2005; Orr 1996; Roye 2007; Shain 1999; Shrier 2001; Smith 1993). These interventions commonly provided factual information about sexual and reproductive health and the transmission and prevention of STIs and gave young women the opportunity to develop practical skills to facilitate safer sexual behaviour. The latter included general communication skills with partners (e.g. discussions about safer sex), assertiveness and negotiation skills (e.g. to engage in safer practices), unsafe sex refusal skills and correct condom use skills (e.g. to prevent condom failure). Skills were practised using techniques such discussion,

role playing and cognitive rehearsal. In general, skills development was facilitated within the context of sexual and reproductive health, though occasionally the context was broader. For example, young women taking part in the trial by Maynard 1994, all of whom were young mothers, were encouraged to take greater control over their lives through discussions about contraception, STIs, relationships, self-esteem, decision making, assertiveness and communication. This was complimented with the teaching of parenting skills, life skills and family management (e.g. time and money management).

2. Information provision, plus skills development plus other component (n = 3 trials) (DiClemente 2009; Koniak-Griffin 2003; Ploem 1997). These trials were similar to those summarised above in category 1, in that they provided information and facilitated skill development, but they also included additional activities/initiatives. In the main these comprised provision of resources to enable young women to put their knowledge and skills into practice. For example, DiClemente 2009 gave young women vouchers to pass onto their male sexual partners to facilitate access to STI screening and treatment.

3. Information only (n = 2 trials) (Peipert 2008; Scholes 2003). As the title suggests these trials provided information about sexual and reproductive health, but did not supplement this with skills development or additional resources. In both trials the information was tailored to the specific requirements of each young woman based on needs assessment. For example, Peipert 2008 provided information about methods of contraception tailored to the individual's readiness to change their condom and contraceptive behaviours (based on the Transtheoretical Model).

4. Information plus other component (n = 1 trial) (Bull 2008). The only trial in this category supplemented information about condom use with the provision of coupons redeemable for male and female condoms and lubricant in a silk carrying case. The authors described this as social marketing.

Types of comparator: The trials were categorised according to the types of comparator against which the efficacy of the behavioural interventions was evaluated. Eleven of the 23 trials had more than two randomised arms (with the maximum number of arms in a trial being four), permitting multiple comparisons of arms. Therefore, these trials are classified in more than one category. A total of four comparisons were created:

Comparison 1) Behavioural intervention versus more basic version(s) of intervention/ standard practice (n = 12 trials) (DiClemente 2009; Jaworski 2001; Jemmott 2005; Kershaw 2009; Maynard 1994; Orr 1996; Peipert 2008; Ploem 1997; Roye 2007; Scholes 2003; Shain 1999; Shrier 2001). Some of the trials in this category compared the behavioural intervention to what the authors described as being standard practice or usual care. For example, the trial involving young mothers by Maynard 1994 compared an enhanced education and parenting skills programme addressing (amongst other things) STI risks, with usual local welfare services provision for teenage mothers (described as limited social and support services available under that programme). This category also includes trials in which the behavioural intervention was compared to one which contained fewer components. An

example is the trial by Jemmott 2005 which compared a skills-based risk reduction intervention that provided young women with information about risks for STIs and the opportunity to practice condom use and negotiation skills with partners, with an intervention which provided information but no skill development. Also in this comparison are trials in which the behavioural intervention was tested against a similar intervention but which had less contact time.

Comparison 2) Behavioural intervention(s) versus general health promotion/attention control (n = 8 trials) (Boyer 2005; Bryan 1996; Choi 2008; Dancy 2009; DiClemente 2004; Jemmott 2005; Koniak-Griffin 2003; Morrison-Beedy 2005). The trials in this category made comparisons between behavioural interventions addressing STIs and interventions matched in terms of format and structure, but lacking any coverage of sexual and reproductive health. The rationale for inclusion of this type of comparator, where stated, was to control for the general effect of participating in a health promotion intervention trial (e.g. the Hawthorne effect), in order to isolate the specific effects of the STI intervention. It mimics the amount of time and attention received by the intervention group but is thought not to have a specific effect upon the participants. For example, Morrison-Beedy 2005 compared an HIV education and skills development intervention with a general health promotion control group, equivalent in terms of type of intervention provider and format (e.g. group exercises and therapeutic exercises), but covering topics such as anger management, caffeine use and nutrition rather than sexual health.

Comparison 3) Behavioural intervention versus similar intervention with a different provider/medium (n = 3 trials) (Dancy 2009; Downs 2004; Ferguson 1998). The purpose of these studies was to test the effect of different methods of delivering interventions that were similar in terms of content. As an example, Downs 2004 evaluated an interactive video which provided young women with information about sexual health and allowed them to practice skills via cognitive rehearsal. This was compared to a book containing the same dialogue and imagery as the video. The authors hypothesised that whilst knowledge would increase irrespective of which intervention was received, there would be more favourable changes in sexual risk behaviour and rates of STIs in the former intervention, given the interactive and engaging nature of the video.

Comparison 4) Behavioural intervention(s) versus no-intervention (control) (n = 4 trials) (Bull 2008; Jaworski 2001; Ploem 1997; Smith 1993). Trials in this category compared groups of young women who received behavioural interventions to groups of young women who either received no intervention at all or who received the intervention at a later time point (e.g. after the evaluation had completed).

The effects of the interventions included in this systematic review are presented according to these four types of comparators (see Effects of interventions).

Intervention providers: The intervention providers were described as health educators in five trials (Choi 2008; DiClemente 2004; DiClemente 2009; Morrison-Beedy 2005; Shrier 2001) and researchers or research assistants in four trials (Boyer 2005; Bryan 1996; Orr 1996; Ploem 1997). In four trials intervention providers were not specified and the study

participants appeared to have had direct access to interventions through brochures placed at community venues (Bull 2008), brochures or videos placed in healthcare settings (Downs 2004), an interactive computer system (Peipert 2008) or mailed self-help materials (Scholes 2003). Two trials described their intervention providers as peer educators (DiClemente 2004) or peer counsellors (Ferguson 1998), in both cases these were females of African-American ethnicity. In the remaining trials the interventions were provided by: a trained midwife or obstetrician (Kershaw 2009); clinical psychology graduate students (Jaworski 2001); degree-qualified women who had worked with inner-city adolescents (Jemmott 2005); mothers of the trial participants (Dancy 2009); trained nurse facilitators (Koniak-Griffin 2003); case managers (Maynard 1994); or clinic staff (Roye 2007); or other female providers (Shain 1999; Smith 1993). In most of the trials a single type of intervention provider was employed and, where reported, interventions and comparators appeared to be delivered by the same type of provider. One trial (DiClemente 2004) used both health educators and peer educators to deliver the intervention, whilst one trial (Shain 1999) used different providers for the intervention (an ethnically-matched female facilitator) and the comparator (a nurse practitioner). A limitation of the reporting of the intervention providers is that it was often unclear how many people were involved in the specified roles.

Intervention length and intensity: There was variation in the total length of the experimental intervention periods (which includes initial sessions and any follow-up 'booster' sessions), from a single 20 minute session, to a series of sessions spread over nine months. Seven of the 23 interventions lasted for a day or less (Bryan 1996; Jaworski 2001; Orr 1996; Ploem 1997; Roye 2007; Smith 1993; Jemmott 2005). For example, Orr 1996 evaluated a brief 10 to 20 minute STI/family planning clinic-based intervention in which women were given information about STIs and instructed in condom use and partner negotiation skills. Some of these shorter interventions were specifically designed to be brief practical interventions that could be delivered at low cost in routine practice (Jaworski 2001). Two interventions lasted between one week and one month (DiClemente 2004, Shain 1999), seven interventions lasted between one and three months (Boyer 2005; Dancy 2009; DiClemente 2009; Ferguson 1998; Maynard 1994; Peipert 2008; Scholes 2003) and two interventions lasted between three and six months (Downs 2004; Shrier 2001). The longest intervention lasted between six months and a year (Kershaw 2009). Booster sessions following the initial intervention period were also included in the trials by Downs 2004, Scholes 2003 and Shrier 2001. The remaining four trials included in this review did not report the duration of the experimental interventions (Bull 2008; Choi 2008; Morrison-Beedy 2005; Koniak-Griffin 2003).

There was also variation in the total intervention contact time, from one hour or less to 20 hours. In five trials the total contact time (defined as the time during which young women attended intervention sessions) was less than one hour (Bryan 1996; Orr 1996; Roye 2007; Shrier 2001; Smith 1993), in three trials it was between one and five hours (Downs 2004; Jemmott 2005; Jemmott 2005), in five trials between five and 10 hours (Boyer 2005; Choi 2008; DiClemente 2009; Koniak-Griffin 2003; Morrison-Beedy 2005), in one trial between 10 and 15 hours (Shain 1999) and in three trials between 15 and 20 hours (DiClemente

2004; Ferguson 1998; Kershaw 2009). The remaining four trials included in this review did not report contact time (Bull 2008; Dancy 2009; Peipert 2008; Scholes 2003).

Behavioural aims: The studies employed a variety of approaches to promote sexual health and prevent STIs. Table 7 shows the various behavioural aims of the interventions evaluated, which ranged from promoting abstinence or partner reduction, to broader risk reduction strategies encompassing a variety of behaviours. The most common aim was to promote condom use for vaginal (and in some cases oral/anal) intercourse, as featured in all 23 included trials (and in seven trials it appeared to be the sole aim: Bryan 1996; Bull 2008; Choi 2008; Jemmott 2005; Ploem 1997; Orr 1996; Smith 1993). In the majority of interventions the male condom was promoted, though some promoted male or female condoms (e.g. Bull 2008; Scholes 2003; Peipert 2008) and in one trial the emphasis was on promoting the female condom (Choi 2008). In the majority of cases the interventions taught the young women about how to obtain and use condoms (e.g. practical demonstrations using anatomical models) and a common message was the need to use them consistently. Some of the trials explored various aspects of condom promotion such as Smith 1993 including 'desensitisation' to encourage young women to be more comfortable about handling and using condoms and to correct misconceptions. Likewise Ploem 1997 emphasised the positive and pleasurable aspects of condoms to make them more acceptable and normalised (e.g. eroticisisation). Some interventions advocated the promotion of effective contraception, of which condoms were one of a number of strategies (these were primarily trials which aimed to prevent unintended pregnancy as well as STIs) (e.g. Maynard 1994; Peipert 2008; Roye 2007). In two of these studies the emphasis was on dual methods of birth control comprising condom and hormonal contraception (Peipert 2008; Roye 2007).

Nine of the trials were classified as encouraging an increase in protective behaviours/ decrease in risk behaviours (Table 7). These were generally broader strategies designed to enable young women to develop skills and set goals and action plans for their own sexual health (e.g. Kershaw 2009; Roye 2007). At least two of these trials encouraged the young women to adopt risk reduction strategies that are more subject to a woman's control, including buying and carrying condoms (Scholes 2003).

In seven of the 23 included trials a facet of the intervention was encouragement to abstain from sex or reduce sexual activity (Table 7). In six of the trials one of the aims was sexual partner reduction (Table 7). However, abstinence or partner reduction were never the sole behavioural aims. For example, in the pregnancy prevention trial by Ferguson 1998, abstinence was the prominent message, but the intervention also addressed the use of effective contraception for those who are having sex, which could include condoms.

As evident from Table 7, it was common for interventions to have more than one behavioural aim (16 out of the 23 trials). In some cases the interventions encompassed multiple behavioural aims to enable young women to minimise their chances of acquiring STIs. For example in the study by Shrier 2001, the young women were given a list of topics and were given the opportunity of choosing the order in which they were discussed and the amount of emphasis each received. Topics included consequences of unprotected sex, risk

perception, preventing pregnancy, preventing STDs, condoms, spermicide, obtaining condoms, secondary abstinence and talking about sex.

STIs addressed: In eight of the trials the intervention appeared primarily to focus on HIV and/or AIDS (Dancy 2009; DiClemente 2004; Kershaw 2009; Koniak-Griffin 2003; Morrison-Beedy 2005; Ploem 1997; Roye 2007; Smith 1993), although one of these trials (Kershaw 2009) reported chlamydia and gonorrhoea instead of HIV/AIDS as biological outcomes. In three trials the intervention covered one or more named STIs, which were: chlamydia (Orr 1996); chlamydia, gonorrhoea, trichomonal infection, syphilis and HIV/AIDS (Shain 1999); and chlamydia, genital herpes, genital warts, gonorrhoea, hepatitis B, trichomoniasis, syphilis and HIV/AIDS (Downs 2004). The trial by Downs 2004 was the only one that specifically named any HPV-related conditions (i.e. genital herpes and genital warts) among the STIs covered by the intervention. In seven trials the intervention appeared to cover STIs in general, including HIV/AIDS (Boyer 2005; Choi 2008; DiClemente 2009; Ferguson 1998; Jemmott 2005; Scholes 2003; Shrier 2001) and in five trials the intervention appeared to cover STIs in general but without specific reference to HIV or AIDS (Bryan 1996; Bull 2008; Jaworski 2001; Maynard 1994; Peipert 2008).

Theory: Nineteen different theoretical models or theoretical backgrounds were referred to as bases for the interventions. Nine of the trials reported that they based their intervention on more than one theory. The most frequently cited theoretical backgrounds were Social Cognitive Theory in six trials (DiClemente 2004; DiClemente 2009; Kershaw 2009; Koniak-Griffin 2003; Roye 2007; Shrier 2001), the Theory of Reasoned Action in five trials (Dancy 2009; Koniak-Griffin 2003; Ploem 1997; Roye 2007; Smith 1993), the Health Belief Model in four trials (Bryan 1996; Orr 1996; Roye 2007; Shain 1999 and the Information, Motivation and Behavioural Skills Model in three trials (Boyer 2005; Jaworski 2001; Morrison-Beedy 2005). Other theoretical backgrounds employed were: Social Learning Theory (Choi 2008; Ploem 1997); the female-specific Theory of Gender and Power (DiClemente 2004; DiClemente 2009); the Theory of Planned Behaviour (Dancy 2009; Smith 1993); the Transtheoretical Model (Peipert 2008; Shrier 2001); Aids Risk Reduction Model, decison-making models, diffusion theory and self-efficacy theory (Shain 1999); Bandura's self-efficacy and skills models (Dancy 2009); mental models in behavioural decision research (Downs 2004); Cognitive Behavioural Theory (Jemmott 2005); the Ecological Model (Kershaw 2009); Sexual Behaviour Sequence Theory (Ploem 1997); motivational interviewing (Shrier 2001); Social Science Theory (Scholes 2003); and social marketing principles (Bull 2008). Two trials did not specify a theoretical background for their interventions (Ferguson 1998; Maynard 1994).

Costs/cost-effectiveness: None of the trials estimated the cost-effectiveness of their interventions. One trial (Roye 2007) commented that their intervention was inexpensive, stating that the cost of a video was approximately US $30 and that participants were paid US $120 in total for their participation and attendance at two follow-up sessions. Thirteen other trials also reported that they paid the young women to participate, either as an incentive or in compensation for travel, childcare and lost earnings (Boyer 2005; Bull 2008; Choi 2008; DiClemente 2004; DiClemente 2009; Downs 2004; Jemmott 2005; Kershaw 2009; Koniak-

Griffin 2003; Morrison-Beedy 2005; Peipert 2008; Roye 2007; Scholes 2003). However, none of the trials provided sufficient financial information to enable the full cost of implementing their interventions to be determined.

Outcomes—Nine trials nominated primary outcome measures, but in one of these (Bull 2008) it was unclear which of several listed outcomes were the primary one(s). One trial (DiClemente 2009) nominated both a behavioural outcome (condom use) and a biological outcome (chlamydia infections) as primary outcomes. Condom use was a primary outcome in four trials altogether (DiClemente 2004; DiClemente 2009; Roye 2007; Scholes 2003), whilst dual methods of contraception (Peipert 2008) and unprotected sexual intercourse (Jemmott 2005) were the other primary behavioural outcomes reported. Biological measures that were reported as a primary outcome were chlamydia infections (DiClemente 2009), chlamydia or gonorrhoea infections (Shain 1999) and a composite measure of an STI and/or unintended pregnancy (Boyer 2005).

Behavioural outcomes

•***Condom use:*** In 19 of the 23 trials behavioural outcomes referred to the use of condoms. Most of the trials that reported condom use outcomes appeared to refer to male condoms, although this was not always explicitly stated. Two trials specifically measured the use of female condoms (Bull 2008; Choi 2008). Condom use was measured in various different ways, most commonly as: the occurrence or frequency of use, during a specified time period (Bull 2008; Choi 2008; DiClemente 2004; DiClemente 2009; Downs 2004; Kershaw 2009; Morrison-Beedy 2005; Ploem 1997; Scholes 2003; Shrier 2001); the occurrence or frequency of use at the last vaginal sexual intercourse act (Bryan 1996; DiClemente 2004; DiClemente 2009; Koniak-Griffin 2003; Orr 1996; Roye 2007; Shrier 2001); or the frequency or time of condom-protected sex acts (Choi 2008; Jaworski 2001; Ploem 1997). In some trials condom use was classified as consistent (DiClemente 2004; DiClemente 2009; Peipert 2008; Ploem 1997; Scholes 2003; Shrier 2001) or inconsistent (Boyer 2005). One trial reported condom failure as an outcome (Downs 2004), one trial reported a score that indicated the frequency of applying condoms on sex partners (DiClemente 2004), one trial reported the number of days of sex without use of a condom in the past three months (Jemmott 2005) and one trial reported a score that reflected the frequency of condom use relative to the number of intercourse occasions (Smith 1993). Some trials specified whether condom use applied to the main sexual partner (Roye 2007; Shrier 2001), to another partner (Scholes 2003; Shrier 2001) or to any partner (Shrier 2001).

• ***Condom-related behaviour:*** Two trials reported condom-related behavioural outcomes. The outcomes were: browsing condoms in store, reading condom packs, condom advertisements and/or an AIDS pamphlet (Smith 1993); and purchasing or carrying of condoms (Bryan 1996).

• ***Other measures of contraception:*** One trial (Ferguson 1998) measured whether participants had used effective (unspecified) contraception, whilst another trial (Maynard 1994) assessed the probability of participants using any contraceptive method or a more or less effective method.

• ***Unprotected sexual intercourse acts:*** The number of unprotected sexual intercourse acts or the proportion of participants engaging in unprotected sexual intercourse during a specified time period were reported as outcomes in seven trials (DiClemente 2004; Jaworski 2001; Jemmott 2005; Kershaw 2009; Koniak-Griffin 2003; Morrison-Beedy 2005; Shain 1999).

• ***Sexual partners:*** Four trials reported the number of sexual partners that their participants had during a specified period (Jemmott 2005; Koniak-Griffin 2003; Morrison-Beedy 2005; Shain 1999). Three trials reported the proportion of participants who had multiple sexual partners (Boyer 2005,Jemmott 2005) or casual sexual partners (Boyer 2005; Roye 2007) during specified periods. Three further trials reported the proportion of participants who acquired a new partner (DiClemente 2004), who experienced a decrease in the number of sexual partners (Jaworski 2001), who currently had a main partner (Shrier 2001) or who had previously had a different partner (Shrier 2001).

• ***Engagement in sexual activity:*** Abstinence from sexual intercourse during a specified time period was reported in two trials (Downs 2004; Jaworski 2001), whilst one trial reported avoidance of sexual activity with a partner who had been incompletely treated or untreated for STI infection (Shain 1999). Ferguson 1998 reported the proportion of females who had never been sexually active and Dancy 2009 reported whether the young women had engaged in sex during the previous six months. DiClemente 2004 reported the mean number of vaginal sex acts in past six months.

• ***Other behavioural outcomes:*** Sexual risk as a behavioural self-state on the wheel of change was reported in one trial (Shrier 2001).

Biological outcomes

• ***Sexually transmitted infections:*** Incidence of STIs was reported as an outcome in 12 of the 23 trials. The three most commonly measured STIs were chlamydia, gonorrhoea and trichomonas infection. Six trials reported the incidence of chlamydia (DiClemente 2004; DiClemente 2009; Downs 2004; Orr 1996; Peipert 2008; Roye 2007) and three separately reported the incidence of both gonorrhoea and trichomoniasis (DiClemente 2004; DiClemente 2009; Peipert 2008). One trial (Downs 2004) reported whether participants had at least one of nine STIs (chlamydia, pubic lice, genital herpes, genital warts, gonorrhoea, hepatitis B, HIV, syphilis and/or trichomoniasis), two trials (Boyer 2005; Jemmott 2005) reported whether participants had at least one of three STIs (chlamydia, gonorrhoea and/or trichomoniasis) and two trials (Kershaw 2009; Shain 1999) reported whether participants had at least one of two STIs (chlamydia and/or gonorrhoea). The remaining trials that reported the incidence of STIs did not name specific infections (Scholes 2003; Shrier 2001). In the majority of trials the infections were biologically confirmed during the course of the trial. Four studies included self-reported STI outcomes, either alone (Scholes 2003; Shrier 2001) or alongside biologically confirmed STI outcomes (Downs 2004; Roye 2007). One of the 12 trials that reported STI outcomes (Downs 2004) included HPV-related infections (i.e. genital herpes and genital warts). However, these were not separable from other STIs that were included in the same outcome.

• ***Pregnancy:*** Five trials assessed pregnancy as an outcome measure. In four trials pregnancy was as a discrete outcome expressed as a frequency or effect size (Ferguson 1998; Kershaw 2009; Maynard 1994; Peipert 2008), whilst the fifth trial reported a composite measure that reflected the incidence of any STI and/or unintended pregnancy (Boyer 2005). These trials had all specified pregnancy reduction as one of their objectives (Table 7).

Other outcomes

• ***Skills:*** The majority of the trials included some form of skills building in their interventions, for example to improve skills in sexual communication and condom use. Eleven of the trials reported skills as an outcome measure. Communication skills were most commonly reported, including communicating with partners or friends about using condoms (Bryan 1996; Kershaw 2009; Scholes 2003; Shrier 2001; Smith 1993) or communication more generally about HIV (DiClemente 2004) or safer sex (DiClemente 2009; Morrison-Beedy 2005). Other skills included the ability to correctly use condoms (DiClemente 2004); pregnancy prevention skills (Ferguson 1998); and sexual assertiveness skills (Jaworski 2001; Peipert 2008).

• ***Knowledge:*** All of the trials included some form of educational component to increase participants' knowledge and 15 of the studies reported knowledge as an outcome measure. The knowledge outcomes covered STIs (Dancy 2009; DiClemente 2004; DiClemente 2009; Jaworski 2001; Kershaw 2009; Morrison-Beedy 2005; Orr 1996; Ploem 1997; Smith 1993), STIs and condom use (Jemmott 2005; Koniak-Griffin 2003), STIs, contraception and other aspects of reproductive health (Downs 2004; Ferguson 1998), the female condom (Choi 2008) and sexual risk (Shrier 2001).

• ***Attitudes:*** Ten trials reported attitudes as an outcome (Bryan 1996; Bull 2008; Choi 2008; Dancy 2009; DiClemente 2004; Jaworski 2001; Orr 1996; Ploem 1997; Shrier 2001; Smith 1993). In all cases the attitudes measured were those towards condoms or condom use. In the trial by Choi 2008 the attitudes reported were those specifically towards female condoms. In the trial of Orr 1996, attitudes to STIs were assessed as well as attitudes towards condoms.

• ***Awareness/beliefs:*** Ten trials measured the participants' awareness/beliefs around safer sex. Commonly this was about their perceived risk/susceptibility to STIs (Bryan 1996; Jaworski 2001; Kershaw 2009; Morrison-Beedy 2005; Orr 1996) and/or about their beliefs about condoms and their effectiveness as a way of protecting one's self (Bryan 1996; Jemmott 2005; Koniak-Griffin 2003; Morrison-Beedy 2005; Peipert 2008). Two trials measured subjective and social norms about safer sex: towards AIDS risk reduction behaviours (Ploem 1997) and subjective norms about safer sex (Smith 1993).

• ***Self-efficacy:*** Eleven trials reported self-efficacy as an outcome. Eight of these trials reported self-efficacy in condom use (Bryan 1996; Choi 2008; DiClemente 2004; DiClemente 2009; Kershaw 2009; Morrison-Beedy 2005; Peipert 2008; Scholes 2003), with the trial by Choi 2008 focusing specifically on selfefficacy for the use of female condoms. Other outcomes reported were perceived control (i.e. self-efficacy) in a range of 11 condom-

related behaviours (expressed as a single score) (Smith 1993) and self-efficacy to refuse sex (Dancy 2009). One trial (Koniak-Griffin 2003) reported summary scores from constructs based on Social Cognitive Theory for assessing overall self efficacy and based on the Theory of Reasoned Action for assessing perceived behavioural control.

• ***Behavioural Intentions:*** Eight trials assessed intentions as an outcome measure. The most common behavioural intention measured was intention to use condoms (Bull 2008; Jemmott 2005; Koniak-Griffin 2003; Smith 1993). Bryan 1996 assessed intentions to buy, carry, practice or discuss use of condoms. Two studies assessed interventions to reduce risk behaviours (Jaworski 2001; Morrison-Beedy 2005) and one study assessed intentions to refuse sex (Dancy 2009).

Excluded studies

We excluded 190 references after obtaining the full text (134 from the 2009/10 literature search and 56 from searches conducted for previous versions of this review - see Search methods for identification of studies). As mentioned in Selection of studies, references could be excluded for more than one reason, but we recorded whichever criterion in our list that they failed to meet first (see the table Characteristics of excluded studies). The most common reason for exclusion was because the trial population did not meet our criteria (n = 103 studies). In most of these cases the females studied were over the age of 25 years. The second most common exclusion was on study design (i.e. not an RCT, n = 65 studies), followed by irrelevant outcome measures (n = 16 studies) and lastly, an irrelevant intervention (n = 6 studies).

Risk of bias in included studies

(See Risk of bias tables in Characteristics of included studies) Due to limitations in reporting many trials were judged to be at uncertain risk of bias. One trial (Kershaw 2009) was at moderate risk of bias as it satisfied four out of the six criteria used to assess risk of bias and the trials by DiClemente 2004 and DiClemente 2009 were at low risk of bias as they satisfied five out of six of the risk of bias items (see Figure 1 and Figure 2).

Allocation—The methods of random sequence generation was reported in 11 of the 23 trials. The methods used were random numbers tables or lists (Boyer 2005; DiClemente 2004; Downs 2004; Shrier 2001); computer generated sequences (details of the software not specified) (Bull 2008; DiClemente 2009; Jemmott 2005; Kershaw 2009; Peipert 2008); and coin tossing (Ferguson 1998; Orr 1996). In the remaining 12 trials the method of sequence generation was unclear, because: no information was provided (Bryan 1996; Dancy 2009; Koniak-Griffin 2003; Maynard 1994; Morrison-Beedy 2005; Peipert 2008; Ploem 1997); aspects of participant allocation to the sequence were described, but not the actual method of generating the sequence (Choi 2008; Shain 1999; Smith 1993); or the trials stated only, without details, that the allocation sequence was random (Jaworski 2001; Scholes 2003). The majority of the trials (19/23) did not provide any information about allocation concealment and were therefore judged to have unclear risk of bias for this domain. Two trials specified that sealed opaque envelopes were used to hide allocation codes (DiClemente 2004; DiClemente 2009). The remaining two trials stated that allocation was concealed

(Kershaw 2009) or that allocation concealment was done by computer (Peipert 2008), without providing any more details.

Blinding—Six of the 23 trials reported that outcome assessors (interviewers or other data collectors) were unaware of the identity of the intervention groups (Bryan 1996; DiClemente 2004; DiClemente 2009; Jemmott 2005; Kershaw 2009; Koniak-Griffin 2003). One trial stated that interviewers were not blinded and not part of the project staff (Scholes 2003). In the remaining 16 trials, it is unclear whether adequate blinding of outcome assessors occurred, either because it was not mentioned at all (Boyer 2005; Bull 2008; Choi 2008; Dancy 2009; Downs 2004; Ferguson 1998; Maynard 1994; Morrison-Beedy 2005; Orr 1996; Ploem 1997; Roye 2007; Shrier 2001; Smith 1993); or because it was reported ambiguously (Jaworski 2001; Peipert 2008; Shain 1999).

Incomplete outcome data—All but one of the of the trials reported attrition. In the trial by Bull 2008, different individuals were sampled at baseline and follow-up, precluding an assessment of attrition. Of the 22 trials that reported attrition, eight provided only a trial-wise attrition rate, not accounting for differences between intervention arms (Choi 2008; Downs 2004; Jaworski 2001; Koniak-Griffin 2003; Maynard 1994; Morrison-Beedy 2005; Orr 1996; Ploem 1997). The reported rates of attrition ranged from 8% (Koniak-Griffin 2003) (at 12 months' follow-up) to 74% (Roye 2007) (at three months' follow up). Most trials reported attrition in the range 10 to 40%. Where reported, differences in attrition rates between intervention arms within a trial were small (6%), except for studies by Ferguson 1998 and Smith 1993 whose≤rates of attrition differed between study arms by 18% and 32% respectively.

Only three of the 23 trials addressed the possibility of incomplete outcome data: Boyer 2005; DiClemente 2004 and DiClemente 2009 provided evidence that the level of attrition and the reasons for attrition were balanced across the trial groups. Three of the trials were judged to be at high risk of bias in terms of incomplete outcome data (Ferguson 1998; Roye 2007; Smith 1993). In these trials attrition rates differed between the randomised groups. The remaining 17 trials were judged to be at uncertain risk of bias (Bryan 1996; Bull 2008; Choi 2008; Dancy 2009; Downs 2004; Jaworski 2001; Jemmott 2005; Kershaw 2009; Koniak-Griffin 2003; Maynard 1994; Morrison-Beedy 2005; Orr 1996; Peipert 2008; Ploem 1997; Scholes 2003; Shain 1999; Shrier 2001). The main reason was because attrition rates and reasons for attrition were not reported according to trial group.

Selective reporting—Based on the descriptions of outcomes given in the methods and introduction sections of the trial publications and the subsequent presentation of the outcomes in the results and conclusions sections, 13 of the 23 trials appear to have reported results for all their measured outcomes. One trial appeared selective in its outcome reporting, as results were presented for only some of the measured behavioural outcomes (Bull 2008). In the remaining nine trials it is unclear whether all measured outcomes were reported. This is because outcomes were reported only vaguely in the methods sections of papers (Bryan 1996; Maynard 1994; Orr 1996; Peipert 2008); some outcomes were only reported in results sections (Roye 2007; Shain 1999; Shrier 2001); the number of sex

partners was only reported for class zero (i.e. abstinence) (Downs 2004); or not all planned behaviour questions were used at baseline (Smith 1993).

Other potential sources of bias—Seven of the trials were judged to be at high risk of other sources of bias. These sources included: imbalance of trial groups at baseline increasing the likelihood of selection bias (Boyer 2005; DiClemente 2004; Ferguson 1998; Maynard 1994; Orr 1996; Peipert 2008; Smith 1993); cluster RCT analysed at the level of the individual rather than the cluster (Ferguson 1998; Orr 1996; Smith 1993); cluster RCT with a limited number of clusters per randomised arm, increasing the likelihood of selection bias(Ferguson 1998; Orr 1996); and dissemination of the intervention to the comparison group which may have biased the results in favour of the latter (Bull 2008).

In 16 studies the risk of other sources of bias was uncertain. In five of these it was because information given suggested the possibility of bias, but due to limitations or ambiguities in the reporting it was not clear whether bias was present. These sources included: a possible imbalance in trial groups at baseline (Bryan 1996; Dancy 2009; Kershaw 2009; Shain 1999); and cluster RCT where the unit of analysis (e.g. cluster or participant) was not explicit (Dancy 2009; Koniak-Griffin 2003). In the remaining 11 studies reporting limitations meant that other bias could not be ruled out.

Effects of interventions

Comparison 1 - Behavioural intervention versus more basic version(s) of intervention/standard practice (n = 12 trials)

Condom use: Table 3 shows the effects of the trials on condom use. Use of condoms was measured in a number of ways as summarised below.

Consistency/frequency of condom use for vaginal intercourse: Six comparison 1 trials reported on this outcome. Two trials reported a statistically significant difference between the behavioural intervention and its more basic version/standard practice. At 12 month follow-up in the trial by DiClemente 2009, a greater percentage of young women receiving the STI/HIV risk reduction intervention reported consistent condom use than in the enhanced usual care comparison group. This was the case for both the previous 14 day period (Risk ratio (RR) 1.70, 95% Confidence Interval (CI) 1.09 to 1.95, P = 0.01) and the previous 60 day period (RR 1.75, 95% CI 1.13 to 2.09, P = 0.007). In the trial by Orr 1996, at six month follow-up the frequency of condom use for STD protection and frequency of condom use for vaginal intercourse was higher for young women receiving the condom use education and practical skills development session compared to the those who received the condom use education session (Odds ratio (OR) 13.2, 95% CI 4.2 to 41.8, P < 0.001 and OR 11.8, 95% CI 3.3 to 41.9, P < 0.001, respectively).

Two trials reported no statistically significant difference between the behavioural intervention and comparator in the percentage reporting consistent condom use: at 24 month follow-up in the trial by Peipert 2008 (period unspecified, adjusted RR 1.26, 95% CI 0.88 to 1.79)); and at six month follow-up in the trial by Scholes 2003 (for the previous three month period, adjusted OR 1.24, 95% CI 0.89 to 1.73, P = 0.21).

In two trials statistical significance for comparisons of interventions was not reported so inferences could not be made. Shrier 2001 reported consistency (every time) and frequency (in the past six months) of condom use at the 12 month follow-up assessment. The percentage of women reporting consistent (every time) condom use with both main and other partners was higher for the safer sex education intervention than the standard care/STD education comparator. Likewise, frequency scores were also marginally higher for the safer sex education intervention. Ploem 1997 reported very small numbers of consistent condom users (less than 5).

Condom use during last sexual intercourse: Five comparison 1 trials reported on this outcome. Only one of these trials reported a statistically significant difference.

At 12 month follow-up in the trial by DiClemente 2009, a greater percentage of young women receiving the STI/HIV risk reduction intervention reported using condoms during last sexual intercourse than those in the enhanced usual care comparison group (RR 1.51, 95% CI 1.06 to 1.68, P = 0.01).

The remaining four trials either reported no statistically significant differences between interventions or did not report statistical significance.

Orr 1996 reported two measures: the probability of having used condoms at last coitus and the effect of the intervention on condom use at last coitus (no further information given). For the former it is described that there is ‘no effect’ and the latter is described as being not statistically significant (no P value given or point estimate reported).

The trial by Maynard 1994 gave the percentage of teenage mothers reporting contraception use at follow-up. Of the various contraception methods, use of condoms was reported by 23% of the young women. However, data were only given for the sample as a whole rather than the randomised intervention groups and for a sub-sample of those who completed the trial.

Roye 2007 reported the percentage who used condoms during last vaginal intercourse with a main partner at both three and 12 month follow-up. The trial compared a video and counselling intervention with counselling only, with video only and with usual care. No quantitative results were given (except for age and ethnicity sub-groups). It was stated that there were no statistically significant differences for any group comparisons (no statistical significance was reported) with the exception of the video and counselling group compared to the usual care group at the three months follow-up. The video and counselling group were two and a half times as likely as to have used a condom during last intercourse with their main partner (stated significant at the 0.06 level based on logistic regression).

In the trial by Shrier 2001 at 12 months follow-up, a greater percentage of young women receiving the safer sex education intervention reported using condoms during the last sexual encounter than those in the comparison group, although statistical significance was not reported.

Protected/unprotected sex acts: Six comparison 1 trials reported this outcome. The results of most of these appear to favour the behavioural interventions.

At 12 month follow-up in the trial by DiClemente 2009, the proportion of condom protected sex acts was greater for young women receiving the STI/HIV risk reduction intervention reported than the enhanced usual care comparison group for the previous 14 days (adjusted mean difference (MD) = 12.79, 95% CI 3.06 to 22.52), P = 0.001) and the previous 60 days (adjusted MD =10.78, 95% CI 3.61 to 17.95, P = 0.002).

Kershaw 2009 reported the mean number of unprotected sex acts in the past 30 days measured at 17, 49 and 75 weeks after baseline. Comparisons were made between women randomised to varying levels of prenatal care: group prenatal care with an integrated HIV component (group 1), group prenatal care (group 2) and individual prenatal care (group 3). In the main the mean number of unprotected acts was lowest for the young women in the group prenatal care with an integrated HIV component arm, though the difference between arms was only statistically significant at the 75 week time point (P < 0.05 for group 1 versus groups 2 and 3). Young women who did not have any sexual partners were coded as having zero partners, though the number of these young women was not reported.

Ploem 1997 reported changes in the proportion of intercourse occasions protected by a condom at the one month follow-up assessment in the subset of 36 (of the 112 randomised) coitally active young women taking part in their trial. The women were classified in terms of those who increased protected occasions, those who decreased and those with no change. A greater proportion of women increased their occasions in the information, condom eroticisation/normalisation and communication skills combination intervention compared to the information only intervention (P = 0.05). Conversley, the proportion of ‘no changers’ was higher in the information only intervention group (P = 0.05). The proportion of young women who decreased condom protected occasions was similar between the two groups and not reported to be statistically significant (P value not given).

In the trial by Scholes 2003 the mean percentage of intercourse episodes in which condoms were used (by a sub-set of 842 sexually active participants from the 1210 randomised) with any male partner in past three months was given for the six month follow-up. The percentage of episodes was statistically significantly higher in the self-help intervention group than the usual care group (adjusted MD = 5.2%, 95% CI 0.4 to 10.4, P = 0.05).

Shain 1999 measured the percentage of unprotected sexual acts from trial entry through to follow-up at 12 months, categorising responses into “fewer than five acts” or “five or more”. The percentage reporting fewer than five acts was statistically significantly higher for the young women receiving the behavioural-cognitive intervention compared to those receiving the nurse practitioner-led counselling (P = 0.03). Similarly, the percentage reporting five or more unprotected acts was significantly lower for the behavioural-cognitive intervention (P = 0.03).

Only one trial did not report statistically significant differences. Jaworski 2001 reported the mean number of vaginal sex acts with and without a condom at two month follow-up (for the previous two months). The mean number of acts with a condom was lower for the

'Intervention-Motivation-Behavioural' skills group compared to the information-only group. Furthermore, the mean number of acts without a condom was higher for the Intervention-Motivation-Behavioural skills group. However, these differences were reported not to be statistically significant based on log odds (no further detail given). Although not explicitly stated, these data may have excluded the sub-group of up to 20% who became sexually abstinent between baseline and two month follow-up.

Other condom use measures: Six comparison 1 trials reported other measures of condom use. In general there were statistically significant differences between trial groups favouring the behavioural intervention over the more basic version(s) of intervention/standard practice.

Jemmott 2005 reported the mean number of days of sex without a condom in past three months at the 12 month follow-up assessment. Those receiving the skills-based HIV/STD risk reduction intervention had a statistically significant lower mean than those receiving the information-based HIV/STD risk reduction comparator intervention (P = 0.03).

Kershaw 2009 measured the mean percentage self-estimated condom use in past six months at 75 weeks after baseline (NB. it is not clear what was meant by mean percentage condom use). The percentage was highest for the group prenatal care with an integrated HIV component (group 1), followed by the individual prenatal care (group 3) and the group prenatal care (group 2) (P = 0.04). The trial also provided the percentage of young women who reported that condom use was for STI protection (rather than pregnancy prevention) at 75 weeks after baseline. This was statistically significantly higher in group 1 compared to groups 2 and 3 which had been combined (P = 0.028). Data for condom use were only presented for those participants who were sexually active in the previous six months, though the number of such participants was not reported. The size of this sub-group relative to the total number randomised is therefore unclear.

Orr 1996 reported the odds of having used condoms for vaginal intercourse and the odds of having used condoms for protection against STIs at six months follow-up, for the brief clinic-based condom use education and practical skills development session group compared to the brief clinic-based condom use education session group. For both outcomes there was a statistically significant effect favouring the education and practical skills development group (OR 3.1, 95% CI 1.4 to 6.8, P = 0.005 and OR 2.4, 95% CI 1.2 to 5.2, P = 0.02 respectively).

Peipert 2008 presented the percentage of young women at the 24 month follow-up who reported use of dual methods for contraception (which could include any of the following: (1) hormonal contraception plus a barrier method; (2) male condoms plus female condoms; (3) condoms plus spermicide; or (4) intrauterine device or sterilization plus a barrier method). The percentage of young women reporting dual use was highest amongst those receiving the individual-tailored dual contraception computer intervention than the enhanced standard care computer comparator intervention and this became statistically significant in an analysis adjusted for baseline covariates (RR 1.70, 95% CI 1.09 to 2.66). The trial by Scholes 2003 gave the percentage of sexually active young women who reported condom use in the past three months at the six month assessment and also for the combined three and six month follow-up assessments (repeated measures analysis). The results were given for

condom use with any partner, a primary partner and a non-primary partner. In general the percentages were statistically significantly higher for young women receiving the self-help intervention than the percentages for those who received the usual care comparator. The exception was the outcome of condom use with a non-primary partner where percentages were similar, with no statistically significant difference. The percentage of sexually active women varied according to the assessment time-point and the type of partner.

Shain 1999 reported results for a composite outcome that reflects unsafe sexual behaviour. Unsafe sex was defined as never using condoms with at least one partner in the past three months or both five or more unprotected sex acts in the past three months and incorrect or problematic condom use. The percentages of participants that practised unsafe sex during 12 months from baseline to follow up according to this definition was lower in the behavioural cognitive intervention group compared to the nurse practitionerled counselling group ($P < 0.001$).

Sexual partners: Four comparison 1 trials reported data on young women's sexual partnerships (Table 5) following behavioural intervention.

In only one of these trials was a statistically significant effect reported. Shain 1999 reported two composite partner outcomes, reflecting whether participants had multiple partners and rapid partner turnover. The outcome for multiple partners was expressed as the proportion of young women who were not mutually monogamous. A mutually monogamous participant was defined as having the same, steady, faithful partner (or no sex partner) during the past six months. The percentage of young women who were not mutually monogamous during the period from baseline to 12 months follow-up was significantly lower in the behavioural-cognitive intervention group than the nurse practitioner group ($P = 0.008$). The outcome for partner turnover defined participants as having rapid partner turnover if they had had a new sex partner, within three months of another sex partner, during the previous six months. The percentage of young women who reported rapid partner turnover during the period from baseline to 12 months follow-up was lower for the behavioural-cognitive intervention intervention group compared to the nurse practitioner group, though the difference was not statistically significant ($P = 0.15$). Jaworski 2001 reported the mean number of sex partners at the two month follow-up assessment. There was a reduction in the number of partners from baseline, with a similar mean number of partners at follow-up in the Intervention-Motivation-Behavioural skills group (IMB) and the information-only comparator group (INFO) (no statistical test was reported for this comparison). This trial also reported the percentage of young women with a decrease in the number of sexual partners from baseline to two month follow-up. The percentage was highest in the Intervention-Motivation-Behavioural skills group (IMB), though this was not statistically significant ($P = 0.33$). Although not explicitly stated, these data may have excluded the sub-group of up to 20% randomised participants who became sexually abstinent between baseline and two month follow-up.

Jemmott 2005 reported the mean number of sexual partners in the past three months at the 12 month follow-up assessment. For both of the active intervention groups there was a reduction in the number of partners from baseline. The lowest number of partners at follow-

up was reported by the skills-based HIV/STD risk reduction intervention compared to the information-based HIV/STD risk reduction intervention, although the difference was not statistically significant (P = 0.17). The trial also presented the mean percentage of young women reporting multiple partners in the past three months at the 12 month follow-up assessment. In common with the mean number of sexual partners reported above, there was a reduction in the percentage reporting multiple (two or more) partners from baseline in the active comparator groups. Again, at follow-up the lowest percentage was reported for the skills-based HIV/STD risk reduction intervention though this was not statistically significant (P = 0.20).

Shrier 2001 reported the percentage of participants who were with a main partner at the time of a follow-up assessment and also the percentage who had been with another partner in the previous six months. At 12 months follow-up the percentages for both these outcomes were lower for the safer sex education intervention group than for the standard care/STD education comparator group. However, the differences at 12 months were not statistically significant (or statistical significance was not reported).

Engagement in sexual activity: Two comparison 1 trials reported this outcome (Table 2). Jaworski 2001 reported the percentage of young women who became sexually abstinent from baseline to two months follow-up. The percentage was higher among young women in the Intervention-Motivation-Behavioural skills group, compared to the Information-only comparator group (INFO), although the difference was not statistically significant (P = 0.10).

Shain 1999 reported the percentage of young women who had had sex with a partner who was untreated or incompletely treated for an STI, during the period from baseline to 12 months follow-up. The percentage was significantly lower for the behavioural-cognitive intervention compared to the nurse practitioner-led counselling group (P = 0.03).

Incidence of STIs: Table 4 shows the effects of the trials on STIs.

Chlamydia: Four comparison 1 trials reported on chlamydia. In only one of these trials was a statistically significant difference reported between behavioural interventions and the more basic version(s) of intervention/standard practice.

In the trial by DiClemente 2009 the cumulative incidence of chlamydia over the 12 month trial period was numerically lower amongst young women receiving the STI/HIV risk reduction intervention compared to the enhanced usual care comparison (P = 0.059, crude RR 0.71, 95% CI 0.50 to 1.02). When the results were analysed over the full 0 to 12 month trial period in a logistic and linear generalised estimating equation (GEE) regression model (designed specifically to control for repeated within-subject measurements) the difference was reported to be statistically significant (P = 0.04, RR 0.65, 95% CI 0.42 to 0.98).

In the trial by Orr 1996 of young women being treated for chlamydia infection there was no statistically significant difference between the brief clinic-based condom use education and

practical skills development intervention and the brief clinic-based condom use education comparator in terms of the percentage reinfected at the six month follow-up (P = 0.3).

Peipert 2008 reported the percentage of young women diagnosed with chlamydia at the 24 month follow-up assessment. The percentage diagnosed with an infection was relatively low (10%) and there was no statistically significant difference between the individual-tailored dual contraception computer intervention group and the enhanced standard care computer comparator intervention (time to event adjusted hazard rate ratio (HRR) 1.31, 95% CI 0.61 to 2.82).

Roye 2007 tested for chlamydia infection at three months follow-up. No data were reported though it was implied that there was no statistically significant difference between the video and counselling, the counselling only, the video only and the usual care intervention groups for this outcome (P > 0.05).

Gonorrhoea: Two comparison 1 trials reported on gonorrhoea. In neither was there a statistically significant difference between trial groups.

In the trial by DiClemente 2009 there was no statistically significant difference between groups in the cumulative incidence of gonorrhoea over the 12 month trial period between young women receiving the STI/HIV risk reduction intervention and young women receiving the enhanced usual care comparison (RR 0.85, 95% CI 0.44 to 1.63, P = 0.62).

Peipert 2008 reported the percentage of young women diagnosed with gonorrhoea at the 24 month follow-up assessment. The percentage diagnosed with an infection was relatively low (around 5%) and there was no statistically significant difference between the individual-tailored dual contraception computer intervention group and the enhanced standard care computer comparator intervention (time to event adjusted HR 1.83, 95% CI 0.61 to 5.50).

Trichomoniasis: Two comparison 1 trials reported on trichomoniasis, with no statistically significant differences between behavioural interventions and the standard care comparison.

In the trial by DiClemente 2009 there was no statistically significant difference in the cumulative incidence of trichomoniasis over the 12 month trial period between young women receiving the STI/HIV risk reduction intervention and young women receiving the enhanced usual care comparison (RR 0.96, 95% CI 0.59 to 1.54, P = 0.87). Peipert 2008 reported the percentage of young women diagnosed with trichomonas at the 24 month follow-up assessment. The percentage diagnosed with an infection was relatively low (around 5%) and there was no statistically significant difference between the individual-tailored dual contraception computer intervention group and the enhanced standard care computer comparator intervention (time to event adjusted HRR 2.41, 95% CI 0.72 to 8.02).

Composite STI outcomes: Seven comparison 1 trials reported composite STI outcome measures. In most trials there was no statistically significant difference between the behavioural intervention and the more basic version(s) of intervention/standard practice.

Shain 1999 presented the percentage of young women reporting episodes (zero, one, two or more) of chlamydia and/or gonorrhoea infection during the 12 month trial period. The percentage reporting zero episodes was statistically significantly higher amongst young women in the behavioural-cognitive intervention relative to the nurse practitioner-led counselling comparator (P = 0.01). This trial also reported the percentage of participants infected with chlamydia and/or gonorrhoea over the 12 month trial period. This percentage was statistically significantly lower amongst young women in the behavioural-cognitive intervention (OR 0.52, 95% CI 0.34 to 0.81, P = 0.004).

The remaining six trials did not report statistically significant differences.

Jemmott 2005 reported the percentage of young women testing positive for an STI (chlamydia, gonorrhoea and/or trichomoniasis) at 12 month follow-up assessment. The percentage decreased from baseline in both the skills-based HIV/STD risk reduction intervention and the information-based HIV/STD risk reduction comparator. At follow-up the percentage was lowest in the former group, although the difference between groups was not statistically significant (P = 0.23).

Kershaw 2009 reported the percentage testing positive for chlamydia and/or gonorrhoea at 75 weeks after baseline. There was no statistically significant difference between the group prenatal care with an integrated HIV component intervention relative to the group prenatal care comparator and the individual prenatal care comparators combined (OR 0.72, 95% CI 0.38 to 1.36, P = 0.32). Peipert 2008 reported the percentage of young women diagnosed with any STI (chlamydia, gonorrhoea, trichomonas, herpes simplex virus, syphilis, PID) at the 24 month follow-up assessment. There was no statistically significant difference in the percentage of young women with a diagnosed infection between the individual-tailored dual contraception computer intervention group and the enhanced standard care computer comparator intervention (time to event adjusted HRR 1.29, 95% CI 0.70 to 2.36).

Roye 2007 assessed self-reported recurrent STIs at three months follow-up. No data were reported though it was implied that there were no statistically significant differences between the video and counselling, the counselling only, the video only and the usual care intervention groups for this outcome (P > 0.05).

In the trial by Scholes 2003 there was no statistically significant difference between the self-help intervention and the usual care comparator in terms of the percentage of sexually active young women (849 out of 1210 randomised) who reported an STI diagnosis in the past three months (at the six month follow-up) (adjusted OR 0.97, 95% CI 0.48 to 1.96, P = 0.93).

Shrier 2001 presented the percentage of young women who reported having an STI since enrolment in the trial, at the 12 month follow-up assessment. The percentage was lower amongst young women receiving the safer sex education intervention compared to the standard care/STD education comparator, although the difference was not statistically significant (P = 0.17).

STI associated complications: One comparison one trial reported on STI associated complications. Peipert 2008 reported the proportion of young women diagnosed with PID at

the 24 month follow-up assessment. The percentage with a diagnosis of PID was very low and there was no statistically significant difference between the individual-tailored dual contraception computer intervention group and the enhanced standard care computer comparator (time to event adjusted HRR 1.03, 95% CI 0.20 to 5.19).

Comparison 2 - Behavioural intervention(s) versus general health promotion/ attention control (n = 8 trials)

Condom use: Table 3 shows the effects of the studies on condom use. Use of condoms was measured in a number of ways as summarised below.

Consistency/frequency of condom use for vaginal intercourse: Two comparison 2 studies reported this outcome, with mixed results.

In the study by DiClemente 2004 the (unadjusted) percentage of young women reporting consistent condom use in the past 30 days at the 12 month follow-up assessment was statistically significantly higher for the HIV prevention intervention group compared to the general health promotion comparator group (OR2.23, 95% CI 1.17 to 4.27, P = 0.02). The same was true for the (unadjusted) percentage of young women reporting consistent condom use in the past six months at the 12 month follow-up assessment (OR 2.14, 95% CI 1.20 to 3.84, P = 0.01). This trial also reported mean frequency scores of applying condoms on sex partners in the preceding six months, measured at 12 month follow-up (rated 1 = never to 5 = every time on a 5-point scale). Significantly higher scores were reported for the HIV prevention intervention group (MD 0.44, 95% CI 0.19 to 0.77, P = 0.003).

In the trial by Boyer 2005 there was a slightly lower percentage of young women reporting inconsistent use of condoms during the full post-intervention period (mean 14 months from baseline) in the cognitive-behavioural intervention compared to the health promotion comparator, although it was not reported whether this was statistically significant.

Condom use during last sexual intercourse: Three comparison 2 trials reported this outcome, two of which reported statistically significant differences favouring the behavioural intervention.

In the trial by Bryan 1996, a statistically significantly higher percentage of young women at the six month assessment in the education and skills development (condom use) intervention reported using a condom during last sexual intercourse relative to the education and skills development (stress management) control comparison group (P < 0.05). This analysis was limited to women who reported having sexual intercourse during the follow-up period (n = 83 of 198 randomised women). Similarly, DiClemente 2004 reported the percentage of young women with condom use during last vaginal sex at the 12 month follow-up assessment. This was statistically significantly higher for the HIV prevention intervention intervention compared to the general health promotion comparison group (OR 3.32, 95% CI 1.86 to 5.92, P < 0.001). In the trial by Koniak-Griffin 2003 condom use during last sex episode increased from baseline in both the HIV prevention programme and its comparator, the healthy living parenting programme. However, at the 12 month follow-up assessment the percentage reporting condom use during last sex episode was similar between the groups (no

statistical tests reported). These data appear to be limited to those who were sexually active during the trial. It is not clear how many of those randomised abstained from sex.

Protected/unprotected sex acts: Four of the comparison 2 trials reported this outcome, with mixed findings.

Two of the trials reported statistically significant differences between the behavioural intervention and the general health promotion/attention control comparators. Choi 2008 reported the percentage of vaginal or anal intercourse acts protected by a female condom, a male condom and any condom at six month follow-up. The percentage of protected acts was higher amongst those who received the female condom skills training intervention compared to those who received the general health promotion comparator intervention, though the difference was only statistically significant for the 'protected by any condom' outcome (P = 0.028). DiClemente 2004 reported the mean number of unprotected vaginal sex episodes in the past 30 days or six months, both at the 12 month follow-up assessment. The mean number of episodes was statistically significantly lower for the HIV prevention intervention group relative to the general health promotion comparator group for both the preceding 30 days (adjusted MD - 1.06, 95% CI - 1.86 to 0.44, P = 0.002) and the preceding six months (Adjusted MD - 5.51, 95% CI - 11.18 to - 0.34, P = 0.02).

No statistically significant effects were reported by the other two trials. In the trial by Koniak-Griffin 2003, the mean number of unprotected sex episodes in the past three months at the 12 months follow-up assessment was slightly higher for the HIV prevention programme relative to the healthy living parenting comparator programme. The difference was not statistically significant (P = 0.634). Those abstinent over the past three months were assigned a zero score, though the number of abstainers was not reported. In the trial by Morrison-Beedy 2005 the frequency of vaginal sex with a condom in the past three months measured at the three month follow-up assessment increased from baseline in both the HIV risk reduction group and the health promotion comparator group. The increase was greater for the comparison group, although the difference between the groups was not statistically significant (P = 0.50). The frequency of vaginal sex without condom in the past three months measured at the three month follow-up assessment decreased from baseline in both the HIV risk reduction group and the health promotion comparator group, with the lowest frequency reported in the HIV risk reduction group. Again, the difference was not statistically significant (P = 0.38).

Other condom use measures: Four comparison 2 trials reported other measures of condom use, with the results generally favouring the behavioural intervention relative to the general health promotion/attention control comparator.

The trial by Choi 2008 reported the percentage of young women who used the female and the male condom at least once at the six month follow-up assessment. There was a statistically significant difference in favour of the female condom skills training intervention relative to the general health promotion comparator in use of female condoms (P < 0.001). However, use of male condoms at least once was generally similar between the groups and not statistically significant (P = 0.417).

DiClemente 2004 presented the percentage of young women who reported using condoms in the past 30 days and the past six months, at the 12 month follow-up assessment. The percentage was statistically significantly higher in the HIV prevention intervention group relative to the general health promotion group for both the past 30 days (MD 21.09, 95% CI 10.73 to 32.20, P = 0.001) and the past six months (MD 18.33, 95% CI 9.46 to 29.86, P = 0.001).

Jemmott 2005 reported the mean number of days of sex without a condom in past three months at the 12 month follow-up assessment. Those receiving the skills-based HIV/STD risk reduction intervention had a statistically significantly lower mean number of days relative to the health promotion comparison group (P = 0.002). The information-based HIV/STD risk reduction intervention also had a lower mean number of days relative to the health promotion comparison group but this was not statistically significant (P = 0.32).

Koniak-Griffin 2003 presented the proportion of young women who reported engaging in 'risky (i.e. unprotected)' sex in the past three months at the 12 month follow-up assessment. At follow-up there was a similar proportion in the HIV prevention programme and the healthy living parenting comparator programme (no statistical test was reported). These data appear to be limited to those who were sexually active during the trial. It is not clear how many of those randomised abstained from sex.

Sexual partners: Five comparison 2 trials reported this outcome (Table 5 and Table 6), with mixed findings.

Three of the trials reported some statistically significant differences between trial groups.

DiClemente 2004 presented the percentage of young women reporting a new vaginal sex partner in the past 30 days at the 12 month follow-up assessment. The HIV prevention intervention had a lower percentage than the general health promotion comparator group, but the difference was not statistically significant (OR 0.59, 95% CI 0.19 to 1.84, P = 0.36). However, when the results were analysed over the full 0-12 month trial period in a logistic and linear generalised estimating equation (GEE) regression model (designed specifically to control for repeated within subject measurements) the difference was reported to be statistically significant (though no percentages were reported) (OR 0.40, 95% CI 0.19 to 0.82, P = 0.01).

Jemmott 2005 reported the mean number of sexual partners in the past three months at the 12 month follow-up assessment. Both the skills-based HIV/STD risk reduction intervention and the information-based HIV/STD risk reduction intervention had a slightly lower mean number of partners compared to the health promotion comparison group. However, only the difference between the skills-based HIV/STD risk reduction intervention and the health promotion comparison group was statistically significant (P = 0.04). The trial also presented the mean percentage of young women reporting multiple (two or more) partners in the past three months at the 12 month follow-up assessment. Both the skills-based HIV/STD risk reduction intervention and the information-based HIV/STD risk reduction intervention had a lower percentage compared to the health promotion comparison group. Again, however,

only the difference between the skills-based HIV/STD risk reduction intervention and the health promotion comparison group was statistically significant (P = 0.002).

In the trial by Koniak-Griffin 2003 the mean number of sex partners in the past three months at the 12 month follow-up assessment was fractionally lower in the HIV prevention programme than in the healthy living parenting comparator programme. The difference was reported to be statistically significant based on a repeated measures ANCOVA adjusted for baseline behavioural intentions (P = 0.042). Those abstinent over the past three months were assigned a zero score, though the number of abstainers was not reported.

In two of the trials statistical tests were not reported or results were not statistically significant. Boyer 2005 presented the percentage of young women who reported having sexual intercourse with multiple sexual partners (two or more) at post-intervention and also the percentage who reported sexual intercourse with a casual partner (mean 14 months from baseline). A similar percentage of young women reported multiple partners/sexual intercourse with a casual partner in the cognitive-behavioural intervention and the health promotion comparator group. No statistical tests were reported. Morrison-Beedy 2005 reported that the mean frequency of male sexual partners in the past three months was slightly lower for the HIV risk reduction intervention group than the health promotion comparison group, although the difference was not statistically significant (P = 0.46).

Engagement in sexual activity: Two comparison 2 trials reported this outcome (Table 2)

Dancy 2009 reported whether or not young women in the trial reported having sex (vaginal, oral, anal) in the last six months at the six month follow-up assessment, in terms of mean scores (where a score of 1 = yes). The MD (-0.71) favoured the combined Mother/Daughter HIV Risk Reduction intervention (MDRR) and Health Expert Risk Reduction intervention (HERR) interventions relative to the Mother/Daughter Health Promotion intervention (MDHP). The difference was not statistically significant (p value not stated).

In the trial by DiClemente 2004 the mean number of vaginal sex acts in the past six months at the 12 month follow-up assessment was slightly lower in the HIV prevention intervention group than the general health promotion comparator group.

Incidence of STIs: Table 4 shows the effects of the trials on sexually transmitted infections.

Chlamydia: One comparison 2 trial reported on chlamydia. In the trial by DiClemente 2004 the crude laboratory-determined chlamydia incidence per 100 person-months over the 12 month trial period was fractionally higher amongst young women receiving the HIV prevention intervention relative to the general health promotion group. When the results were analysed over the full 0 to 12 month trial period in a logistic and linear generalised estimating equation (GEE) regression model (designed specifically to control for repeated within-subject measurements) the difference between groups was statistically significant, favouring the HIV prevention intervention (OR 0.17, 95% CI 0.03 to 0.92, P = 0.04).

Gonorrhoea: One comparison 2 trial reported on gonorrhoea. In the trial by DiClemente 2004 the crude laboratory-determined gonorrhoea incidence per 100 person-months over the

12 month trial period was slightly higher amongst young women receiving the HIV prevention intervention relative to the general health promotion group. However, the difference between groups was not statistically significant (OR 0.14, 95% CI 0.01 to 3.02, P = 0.21).

Trichomoniasis: One comparison 2 trial reported on trichomoniasis. In the trial by DiClemente 2004 the crude laboratory-determined trichomoniasis incidence per 100 person-months over the 12 month trial period was slightly lower amongst young women receiving the HIV prevention intervention relative to the general health promotion group. However, the difference between groups was not statistically significant (OR 0.37, 95% CI 0.09 to 1.46, P = 0.16).

Composite STI outcomes: Two comparison 2 trials reported composite STI outcomes, with mixed results.

Jemmott 2005 reported the percentage of young women testing positive for an STI (chlamydia, gonorrhoea and/or trichomoniasis) at the 12 month follow-up assessment. At follow-up the percentage was lowest in the skills-based HIV/STD risk reduction intervention, followed by the information-based HIV/STD risk reduction intervention group and then the health promotion comparator group. The difference between the skills-based HIV/STD risk reduction intervention and the health promotion comparator group was statistically significant (P = 0.05), however the difference between the information-based HIV/STD risk reduction intervention group and the health promotion comparator group was not significant (P = 0.44).

Boyer 2005 reported the percentage of the total trial population with a diagnosis of any of three STIs (chlamydia, gonorrhoea and trichomoniasis) at follow-up (mean 14 months from baseline). The percentage was slightly lower for the cognitive-behavioural intervention relative to the health promotion comparator, although no statistical tests were reported. Caution is advised as 486 (23%) of the 2157 randomised women were not screened for STIs at the second post-intervention follow-up because of limited trial resources.

Comparison 3 - Behavioural intervention versus similar intervention with a different provider/medium (n = 3 trials)

Condom use: Table 3 shows the effects of the studies on condom use.

Condom use during last sexual intercourse: One comparison 3 trial reported this outcome. Ferguson 1998 presented the percentage of young women who reported use of effective contraceptives at most recent sexual intercourse at the three month follow-up assessment. Of those young women who responded to this question 100% reported condom use as a method of contraception. The percentage was lower amongst recipients of the culturally specific peer-led education and skills based pregnancy prevention programme relative to the individual-led pregnancy prevention programme. No statistical tests were reported and data are applicable only to the relatively small sub-group of randomised young women who were sexually active at the start of the trial (24% and 40% of the two trial groups, respectively).

Consistency/frequency of condom use for vaginal intercourse: One comparison 3 trial reported this outcome. Downs 2004 compared an interactive video intervention with a content-matched control group (intervention delivered via book) and a topicmatched control group (delivered via brochures) in terms of the frequency of condom use in the past three months (based on a six-point scale) at the six month follow-up assessment (Table 3). Mean data values for the respective groups were not reported although it was stated that there were no differences between the groups and there was no statistically significant difference between the interactive video intervention and the two control groups combined (P = 0.15). Participants who were sexually abstinent were omitted from this analysis (up to 20%, depending on trial group).

Other condom use measures: One comparison 3 trial (Downs 2004) reported the number of condom failures in the past three months. The number of failures was statistically significantly lower in the interactive video intervention group than in the content-matched control group (delivered via book) and topic-matched control groups (delivered via brochures) combined (P = 0.02).

Engagement in sexual activity: Three comparison 3 trials reported this outcome. Differences in effects between the behavioural interventions and similar interventions with a different provider/medium were either not statistically significant or unclear.

Dancy 2009 presented whether or not young women in the trial reported having sex (vaginal, oral, anal) in the last six months at the six month follow-up assessment, in terms of mean scores (where a score of 1 = yes). The MD favoured the combined Mother/Daughter HIV Risk Reduction intervention (MDRR) compared to the Health Expert Risk Reduction (HERR) comparator intervention. However, the difference was not statistically significant (p value not stated).

In the trial by Downs 2004 the percentage of young women self-reporting sexual abstinence during the previous three months was higher in the interactive video intervention compared to the content-matched control group (via book) and topic-matched control groups (via brochures) combined (OR 1.45), although the difference was not statistically significant (P = 0.344).

Ferguson 1998 reported the frequency of sexual intercourse in the past four weeks at the three month follow-up assessment. The percentage reporting no partners was slightly higher for the culturally specific peer-led education and skills based pregnancy prevention programme relative to the individual-led pregnancy prevention comparator programme. No statistical tests were reported and data are only applicable to the relatively small sub-group of randomised young women who were sexually active at the start of the trial (24% and 40% of the two trial groups, respectively).This trial also presented the percentage of young women who had reported never being sexually active at the three month follow-up assessment. The percentage was higher in the culturally specific peer-led education and skills based pregnancy prevention programme relative to the individual-led pregnancy prevention comparator programme. However, no statistical tests were reported and at

baseline a lower percentage of the individual-led pregnancy prevention comparator programme participants were sexually active, which may confound the results.

Incidence of STIs: Table 4 shows the effects of the trials on sexually transmitted infections.

Chlamydia: One comparision 3 trial reported on chlamydia. Downs 2004 presented the percentage of young women with a self-reported diagnosis of chlamydia during the previous three months at the six month follow-up assessment. At follow-up the lowest percentage was for the interactive video intervention group compared to the content-matched control group (delivered via book) and the topic-matched control group (delivered via brochures) combined. The difference was statistically significant (OR 7.75, P = 0.05). This trial also presented the percentage with clinically-determined chlamydia at the six month follow-up assessment. No data are given for the respective trial groups although it is reported that there was no statistically significant difference between the interactive video intervention group and the other two groups combined (OR 2.79, P = 0.56). However, caution is advised as, reported by the authors, the trial was not adequately statistically powered for this outcome measure (only 12% power at alpha = 0.05).

Composite STIs outcomes: One comparison 3 trial reported a composite STI outcome. Downs 2004 presented the percentage of young women with a self-reported diagnosis with any of nine STIs (chlamydia, pubic lice, genital herpes, genital warts, gonorrhoea, hepatitis B, HIV, syphilis or trichomoniasis) during the previous three months at the six month follow-up assessment. The percentage was statistically significantly lower in the interactive video intervention group compared to the content-matched control group (delivered via book) and the topic-matched control group (delivered via brochures) combined (OR 2.79, P = 0.05).

Comparison 4 - Behavioural intervention(s) versus no-intervention (control) (n = 4 trials)

Condom use: Table 3 shows the results of the trials for condom use.

Consistency/frequency of condom use for vaginal intercourse: Two comparison 4 trials reported this outcome, with unclear results.

Smith 1993 presented self-reported condom use at the two month follow-up assessment, expressed in terms of an index reflecting frequency of condom use over the previous two months divided by the frequency of intercourse occasions, multiplied by 100. The index score was slightly higher for the no-intervention control group relative to the condom desensitisation and AIDS education group, although described by the authors as virtually equivalent. There was no statistically significant difference between the groups (P = 0.19). These data are based on a sub-set of 58 young women (from 380 randomised). Notwithstanding attrition it is not clear whether this sub-set, which was smaller than that used for nonbehavioural outcomes, is limited to those who were sexually active during the trial.

Ploem 1997 reported the number of young women reporting consistent condom use at the one month follow-up assessment. The number of consistent condom users was very small across the three trial groups (less than 5).

Protected/unprotected sex acts: Two comparison 4 trials reported this outcome, with mixed findings.

Ploem 1997 reported changes in the percentage of vaginal intercourse occasions protected by a condom in the subset of 36 (of the 112 randomised) coitally active young women taking part in their trial. The women were classified in terms of those who increased protected occasions, those who decreased and those with no change at the one month follow-up assessment. The information, condom eroticisation/normalisation and communication skills combination intervention contained the greatest proportion of young women increasing protected occasions, followed by young women in the no-intervention control group and then those in the information only group in which there was no increase at all ($P < 0.05$). The percentage of 'no changers' was highest in the information only intervention group, followed by the no-intervention control group and then the information, condom eroticisation/normalisation and communication skills combination intervention ($P < 0.05$). The percentage of women decreasing protected occasions was generally low (< 20%) and evenly distributed across the three trial groups.

Jaworski 2001 reported the mean number of vaginal sex acts with and without a condom at two month follow-up (for the previous two months). The mean number of acts with a condom was highest for the 'Intervention-Motivation-Behavioural' skills group, followed by the waiting list control group and then the information-only group. Furthermore, the mean number of acts without a condom was highest for the waiting list control group, followed by the Intervention-Motivation-Behavioural skills group and then the information-only group. However, these differences were reported not to be statistically significant based on log odds (no further detail given). Although not explicitly stated, these data may have excluded the sub-group of up to 20% who became sexually abstinent between baseline and two month follow-up.

Other condom use measures: Bull 2008 presented the percentage of young women who reported ever using a female condom for vaginal or anal sex. Data are presented for each of the six individual neighbourhood sites in the 'POWER for Reproductive Health' social marketing intervention and the no-intervention comparison group (from separate pre- and post-intervention cross-sectional surveys). The findings were mixed with some sites increasing and some decreasing their percentage of condom users, in both trial groups. The overall difference between the two trial groups was not statistically significant ($P = 0.347$). It should be acknowledged that only women who had heard of female condoms were asked to answer questions related to female condoms. At follow-up 1,912 (64%) of the total trial sample (n = 3,003) had heard of the female condom. Furthermore, questions on condom use appear to be limited to those young women ever reporting having had sex (n = 2,005 (67%) of the total follow-up sample of 3,003). The sub-group of young women in each trial group who answered questions on condom use is therefore unclear.

Sexual partners: Jaworski 2001 reported the mean number of sex partners at the two month follow-up assessment (Table 5). There was a reduction in the number of partners from baseline in the intervention-Motivation-Behavioural skills group (IMB) and the information-only comparator group (INFO) but no change in the waiting list control group. The mean number of partners was highest in the waiting list control group at follow-up although no statistical tests were reported. This trial also reported the percentage of young women with a decrease in the number of sexual partners from baseline to two month follow-up. The percentage was highest in the Intervention-Motivation-Behavioural skills group (IMB) and lowest in the waiting list control group with a statistically significant difference between these two groups (P = 0.04).

Engagement in sexual activity: Jaworski 2001 reported the percentage of young women who became sexually abstinent from baseline to two months follow-up (Table 2). The percentage was highest among young women in the Intervention-Motivation-Behavioural skills group, followed by the Information-only comparator group (INFO) and then the waiting list control group, although the difference between groups was not statistically significant (P = 0.10).

Incidence of STIs: No comparison 4 trials reported STIs as an outcome.

DISCUSSION

Summary of main results

The results of this systematic review of the effectiveness of behavioural interventions are mixed. Statistically significant effects for behavioural outcomes were common, though not universal, varying according to different types of outcome. There were few statistically significant effects for biological (STI) outcomes.

Behavioural outcomes—Condom use was the most widely reported behavioural outcome measure and was assessed in a variety of ways. Many of the trials reported statistically significant differences favouring the behavioural intervention, notably on measures such as decreasing the number of episodes of unprotected sex/increasing the number of episodes of protected sex (nine out of 12 trials that measured this) and on a variety of outcomes classified as ‘other’ measures of condom use (e.g. the proportion using condoms over a given period; the mean number of days of sex without a condom, etc) (nine out of 11 trials).

Comparatively fewer significant effects were reported for consistent condom use/increasing the frequency of use (three out of 11 trials) or reported use of condoms during most recent intercourse (three out of nine trials). It could be suggested that consistent condom use, particularly with multiple casual partners, is an important goal in terms of reducing the likelihood of STI transmission. However, it may not be a realistic strategy for young women in established relationships where, for intimacy, couples may prefer to use other methods of contraception. This was noted by Jaworski 2001 in which 53% of participants were in committed relationships at the start of the trial and were not using condoms. The authors commented that initiating condom use in an established relationship can be interpreted as

questioning commitment and interpersonal trust and speculated that this may explain the lack of statistically significant differences between groups in their trial. This underlines the need for evaluators to choose outcome measures that are appropriate to the relationship status of their particular sample.

Young women who received the behavioural intervention reported fewer sexual partners at follow-up (four out of 10 trials), though statistically significant differences were more common in trials comparing behavioural intervention(s) to a general health promotion/ attention control groups (comparison 2) (although more trials in this comparison than other comparisons reported this outcome). Even fewer trials reported changes in sexual activity, such as how many young women engaged in sex or reduced their number of sexual episodes or became sexually abstinent. In all of these trials the differences between groups favoured the behavioural intervention (i.e. more young women reduced their sexual activity), though differences were statistically significant in only one out of the eight trials that measured this (see Agreements and disagreements with other studies or reviews).

Biological outcomes—Fewer trials reported occurrence of STIs as an outcome measure and where this was assessed the effects of the interventions were less favourable than they were for behavioural outcomes. Where individual STIs were reported the only statistically significant effects were for chlamydia (three out of five trials), with none for gonorrhoea or trichomoniasis. None of the trials explicitly reported measuring HPV as a single outcome measure, which would have given a stronger indication of the potential of behavioural interventions to prevent cervical cancer. Ten trials trials reported composite outcomes in which the proportion of young women testing positive for one or more STIs were reported. These trials ranged from those with one or more specified STIs were reported (e.g. chlamydia, gonorrhoea, trichomoniasis), to those in which a positive diagnosis of any STI was recorded. Only three of these trials reported a statistically significant difference between trial groups. A possible explanation for the lack of effects is that the trials were not adequately powered, in terms of sample size, to detect a statistically significant effect on STI outcomes. As mentioned above (Description of studies), only eight of the 23 trials included in this review reported a sample size calculation and in only six of these was the sample size calculation performed for the primary outcome. Only two of these trials featured STIs as their primary outcome measure (Boyer 2005; DiClemente 2009). The majority of trials measuring STI outcomes in this review therefore did so as a secondary measure with no reported sample size calculation. It is likely that these trials were not adequately powered to detect significant effects, particularly as incidence of some STIs may be relatively low. Trials of rare events generally require larger sample sizes in order to be able to show statistically significant effects. This phenomenon was noted by one of the trials included in this review (Downs 2004) which commented that in the analysis of the nine STIs measured, only one had sufficient statistical power to detect a difference (self-reported chlamydia, which is, in general, one of the most common STIs). All other STIs had less than 20% power and therefore they did not report results for them as individual measures, instead combining them as a composite outcome (see below). They also commented that clinically confirmed chlamydia, which was not statistically significant, was underpowered (only 12% power at alpha = 0.05).

Only one trial explicitly included genital warts within a composite STI outcome (Downs 2004) and it reported a statistically significant effect for the behavioural intervention (interactive video) relative to its comparators (content-matched control group and topic-matched control group) at the six month follow-up assessment. However, genital warts were only one of nine STIs included within the composite measure, so out of those reporting an STI it is not possible to delineate how many were HPV/genital wart infections. Furthermore, this trial was judged unclear on four out of five risk of bias domains, casting further uncertainty over its results (see Characteristics of included studies).

Comparators—The differences between trial groups generally favoured the behavioural interventions relative to their comparators. However, there were a handful of occasions when the differences favoured the comparators, such as Jaworski 2001 where the mean number of vaginal sex acts with a condom was lower for the 'Intervention-Motivation-Behavioural' skills group compared to the 'Information-Only' comparator group. Similarly in the trial of Koniak-Griffin 2003 the mean number of unprotected sex episodes in the past three months at the 12 months follow-up assessment was slightly higher for the HIV prevention programme relative to the healthy living parenting comparator programme. In DiClemente 2004 gonorrhoea incidence was slightly higher amongst young women receiving the HIV prevention intervention relative to the general health promotion group. However, in all of these cases the differences were not statistically significant. Therefore, it is unlikely that behavioural interventions are associated with undesirable effects. Due to the diversity of comparators used by the trials included in this review we classified trials into four separate groups based on the type of comparison being made. Many of the trials hypothesised that providing a more enhanced intervention that supplemented information provision on STIs with an element of skills development for safer sex and (in a handful of trials) other activities (e.g. provision of free condoms) would result in more favourable changes in behavioural, biological and other outcomes than standard service provision (comparison 1 trials). The general trend was for the behavioural interventions to be more effective than their more basic/standard practice comparators (notwithstanding the variability discussed above in statistically significant effects across different outcomes). This suggests that the addition of skills development activities to the provision of information enables young women to put their knowledge and skills into practice, thus facilitating behaviours that reduce their likelihood of acquiring STIs (though note we did not extract results for knowledge and skills outcomes in this review).

The results also suggest that, in general, providing a behavioural intervention that supplemented information provision on STIs with an element of skills development for safer sex resulted in more favourable changes in outcomes compared to provision of general health promotion that does not specifically cover sexual health issues (comparison 2 trials) (as above, with caveats about variability in statistically significant effects according to different outcome measures). The results of comparing skills and information behavioural interventions with similar interventions delivered by a different provider/medium (comparison 3 trials) or with nointervention control groups (comparison 4 trials) showed fewer significant differences, though there were fewer such trials making these comparisons and statistical comparisons were not always reported.

It could be expected that the effects of behavioural interventions compared to general health promotion (comparison 2 trials) and to a no-intervention control (comparison 4 trials) would be more pronounced than comparisons between behavioural interventions and their more basic/standard practice comparators (comparison 1 trials). The reason for this is that in the latter category of trials the comparison group are likely to benefit somewhat from the standard information provision on STIs, whereas in the former categories the comparison groups will have not received any STI relevant content and therefore the difference in outcomes between trials groups potentially could be wider. A handful of trials in our review included multiple trial groups permitting such comparisons to be made.

For example, Jaworski 2001 compared an ‘Information-Motivation-Behavioural skills (IMB)’ with motivational enhancement intervention to a more basic version which provided only information and also to a waiting list control group. The proportion of young women with a decrease in sexual partners from baseline to the two month follow-up was highest in the IMB group, followed by the information only group and then the control group (though only the comparison between IMB and the control group was statistically significant). Likewise, the mean number of sexual partners at the follow-up was lowest in the IMB group, followed by the information only group and then the waiting list control group (though no statistical comparisons were reported).

A similar pattern was evident in the trial by Jemmott 2005, in which a safer sex skills and information behavioural intervention was compared against an STI information only intervention and to a group receiving a general health promotion information and skills development intervention. The mean number of sexual partners at the 12 month follow-up was lowest in the safer sex skills and information intervention, followed by the information group and then the general health promotion group (only the comparison between the safer sex skills and information intervention and the general health promotion group was statistically significant). The same pattern was observed at the 12 month follow-up assessment for the percentage of young women reporting multiple sexual partners, the mean number of days of sex without a condom in the past three months and the percentage testing positive for chlamydia, gonorrhoea and/or trichomoniasis (i.e. lowest in the safer sex skills and information intervention and highest in the general health promotion group).

The results of these two trials therefore suggest that the more comprehensive the behavioural intervention, in terms of supplementing information provision with motivation and skills building specific to STIs and sexual health, the greater the benefit.

Duration of effects—The length of follow-up for outcome assessment employed in the trials varied from up to one month post-intervention to around two years. The most common length of follow-up was 6 to 12 months. The length of follow-up could be considered to be relatively short considering that behaviour change requires adequate time to become routine. On the other hand some behaviour change may not necessarily be sustained over time, with rates of condom use and other risk reduction behaviours returning to their baseline levels. This is not uncommon in evaluations of health promotion interventions where, in the absence of booster sessions, changes in health-related behaviour are not always maintained. Longer follow-up assessments would provide a stronger indication about the potential of

behavioural interventions to encourage lasting safer sexual behaviours as young women progress into adulthood and to reduce the likelihood of morbidity and mortality associated with cervical cancer in later years.

Many of the trials included in this review measured outcomes at one or more interim time points, facilitating analysis of the duration of effects over time (interim and final results are presented in Table 3 to Table 2). In the majority of these trials the final follow-up assessment was 12 months, providing some consistency to this analysis. A mixed pattern is evident, with some trials showing an increase in the adoption of safer sexual behaviours/a decrease in STIs between end of the - intervention and final outcome assessment (DiClemente 2009; Jemmott 2005; Shain 1999) and other trials showing an attenuation of effects between an initial post-intervention improvement and the final outcome measurement (Koniak-Griffin 2003). In some trials there was improvement over time in some outcomes, but deterioration over time for others (Choi 2008; Kershaw 2009; Shrier 2001). It is not clear why there was such variability in the duration of effects. Differences between the trials in the characteristics of the young women (e.g. age, sexual experience, relationship status) and the characteristics of the intervention (e.g. duration, contact time, content) are possible explanations. Jemmott 2005 offer an explanation for the delayed effects observed in their trial, suggesting that some people have difficulty introducing safer-sex practices into existing relationships. Shrier 2001 provided booster sessions at one, three and six months following the initial intervention session, in accordance with the theoretical concepts of the Transtheoretical Model, in which individuals move through a number of stages of behaviour change over time. The occurrence of these booster sessions may have facilitated the favourable changes observed in some of the behavioural outcomes over time.

Overall completeness and applicability of evidence

Generalisaibility and replicability—When generalising the results of this systematic review to other settings it is important to consider the heterogeneous characteristics of the behavioural interventions and populations studied.

Intervention characteristics: The behavioural interventions most commonly provided factual information about sexual and reproductive health (including STIs) plus the development of assertiveness and negotiation skills (e.g. to engage in safer practices), unsafe sex refusal skills and correct condom use skills, via discussion, role playing and cognitive rehearsal. A handful of trials supplemented this with provision of resources, such as vouchers redeemable for sexual health screening and treatment services. Behavioural interventions relying only on information provision were in a minority.

There was variability in the duration and intensity (in terms of contact time) of the interventions. Some were brief one-session interventions lasting less than a day, whilst others were spread out over weeks or months (though none longer than a year). Some interventions were intended to be brief so as to be practical to deliver in routine practice, such as the information and skills motivation intervention evaluated by Jaworski 2001 which was provided in a university health and behaviour centre. The results of the trials included in this review may not be generalisable to longer-term sexual health projects and services.

In terms of setting, the majority of the interventions were delivered in health care clinics, notably sexual health/STI and family planning clinics. There were fewer trials in community settings or in schools and colleges. Studies of behavioural interventions to prevent STIs and prevent pregnancy in mixed sex schools appear to be more common (Owen 2010; Shepherd 2010), possibly reflecting the predominance of such schools compared to single sex schools.

It is important to acknowledge that this review is restricted to interventions which are solely aimed at young women and it may not necessarily encompass the full range of interventions that young women may be exposed to. For example, the review does not include trials of mixed sex groups (e.g. school/college or community settings, as above) or interventions including young women and their male partners or young women and family members (e.g. their mothers). It should therefore be acknowledged that there is a wider evidence base for the effectiveness of preventing STIs/cervical cancer in young women. There do not appear to have been any published systematic reviews of such interventions, therefore this may be an appropriate area for future evidence synthesis.

Topic focus: Although the focus of this systematic review is the prevention of HPV and cervical cancer, the included trials were primarily concerned with prevention of HIV and other STIs and also, in some cases, pregnancy prevention. Few trials made explicit reference to HPV or to the long-term consequences of STIs such as cervical cancer or even pelvic inflammatory disease. The interventions in this review encourage safer sexual behaviours such as condom use and partner reduction, which can lower the risk of acquiring STIs and therefore potentially afford some protection against cervical cancer. However, there appears to be a gap in the evidence base for RCTs of behavioural interventions integrating messages about STIs and their longer-term sequale, particularly cervical cancer. Options for cervical cancer prevention include the HPV vaccine for teenage girls and screening programmes for women in their twenties upwards. Nonetheless, primary behavioural interventions for cervical cancer, addressing HPV and other risk factors such as co-infection with chlamydia/herpes simplex virus, smoking and alcohol are warranted (Moscicki 2005).

Age: Although the focus of this systematic review was young women up to the age of 25 years it cannot be assumed that females in this age group are homogenous in terms of their sexual maturity, sexual experience, relationship status and sexual health needs. Some interventions were specifically designed to meet the needs of younger teenagers, whilst others were geared towards women in their mid to late teens or early twenties. For example, in the trial by Ferguson 1998, the community-based intervention aimed to delay onset of sexual activity (though it did encourage condom use for those who were already sexually active) to prevent pregnancy and STIs amongst a population (age range 12 to 16 years, mean age of 13 years) most of whom were sexually inactive. In contrast, in the study by Scholes 2003, the intervention was designed for sexually active non-monogamous women aged between 18 and 24 years (mean age 21) who had attended health care clinics and who were considered to be at risk for STI infection. The intervention, which focused primarily on the promotion of condoms, was tailored to the women's individual needs taking into account the number and types of sexual partner (primary or non-primary), ethnicity, use of alcohol, STI

history and oral contraceptive use. The effects of the behavioural interventions included in this systematic review may not, therefore, be generalisable to all age groups under 25 years.

Pregnancy and motherhood: Three of the trials included in this systematic review specifically included young women who were pregnant and/or teenage mothers (Kershaw 2009, Koniak-Griffin 2003; Maynard 1994). The rationale for these interventions was that pregnancy is a potentially effective time for STI education given that these young women are likely to have put themselves at risk for STIs and will be receiving increased contact with health services. It is also a time of change for young women in which they may re-evaluate their sexual and reproductive health. All three of the trials provided education and skills development for the prevention of STIs, though in slightly differing contexts. The intervention evaluated by Kershaw 2009 integrated HIV/STI information and safer sex skills development within an antenatal care programme, delivered by a midwife/obstetrician in obstetric clinics. The aim was to encourage young women (mean age around 20 years) to reduce sexual risk behaviour during and following pregnancy to prevent STIs and repeat pregnancies. Most of the young women were African-American and it was implied that they were on low incomes. Koniak-Griffin 2003 included pregnant females as well as young mothers in their trial, who were predominantly Latina, from poor backgrounds and attending schools running pregnant minors or young parents' programmes. The emphasis was on encouraging the young women to take more responsibility for their sexual health within the context of motherhood. The focus of the community-based trial of teenage mothers (mean age around 18 years) by Maynard 1994 was broader, covering the prevention of repeat pregnancies, education for prevention of STIs, plus parenting and general life skills. The young women were predominantly African-American or Hispanic and mostly reliant on welfare services. It is important, therefore, to acknowledge that the effects of these trials are not generalisable to young women who are not pregnant/who don't have children. They may be most relevant to pregnant teenagers/teenage mothers from ethnic minorities, living in the US and with low socio-economic status.

Country: The overwhelming majority of trials included in this systematic review were conducted in the US, limiting the applicability of the evidence to other countries. This is not surprising given the strong tradition of experimental evaluation in health and the social sciences in the US (Oakley 1998; Oakley 2000) and the fact that other systematic reviews of sexual health promotion or health promotion in general have also noted a strong preponderance of US studies (Johnson 2003; Kavanagh 2009; Rees 2006; Shepherd 2006; Shepherd 2010). The effects of the interventions in this systematic review may not necessarily be generalisable to other countries, either in the developed or developing world. The effects may not even necessarily be generalisable to all locations/populations within the US. For example, some studies evaluated interventions that were culturally specific to African-Americans or Latinas residing in inner-city locations, classified as being socially and economically disadvantaged. Replications of these interventions in other locations should include pilot research to assess socio-cultural and socio-economic applicability (Bell 2007).

Exemplar trials—As reported earlier (see Risk of bias in included studies) there were three trials included in this review that were considered to be at least risk of bias (DiClemente 2004; DiClemente 2009; Kershaw 2009). Greater confidence can be placed in their results as they are less likely to be biased due to confounding factors. The trials by DiClemente 2004 and DiClemente 2009 in particular demonstrated a number of favourable effects for behavioural outcomes and certain biological outcomes (chlamydia) up to 12 months. They can be considered exemplar trials that policy makers and practitioners may chose to adapt and replicate in their own localities. The key features common to both trials, which should be taken into account in any replications, included: being implemented in the United States, targeting sexually active young African-American women (between approximately 14 and 21 years old) of low socio-economic status, who reported sexual risk behaviour and were attending sexual health clinics/family medicine clinic in urban areas. African American women health educators delivered the interventions in both trials (and assisted by peer educators in DiClemente 2004). The interventions comprised consecutive weekly small group sessions (e.g. eight to 12 participants) lasting four hours (on four occasions in DiClemente 2004 and in two in DiClemente 2009). In the DiClemente 2009 trial young women also received four 15 minute follow-up phone calls spread over a nine month period.

Cultural relevance—The interventions were designed to be culturally relevant to African-American young women. The interventions also emphasised ethnic pride and addressed hygenic practices commonly performed by this group such as vaginal douching (which is associated with increased risk for STIs, PID and cervical cancer) (DiClemente 2009). Both interventions provided information about the transmission and prevention of STIs and facilitated sexual communication and negotiation skills development through interactive methods such as role plays. DiClemente 2009 also attempted to address structural factors (e.g. lack of access to health services) by providing the women with $20 vouchers to give to their male partners to redeem at sexual health clinics. This component may not necessarily be relevant to all health systems, particularly those which are free at the point of care (e.g. The UK National Health Service). However, facilitating the greater uptake of sexual health services is a relevant goal for most health care systems, particularly given the greater emphasis given to testing for undiagnosed STIs in recent times.

Behavioural aims—In terms of behavioural aims DiClemente 2004 promoted a variety of risk reduction messages including the importance of effective communication with partners to ensure safer sexual behaviours in general, plus the importance of consistent condom use (see Table 7). The intervention also encouraged reduction of sexual partners, abstinence from sex and prevention of pregnancy. In contrast, DiClemente 2009 focused mainly on the effective use of condoms and persuasive communication from young women to their male partners to take more responsibility for condom use. Uptake of STI screening and treatment services was also a distinctive feature. There did not appear to be any encouragement for sexual abstinence.

Temporal relevance—The intervention evaluated by DiClemente 2004 was carried out in the mid to late 1990s, whilst the intervention by DiClemente 2009 is more recent (conducted

between 2002 and 2004). However, both interventions, particularly DiClemente 2004, may not necessarily be reflective of current practice given the time that has elapsed since they were evaluated. Neither of the trials provided an indication of the costs of mounting the interventions, other than nominal incentives provided (e.g. $20 vouchers to give to their male partners to redeem at clinics for sexual health services DiClemente 2009) or reimbursements ($25 for travel and child care to attend intervention sessions and complete assessments DiClemente 2009).

In summary, the results of the exemplar trials by DiClemente 2004 and DiClemente 2009 are mainly applicable to young African-American women engaging in STI risk behaviour, who were attending sexual health clinics. The interventions featured information on STIs, skills development for effective partner communication and negotiation of consistent condom use, delivered by African-American peer and other educators in a small group format over a two to four week period, with follow-up phone calls over a nine month period. The interventions were designed to be culturally and gender relevant.

Quality of the evidence

A total of 23 studies were included in this systematic review and all were RCTs. The quality of the evidence appears to be variable and for some outcomes there is inconsistency in the results given. As discussed, sample size calculations were reported in only a minority of the trials, meaning that trials may not have been adequately powered to show a statistically significant effect. In many cases the risk of bias of the included trials could only be judged to be unclear due to ambiguities and omissions in the reporting of the methodological details in the trial publications (see Risk of bias in included studies). For example, it was common for trials not to report the level of attrition for each randomised trial group and the reasons for such losses. Procedures for handling missing data such as intention to treat analyses were not always reported or reported ambiguously, preventing us from judging whether they were adequate. It is unfortunate that significant limitations in the reporting of methodological details remain, despite initiative such as the CONSORT (consolidated standards of reporting trials) statement (Moher 1998; Moher 2001).

In terms of specific risk of bias domains, the method of random sequence generation was judged to be adequate in only just under half of the trials. In the remaining trials the method was either not reported at all or not fully reported. Moreover, the vast majority of trials failed to give any information on whether and how the random allocation process was concealed from personnel involved in the conduct of the trial. Given the potential for selection bias arising from inadequate randomisation and allocation concealment this should be recognised as a major uncertainty in this evidence base (Kjaergard 2001; Schulz 1995).

A recent meta-epidemiological study found that average bias is stronger in trials with inadequate or unclear allocation concealment that measure subjective outcomes than those that measure objective outcomes (Wood 2008). In such trials the effect sizes tend to be exaggerated. The study also found that average bias is stronger in trials with inadequate or unclear blinding that measure subjective outcomes compared to those with objective outcomes (Wood 2008). This remained the case when allocation concealment was judged to be adequate. As discussed earlier (see Assessment of risk of bias in included studies) it is

usually not feasible to blind participants or intervention providers in health promotion evaluations to which study group they have been allocated. However, it is more feasible to conceal study group assignment to some outcome assessors. Only just over a quarter of the trials in our review reported that outcome assessors (e.g. interviewers or other data collectors) were unaware of the identity of the intervention groups. The preponderance of self-reported (subjective) outcome measures used in the trials included in this review, plus the lack of reporting of outcome assessor blinding and the fact that in a large number of trials it was unclear whether allocation to trial groups had been concealed, adds further uncertainty to the effects observed. A conservative assumption is that the effects on behavioural and biological outcomes may have been over-estimated.

Some of the trials in this review attempted to minimise biases associated with self-reported outcomes. Disclosure of sensitive personal information such as sexual behaviour may be subject to social desirability bias, whereby individuals may tend to over-report behaviours they perceive to be socially acceptable (e.g. that they have had fewer numbers of sexual partners). Methods used by studies to address such bias included using coded rather than named data records (e.g. DiClemente 2004; Jaworski 2001), a computer administered self interview (suggested to increase privacy, recall and limit social desirability bias) (Roye 2007); and use of a published social-desirability scoring system extensively used with adolescents, in which the scores were unrelated to self-reported sexual behavior in the analysis (Jemmott 2005). The potential for recall bias was also addressed by DiClemente 2004 who asked participants to report their behaviours over relatively brief time intervals, giving them calendars specifying the reporting intervals.

Potential biases in the review process

The strenghts of this review include: a comprehensive search of bibliographic electronic bibliographic databases; screening of titles and abstracts independently by more than one person to ensure the application of inclusion criteria was reliable; and systematic and detailed trial data extraction to enable the generalisability and replicability of the included interventions to be judged. In terms of study design we restricted inclusion to RCTs as these are generally accepted as providing evidence of effectiveness that is subject to the least risk of bias.

This review is subject to certain limitations however. First, we only included studies published in the English language, raising the possibility of publication bias. However, all of the non-English language references screened on title and abstract (all of the abstracts were in English) did not meet the review’s criteria.

A second limitation is that this review did not report non-behavioural or biological outcomes such as changes in knowledge, self-efficacy, attitudes and intentions. These are considered as mediators of health-related behaviour and were reported by many of the included trials. Although changes in health-related behaviour and biological outcomes (such as infection rates) are generally considered to be more indicative of the potential of an intervention to benefit health, positive changes in mediating outcomes are nonetheless meaningful to many stakeholders, including health promotion practitioners.

Finally, we decided it would not be appropriate to conduct a metaanalysis of the included trials, due to wide variability in the types of intervention and outcome measure. Whilst a meta-analysis has advantages in terms of providing a pooled quantitative effect estimate and greater precision to detect a statistically significant effect, it may not be meaningful in reviews such as this where heterogeneity is present. Consequently the synthesis is soley narrative, with effects generally presented for each trial in terms of whether or not there were statistically significant differences between randomised groups. However, it can be misleading to summarise effects in terms of how many trials reported statistically significant differences. As discussed, some trials may not be sufficiently powered to detect a statistically significant effect and some do not report significance tests at all. In such trials the statistical significance of the results are uncertain and where this was the case we have advised caution to the reader in the results section of this review.

Agreements and disagreements with other studies or reviews

To our knowledge there are no other similar published systematic reviews assessing the effectiveness of behavioural interventions targeted specifically at young women to prevent HPV/cervical cancer. However, we did identify a systematic review from our literature searches assessing the effectiveness of HIV prevention interventions in adolescent girls (Morrison-Beedy 2004). That systematic review was restricted to RCT study designs, females aged 19 years and under and sexual behaviour/biological outcomes. Six RCTs were included, of which four were also included in our systematic review. The authors concluded that most studies have been effective in terms of encouraging sexual risk reduction behaviours, to varying degrees. Clinically relevant components of effective interventions included the combination of information provision, behavioural skills training and motivation enhancement for behaviour change. The use of theory to guide intervention development was also noted to be crucial.

As discussed above (see Overall completeness and applicability of evidence), systematic reviews of similar behavioural interventions in mixed sex groups of young people have been published. All of these reviews have been conducted within the context of preventing HIV/STIs and pregnancy, rather than cervical cancer. The results of these reviews varied but generally show that the interventions can encourage safer sexual behaviours amongst young people.

Our own recent HTA systematic review of school-based education plus skills development behavioural interventions had mixed findings (Shepherd 2010). Fifteen RCTs were included, the majority of which were conducted in the USA and of these 12 were judged to be methodologically sound enough to support conclusions and recommendations. Statistically significant effects were common for outcomes such as increased knowledge and increased self-efficacy, but were scarce for sexual behavioural outcomes. With the exception of one study of an all male population, all of the trials included in that review comprised males and females. Some trials reported outcomes separately by gender which, for the purposes of the current systematic review, provides an indication of the impact of the interventions on young women. For example, the RIPPLE trial of peer-led sex education conducted in English schools (Stephenson 2004) found no statistically significant difference between the

peer-led intervention and control group females in the estimated cumulative proportion reporting unprotected first heterosexual intercourse by age 16 (the same was reported for young males). There were also no statistically significant differences between young women receiving the intervention and those receiving the control in the proportion using a condom at first sex or at last sex at the 18 month follow-up. However, young women in the peer-led group were statistically significantly less likely to report having had sex by age 16 years than were those in the control group (no difference was noted for young males). The RCT of school-based sex education conducted in Scotland (the SHARE trial) (Wight 2002) reported no statistically significant differences between intervention and control on any behavioural outcomes, for young women or young men. These results of these two trials, whilst illustrative, are not necessarily comparable to the results of the trials in this systematic review as the interventions were designed for mixed sex groups and therefore may differ in content and approach to interventions designed exclusively for young women.

A Cochrane review of ‘abstinence-plus’ interventions (i.e. promotion of abstinence from sexual activity, but also of condom use and other safer sex practices) included 39 randomised or quasirandomised trials (Underhill 2008).The mean age of the participants varied between 11 to 19 years and the studies were based in the USA, Canada or the Bahamas. In common with our current systematic review, a meta-analysis was not performed due to the heterogeneous nature of the interventions and lack of appropriate data. Of the 39 trials, 24 reported a significantly protective intervention effect on any sexual risk behaviour or biological outcomes. The number of trials reporting statistically significant results in favour of the intervention varied according to different behavioural outcomes: self-reported frequency of unprotected vaginal sex (6 out of 12 trials); incidence and frequency of all sex (5 out of 21 trials); number of partners (4 out of 13 trials); condom use (14 out of 26 trials); and sexual initiation (4 out of 19 trials). Statistically significant effects on knowledge in favour of the intervention were reported in many studies. It was concluded that many abstinenceplus programmes reduce short and long-term HIV risk behaviour. The same authors also conducted a systematic review of ‘abstinence-only’ interventions in high income countries and came to less optimistic conclusions (Underhill 2007). Of the 13 randomised or quasi-randomised trials included, there was no consistent effect on unprotected vaginal intercourse, frequency of vaginal sex, number of partners, sexual initiation or condom use. In our current systematic review there were few trials which aimed to promote abstinence/reduce numbers of partners and in all of these studies this was never the sole aim (Table 7). In some of these studies only a low proportion of young women were sexually active at the start of the study, whilst in others all of them were. Our results and those of Underhill 2007, call into question the efficacy of such an approach. In our review whilst there were some statistically significant effects in terms of reducing the number of sexual partners, there were no statistically significant effects for abstinence outcomes.

AUTHORS’ CONCLUSIONS

Implications for practice

The results of this systematic review show that behavioural interventions which aim to promote sexual behaviours protective of STI transmission can encourage condom use for

sexual intercourse. However, significant intervention effects were not universal and varied according to different types of behavioural outcome. There was less impact in terms of encouraging consistent condom use, increasing the frequency of use or use of condoms at most recent intercourse. There was some evidence that behavioural interventions can encourage reductions in the number of sexual partners though this outcome was measured by fewer trials and effects were not consistent across trials. Participation in sexual activity, such as how many young women reduced their number of sexual episodesor were sexually abstinent were measured in only a minority of trials and effects were either not statistically significant or statistical comparisons were not reported. There were few statistically significant effects for biological (STI) outcomes, though only around half of the included trials measured such outcomes. HPV was not included in measures of STI and none of the interventions explicitly focused on the long term of sequelae of STI infection, including cervical cancer.

Behavioural interventions addressing STIs, particularly HPV, should be provided (and evaluated - see Implications for research), where feasible, as one of the key strategies for the prevention of cervical cancer. The exemplar evaluations in our systematic review that were subject to the least risk of bias demonstrated favourable effects for behavioural outcomes and chlamydia up to 12 months. These interventions were designed to be socially and culturally relevant (to African-American young women of low socio-economic status, who reported sexual risk behaviour) and provided information about the transmission and prevention of STIs, as well as facilitating sexual communication and negotiation skills development. They promoted a variety of risk reduction messages including the importance of effective communication with partners to ensure safer sexual behaviours in general, plus the importance of consistent condom use.

Practitioners considering replicating these exemplar interventions should consider applicability to their localities and adapt them as necessary to ensure social, demographic and cultural relevance. Any adaptations should be subjected to monitoring and evaluation to assess relevance and impact.

Implications for research

Future evaluations of behavioural interventions to prevent STIs should not just focus on the short term implications of infection, but also the longer-term sequelae. A greater focus on HPV and its link to cervical cancer should be given and the impact of this evaluated particularly in terms of raising awareness of cervical cancer amongst young women. Such interventions could also be mounted in conjunction with HPV vaccination programmes to assess the impact of a two-pronged approach to cervical cancer prevention: vaccination plus encouragement for safer sexual behaviour as and when girls become sexually active (this is particularly important given that the vaccine only protects against around 70% of the oncogenic HPV sub-types). Many of the interventions included in this systematic review were relatively brief in terms of duration, with fewer examples of longer-term initiatives (e.g. beyond six months). It would be useful to assess the impact of longer interventions sustained beyond a year with booster sessions, to help young women to continue to protect themselves as they mature and become sexually active. There was an absence of school-

based studies in this review, however the HPV vaccination programme which, in the UK, takes place in secondary schools may offer an opportunity for behavioural interventions to be delivered to girls. Furthermore, given the predominance of US studies in this systematic review evaluations conducted in other countries would be particularly useful.

Outcome measures should be chosen that are appropriate to the age, development and relationship status of young women. For example, condom use may not always be the most appropriate measure of protection against STIs for all young women. Biological outcomes (including HPV) and longer term health outcomes should be measured. Follow-up assessment should be of sufficient length to allow for protective behaviours to be adopted and become routine as girls develop into young women. Follow-up should also ideally be long enough to assess impact on progression to CIN and cervical cancer.

Evaluations should use a multi-centre RCT design where possible and include process evaluation to assess factors such as the implementation of the intervention (to facilitate replication if successful) and the acceptability and appropriateness of the intervention to young women. Studies should include an integrated cost-effectiveness analysis (or at the very least a cost analysis) to provide decision makers with an estimate of the likely cost of mounting effective interventions and benefits such as improved health-related quality of life as a result of avoiding infection.

All evaluation publications should conform to CONSORT guidelines on reporting, to ensure methods and results are transparent to all. This will enable future evidence syntheses to fully assess risk of bias and methodological quality, thus facilitating evidence-based recommendations for policy and practice. Where possible, studies should be designed and reported to allow the differential impact to be assessed according to age, race/ethnicity and socioeconomic status. This is particularly important given the policy focus on reducing health inequalities in many countries.

In terms of evidence synthesis there appears to be a knowledge gap for interventions that young women may receive with their male partners or family members. These interventions were beyond the scope of this review but primary studies of this kind were identified in our literature search.

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Appendix 1. CENTRAL search strategy

(CENTRAL Issue 4 2009)

#1	MeSH descriptor Health Promotion explode all trees
#2	MeSH descriptor Health Education explode all trees
#3	MeSH descriptor Primary Prevention explode all trees
#4	health* and (promotion* or campaign* or program* or initiative* or information or intervention*)
#5	prevent* and program*
#6	(behaviour* or behavior*) and intervention*
#7	educat*
#8	(#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7)
#9	MeSH descriptor Sexual Behavior explode all trees
#10	sex* and (safe or safer or unsafe or risk or high-risk or unprotected or abstinence or behaviour* or behavior* or activit* or partner*)
#11	MeSH descriptor Contraception Behavior explode all trees
#12	MeSH descriptor Condoms explode all trees
#13	condom* near/3 (usage or use* or using)
#14	MeSH descriptor Sexually Transmitted Diseases explode all trees with qualifiers: EP,PC
#15	(STI or STIs or STD or STDs) and (incidence or prevalen* or prevent* or control* or risk* or reduc*)
#16	(sexually transmitted disease* or sexually transmitted infection*) and (incidence or prevalen* or prevent* or control* or risk* or reduc*)
#17	MeSH descriptor HIV Infections explode all trees with qualifiers: EP,PC
#18	MeSH descriptor Acquired Immunodeficiency Syndrome explode all trees with qualifiers: EP,PC
#19	(HIV or AIDS or acquired immunodeficiency syndrome) and (incidence or prevalen* or prevent* or control* or risk* or reduc*)
#20	MeSH descriptor Herpes Genitalis explode all trees with qualifiers: EP,PC

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#21 MeSH descriptor Condylomata Acuminata explode all trees with qualifiers: EP,PC

#22 (genital* or venereal) and wart* and (incidence or prevalen* or prevent* or control* or risk* or reduc*)

#23 (HPV or human papilloma*) and (incidence or prevalen* or prevent* or control* or risk* or reduc*)

#24 MeSH descriptor Papillomavirus Infections explode all trees with qualifiers: EP,PC

#25 MeSH descriptor Uterine Cervical Neoplasms explode all trees with qualifiers: EP,PC

#26 cervi* and (cancer* or neoplas* or malignan* or tumor* or tumour* or carcinoma*) and (incidence or prevalen* or prevent* or control* or risk* or reduc*)

#27 (#9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26)

#28 MeSH descriptor Adolescent explode all trees

#29 adolescen* or teenage* or youth*

#30 young* near/3 (women or woman or female*)

#31 girls

#32 (#28 OR #29 OR #30 OR #31)

#33 (#8 AND #27 AND #32)

Appendix 2. MEDLINE search strategy (Ovid)

(MEDLINE Ovid 2001 to November week 3 2009)

1. exp Health Promotion/
2. exp Health Education/
3. exp Primary Prevention/
4. (health* and (promotion* or campaign* or program* or initiative* or information or intervention*)).mp.
5. (prevent* and program*).mp.
6. ((behaviour* or behavior*) and intervention*).mp.
7. educat*.mp.
8. or/1-7
9. exp Sexual Behavior/

10. (sex* and (safe or safer or unsafe or risk or high-risk or unprotected or abstinence or behaviour* or behavior* or activit* or partner*)).mp.
11. Contraception Behavior/
12. exp Condoms/
13. (condom* adj3 (usage or use* or using)).mp.
14. exp Sexually Transmitted Diseases/pc, ep
15. ((STI or STIs or STD or STDs) and (incidence or prevalen* or prevent* or control* or risk* or reduc*)).mp.
16. ((sexually transmitted disease* or sexually transmitted infection*) and (incidence or prevalen* or prevent* or control* or risk* or reduc*)).mp.
17. exp HIV Infections/ep, pc
18. exp Acquired Immunodeficiency Syndrome/ep, pc
19. ((HIV or AIDS or acquired immunodeficiency syndrome) and (incidence or prevalen* or prevent* or control* or risk* or reduc*)).mp.
20. Herpes Genitalis/pc, ep
21. Condylomata Acuminata/pc, ep
22. ((genital* or venereal) and wart* and (incidence or prevalen* or prevent* or control* or risk* or reduc*)).mp.
23. ((HPV or human papilloma*) and (incidence or prevalen* or prevent* or control* or risk* or reduc*)).mp.
24. Papillomavirus Infections/pc, ep
25. exp Uterine Cervical Neoplasms/pc, ep
26. (cervi* and (cancer* or neoplas* or malignan* or tumor* or tumour* or carcinoma*) and (incidence or prevalen* or prevent* or control* or risk* or reduc*)).mp.
27. or/9-26
28. Adolescent/
29. (adolescen* or teenage* or youth*).mp.
30. (young* adj3 (women or woman or female*)).mp.
31. girls.mp.
32. or/28-31
33. 8 and 27 and 32
34. randomized controlled trial.pt.
35. controlled clinical trial.pt.

36. randomized.ab.
37. placebo.ab.
38. clinical trials as topic.sh.
39. randomly.ab.
40. trial.ti.
41. or/34-40
42. 33 and 41

key:

mP = title, original title, abstract, name of substance word, subject heading word, unique identifier

ab=abstract

pt=publication type

sh=subject heading

Appendix 3. EMBASE search strategy (Ovid)

(EMBASE Ovid 2001 to 2009 week 47)

1. exp health education/
2. exp primary prevention/
3. (health* and (promotion* or campaign* or program* or initiative* or information or intervention*)).mp.
4. (prevent* and program*).mp.
5. ((behaviour* or behavior*) and intervention*).mp.
6. educat*.mp.
7. or/1-6
8. exp sexual behavior/
9. (sex* and (safe or safer or unsafe or risk or high-risk or unprotected or abstinence or behaviour* or behavior* or activit* or partner*)).mp.
10. exp condom/
11. (condom* adj3 (usage or use* or using)).mp.
12. exp sexually transmitted disease/ep, pc [Epidemiology, Prevention]
13. ((STI or STIs or STD or STDs) and (incidence or prevalen* or prevent* or control* or risk* or reduc*)).mp.
14. exp Human immunodeficiency virus infection/ep, pc [Epidemiology, Prevention]

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15. exp acquired immune deficiency syndrome/ep, pc [Epidemiology, Prevention]
16. ((HIV or AIDS or acquired immunodeficiency syndrome) and (incidence or prevalen* or prevent* or control* or risk* or reduc*)).mp.
17. ((genital* or venereal) and wart* and (incidence or prevalen* or prevent* or control* or risk* or reduc*)).mp.
18. ((HPV or human papilloma*) and (incidence or prevalen* or prevent* or control* or risk* or reduc*)).mp.
19. exp papilloma virus/
20. exp uterine cervix tumor/ep, pc [Epidemiology, Prevention]
21. (cervi* and (cancer* or neoplas* or malignan* or tumor* or tumour* or carcinoma*) and (incidence or prevalen* or prevent* or control* or risk* or reduc*)).mp.
22. or/8-21
23. adolescent/
24. (adolescen* or teenage* or youth*).mp.
25. (young* adj3 (women or woman or female*)).mp.
26. girls.mp.
27. or/23-26
28. 7 and 22 and 27
29. crossover procedure/
30. double blind procedure/
31. randomized controlled trial/
32. single blind procedure/
33. random*.mp.
34. factorial*.mp.
35. (crossover* or cross over* or cross-over*).mp.
36. placebo*.mp.
37. (doubl* adj blind*).mp.
38. (singl* adj blind*).mp.
39. assign*.mp.
40. allocat*.mp.
41. volunteer*.mp.
42. or/29-41

43. 28 and 42

key:

mP = title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name

Appendix 4. CINAHL search strategy (EBSCO)

(12/2001 to 1/2010)

S33 S32 AND S31 AND S30

S32 S24 or S25 or S26 or S27 or S28 or S29 or S31

S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8 or S9 or S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17 or S18 or S19 or S20 or S21 or S22 or S23

S30 TX “RCT*” OR “randomi#ed controlled trial*” OR “controlled trial*” OR “controlled stud*” OR “experimental stud*” OR “clinical trial* OR ”prospective stud*”

S29 TX primary W5 prevention

S28 MH “Adolescent Health Services”

S27 MH “Condoms Education”

S26 TX behavior* N10 intervention*

S25 TX health* AND (promotion* OR campaign* OR program* OR programme* OR initiative* OR information OR intervention* OR education)

S24 TX prevent* AND (program* OR programme*)

S23 MH “Safe Sex”

S22 TX (sex* OR coit* OR reproduct*) AND (safe* OR protect* OR unsafe OR unprotected OR responsible OR risk* OR “high risk” OR abstinen* OR behavio#r* OR activit* OR practi* OR partner* OR promiscu* OR celiba*)

S21 TX “contracept* behavio#r*”

S20 MH “Risk Taking Behavior Prevention and Control”

S19 TX “sex* behavio#r*”

S18 MH “Contraception In Adolescence”

S17 TX (condom* OR contracept* OR intrauterine OR “IUD”) AND (usage OR use* OR using)

S16 MH “Condoms Utilization”

S15 TX condom*

S14 MH “Sexually Transmitted Diseases Prevention and Control”

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S13 TX “sexually transmitted infect*” OR “STI” OR “STIs”

S12 TX “sexually transmitted disease*” OR “STD” OR “STDs”

S11 TX (“STD” OR “sexually transmitted disease*” OR “STI” OR “STIs” OR “sexually transmitted infect*”) AND (incidence OR prevalen* OR prevent* OR control* OR risk* OR reduc*)

S10 MH “HIV Infections - Prevention and Control”

S9 TX (“HIV” OR “human immunodeficiency virus”) AND infection*

S8 TX (“HIV” OR “human immunodeficiency virus” OR “AIDS” OR “acquired immunodeficiency syndrome”) AND (incidence OR prevalen* OR prevent* OR control* OR risk* OR reduc*)

S7 TX (“herpes genitalis” OR “genital herpes” or “herpes#virus” OR “HSV” OR chlamydia OR syphilis OR gonorrh#ea OR “Neisseria gonorrh#eae” OR chancroid OR “Haemophilus ducreyi”)

S6 TX (genital* OR venereal OR condylom* OR anal OR anogenital*) AND wart* AND (incidence OR prevalen* OR prevent* OR control* OR risk* OR reduc*)

S5 TX “condylomata acuminata”

S4 TX (“HPV” OR “human papilloma*”) AND (incidence OR prevalen* OR prevent* OR control* OR risk* OR reduc*)

S3 TX papilloma#virus AND infect*

S2 TX (uterine cervi*) AND (neoplas* OR dysplas*)

S1 TX (cervi* AND (cancer* OR neoplas* OR malignan* OR tumo#r* OR carcinoma*)) AND (incidence OR prevalen* OR prevent* or control* or risk* or reduc*)

Appendix 5. Psychinfo search strategy (EBSCO)

(12/2001 - to 1/2010)

S34 S31 AND S32 AND S33

S33 S23 or S24 or S25 or S26 or S27 or S28 or S29 or S30

S32 S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8 or S9 or S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17 or S18 or S19 or S20 or S21 or S22

S31 TX “RCT*” OR “randomi#ed controlled trial*” OR “controlled trial*” OR “controlled clinical trial*” OR “controlled stud*” OR “Empirical Study” OR “Treatment Outcome/Clinical Trial”

S30 TX primary W5 prevention

S29 DE Social Skills Training

S28 TX educat*

S27 TX behavio#r* N10 intervention*

S26 TX health* N10 educat*

S25 DE Health Promotion OR Health Education

S24 TX health* AND (promotion* OR campaign* OR program* OR programme* OR initiative* OR information OR intervention*)

S23 TX prevent* AND (program* OR programme*)

S22 TX (sex* OR coit* OR reproduct*) AND (safe* OR protect* OR unsafe OR unprotected OR responsible OR risk* OR “high risk” OR abstinen* OR behavio#r* OR activit* OR practi* OR partner* OR promiscu* OR celiba*)

S21 TX “contracept* behavio#r*”

S20 DE Psychosexual Behavior OR Behavior Change OR Risk Taking OR Sexual Risk Taking

S19 TX “sex* behavio#r*”

S18 TX (condom* OR contracept* OR intrauterine OR “IUD”) AND (usage OR use* OR using)

S17 TX contracept* AND (usage OR use* OR using)

S16 DE Condoms

S15 TX condom*

S14 DE Sexually Transmitted Diseases

S13 TX “sexually transmitted infect*” OR “STI” OR “STIs”

S12 TX “sexually transmitted disease*” OR “STD” OR “STDs”

S11 TX (“STD” OR “sexually transmitted disease*” OR “STI” OR “STIs” OR “sexually transmitted infect*”) AND (incidence OR prevalen* OR prevent* OR control* OR risk* OR reduc*)

S10 DE AIDS Prevention

S9 TX (“HIV” OR “human immunodeficiency virus”) AND infection*

S8 TX (“HIV” OR “human immunodeficiency virus” OR “AIDS” OR “acquired immunodeficiency syndrome”) AND (incidence OR prevalen* OR prevent* OR control* OR risk* OR reduc*)

S7 TX (“herpes genitalis” OR “genital herpes” or “herpes#virus” OR “HSV” OR chlamydia OR syphilis OR gonorrh#ea OR “Neisseria gonorrh#eae” OR chancroid OR “Haemophilus ducreyi”)

S6 TX (genital* OR venereal OR condylom* OR anal OR anogenital*) AND wart* AND (incidence OR prevalen* OR prevent* OR control* OR risk* OR reduc*)

S5 TX “condylomata acuminata”

S4 TX (“HPV” OR “human papilloma*”) AND (incidence OR prevalen* OR prevent* OR control* OR risk* OR reduc*)

S3 TX papilloma#virus AND infect*

S2 TX papilloma#virus AND infect* S2 TX (uterine cervi*) AND (neoplas* OR dysplas*)

S1 TX (cervi* AND (cancer* OR neoplas* OR malignan* OR tumo#r* OR carcinoma*)) AND (incidence OR prevalen* OR prevent* or control* or risk* or reduc*)

Appendix 6. ERIC search strategy (CSA)

(12/2001 to 12/2009)

40 11 and 21 and 37

37 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36

36 (AB=(control* OR experimental) within 3 (trial* OR study OR studies OR group))

35 TI=(effectiveness OR trial)

34 (TI=(control* OR experimental) within 3 (trial* OR study OR studies OR group))

33 (KW=(control* OR experimental) within 3 (trial* OR study OR studies OR group))

32 (KW=(random*) within 3 (trial* OR study OR allocat*))

31 (TI=(random*) within 3 (trial* OR study OR allocat*))

30 (AB=(random*) within 3 (trial* OR study OR allocat*))

29 (TI=(compar*) within 3 (study OR studies OR analys* OR evaluat* OR measur*))

28 (AB=(compar*) within 3 (study OR studies OR analys* OR evaluat* OR measur*))

27 (KW=(compar*) within 3 (study OR studies OR analys* OR evaluat* OR measur*))

26 DE=(“comparative analysis” or “comparative testing”)

25 DE=(“measurement” or “medical evaluation” or “program evaluation”)

24 DE=“evaluation”

23 DE=“program effectiveness”

22 21 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20

21	12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20
20	DE=(“behavior change”)
19	DE=(“behavior modification”)
18	(AB=(educ* OR prevent* OR reduc* OR promot* OR increas* OR decreas* OR facilitat* OR barrier* OR encourag* OR educat*) within 3 (sex* OR HIV OR STI OR STIs OR STD* OR sexually transmit*))
17	(KW=(educ* or prevent* OR reduc* OR promot* OR increas* OR decreas* OR facilitat* OR barrier* OR encourag* OR educat*) within 3 (sex* OR HIV OR STI OR STIs OR STD* OR sexually transmit*))
16	(TI=(educ* or prevent* OR reduc* OR promot* OR increas* OR decreas* OR facilitat* OR barrier* OR encourag* OR educat*) within 3 (sex* OR HIV OR STI OR STIs OR STD* OR sexually transmit*))
15	TI=(behavio* within 2 intervent*)
14	DE=(“health promotion” or “comprehensive school health education” or “condoms” or “health programs” or “prevention” or “preventive medicine” or “safe sex”)
13	DE=((public health) or (preventive medicine))
12	DE=“sex education”
11	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10
10	TI=(HIV OR Acquired Immun*)
9	AB=(HIV OR Acquired Immun*)
8	AB=(chancroid OR chlamydia OR lymphogranuloma OR gonorrhea OR syphilis OR herpes OR HPV OR human papilloma OR genital wart* OR venereal wart* or veneral disease* OR STI OR STIs OR STD OR STDs)
7	TI=(chancroid OR chlamydia OR lymphogranuloma OR gonorrhea OR syphilis OR herpes OR HPV OR human papilloma OR genital wart* OR venereal wart* or veneral disease* OR STI OR STIs OR STD OR STDs)
6	KW=(chancroid OR chlamydia OR lymphogranuloma OR gonorrhea OR syphilis OR herpes OR HPV OR human papilloma OR genital wart* OR venereal wart* or veneral disease* OR STI OR STIs OR STD OR STDs)
5	DE=(“acquired immune deficiency syndrome”)
4	DE=(“sexually transmitted diseases”)
3	(AB=(cervi*) within 3 (cancer* OR neoplas* OR dysplas* OR malignan* or tumo* OR carcinoma*))
2	(TI=(cervi*) within 3 (cancer* OR neoplas* OR dysplas* OR malignan* or tumo* OR carcinoma*))

1 (KW=(cervi*) within 3 (cancer* OR neoplas* OR dysplas* OR malignan* or tumo* OR carcinoma*))

Appendix 7. Social Science Citation Index search strategy

(2/2001 to 11/2009)

#29 #28 AND #27 AND #26 AND #25

#28 #24 OR #23

#27 #22 OR #21 OR #20 OR #19

#26 #18 OR #17 OR #16 OR #15 OR #14 OR #13 OR #12 OR #11 OR #10 OR #9 OR #8 OR #7 OR #6 OR #5 OR #4 OR #3 OR #2 OR #1

#25 TS=(random* OR “RCT*” OR controlled OR “controlled clinical trial*” OR “controlled stud*”)

#24 TS=(young* OR adolescen* OR teenage* OR youth*) SAME TS=(girl* OR wom?n* OR female*)

#23 TS=(adolescen* OR teenag* or youth* OR young*)

#22 TS=(primary SAME prevent*)

#21 TS=(educat* OR counsel*)

#20 TS=(health* OR condom* OR contracept* OR sexual* OR “safe* sex” OR AIDS OR HIV OR pregnan* OR theor* OR behav*) SAME TS=(promotion* OR campaign* OR program* OR programme* OR initiative* OR information OR intervention*)

#19 TS=(prevent* SAME program*)

#18 TS=(sex* OR coit* OR reproduct*) SAME TS=(safe* OR protect* OR unsafe OR unprotected OR responsible OR risk* OR “high risk” OR abstinen* OR behavio$r* OR activit* OR practi* OR partner* OR promiscu* OR celiba*)

#17 TS=“contracept* behavio$r*”

#16 TS=“sex* behavio$r*”

#15 TS=(condom* OR contracept* OR intrauterine OR “IUD”) SAME TS=(usage OR use* OR using)

#14 TS=(contracept* SAME (usage OR use* OR using))

#13 TS=condom*

#12 TS=(“sexually transmitted infect*” OR “STI” OR “STIs”)

#11 TS=(“sexually transmitted disease*” OR “STD” OR “STDs”)

#10 TS=(“STD” OR “STDs” OR “sexually transmitted disease*” OR “STI” OR “STIs” OR “sexually transmitted infect*”) SAME TS=(incidence OR prevalen* OR prevent* OR control* OR risk* OR reduc*)

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#9 TS=(“HIV” OR “human immunodeficiency virus”) SAME TS=infection*

#8 TS=(“HIV” OR “human immunodeficiency virus” OR “AIDS” OR “acquired immunodeficiency syndrome”) SAME TS= (incidence OR prevalen* OR prevent* OR control* OR risk* OR reduc*)

#7 TS=(“herpes genitalis” OR “genital herpes” or “herpes SAME virus” OR “HSV” OR chlamydia OR syphilis OR gonorrh*ea OR “Neisseria gonorrh*eae” OR chancroid OR “Haemophilus ducreyi”)

#6 TS=(genital* OR venereal OR condylom* OR anal OR anogenital*) SAME TS=wart* SAME TS=(incidence OR prevalen* OR prevent* OR control* OR risk* OR reduc*)

#5 TS=“condylomata acuminata”

#4 TS=(HPV OR human papilloma*) SAME TS=(incidence OR prevalen* OR prevent* OR control* OR risk* OR reduc*)

#3 TS=papilloma*virus SAME TS=infect*

#2 TS=(uterine cervi*) SAME TS=(neoplas* OR dysplas*)

#1 TS=(cervi* SAME (cancer OR neoplas* OR malignan* OR tum$r* OR carcinoma*) SAME (incidence OR prevalen* OR prevent* or control* or risk* or reduc*))

Appendix 8. TRoPHI search strategy

(to 11/2009)

1 What type of study does this report describe?: outcome evaluation OR RCT OR trial

2 Focus of the report: pregnancy prevention OR sexual health OR STD

3 Focus of the report: cancer

4 2 AND 3

5 Freetext: “sexually transmitted”

8 Freetext: “sexual health”

9 Freetext: STI

10 Freetext: HIV

11 Freetext: papilloma

12 Freetext: “human papillomavirus”

13 Freetext: HPV

14 Freetext: chlamydia

15 Freetext: warts

16	5 OR 8 OR 9 OR 10 OR 11 OR 12 OR 13 OR 14 OR 15
17	2 OR 16
18	4 OR 17
19	Characteristics of the study population: young people
20	Characteristics of the study population: female
21	19 AND 20
	1 AND 18 AND 21 = 71

CHARACTERISTICS OF STUDIES

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

Boyer 2005

Methods	DESIGN: Single centre cluster RCT LENGTH OF FOLLOW-UP: First follow-up conducted on average 1 month following graduation from training (i.e. end of the intervention) (median = 34.5 days, range = 11 to 146 days). Second follow-up conducted on average at 14 months after baseline assessment (median = 12.8 months, range = 6.2 to 31.7 months) DATA ANALYSIS: Not stated whether ITT or intervention received. From the results presented it appears that not all of the randomised participants were analysed at post-intervention ATTRITION RATE: At second follow-up 686 (64.5%) (intervention group) and 695 (63.4) (control group) completed the trial UNIT OF DATA ANALYSIS: Clusters (platoons) randomised, but individuals analysed SAMPLE SIZE CALCULATION: Assumed within-group cluster correlation was 0.01 based on 25 individuals per cluster to give sample size of 568 per group. Sample size was further increased to 1,000 participants per study group EQUIVALENT STUDY GROUPS AT BASELINE: Authors state that there were statistically significant differences between study groups on 4 variables (P = 0.006 to 0.043) . Intervention group more likely to be married, to ever had a casual sexual partner, to have used condoms <100% time and to have prior history of N.gonorrhoeae PROCESS EVALUATION: Not stated
Participants	NUMBER RANDOMISED: 2157 AGE: Group 1: 17 to 18 years = 561 (52.8%); 19 to 21 years = 389 (36.6%); ≥ 22 years = 112 (10.5%). Group 2: 17 to 18 years = 603 (55.1%); 19 to 21 years = 391 (35.7%); ≥ 22 years = 101 (9.2%) SOCIO-ECONOMIC STATUS: Group 1: High school diploma or GED = 780 (73. 4%); Any college ofvocational/technical = 282 (26.6%). Group 2: High school diploma or GED = 829 (75.5%); Any college ofvocational/technical = 266 (24.3%) ETHINCITY/RACE: Group 1: Caucasian = 593 (55.8%); Latina = 211 (19.9 %); African American =165 (15.5%); Asian/Pacific Islander = 29 (2.7%); Native American = 29 (2.7%); Other or mixed = 35 (3.3%). Group 2: Caucasian = 613 (56.0%); Latina = 215 (19.6%); African American = 183 (16.7%); Asian/Pacific Islander = 38 (3.5%); Native American = 24 (2.2%); Other or mixed = 22 (2.0%) LOCATION: USA (California, Carolina). Group 1: Urban = 839 (79.1%); Rural = 222 (20.9%). Group 2: Urban = 860 (78.8%); Rural = 231 (21.2%)

	PREVIOUS STI (self-report): Group 1: Yes = 104 (11.6%); No = 789 (88.4%). Group 2: Yes = 105 (11.2%); No = 835 (88.8%) SEXUAL RISK BEHAVIOUR: Number of sexual partners (lifetime). Group 1: 1 partner = 149 (17.1%); ≥ 2partners = 722 (82.9%). Group 2: 1 partner = 174 (18.9%); ≥ 2 partners = 745 (81.1%) Frequency of condom use (lifetime). Group 1: <100% = 703 (80.3%); 100% = 173 (19. 7%). Group 2: <100% = 708 (76.7%); 100% = 215 (23.3 %) Other measures reported (but not extracted) were frequency ofcontraception use; number of casual partners (lifetime); history of pregnancy (self-report) and STI screening
Interventions	**GROUP 1: Cognitive-behavioural intervention** (n = **1062**) YEAR STARTED: 2000 PROVIDER(S): trained civilian research assistants (2x per session) SETTING(S): Not explicitly stated but participants were US female Marine recruits who received the intervention during their 13 week recruit training period TYPE: Information/Education to increase knowledge about risks for unintended pregnancy and STIs; Practical skill development (communication skills; condom use skills) DURATION: Four 2 hour sessions in weeks, 1,2,4 and 12 of the 13 week recruit training period THEORETICAL BASIS: Information, motivation and behavioural skills model (IMB) STIs COVERED: STIs in general, including HIV/AIDS **GROUP 2: Health promotion control** (n = **1095**) YEAR STARTED: 2000 PROVIDER(S): As group 1 SETTING(S): As group 1 TYPE: Identical to Group 1 in educational strategies but designed to improve physical performance through healthier food choices, to reduce risk of sports or physical training injuries and examine risk and prevention of cervical and breast cancer in young women THEORETICAL BASIS: Not stated DURATION: As group 1
Outcomes	PRIMARY: Composite measure ofany STI or unintended pregnancy (UP). Any single measure of post-intervention STIs (C. *trachomatis*, N. *gonorrhoeae*, T. *vaginalis*) or UP SECONDARY: Sexual intercourse with multiple sex partners (two or more partners) Sexual intercourse with casual sexual partners inconsistent consistent condom use (100% versus <100%)
Notes	COST DATA: The only data given was for incentives to participate in the second follow-up assessment. They received a US$5.00 phone card or small gift bag containing cosmetics

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Adequate sequence generation?	Low risk	Platoons (groups of 50 to 75 women) were randomly assigned to experimental intervention or control groups

		using a computer-generated random numbers table established before the start of the study
Allocation concealment?	Unclear risk	Not stated
Blinding? All outcomes	Unclear risk	Not stated for biological outcomes (pri-mary outcome). Behavioural outcomes were self-report
Incomplete outcome data addressed? All outcomes	Low risk	Second post-intervention questionnaires and biological screenings were conducted only in the 3 key regions where the female Marines were stationed, on grounds of cost. Those who were not stationed in the three regions only completed the questionnaires and did not undergo the biological screening. Thus, results for the primary outcome are based only on a sub-set of the randomised population. Not stated whether ITT or intervention received analysis was done. From the results presented it appears that not all of the randomised participants were analysed at post-intervention However, attrition rates were balanced between study groups and reasons for attrition were given (which did not differ between groups)
Free of selective reporting?	Low risk	Results for all outcome measures appear to have been reported
Free of other bias?	High risk	There were some imbalances in baseline variables between the trial groups which may bias the results (see under ‘Methods’)

Bryan 1996

Methods	DESIGN: Single centre RCT (university). LENGTH OF FOLLOW-UP: 6 weeks and 6 months after intervention (all outcomes) DATA ANALYSIS: Unclear. Not explicitly stated but sample sizes for outcome assessments (given in Table 3) suggest analysis was based on intervention received (i.e. excluding attrition) ATTRITION RATE: Attrition at 6-week and 6-month follow up interviews: Group 1: Condom promotion group; 6 weeks: 21%; 6 months 27%. Group 2: Stress management control group: 6 weeks 23%; 6 months 27% UNIT OF DATA ANALYSIS: Individuals SAMPLE SIZE CALCULATION: No information provided EQUIVALENT STUDY GROUPS AT BASELINE: The groups were similar in terms of age, ethnicity, % having had intercourse, age at first intercourse, number of sexual partners, % who used condoms all the time and % who used other birth control all the time. The groups thus appear to be equivalent. Authors stated that no differences were found between conditions at pretest. Note however that no socio-economic information was reported PROCESS EVALUATION: A process evaluator monitored each experimental programme presentation and noted on a checklist which of 37 (unspecified) points of the programme was mentioned. The authors stated that the condom use intervention was implemented with high accuracy, with each of the 37 critical points delivered in all presentations. In every session all women participated in the condom use practical exercises. No other details of process evaluation were provided
Participants	NUMBER RANDOMISED: 198 AGE (years): Mean (SD): Group 1: 18.63 (1.23); Group 2: 18.63 (1.42)

	GENDER: All female (unmarried undergraduate students). SOCIO-ECONOMIC STATUS: Not stated. ETHINCITY/RACE: 79% Caucasian; 8% Hispanic; 5% Asian American; 4% native American; 3% African American; 1% other LOCATION: USA; region not stated (location reported only as a large south western university) PREVIOUS STI: 7% of all the women reported ever having had an STI SEXUAL RISK BEHAVIOUR: Unmarried female undergraduate students of which 76% were sexually active (had had intercourse at least once) (Group 1: 72%; Group 2: 81%). Mean duration of sexual activity: 2.4 years. Mean (SD) age (years) at first intercourse: Group 1: 16.11 (1.13); Group 2: 16.31 (1.55). Of this sexually active group only 16% reported using condoms 100% of the time and 73% had had more than one partner in their lifetime
Interventions	NAME OF STUDTY: Not stated **GROUP 1: Education and skills development intervention: condom promotion and use** (n = **100**) YEAR STARTED: Not reported. PROVIDER(S): Researcher (female graduate student plus an assistant) SETTING: Education (university, undergraduate population) TYPE: Information/Education; Practical skill (stress management; the ability to discuss condom use with sexual partners; modelling correct condom use) DURATION: One 45-minute session. THEORETICAL BASIS: Health Belief Model; Traditional Education. Bryan et al. (1997) also mention the Theory of Reasoned Action as background to the intervention, though Bryan et al. (1996) did not refer to this. STIs COVERED: STIs in general; none specifically mentioned. **GROUP 2: Education and skills development control: stress management** (n = **98**) This was comparable in format to the experimental programme, including an interactive format between presenter and audience and group participation in stress-reducing exercises
Outcomes	PRIMARY: No outcomes were explicitly nominated as primary and no statistical power calculations were reported SECONDARY: Attitudes (affective attitudes towards condoms) Awareness/Beliefs (perceived susceptibility to STIs; perceived severity of STIs; perceived benefits of using condoms; control over the sexual encounter) Behaviour: recorded for all participants (has purchased condoms; has carried condoms; has practiced telling partners to use condoms; has discussed condom use with partner); recorded for sexually active participants (has used condom at last intercourse) Intentions (to buy, carry, practice discussing, discuss with a partner or use condoms) Self-efficacy/self-esteem/self-confidence (condom use self-efficacy)
Notes	COST DATA: None reported.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Adequate sequence generation?	Unclear risk	No information provided; stated only that the design was a randomised experiment
Allocation concealment?	Unclear risk	No information provided.

Blinding? All outcomes	Low risk	The research assistants who conducted the follow-up telephone interviews were unaware of the experimental group
Incomplete outcome data addressed? All outcomes	Unclear risk	The proportion of data missing was similar for the experimental and control groups but no reasons for the missing data were provided
Free of selective reporting?	Unclear risk	The paper lacks a clear *a priori* statement of all measured outcomes. The five listed behavioural outcomes were mentioned briefly at the end of the methods section and also reported on in the results section. Other outcomes were introduced at the same time as their results were presented (e.g. in Fig. 2), which makes a judgement of selective reporting difficult
Free of other bias?	Unclear risk	Although the trial groups were equivalent at baseline in terms of sexual behaviour and demographic characteristics, it is unclear whether they were equivalent in terms of socio-economic status

Bull 2008

Methods	DESIGN: Cluster RCT LENGTH OF FOLLOW-UP: Post-campaign surveys (April-July 2005) were initiated immediately following the campaign period (September 2004 - March 2005) DATA ANALYSIS: Primary analysis (using permutation tests) was not stated explicitly as intention to treat but included all randomised units (neighbourhoods). There was evidence of contamination across neighbourhoods (see participants section below) whereas the primary analysis kept the neighbourhoods to their allotted intervention groups. The analysis thus appears to be equivalent to an intention to treat analysis. A secondary, post-hoc, analysis based on logistic regression was carried out to investigate the effect on outcomes of actual exposure to the intervention (data not extracted as not reported by study group) ATTRITION RATE: Attrition was not reported because pre-campaign and post-campaign outcomes were based on different groups of participants (cross-sectional samples nested within study groups at pre-intervention and post-intervention). Also, this was a cluster RCT and none of the clusters (neighbourhoods) were omitted. Of 16,478 and 12,183 women who appeared eligible at baseline and post-campaign respectively, 3407 and 3003 provided pre-campaign and post-campaign data UNIT OF DATA ANALYSIS: Neighbourhoods were the units randomised and also the units analysed statistically (permutation tests conducted on 12 neighbourhoods stratified by 4 regions and two study arms = 144 possible arrangements of groups to conditions) SAMPLE SIZE CALCULATION: Intraclass correlation coefficient assumed to be 0.02 from a pilot study in Denver. For adequate (unspecified) power it was assumed that data from 12 neighbourhoods with 300 women per neighbourhood would be required. It ws also assumed that inclusion of 250 women per neighbourhood would not substantially reduce power (actual sample sizes ranged 229 to 301 per neighbourhood) EQUIVALENT STUDY GROUPS AT BASELINE: Not reported in the results, but stated that following the baseline survey neighbourhoods were stratified within regions to ensure adequate comparability between campaign and comparison neighbourhoods PROCESS EVALUATION: Exposure of participants to the social marketing campaign was assessed and analysed (data not extracted)

Participants	NUMBER RANDOMISED: 12 neighbourhoods (comprising 3407 respondents to baseline survey; 3003 respondents to follow up survey) AGE: (number (%) of 3407 respondents; not reported separately by study group): 15 to 17 years = 1428 (41.9); 18 to 19 years = 663 (19.5); 20 to 25 years = 1299 (38.1); missing data: 17 (0.5) SOCIO-ECONOMIC STATUS: Not reported. ETHINCITY/RACE: (number (%) of 3407 respondents; not reported separately by study group): African American = 1124 (33.0); Latina = 1420 (41.7); Other = 788 (23. 1); missing data = 75 (2.2) LOCATION: USA; 12 urban neighbourhoods: 10 in California (4 in San Francisco Bay area, 4 in Los Angeles, 2 in San Diego) and 2 in Nevada (Las Vegas) PREVIOUS STI: Not reported. Stated that the neighbourhoods were selected as they had the highest rates of chlamydia, gonorrhoea and teen births for 15 to 25 year old women in the campaign area SEXUAL RISK BEHAVIOUR: (number (%) of 3407 respondents; not reported separately by study group): Ever had sex, answer yes = 2342 (68.7); Ever had sex, answer no = 1014 (29.8); missing data = 51 (1.5); had sex in past 90 days = 1853 (54.4) OTHER: Cross-contamination ofrandomised groups (exposure to intervention assessed by self-report questionnaire): Women in comparison (control) neighbourhoods were able to define unique elements of the POWER campaign intervention. Of 87 women who said they received a silk purse (provided only in intervention neighbourhoods), 39% were from control neighbourhoods
Interventions	**GROUP 1: POWER (Prevention Options for Women Equals Rights) Reproductive Health social marketing campaign** (n = **6 neighbourhoods**) YEAR STARTED: September 2004 to March 2005. PROVIDER(S): Not stated but appears to be that participants self-accessed intervention materials which were placed at community venues SETTING(S): Urban neighbourhood community venues (unspecified) (n = 400 sites) that were frequented by the target population of adolescent women (mentioned only bathrooms, stalls and bulletin boards) TYPE: Information/Education about condom efficacy and use; Resource provision (included take-away information cards and coupons redeemable for male and female condoms in a silk carrying case with lubricant and instructions for use). Described as social marketing DURATION: Not reported. The intervention was implemented during September 2004 to March 2005 but it is unclear whether implementation in the different neighbourhoods was simultaneous or staggered within this period THEORETICAL BASIS: Based on social marketing principles. Stated only that a theoretical framework to affect attitudes, knowledge and beliefs about female as well as male condoms guided the campaign STIs COVERED: STIs in general. **GROUP 2: Comparison group** (n = **6 neighbourhoods**) YEAR STARTED: As Group 1. PROVIDERS: None (no intervention). SETTINGS: As Group 1. TYPE: None (no intervention). DURATION: None (no intervention). THEORETICAL BASIS: None (no intervention). STIs COVERED: None (no intervention).
Outcomes	Several outcomes were reported in different places on page 74 to be the primary outcomes:

	Attitudes to condom use Intentions to use condoms Behaviour: - Ever having used male or female condoms for vaginal or anal sex; - Having used male or female condoms at last vaginal or anal sex; - The proportion of protected vaginal or anal sex acts in the past 90 days (No secondary outcomes were explicitly defined.)
Notes	COST DATA: Stated only that women were offered a $10 coupon to a local store for participation

Risk of bias

Bias	Authors' judgement	Support for judgement
Adequate sequence generation?	Low risk	Stated that the six campaign neighbourhoods were selected at random using a computer-generated program (no other details provided)
Allocation concealment?	Unclear risk	No information provided.
Blinding? All outcomes	Unclear risk	No information provided.
Incomplete outcome data addressed? All outcomes	Unclear risk	All randomised units were analysed. However, within the randomised units there were missing data and it is not stated whether or how, these were accounted for in the primary analysis (permutation tests) . (Stated that missing data were imputed in a secondary regression-based analysis; however data were not extracted as not reported separately by study groups). In summary, it is unclear whether there was imbalance within the study groups and, if present, whether this would lead to risk of bias
Free of selective reporting?	High risk	Results are presented only for ever using a female condom (no information provided on male condom use or condom use for last sex or for last 90 days)
Free of other bias?	High risk	There was contamination between intervention and comparison neighbourhoods which may have biased the results (see 'Methods' and 'Participants' above)

Choi 2008

Methods	DESIGN: Multi-centre RCT LENGTH OF FOLLOW-UP: 3 and 6 months post-intervention DATA ANALYSIS: Not reported whether data analysis was ITI or intervention received. It is not clear from the results whether the analysis is based on all randomised participants or only those remaining at follow-up (no n's reported only %)

	ATTRITION RATE: Retention rates were 85% at both 3 and 6 month follow-up. Rates for each study group are not reported. However it is mentioned that there were no significant group difference in retention rates at 3 (P = 0.195) or 6 months (P = 0.148) UNIT OF DATA ANALYSIS: Appears to be individual. SAMPLE SIZE CALCULATION: Not reported EQUIVALENT STUDY GROUPS AT BASELINE: Authors state they found no differences in demographics, sexual behaviours or condom use between groups at baseline. From data presented they appear reasonably balanced PROCESS EVALUATION: Not reported
Participants	NUMBER RANDOMISED: 409 AGE: Mean age 22 years, 77% were aged between 18 to 24 years Group 1: 18 to 19 years = 49 (23%); 20 to 24 years = 114 (54%); 25 to 29 years = 29 (14%); 30 to 34 years = 14 (7%); 35 to 39 years = 7 (3%). Group 2: 18 to 19 years = 45 (23%); 20 to 24 years = 97 (49%); 25 to 29 years = 36 (18%); 30 to 34 years = 12 (6%); 35 to 39 years = 6 (3%) SOCIO-ECONOMIC STATUS: Group 1: Less than high school education = 94 (44%) ; High school education = 82 (38%); Some college education or college graduate = 37 (17%). Group 2: Less than high school education = 80 (41%); High school education = 88 (45%); Some college education or college graduate = 28 (14%) ETHINCITY/RACE: Group 1: African American = 27 (13%); Asian =14 (7%); Latina = 33 (15%); White = 139 (65%). Group 2: African American = 17 (9%); Asian = *10 (10%); Latina = 35 (18%); White = 122 (63%) *appears to be a mistake in the trial publication. It should be 20 not 10, though the total number would only sum to 194, rather than the 196 randomised LOCATION: 4 named San Fransisco Bay Area Cities, US. PREVIOUS STI: Group 1: 75 (35%); Group 2: 63 (32%) SEXUAL RISK BEHAVIOUR: Number of sexual partners in past 3 months. Group 1: 0 partners = 7 (3%); 1 partner = 119 (56%); 2 partners = 52 (24%); ≥ 3 partners = 35 (16%). Group 2: 0 partners = 6 (3%); 1 partner = 109 (56%); 2 partners = 51 (26%); ≥ 3 partners = 30 (15%) Used a male condom at least once during past 3 months. Group 1: 146 (68%). Group 2: 126 (64%) Ever used female condom. Group 1:10 (5%); Group 2: 7 (4%)
Interventions	NAME OF STUDY: Not reported **GROUP 1: Female condom skills training intervention** (n = **213**) YEAR STARTED: 2003/4 PROVIDER(S): Health Educators SETTING(S): Family planning clinics where the participants were originally attendees TYPE: Information/Education about HIV/STIs and safer sexual practices and assessment of personal risk. Practical skill development to learn how to use female condoms and how to communicate with sexual partners and negotiate the use offemale condoms. Examination ofpersonal barriers to using female condoms. Condoms (male and female) were supplied throughout and beyond the intervention period. Intervention was deliv- ered individually except session 3 which was in small groups of 6 to 10 participants DURATION: 4 sessions over an unspecified period of time. First 2 sessions lasted 2 hours each, the third lasted 2.5 hours and the 4th session lasted 30 minutes THEORETICAL BASIS: Social Learning Theory. STIs COVERED: HIV and STIs **GROUP 2: General health promotion intervention** (n = **196**)

	YEAR STARTED: 2003/4 PROVIDER(S): As Group 1 SETTING(S): As Group 1 TYPE: Information/Education about general health issues such as cancer and heart disease, to improve motivation to change health risk behaviours. Condoms supplied as per Group 1 DURATION: As Group 1. THEORETICAL BASIS: Not stated STIs COVERED: N/A
Outcomes	PRIMARY: Not explicitly stated that these were their primary outcomes but behavioural outcomes appear to be the focus of the evaluation. Measures included: use of male or female condoms at least once during vaginal and anal intercourse in the past 3 months; percentage of vaginal and anal sexual acts protected by female condoms, by male condoms or by any (female or male) condom in the last 3 months. These measures were repeated for each sexual partner the participants had reported (up to 10 times as necessary) SECONDARY: Not explicitly stated that these were their secondary outcomes, but they measured impact on knowledge about female condoms, attitudes to female condoms and female condom use self-efficacy
Notes	COST DATA: All participants received monetary incentives after completing each session (i.e. $20 each at sessions 1 and 2, $30 at session 3 and $10 gift card at session 4)

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Adequate sequence generation?	Unclear risk	Reports that randomisation was stratified by site and race/ethnicity. Prior to the study stratum-specific sequential identification numbers were generated and randomly pre-assigned to intervention groups in blocks of4 (i.e. 2 intervention and 2 control participants per block). No detail given on the actual method of random sequence generation
Allocation concealment?	Unclear risk	Not stated
Blinding? All outcomes	Unclear risk	Not stated
Incomplete outcome data addressed? All outcomes	Unclear risk	Authors report that there were no statistically significant differences between study groups in attrition (note though that they don't actually provide the numbers, only an overall figure for the study population as a whole (85% retention)). No reasons for attrition are given. It is not clear whether the reasons for attrition differed between the groups
Free of selective reporting?	Low risk	All outcomes specified in the methods of the study appear to be reported on in the results
Free of other bias?	Unclear risk	Unclear

Dancy 2009

Europe PMC Funders Author Manuscripts

Methods	DESIGN: Cluster RCT LENGTH OF FOLLOW-UP: immediate post-intervention (T2) and 6 months post-intervention (T3) (Baseline was T1) DATA ANALYSIS: Mentions following the ITI principle for those who declined to answer the question 'ever had sex' at any of the three timepoints (n = 36). These were treated, conservatively, as having had sex. No mention is made regarding ITI for other outcomes ATTRITION RATE: Group 1: 23.6%, Group 2: 23.6%, Group 3: 23.3%. It is not possible to work out the n/N for each group as it is not clear how many participants there were in the three study groups prior to attrition. The overall attrition rate was n = 130/553 (23.5%) UNIT OF DATA ANALYSIS: Not clear whether cluster or individuals, but probably the former. Authors report multilevel analysis which takes into account intra-group clustering effects (the 'group' being each group of around 20 participants within each of the three trial groups). Note that hypothesis 1 was not supported at T2 (i.e. no differences between Groups 1 and 2). Therefore groups 1 and 2 were collapsed into one trial group (a single risk reduction group, irrespective of whether provided by mothers or health educators) and compared with Group 3 in order to answer hypothesis 2 SAMPLE SIZE CALCULATION: Not comment is made on sample size for clusters. Each intervention group contained only one site, therefore is is likely that the study is not adequately powered show a statistically significant difference in outcomes. At each intervention site a convenience sample of participants was taken EQUIVALENT STUDY GROUPS AT BASELINE: Intervention sites described as being similar in terms of poor health indicators related to teen birth rates and STIs. Authors mention that groups only differed on sexual activity in the last 6 months (5% Group 1; 4% Group 2 and 12% Group 3) at baseline, based on analyses of variance. Baseline characteristics are presented for the sample as a whole, rather than individual groups, therefore it is not possible to make an independent assessment of comparability. Given the fact that there was only one cluster per randomised study group selection bias maybe likely. Note that participants who refused to answer the question 'ever had sex' were over-represented in Group 3 at baseline and it is stated that non-response interacted with intervention condition to predict some outcomes (though the authors appear to have dealt with this using response group dummy variables)
Participants	PROCESS EVALUATION: Not reported NUMBER RANDOMISED: 3 sites were randomised to the three interventions AGE: Mean = 12.29 (SD 1.17), range 11 to 14 SOCIO-ECONOMIC STATUS: Sample sites described as having large numbers of low income/single mother headed homes and poor health indicators related to teen birth rates and STIs, including HIV/AIDS. Sites had indicators of poor health to a greater degree than practically anywhere else in Chicago and were populated predominantly by African Americans. Selection criteria stipulated income below the federal poverty line Education grades earned: As = 28.75%, Bs = 44.47%, Cs = 22.36%, Ds = 3.44%, Fs = 0.98% Plan to attend college = 95.4% Participate in after school activity = 73.2% ETHINCITY/RACE: African-American = 100% LOCATION: USA.The three sites were geographically distinct but environmentally and demographically similar, in the Chicago area PREVIOUS STI: Not reported SEXUAL RISK BEHAVIOUR: Sexual activity in last 6 months = Group 1, 5%; Group 2, 4%; Group 3, 12% OTHER: Number of siblings: Mean = 4.06 (SD 2.77), range 0 to 16 Number of siblings in household: Mean = 2.15 (SD 1.75), range 0 to 13
Interventions	NAME OF STUDY: Not stated

	GROUP 1: Mother/Daughter HIV Risk Reduction intervention (MDRR) n = **135*** YEAR STARTED: Not stated PROVIDER(S): Mothers (to their daughters) SETTING(S): Not stated TYPE: Information/Education and practical skills development around HIV delivered in small groups (approx 20 groups, average of 9 daughters per group). Very little other information provided DURATION: Six sessions delivered weekly THEORETICAL BASIS: Bandura's self-efficacy and skills modelling models; Theory of Reasoned Action and Theory of Planned Behaviour STIs COVERED: HIV **GROUP 2: Health Expert Risk Reduction intervention** (HERR) n = **127*** YEAR STARTED: Not stated PROVIDER(S): Female health professionals SETTING(S): Not stated TYPE: As Group 1 DURATION: As Group 1 THEORETICAL BASIS: As Group 1 STIs COVERED: As Group 1 **GROUP 3: Mother/Daughter Health Promotion intervention** (MDHP) n = **141*** YEAR STARTED: Not stated PROVIDER(S): Mothers SETTING(S): Not stated TYPE: Not explicitly stated but mentions that it covers content related to nutrition and exercise and was delivered in small groups (approx 20 groups, average of 9 daughters per group) DURATION: As group 1 THEORETICAL BASIS: Not stated STIs COVERED: N/A * Number remaining after attrition
Outcomes	PRIMARY: SECONDARY: It is not explicitly stated which were their primary or secondary outcomes. In their hypotheses they mention the outcomes are 'not engaging in sex in the last 6 months' (oral, vaginal or anal), HIV transmission knowledge, self-efficacy to refuse sex, intention to refuse sex, condom attitudes, self-efficacy to use condoms and intention to use condoms at T2 and T3 Note that the intention seems to have been to measure other behavioural outcomes including consistent condom use, reducing the number of sexual partners and reducing the frequency of sexual activity. However, the number of girls reporting engaging in sex in the last 6 months was too small to permit comparison between the groups
Notes	COST DATA: Not reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**

Adequate sequence generation?	Unclear risk	No information given on randomisation sequence used. Three geographically distinct but environmentally and demographically similar sites were randomised to one of the three interventions. However, it is likely that the study is underpowered with only one cluster per trial group. Furthermore the authors combined Groups 1 and 2 into one group to compare against Group 3 which compromises randomisation
Allocation concealment?	Unclear risk	Not stated
Blinding? All outcomes	Unclear risk	Not reported
Incomplete outcome data addressed? All outcomes	Unclear risk	Attrition rates were similar between groups at 6 months post-intervention, but no reasons given for attrition. Based on t-tests it is stated that there were no pre-existing differences between the 430 participants who completed the study and the 150 who dropped out (n = 130 through attrition and 20 who underwent list wise deletion due to missing data). It is stated that non-response to the question 'ever had sex' interacted with intervention condition to predict some outcomes (though the authors appear to have dealt with this using response group dummy variables). In summary, there is not enough information to judge whether incomplete outcome data were addressed as the reasons for attrition from the respective study groups are not given
Free of selective reporting?	Low risk	All outcomes specified in the study hypotheses are reported on
Free of other bias?	Unclear risk	This was a cluster RCT but the unit of data analysis (e.g. cluster or individual) is not explicit (see 'Methods' above). It is uncertain whether the trial groups were wholly equivalent at baseline, raising the possibility of selection bias

DiClemente 2004

Methods	DESIGN: Single-centre RCT. LENGTH OF FOLLOW-UP: 6 and 12 months. DATA ANALYSIS: Stated that an intention to treat (ITT) protocol was used in which participants were analysed in their originally assigned trial conditions irrespective of the number of sessions attended. However, this definition of ITT does not explicitly include attrition and no explanation was provided as to how missing data were included in the analysis for outcomes reported at 6 months and 12 months follow up (analyses over the whole 12-month follow up period could account for missing data as they were based on more flexible general estimating equations) ATTRITION RATE: Completed 6 month follow up: Group 1 = 226/251 (90%); Group 2 = 243/271 (89. 7%); difference between groups: P = 0.89 Completed 12 month follow up: Group 1 = 219/251 (87.3%); Group 2 = 241/271 (88. 9%); difference between groups: P = 0.56

	UNIT OF DATA ANALYSIS: Individuals, as randomised. SAMPLE SIZE CALCULATION: Based on previous research which identified approximately 25% consistent condom use, the authors projected a clinically meaningful effect size of a 50% increase in consistent condom use in Group 1. Estimating 20% attrition over the 12-month follow up period and setting the type I error rate at 0.05 for a 2-tailed test with power=0.80 required enrolling 250 participants per study group to detect the specified effect size. For STI incidence, the authors stated that sample size and statistical power were limited for each assessment interval, so STI incidence was determined only for the entire 12 month follow up period EQUIVALENT STUDY GROUPS AT BASELINE: Stated that at baseline significant differences were observed for several variables associated with HIV-related sexual behaviours and were included as covariates in subsequent (=adjusted) analyses; no differences were observed for socio-demographic characteristics, the primary outcome measure, or other outcome measures PROCESS EVALUATION: Not reported in detail, but stated that nearly 98% of activities in each study condition were implemented with fidelity, 95.2% of participants completed all intervention sessions and 94.5% of participants completed all general health promotion sessions. Participants' mean±SD ratings of session content and delivery, recorded on a 5-point scale, were comparably high for both Group 1 (4.82±0.11) and Group 2 (4.76±0.09)
Participants	NUMBER RANDOMISED: 522 AGE, mean (SD): Group 1 = 15.99 (1.25) years; Group 2 = 15.97 (1.21) years SOCIO-ECONOMIC STATUS (*indicates an error in the % value reported in the primary publication; the correct value is given here): Did not complete 10th grade, n (%): Group 1 = 115 (45.8); Group 2 = 132 (48.7) Recipient of public assistance, n (%): Group 1 = 45 (17.9); Group 2 = 50 (18.5) Living in single-parent home, n (%): Group 1 = 146 (58.2*); Group 2 = 162 (59.8*) Living with someone other than a parent, n (%): Group 1 = 54 (21.5); Group 2 = 47 (17.3) Employed, n (%): Group 1 = 40 (15.9*); Group 2 = 53 (19.6*). Has children, n (%): Group 1: 60 (23.9); 63 (23.2). ETHINCITY/RACE: All African American. LOCATION: USA; Birmingham, Alabama, area. PREVIOUS STI (* indicates a slight difference in the reported and correct calculated percentages; the correct value is given here): Chlamydia, n (%): Group 1 = 48 (19.1*); Group 2 = 43 (15.9). Gonorrhoea, n (%): Group 1 = 14 (5.6); Group 2=13 (4.8). Trichomonas, n (%): Group 1 = 33 (13.1*); Group 2 = 33 (12.2*) SEXUAL RISK BEHAVIOUR (information in square brackets was not explicitly stated; assumed by review author ands): Mean (SD) % condom use in past 30 days: Group 1 = 79.23 (38); Group 2 = 77.47 (38) Mean (SD) % condom use in past 6 months: Group 1 = 72.44 (37); Group 2 = 70.38 (38) [Mean (SD) no. of] unprotected vaginal sex [acts] in past 30 days, n (%): Group 1 = 1. 12 (2.84); Group 2 = 0.84 (2.01) [Mean (SD) no. of] unprotected vaginal sex [acts] in past 6 months, n (%): Group 1 = 4.81 (16.01); Group 2 = 4.23 (10.25) Put condom on partner in past 6 months, 1 to 5 scale [mean (SD)]: Group 1 = 1.49 (1. 01); Group 2= 1.46 (0.98) Condom use skills (assessed by interviewer), scale scores [mean (SD)]: Group 1 = 2.91 (1.30): Group 2 = 3.03 (1.18) OTHER SEXUAL RISK OUTCOMES (*indicates an error in the % value reported in the primary publication; the correct value is given here):

	Consistent condom use in past 30 days: Group 1 = 60 (24.0*); Group 2 = 75 (27.7*)
	Consistent condom use in past 6 months, n (%): Group 1 = 101 (40.2*); Group 2=119 (43.9*)
	Condom use during last sex, n (%): Group 1 = 74 (29.5*); Group 2 = 79 (29.2*)
	Vaginal intercourse in the preceding 6 months was stated as a trial inclusion criterion
Interventions	**GROUP 1: HIV prevention intervention** (n = **251**)
	YEAR STARTED: December 1996 to April 1999.
	PROVIDER(S): A trained female health educator and 2 female peer educators, all African American
	SETTING(S): Family medicine clinic.
	TYPE: Four group sessions each attended by 10 to 12 participants providing information/ education and practical skills development. The sessions covered ethnic gender and ethnic pride; HIV risk reduction strategies, sex refusal and safer sex negotiation and healthy relationships. The practical skills components involved practising safer sex negotiation, including sex refusal and developing condom skills as modelled by the peer educators
	DURATION: Four 4-hour sessions implemented weekly on consecutive Saturdays
	THEORETICAL BASIS: Social cognitive theory and the theory of gender and power
	STIs COVERED: HIV
	GROUP 2: General health promotion group (n = **271**)
	YEAR STARTED: As Group 1.
	PROVIDER(S): Not reported; assumed as Group 1.
	SETTING(S): Not reported; assumed as Group 1.
	TYPE: Information/education. Four group sessions each attended by 10 to 12 participants; 2 of the sessions emphasised nutrition and 2 emphasised exercise
	DURATION: As Group 1.
	THEORETICAL BASIS: None reported.
	STIs COVERED: None.
Outcomes	PRIMARY:
	Self-reported consistent condom use (during every episode of vaginal intercourse), expressed as the total number of vaginal intercourse episodes divided by the total number of times a male condom was used, with a score of 1 representing consistent condom use
	SECONDARY:
	Condom use at last vaginal intercourse; percentage of condom-protected vaginal intercourse acts in the preceding 30 days and 6 months; number of unprotected vaginal intercourse acts in the preceding 30 days and 6 months; whether participants had a new vaginal sex partner in the preceding 30 days; and self-reported pregnancy
	Frequency with which participants applied condoms on their sex partners in the preceding 6 months, on a 5-point scale from ‘never’ to ‘every time’
	Frequency of vaginal sex acts in the previous 6 months.
	Incidence of chlamydia, trichomonas and gonorrhoea (HIV test not conducted due to expected low incidence)
	HIV knowledge; psychosocial mediators of condom behaviour (condom attitudes; condom barriers; condom self-efficacy; condom use skills; frequency of communication with partner about HIV preventive practices)
Notes	COST DATA: Reported only that participants were compensated $25 for travel and child care to attend intervention sessions and complete assessments

Risk of bias

Bias	Authors' judgement	Support for judgement
Adequate sequence generation?	Low risk	Stated that prior to enrolment, an investigator used a random-numbers table to generate the allocation sequence
Allocation concealment?	Low risk	Stated that allocation concealment procedures were defined by protocol and compliant with published recommendations; as participants completed baseline assessments, sealed opaque envelopes were used to execute the assignments
Blinding? All outcomes	Low risk	Stated that face-to-face interviewers who assessed participants' sexual behaviours were blind to group assignment. Not reported whether clinicians who diagnosed STIs based on participant-provided swabs were also blinded
Incomplete outcome data addressed? All outcomes	Low risk	Stated that no differences were observed in baseline variables for either group in participants retained in the trial compared with those unavailable for follow up. Although the GEE regression model used for analysing data over the 12 months post-baseline can account for missing data, the number ofvalues missing was not reported. For STI incidence, the authors stated that missing data for some covariates may affect the precision of effect estimates, but the co-variates in question were not stated However, attrition rates were balanced between study groups and reasons for attrition were given (which did not differ between groups)
Free of selective reporting?	Low risk	All outcomes presented in the methods section were also reported in the results section. Note that incidence of chlamydia, trichomonas and gonorrhoea was reported as an outcome although not explicitly stated as such in the methods section
Free of other bias?	High risk	Although adjusted for in the analysis, the trial groups were not equivalent at baseline on certain sexual behaviours

DiClemente 2009

Methods	DESIGN: Multi-centre RCT LENGTH OF FOLLOW-UP: 6 and 12 months post-intervention DATA ANALYSIS: States intention to treat protocol with participants analysed in their original assigned study groups irrespective of the number of sessions attended. However, it does not appear that all randomised participants were analysed, as only 605 (85%) of the 715 randomised were included in the primary analysis at 12 months follow-up (289/ 83% in Group 1 and 316/86% in Group 2) ATTRITION RATE: Group 1 = 289 (83%) completed 12 month follow-up; Group 2 = 316 (86%) completed 12 month follow-up. No differences in retention observed at 6 months (P = 0.98) or 12 month (P = 0.28) assessment UNIT OF DATA ANALYSIS: Individual SAMPLE SIZE CALCULATION: Reported for primary biological outcome (20% reduction in incident chlamydial infections over 12 months, assuming 80% retention, type 1 error rate of 0.05, power = 0.80, requiring 700 participants) EQUIVALENT STUDY GROUPS AT BASELINE: The study groups appeared generally similar at baseline. There were few statistically significant differences between study groups on socio-demographic variables, sexual behaviour, STI status, psycho-social mediators or other covariates

	PROCESS EVALUATION: Attendance at experimental intervention/comparison sessions was recorded. Participants rated their satisfaction with session delivery and value of session content. Fidelity ofexperimental and comparison interventions rated by trained monitors
Participants	NUMBER RANDOMISED: 715 AGE: Group 1 Mean = 17.79 (SD 1.71); Group 2 Mean = 17.78 (SD 1.73) SOCIO-ECONOMIC STATUS: Poor neighbourhood quality: Group 1 = 0.58 (SD 0.93), Group 2 = 0.62 (SD 0.95) Family aid index: Group 1 = 0.78 (SD 0.95); Group 2 = 0.91 (SD 1.07) Employed, n (%): Group 1 = 106 (30.5); Group 2 = 104 (28.3) Currently in school, n (%): Group 1 = 230 (66.1); Group 2 = 237 (64.6) ETHINCITY/RACE: Eligibility criteria specified identifying as an African-American LOCATION: Clinics providing sexual health services to predominantly inner-city adolescents located in downtown Atlanta, Georgia, USA. PREVIOUS STI: Approximately 46% of the participants had an STD at baseline chlamydia n (%): Group 1 = 110 (31.6); Group 2 = 107 (29.2) Gonorrhoea n (%): Group 1 = 51 (14.7); Group 2 = 48 (13.1) Trichomoniasis n (%): Group 1 = 72 (20.7); Group 2 =60 (18.0) SEXUAL RISK BEHAVIOUR: Condom use in past 14 days, mean (SD): Group 1 = 50.42 (44); Group 2 = 53.29 (45) Condom use in past 60 days, mean (SD): Group 1 = 51.00 (41); Group 2 = 52.22 (41) Consistent condom use in past 14 days, No (%)*: Group 1 = 97 (35.1); Group 2 = 128 (41.6) Consistent condom use in past 60 days, No (%)*: Group 1 = 69 (23.1); Group 2 = 86 (27.2) Condom use during last sex, No (%)*: Group 1 = 152 (43.9); Group 2 = 153 (41.7) Casual sex partner, No (%)*: Group 1 = 105 (30.2); Group 2 = 120 (32.7) In past 60 days number of vaginal sex partners, mean (SD): Group 1 = 1.54 (1.38); Group 2= 1.60 (1.44) In past 60 days number of times having vaginal sex, mean (SD): Group 1 = 13.08 (16. 63); Group 2= 11.90 (14.36) OTHER: * percentages do not appear to have been calculated on the total number randomised
Interventions	NAME OF STUDY: **GROUP 1: STI/HIV risk reduction intervention** (**Horizons**) (n = **348**) YEAR STARTED: March 2002 to August 2004 PROVIDER(S): African American women health educators SETTING(S): Sexual health clinic TYPE: Information/education on STD/HIV risk reduction. Practical skill development (condom use skills, negotiation skills). Provision of resources (vouchers for females to give to their male sexual partners to facilitate access to STD screening/treatment) DURATION: 2 x 4 hour sessions over 2 consecutive Saturdays (on average 8 participants attending each session). 4 x brief (15 minute) telephone contacts: 1 contact 3 to 4 weeks following completion of baseline assessment; a second contact 10 to 12 weeks following baseline assessment, a third contact 3 to 4 weeks following

	the 6 month follow-up assessment and final contact 10 to 12 weeks following the 6 month follow-up assessment THEORETICAL BASIS: Social cognitive theory, Theory of Gender and Power STIs COVERED: STIs in general/HIV **GROUP 2: Enhanced usual care comparison** (n = **367**) YEAR STARTED: As Group 1 PROVIDER(S): As Group 1 SETTING(S): As Group 1 TYPE: Information/education on STD/HIV risk reduction DURATION: 1 hour group session THEORETICAL BASIS: Not stated STIs COVERED: STIs in general/HIV
Outcomes	PRIMARY: Primary biological outcome measure was number of incident chlamydial infections at 6 and 12 month assessments. Primary behavioural outcome was the proportion ofcondom protected sex acts in the 60 days prior to 6 and 12 month assessments SECONDARY: Incidence of gonorrhoea and trichomoniasis. Number of lifetime sexual partners, condom use at last sex, consistent condom use, frequency of douching. Knowledge of STD/ HIV prevention, condom use self-efficacy, communication frequency
Notes	COST DATA: Not reported (other than women were given $20 vouchers to give to their male partners to redeem at clinics for sexual health services)

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Adequate sequence generation?	Low risk	Used a computer algorithm to generate random allocation sequence
Allocation concealment?	Low risk	Assignment adhered to concealment of allocation procedures defined by protocol and compliant with published recommen-dations, using opaque envelopes
Blinding? All outcomes	Low risk	For self-reported outcomes (e.g. sexual behaviour) data collectors (Audio Computer Assisted Self Interview monitors) were blind to participants condition assignment. Not reported whether those analysing vaginal swabs for STIs were blinded to intervention assignment, but as this could be considered a more objective outcome measure the lack of blinding may not pose a great risk of bias
Incomplete outcome data addressed? All outcomes	Low risk	Attrition was generally balanced between the two study groups (retention at 12 months follow-up was 83% to 86%). Reasons are specified and appear balanced between groups. It is stated that there were no differences for variables at baseline for participants retained in the trial compared to those unavailable for follow-up
Free of selective reporting?	Low risk	Results for all outcomes specified in the methods section of the trial publication are reported, with the exception of lifetime number ofpartners (which was a secondary outcome)

Free of other bias?	Unclear risk	Unclear

Downs 2004

Methods	DESIGN: Multi-centre RCT but data were pooled across centres (no indication of inter-centre variability provided) LENGTH OF FOLLOW-UP: 1 month (knowledge outcomes only); 3 months (knowledge, self-reported behavioural and STI outcomes); and 6 months (knowledge, self-reported behavioural and STI outcomes and self-administered introital swab for clinical screening for chlamydia acquisition) DATA ANALYSIS: Stated that all participants who provided data at the 6-month visit were retained in analysis, whether or not they had missed interim ("booster") sessions. It appears that losses to follow up were not accounted for in the analysis ATTRITION RATE: Reported only for the overall population, not by study group. Stated that there was a 14% attrition rate between baseline and the final visit (6 months) . Of those that participated in the final visit, 12.4% had missed one interim visit (1 month or 3 months) and 3.9% had missed both interim visits UNIT OF DATA ANALYSIS: Individuals. SAMPLE SIZE CALCULATION: Not reported, but stated that this study was designed as a preliminary evaluation with a moderate sample size to determine whether the video intervention warranted further study with a larger sample. It was reported where statistical tests were under-powered (for 8 of 9 self-reported STIs, tests of difference between groups had <20% power and hence were not reported; only a test for self-reported chlamydia had power (not stated) that was considered adequate). For a test of clinically-determined chlamydia power was 12% for alpha=0.05 (results presented with a narrative caveat) EQUIVALENT STUDY GROUPS AT BASELINE: Stated narratively only that there were no significant differences between the intervention groups in demographic characteristics (age, race, type of school, plans to finish school or age at first intercourse). Also stated that there were no baseline differences between conditions on any of the outcome measures except abstinence, where those in the video condition were more likely to be abstinent than controls, $\chi^2 = 5.76$; $P < 0.05$. PROCESS EVALUATION: None reported OTHER: Stated that this was designed as a preliminary study with a moderate sample size, to determine whether the video intervention warrants further study with a larger sample and more extensive biological measures
Participants	NUMBER RANDOMISED: 300 AGE: Mean or median not reported. Stated that participants had to be aged 14 to 18 years to be eligible SOCIO-ECONOMIC STATUS: Not reported. ETHINCITY/RACE: Not reported separately by study group. Stated that 75% of participants classified themselves as African American, 15% white and 10% other or mixed race LOCATION: USA; Pittsburgh; urban PREVIOUS STI: Not reported separately by study group. A total of 25.6% of participants reported having been diagnosed with an STI in the previous 3 months. chlamydia prevalence was 16%, which the authors note is consistent with other studies of sexually active urban adolescent females SEXUAL RISK BEHAVIOUR: Not reported separately by study group. Participants had to have been sexually active in the 6 months prior to recruitment to be eligible for the study, but 7.7% reported having been abstinent in the 3 months prior to baseline. On average, participants who were not abstinent reported using condoms more than halfthe time and those who had used a condom in the 3 months prior to baseline experienced on average 0.87 condoms breaking, leaking or falling off in that time

Interventions	**GROUP 1: Interactive video intervention** (**n: not reported**) YEAR STARTED: Not reported (wording in Acknowledgements section suggests work was done prior to 2000) PROVIDER(S): Not reported. The interventions were of a self-study type, with content delivered by video or brochures and were designed for "stand alone" use in (unspecified) healthcare settings SETTING(S): Primary care sites (unspecified). TYPE: Information/education on STIs, STI sexual risk reduction and reproductive health, delivered by an interactive video developed for the intervention. Provided in four sections: "sexual situations", "risk-reduction", "sexual health" "STDs". Also practical skills development: "Users perform cognitive rehearsal imagining what they would say or do, then practice it in their heads" (cognitive rehearsal) DURATION: Not precisely reported. Video duration was 1 hour, with still material on STIs also provided. However, viewers did not typically watch the entire intervention (the interactive nature of the video allowed guiding viewers to the portions they selected). The interventiion was administered at baseline, with booster sessions at 1, 3 and 6 months. At baseline participants spent 30 min restricted to the first 2 intervention sections. At each follow up (=booster session; 1, 3 and 6 months), participants spent "at least 15 mins with access to all sections to their intervention" THEORETICAL BASIS: Theoretically grounded in behavioural decision research. Based on the "mental models" approach, which identifies context-specific aspects of behaviour that are most relevant to the decisions of the target population in relation to the intervention. The intervention also included some cognitive rehearsal (Bandura) by encouraging participants to stop and think before continuing with the video STIs COVERED: chlamydia, genital herpes, genital warts, gonorrhoea, hepatitis B, trichomoniasis, syphilis and HIV **GROUP 2: Content-matched control** (**n: not reported**)* All details as Group 1 except: TYPE: Content and sections as Group 1 but delivered by a 127-page book developed for the intervention which contained all the dialogue and selected images from the Group 1 video DURATION: Not reported (self study involving participants reading a book). At baseline participants spent 30 min restricted to the first 2 intervention sections. At each follow up (=booster session; 1, 3 and 6 months), participants spent "at least 15 mins with access to all sections to their intervention" **GROUP 3: Topic-matched control** (**n: not reported**)* All details as Group 2 except: TYPE: As Groups 1 and 2 but delivered by commercially available brochures and research brochures chosen by the investigators to be as similar as possible in content. Unclear whether practical skills component (cognitive rehearsal) was included DURATION: Not reported (self study involving participants reading brochures). At baseline participants spent 30 min restricted to the first 2 intervention sections. At each follow up (=booster session; 1, 3 and 6 months), participants spent "at least 15 mins with access to all sections to their intervention" THEORETICAL BASIS: Not reported (assumed broadly consistent with Groups 1 and 2 as content was matched) STIs COVERED: Not reported (assumed similar to Groups 1 and 2 as content was matched) *Results from groups 2 and 3 were found not to differ significantly on outcomes of interest and were pooled for comparison with results from group 1
Outcomes	Not stated whether primary or secondary: Knowledge (STIs, reproductive health, condoms) Behaviour (self-reported, in last 3 months): - Number of sexual partners (0=abstinent) - Frequency of condom use (6-point scale)

	- Incorrect condom use (condoms broke, leaked or fell off) Health problem: STI incidence: - Self-reported STI acquisition (whether diagnosed with any of 9 STIs including viruses such as genital warts, HIV and hepatitis B) - Clinic measure of chlamydia trichomatis based on self-provision of an introital swab
Notes	COST DATA: Stated only that participants received $10 and a trinket for each visit, with an extra $10 at the final visit

Risk of bias

Bias	Authors' judgement	Support for judgement
Adequate sequence generation?	Low risk	Stated that participants were assigned to either the interactive video or one of the two controls using a random numbers table
Allocation concealment?	Unclear risk	No information provided.
Blinding? All outcomes	Unclear risk	No information provided.
Incomplete outcome data addressed? All outcomes	Unclear risk	No information provided on numbers randomised per study group or on those completing follow up in each group. No reasons given for attrition. Sample sizes not provided for any outcome measures
Free of selective reporting?	Unclear risk	Most outcomes reported in the methods also appear in the results. However, the number of sexual partners is only reported for the category zero (=abstinence). It is unclear from the methods section whether this represents selective reporting or an *a priori* intentional focus on abstinence within this broader outcome
Free of other bias?	Unclear risk	Unclear

Ferguson 1998

Methods	DESIGN: Cluster RCT LENGTH OF FOLLOW-UP: 8 weeks and 3 months post treatment DATA ANALYSIS: Intervention received (only participants who completed follow up were included in analysis). ATTRITION RATE: Overall attrition rate 11 (17%). Attrition at 8 weeks and 3 months respectively: Group 1: 0/33 (0%); 3/33 (9%); Group 2: 0/30 (0%); 8/30 (27%) UNIT OF DATA ANALYSIS: Individuals (not neighbourhoods). No intra-class correlation coefficient reported SAMPLE SIZE CALCULATION: Powered 0.8 with alpha=0.05 to detect an effect size of 0.5. However it is not stated to which outcome(s) this applies and the calculation does not appear to take into account the cluster design. Stated that an effect size of 0. 5 with sample size of 63 is low and one or more hypothesis tests would be expected to yield non-significant results

	EQUIVALENT STUDY GROUPS AT BASELINE: Limited baseline data were provided and suggest that the experimental and comparison groups were similar in terms of their knowledge, age and college grade. Socio-economic and sexual health data were not provided, though the author stated that the neighbourhoods were homogeneous in their average household income ranges. However, there were differences between groups at the study outset in the proportion who were sexually active (76% versus 60%). As only four communities were randomised, with only two per arm, other unreported chance imbalances may be likely PROCESS EVALUATION: Not reported
Participants	NUMBER RANDOMISED: 63 AGE: mean 13; range 12 to 16 years GENDER: All female SOCIO-ECONOMIC STATUS: Not reported specifically for participants but mentioned for the setting in general (see Setting below) ETHINCITY/RACE: African-American (100%) LOCATION: USA; Charlottesville, Virginia; urban. PREVIOUS STI: Not reported SEXUAL RISK BEHAVIOUR: The majority of participants (76% in experimental group and 60% in comparison group) reported not ever having been sexually active at the start of the study. Of those who were sexually active, use of effective contraceptives for the most recent sexual intercourse at the start (pretest) was reported by 63% in the experimental group and 83% in the comparison group OTHER: Inclusion of participants was contingent upon: having already successfully completed a pregnancy prevention programme (Camp Horizon); not being pregnant; and having never given birth
Interventions	NAME OF STUDY: Not stated **GROUP 1: Intervention: Culturally specific peer-led education and skills based pregnancy prevention programme** (n = **33**) YEAR STARTED: Not stated PROVIDER(S): African-American females aged 12 to 16 years who had been selected as peer counsellors and had received a 10-week training programme devised by the author. Four were assigned to one experimental neighbourhood group and five to another. They led group discussions and facilitated role playing sessions SETTING(S): Not explicitly stated but community based (urban public housing developments) in which average household income was 125% of federal poverty level, 80% of families were headed by adolescent mothers and 98% of residents were African-American TYPE: Information/education (contraception use; preventing pregnancy; delaying sexual activity); Practical skills (leadership skills; communication skills; sexual assertiveness skills) DURATION: 2 hours per week for 8 weeks THEORETICAL BASIS: Not reported STIs COVERED: STIs in general and HIV/AIDS **GROUP 2: Comparison group: Individual-led pregnancy prevention programme** (n = **30**) Limited details provided. The comparison group differed primarily from the peer-led experimental group in that the author alone taught the content, which was described as containing life management, family relations, academic and career modules and sexual and reproductive education
Outcomes	PRIMARY/SECONDARY: Not stated which outcomes were primary. A statistical power calculation was provided, but it was not stated to which outcomes it applies (the power calculation might apply to one or both of two survey instruments that were used to assess most of the outcomes; if so, the outcomes would effectively all be co-primary - however, this is unclear) Behaviour (pregnancy prevention skills; frequency of sexual activity; delayed first intercourse; effective contraceptive use)

	Knowledge (about reproduction, contraception and STIs)
	Health problem or state (pregnancy)
Notes	COST DATA: None reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Adequate sequence generation?	Low risk	Neighbourhoods were randomly allocated to intervention by coin tossing. However, individuals (the unit of analysis) do not appear to have been randomly allocated. No explanation was given of how individuals were allocated within the cluster design
Allocation concealment?	Unclear risk	No information provided.
Blinding? All outcomes	Unclear risk	No information provided. The author was involved in the conception, conduct and analysis of the study
Incomplete outcome data addressed? All outcomes	High risk	Incomplete outcome data were not assessed in the analysis. However, the author noted that 8 females who dropped out ofthe comparison group had very low scores (not clear which scores) on the pre-test and 8-week post test and this may have possibly affected the overall 3-month findings for the comparison group. The author also observed that although 11 females dropped out of the study by 3 months, the average age and college grade remained the same. Note also that there was missing data on effective use of contraceptives due to under-reporting. A potential barrier to evaluation was that many sexually active participants did not answer the question on contraceptive use, leading to a small number of participants who reported using protection Attrition rates were higher in Group 2. No reasons given for attrition
Free of selective reporting?	Low risk	The outcomes were not clearly stated *a priori* and it is unclear which were primary or secondary. However, the reported outcomes each link to an hypothesis or question mentioned in the introduction, suggesting that outcome reporting was probably complete
Free of other bias?	High risk	There were differences between trial arms at baseline in the proportion ofyoung women sexually active. There were only two clusters per randomised trial group and the unit of analysis was individuals rather than clusters

Jaworski 2001

Methods	DESIGN: Single centre RCT
	LENGTH OF FOLLOW-UP: Immediately post-intervention and 2 months after intervention
	DATA ANALYSIS: Used an intention to treat analysis with last observations carried forward in lieu of missing data
	ATTRITION RATE: Not reported separately by group. Overall 70/78 participants attended the immediate post-intervention test (90%) and 67/78 participants completed 2 month follow up (86%)
	UNIT OF DATA ANALYSIS: Individuals; same as the unit of randomisation

	SAMPLE SIZE CALCULATION: Stated that power analyses using effect sizes from earlier work (reference provided) indicated that a sample size of 17 per group would provide 'good' (i.e. $\beta > 0.80$) power EQUIVALENT STUDY GROUPS AT BASELINE: Stated that the only difference between groups found was on decisional balance, where Group 3 scored higher (mean = 13.58) than Group 1 (mean = 12.91) and Group 2 (mean = 10.89); P = 0.05 Stated that, of 31 participants who reported exposure to other STD programmes (e.g. television), there were no differences between groups 1 and 2 (P = 0.21) or between groups 1 and 3 (P = 0.80) PROCESS EVALUATION: A 7-item group experience measure assessed participants' perceptions of the session delivery and their comfort and enjoyment of the group (data presented but not extracted)
Participants	NUMBER RANDOMISED: 78 AGE: Not reported separately by group. Overall mean = 20 years SOCIO-ECONOMIC STATUS: Not reported. ETHINCITY/RACE: Not reported separately by group. Overall 76% of participants were European-American LOCATION: USA; Syracuse, New York. PREVIOUS STI: Stated that only a small proportion of women reported a recent STD (no further details provided) SEXUAL RISK BEHAVIOUR: Not reported separately by group. Women had to be sexually active during the previous 2 months for inclusion in the trial, but were excluded if they used condoms at every episode of vaginal, oral and anal sex during the previous 2 months or if pregnant or trying to become pregnant. Overall, 48% reported ≥ 3 lifetime sexual partners; 65% reported unprotected vaginal sex in the previous 2 months; and 53% were in committed relationships and not using condoms OTHER: Participants were those who volunteered for a study of 'College Women's Health' for either partial fulfilment of course requirements or for extra credit in undergraduate psychology courses (suggests the population was limited to psychology undergraduates)
Interventions	**GROUP 1: Information-Motivation-Behavioural skills (1MB) group with motivational enhancement (n randomised not reported)** YEAR STARTED: Not reported. PROVIDER(S): Two facilitators who were advanced graduate students in clinical psychology with training in sexual health SETTING(S): Not explicitly stated but appears to be a university health and behaviour centre TYPE: Small-group intervention with approximately 8 participants per group in which sexual risk reduction was normative and supported and the threat of STIs and promotion of behaviour change was personalised. Comprised information/education about STI transmission, consequences, prevention and treatment. Also included practical skills development, based on sexual communication role playing, with a focus on assertive-ness skills. Facilitators followed detailed manuals to protect against facilitator drift and contamination of intervention components DURATION: One session lasting 150 minutes conducted 1 week after the baseline survey. The session was divided into six consecutive segments, of duration 10, 30, 20, 45,15 and 30 minutes, for each of which a detailed description is provided (information not extracted) THEORETICAL BASIS: Based on the Information-Motivation-Behavioural skills model (IMB) strengthened with a motivational enhancement approach to personalise the threat of STIs and promote behaviour change STIs COVERED: STIs in general. **GROUP 2: Time-matched information provision group (INFO) (n randomised not reported)** YEAR STARTED: Not reported. PROVIDER(S): As Group 1.

	SETTING(S): As Group 1. TYPE: Structured as Group 1 but based on information provision only (information/education about STI transmission, consequences, prevention and treatment). Facilitators avoided personalising the threat of STIs DURATION: As Group 1. THEORETICAL BASIS: None specified; information provision only STIs COVERED: As Group 1. **GROUP 3: Waiting list control group (n randomised not reported)** Received an intervention identical to Group 2, but this occurred after Group 3's follow-up survey
Outcomes	(Not stated which were primary): Knowledge: about STI transmission, consequences, prevention and treatment; Attitudes towards condoms and perceptions of sexual risk (assessed with 3 instruments); Behavioural intentions (based on an 8-item instrument); Behavioural skills: sexual assertiveness scores; Self-reported sexual behaviour: vaginal sex without condom; vaginal sex with condom; oral sex without condom; oral sex with condom; number of sexual partners
Notes	COST DATA: None reported.

Risk of bias

Bias	Authors' judgement	Support for judgement
Adequate sequence generation?	Unclear risk	Stated only that participants were assigned randomly, with no explanation of the method used
Allocation concealment?	Unclear risk	Stated that participants generated code names to ensure confidentiality and reduce error from self-presentation bias. However, it is unclear whether this would have resulted in allocation concealment
Blinding? All outcomes	Unclear risk	Stated that immediately post-intervention the survey was administered by a research assistant who was not present at the groups and who was masked to the study condition. But not stated whether the research assistants who administered the 2 month follow up survey were also blinded
Incomplete outcome data addressed? All outcomes	Unclear risk	An intent to treat analysis was used, with last observations carried forward to account for missing data. Stated that the 67 completers at 2 month follow up did not differ from the dropouts (n = 11) as a function of group assignment (P = 0.44) and that no differences were found on the dependent measures between the completers and dropouts Note however that attrition was not reported separately by study group and no reasons were given for attrition
Free of selective reporting?	Low risk	All outcomes mentioned in the methods section were reported in the results section

Free of other bias?	Unclear risk	Unclear

Jemmott 2005

Methods	DESIGN: Single centre RCT. LENGTH OF FOLLOW-UP: 3, 6 and 12 months after intervention. DATA ANALYSIS: Analysis appears to be based on the numbers completing follow up. Sample sizes not reported for outcome point estimates ATTRITION RATE: Completed 3 months: Group 1=208/219, 95%); Group 2=210/228 (92%); Group 3= 225/235 (96%) Completed 6 months: Group 1=206/219 (94%); Group 2=206/228 (90%); Group 3= 221/235 (94%) Completed 12 months: Group 1 = 199/219 (91%); Group 2=196/228 (86%); Group 3= 209/235 (89%) Reported that there were no significant differences between the groups in the numbers who attended at least one, two or all three follow up assessments Overall, 87.8% and 82.3% returned, respectively, for 6 and 12 month STI examinations; reported that the return rates did not differ significantly between the groups UNIT OF DATA ANALYSIS: Individuals (as randomised). SAMPLE SIZE CALCULATION: With a=0.05, 2-tailed, a total sample size of 506 participants completing the trial was projected to provide a power of 80% to detect a 0. 25 SD difference in self-reported frequency of unprotected sex between each of Groups 1 and 2 and Group 3 EQUIVALENT STUDY GROUPS AT BASELINE: The groups appear balanced and analyses found no statistically significant group differences, for age, proportion African-American, proportion with children, proportion living with mother, knowledge of STIs and condom use, beliefs or sexual behaviour variables PROCESS EVALUATION: Participants reported their satisfaction with the intervention and its learning value (data not extracted)
Participants	NUMBER RANDOMISED: 682 AGE, mean (SE) years: Group 1 = 15.53 (0.10); Group 2=15.49 (0.10); Group 3=15.52 (0.10); overall range 12 to 19 SOCIO-ECONOMIC STATUS: Not reported other than setting was a low income inner city location ETHINCITY/RACE: Overall 68% African-American; 32% Latino (of whom 92.7% were Puerto Rican) Proportion African-American: Group 1=68.1%; Group 2=68.0%; Group 3=67.6% LOCATION: USA, Pennsylvania; inner city area ofPhiladelphia PREVIOUS STI: Tested positive for chlamydia, gonorrhoea or trichomoniasis at baseline: Group 1=22.8%; Group 2=26.0%; Group 3=16.9% SEXUAL RISK BEHAVIOUR: Participants were all sexually experienced but not pregnant % sexually active in past 3 months: Group 1=85.6; Group 2=85.8; Group 3=89.8 Mean (SE) number of days unprotected sex in past 3 months: Group 1=2.52 (0.50); Group 2=3.22 (0.45); Group 3=3.02 (0.50)

	Mean (SE) number of sex partners in past 3 months: Group 1 = 1.04 (0.05); Group 2=1. 14 (0.05); Group 3=1.11 (0.04) % with multiple partners in past 3 months: Group 1 = 12.3; Group 2=18.9; Group 3= 16.4 OTHER: Participants had volunteered for the Women's Health Project and were patients at the adolescent medicine clinic where the interventions took place
Interventions	**GROUP 1: Skills-based HIV/STI risk reduction intervention** (n = **235**) YEAR STARTED: Not reported. PROVIDERS: 14 African-American women of mean age 38.2 years and with at least a degree qualification and experience working with inner-city adolescents (not reported how the 14 were distributed across the intervention groups) SETTING: Inner city hospital-based adolescent medicine clinic that provided confidential and free family planning services for low income youth TYPE: Single session with groups of 2 to 10 (mean 5.3) participants involving videotapes, games and experiential exercises providing information/education about HIV/STI risks & transmission, risk reduction responsibilities & condom use. Also provided practical skills development for condom use (with an anatomical model) and condom negotiation (based on role playing) DURATION: 250 minutes; single session. THEORETICAL BASIS: Based on Cognitive Behavioural Theory (references provided) and formative elicitation research STIs COVERED: HIV and STIs in general. **GROUP 2: Information-based HIV/STI risk reduction intervention** (n = **228**) TYPE: As Group 1 in structure, information content and timing, but omitted practical skills development (condom practice and condom negotiation role play) components All other details as Group 1. **GROUP 3: Health promotion control intervention** (n = **219**) TYPE: Participants received a health promotion control intervention designed to be as valuable and enjoyable as the Group 1 and Group 2 interventions. It covered information/education, beliefs and practical skills development in relation to reducing the risks of cardiovascular disease, cancer and stroke. The focus was on food selection and preparation, physical activity, breast self examination, smoking and alcohol use. There was no HIV/STI content STIs covered: None. All other details as Group 1.
Outcomes	PRIMARY: Self-reported number of days of unprotected sexual intercourse in the previous 3 months SECONDARY: Number of days of sexual intercourse whilst intoxicated (drugs and alcohol) in the previous 3 months; Number of days of unprotected sex whilst intoxicated (drugs and alcohol) in the previous 3 months; Number of sexual partners in the previous 3 months; Incidence of biologically confirmed chlamydia, gonorrhoea and/ or trichomoniasis in the previous 3 months; Intentions to use condoms; Knowledge about STIs and condom use; Beliefs about using condoms.

Notes	COST DATA: Reported that participants were reimbursed up to $120 for participation ($40 for completing pre- and post-intervention questionnaires; $25, $25 and $30 for attending 3, 6 and 12 months follow up respectively)

Risk of bias

Bias	Authors' judgement	Support for judgement
Adequate sequence generation?	Low risk	Stated that participants were stratified by age and randomly allocated to the intervention groups based on computer-generated random number sequences (no other details provided)
Allocation concealment?	Unclear risk	No information provided.
Blinding? All outcomes	Low risk	Stated that proctors blind to the participants' intervention assignment collected questionnaire data and that STI screening was done by clinicians blind to participants' intervention assignment. However, it is unclear whether the proctors were involved in outcome assessment or just data collection
Incomplete outcome data addressed? All outcomes	Unclear risk	Analysis appears to be based only on those who completed follow up, but sample sizes were not reported for outcomes. Stated that there were no significant differences between groups in the numbers who attended follow up assessments or who returned for STI examinations. However, statistically significant differences were observed between completers and drop outs for: frequency of sex while intoxicated, frequency of unprotected sex while intoxicated, proportion not living with mother (all were higher among drop outs); and ethnicity (Latinos were more likely to drop out than African-Americans)
Free of selective reporting?	Low risk	Data for all the outcomes reported in the methods section were provided in the results section
Free of other bias?	Unclear risk	Unclear

Kershaw 2009

Methods	DESIGN: Multi-centre RCT (conducted at 2 clinics) LENGTH OF FOLLOW-UP: Based on the chronology of pregnancy, where baseline was at the 2nd trimester (a mean of 18 weeks of gestation) Follow up dates: 3rd trimester (mean 35 weeks gestation; circa 17 weeks after baseline) ; 6 months postpartum (mean 27 weeks postpartum; circa 49 weeks after baseline); 12 months postpartum (mean 53 weeks postpartum; circa 75 weeks after baseline) DATA ANALYSIS: Based on intention to treat, using a random-effects regression approach that allows missing data to be included in the analysis. However, it was not explained how the missing data were analysed. Stated that analyses were not statistically different on primary outcomes by study site (all $P > 0.05$) and all analyses were therefore combined across the two study sites. The analyses corrected for differences among the groups in baseline variables which included health state. However, no information was provided on how health state was measured (it can be inferred that it was a composite measure expressed as a score) ATTRITION RATE: Stated there were no significant differences between the groups in retention at each follow up Number (%) completing each assessment: 3rd trimester: Group 1=287 (90); Group 2= 292 (87); Group 3=355 (90); 6 months postpartum: Group 1=250 (79); Group

	2=241 (72); Group 3=296 (75); 12 months postpartum: Group 1=261 (82); Group 2=273 (81) ; Group 3=306 (78) UNIT OF DATA ANALYSIS: Individuals (as randomised). SAMPLE SIZE CALCULATION: Not reported. Study was powered statistically to detect differences in incident STI, but no quantitative information on power was presented. A secondary power analysis was conducted for detecting a reduction in preterm births EQUIVALENT STUDY GROUPS AT BASELINE: Reported that after randomisation, by chance, Group 1 were more likely to be African-American (86%) than Group 2 (80%) (P = 0.003) and Group 1 were less likely to have positive health behaviours (Group 1 mean score=33.3; Group 2=33.3; Group 3=34.3) (P = 0.026). No other baseline data were provided PROCESS EVALUATION: None reported.
Participants	NUMBER RANDOMISED: 1047 AGE: Not reported separately by study group. Overall mean (SD) = 20.4 (2.6) years (range 14 to 25 years); 49% were aged < 20 years SOCIO-ECONOMIC STATUS: Implied that the study participants were low income ETHINCITY/RACE: Not reported separately by study group. Overall, African-American = 80%; Latina=13%; White=6%; Other or mixed race=1% LOCATION: USA; Atlanta, Georgia (1 clinic; 546 participants = 52%) and New Haven, Connecticut (1 clinic; 503 participants = 48%) (numbers do not sum exactly to the total number randomised) PREVIOUS STI: Not reported separately by study group. Stated only that more than half had a history of an STI diagnosis SEXUAL RISK BEHAVIOUR: The only sexual risk information reported at baseline was mean (SE) % condom use in the past 6 months [Group 1=39.29 (37.7); Group 2= 35.54 (37.0); Group 3=35.93 (38.1)] and mean (SE) number of unprotected sex acts in the past 30 days [Group 1=5.26 (6.8); Group 2=6.45 (8.3); Group 3=5.66 (7.6)]
Interventions	**GROUP 1: Group prenatal care with an integrated HIV component** (**Centering Pregnancy Plus**) (n = **318**) YEAR STARTED: September 2001 to December 2004 PROVIDER(S): A trained practitioner (e.g. midwife or obstetrician) (unclear whether one or more) SETTINGS: Two widely separated (Georgia & Connecticut, USA) public obstetrics clinics in university-affiliated hospitals TYPE: 10 structured group sessions, each with 8 to 12 women (on average 8), providing antenatal support during pregnancy. In each of sessions 4, 5 and 7 some content was devoted to practical skills development (HIV prevention skills): Session 4 included participants viewing testimonials of adolescents with HIV to reinforce risk perception; group discussion of the pros and cons of condom use; and goal setting for appropriate sexual behaviour. Session 5 developed partner communication skills through role play and modelling. Session 7 reinforced these skills and revisited behaviour goals DURATION: 10 sessions, each of 120 minutes (total intervention time 20 hours across the pregnancy; session spacing not reported). The time devoted to HIV prevention skills was 40 minutes in each of sessions 4, 5 and 7 (total HIV-related time 2 hours). The intervention was delivered during weeks 16 to 40 of gestation THEORETICAL BASIS: The HIV prevention components were based on Social Cognitive Theory and the Ecological Model, adapted from previous interventions STIs COVERED: HIV, chlamydia and gonorrhoea (focus appears to be on HIV but chlamydia and gonorrhoea were reported as biological outcomes) **GROUP 2: Group prenatal care** (**Centering Pregnancy**) (n = **335**) YEAR STARTED: As Group 1. PROVIDER(S): As Group 1.

	SETTING(S): As Group 1. TYPE: As Group 1 except there was no HIV content or focus on skills building DURATION: As group 1 (total time 20 hours), but none of this devoted to HIV prevention THEORETICAL BASIS: None reported. STIs COVERED: None (prenatal care programme). **GROUP 3: Individual standard prenatal care** (n = **394**) YEAR STARTED: As Group 1. PROVIDER(S): As Group 1. SETTING(S): As Group 1. TYPE: Structured as for Groups 1 and 2, but there was no HIV prevention component and participant contact time was less, consistent with traditional prenatal care. Individual rather than group based DURATION: Number of sessions as Group 1 but each session shorter duration (10 to 15 minutes) (total time across the pregnancy 2 hours) THEORETICAL BASIS: None reported. STIs COVERED: None (prenatal care programme).
Outcomes	(Not reported whether primary or secondary): Incidence of chlamydia and/or gonorrhoea; Repeat pregnancy (6 and 12 months postpartum); Sexual behaviour: % condom use among sexually active participants; number of unprotected sex occasions; Sexual communication (4 items, including condom negotiation); Risk perception for HIV and STIs; Self efficacy of condom use; Knowledge of HIV and STI risks.
Notes	COST DATA: Reported only that participants were paid $20 for each interview (total $60 for all follow up interviews)

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Adequate sequence generation?	Low risk	Participants were allocated using a password-protected computer-generated randomisation sequence with the allocation goal of 30% to Group 1, 30% to Group 2 and 40% to Group 3. No other details reported
Allocation concealment?	Low risk	Reported that allocation was concealed from participants and research staffuntil eligibility screening was completed and study condition was assigned
Blinding? All outcomes	Low risk	Stated that it was not possible to have treatment blinded, but all measurement and data collection were conducted in blinded fashion independently of the care setting. From this description it is unclear whether the outcome assessors who analysed and interpreted the data were blinded

Incomplete outcome data addressed? All outcomes	Unclear risk	The analysis was reported to have included missing data on an intention to treat basis. However, too few analytical details were provided to be sure how the missing data were handled Attrition rates were balanced between trial groups but the reasons for attrition were not reported and therefore it is unclear whether they were similar between the groups
Free of selective reporting?	Low risk	All outcomes mentioned in the methods section were also reported on in the results section. But note partial reporting of effect sizes (d) for some group comparisons, outcomes and follow up times
Free of other bias?	Unclear risk	Statistically significant differences between trial groups at baseline on two variables. Limited baseline data presented prohibiting full assessment of baseline equivalence (see 'Methods' above)

Koniak-Griffin 2003

Methods	DESIGN: Cluster RCT LENGTH OF FOLLOW-UP: 3, 6 and 12 months DATA ANALYSIS: Stated that an intention to treat procedure was used with participants remaining in the analyses regardless of the number of sessions attended. However, results were only presented for 497 participants (87%) who provided data for 'all five time points' (unclear what the five time points equate to, as baseline, 3, 6 and 12 months equates to 4 time points) ATTRITION RATE: Attrition was reported as 525/572 participants (8%) at 12 months. Not reported separately by study group but stated that differential attrition was not observed across the groups. No reasons given for attrition UNIT OF DATA ANALYSIS: Stated that data from all sites were analysed collectively because the same curriculum was offered at each site (=school) and the questionnaires administered were identical across sites. The unit of analysis appears to be individuals (data reported as numbers and proportions of the population) whereas the unit of randomisation was schools SAMPLE SIZE CALCULATION: Not reported. No intra-cluster correlation coefficient mentioned EQUIVALENT STUDY GROUPS AT BASELINE: Stated that the study groups were nearly equivalent in terms of socio-demographics and that there were no differences between the groups in scores from the social desirability scale. Statistically significant group differences at baseline were: Proportion pregnant: Group 1=70%; Group 2=58%; $P < 0.01$. Intention to use condoms score: stated lower in Group 1 (no data provided); $P < 0.05$ AIDS knowledge score: stated lower in Group 1 (no data provided); $P < 0.01$ Hedonistic beliefs about condom use score: stated lower in Group 1 (no data provided) ; $P < 0.05$ PROCESS EVALUATION: Observations on a sub-sample of classes (number not specified) were done to maintain quality assurance of the curriculum. Intervention and control were rated by participants on a 5-point Likert-type scale (e.g. 'average', 'outstanding'). Stated that participants' reactions did not differ between the two groups (data not extracted)
Participants	NUMBER RANDOMISED: 572 (of which 497 analysed) AGE: mean (SD), years: Group 1 = 16.64 (1.16); Group 2=16.74 (1.04) SOCIO-ECONOMIC STATUS:

	Mean (SD) Hollingshead 4-factor score: Group 1=30.06 (10.64); Group 2=30.97 (10. 63) Mean (SD) grade level (range 7 to 12): Group 1 = 10.43 (1.14); Group 2=10.63 (1.09) Mean (SD) acculturation score (Latinas only; range 1 to 5): Group 1=3.43 (0.84); Group 2=3.52 (0.85) Marital status, n (%): Group 1: single=247 (73%*); married=19 (6%*); living together= 72 (21%). Group 2: single=110 (73%); married=6 (4%); living together=31 (21%) ETHINCITY/RACE, n (%): Group 1: Latina=266 (77.8%*); African-American = 60 (17.5%*); Asian = 9 (2.6%); White=6 (1.8%); Other=1 (0.3%). Group 2: Latina=114 (77.6%*); African-American = 29 (19.7%*); Asian = 0; White=3 (2.0%); Other=1 (0. 7%) LOCATION: USA; California; 4 school districts in LA County. PREVIOUS STI: Not reported. SEXUAL RISK BEHAVIOUR, baseline data: Sexually active during past 3 months, n (%): Group 1=264 (76%); Group 2=109 (73%) Steady partner=yes, n (%): Group 1=304 (88%); Group 2=131 (87%) Steady partner=no, n (%): Group 1=41 (12%); Group 2=19 (13%) Pregnant=yes, n (%): Group 1=241 (70%); Group 2=87 (58%). Pregnant=no, n (%): Group 1 = 105 (30%); Group 2=63 (42%).
Interventions	NAME OF STUDY: Project CHARM (Children's Health And Responsible Mothering) **GROUP 1: HIV prevention programme** (**CHARM 1**) (n = **347 analysed; number randomised not reported by group**) YEAR STARTED: Not reported. PROVIDER(S): Trained nurse facilitators delivered content. Questionnaires were read to small groups by specially trained research staff SETTING(S): Schools with pregnant minor or young parents' programmes TYPE: Information/Education about the impact of HIV and AIDS on pregnant women and their children, prevention of HIV, sexual risk reduction and sexual responsibility. Practical skills development (unspecified skill-building activities). Resource provision: Participants were given coupons to be redeemed for free condoms throughout the study DURATION: Four 2-hour sessions. Completion of questionnaires took45 to 90 minutes (not stated whether this was per questionnaire or in total) THEORETICAL BASIS: Social Cognitive Theory and the Theory of Reasoned Action; based on the 'Be Proud! Be Responsible!' programme STIs COVERED: HIV/AIDS. **GROUP 2: Health promotion programme** (**CHARM 2**) (n = **150 analysed; number randomised not reported by group**) YEAR STARTED: Not reported. PROVIDER(S): Trained nurse facilitator who was not involved in group 1 delivered the content. Questionnaires were read to small groups by specially trained research staff SETTING(S): As group 1. TYPE: Information/Education about healthy living parenting. Practical skills development (unspecified skill-building activities, e.g. coping and communications). Resource provision: As group 1 DURATION: As group 1. THEORETICAL BASIS: None stated. STIs COVERED: None stated.

Outcomes	Not reported whether primary or secondary: Knowledge of: AIDS; condom use. Behavioural intentions for: Condom use. Behaviour (reported) for: Number of episodes of unprotected sex in the past 3 months; number of sex partners in the past 3 months; condom use Awareness/Beliefs: Self-efficacy beliefs (reported as beliefs rather than self-efficacy per se); condom use beliefs (hedonistic and prevention); partner reaction beliefs; perceived behavioural control.
Notes	COST DATA: Stated only that participants received: $15 on completion of each set of questionnaires as partial compensation for their time and expenses; $10 per class attended; and, upon completion of the study, a charm with the birthstone of their baby

Risk of bias

Bias	Authors' judgement	Support for judgement
Adequate sequence generation?	Unclear risk	No information provided
Allocation concealment?	Unclear risk	No information provided
Blinding? All outcomes	Low risk	Stated that the specially trained research staff who read questionnaires to women were blind to the experimental conditions. However, no details ofthe blinding method were reported and it is unclear whether other outcome assessors, e.g. data analysts, were also blinded
Incomplete outcome data addressed? All outcomes	Unclear risk	Although an intention to treat analysis was stated, the analysis was performed only on those participants who completed all follow-up sessions Attrition rates were not reported separately by trial group, though the authors state that no differential attrition was found. No reasons were given for attrition and it is therefore not clear whether reasons for attrition differed between trial groups
Free of selective reporting?	Low risk	Results were presented for all outcomes mentioned in the methods section (note that condom use was also reported in the results, although not mentioned in the methods section)
Free of other bias?	Unclear risk	The unit ofanalysis appears to be individuals (data reported as numbers and proportions ofthe population) whereas the unit of randomisation was schools (see 'Methods' above)

Maynard 1994

Methods	DESIGN: Multi-centre RCT LENGTH OF FOLLOW-UP: Minimum 25 months after enrolment; mean 29 months (range of means 28 to 30 months depending upon location); 3% of participants had follow up at or beyond 42 months

	DATA ANALYSIS: Only participants who completed follow-up were analysed. In addition, mentioned in Table 3 that sample sizes for some items were smaller due to further missing values ATTRITION RATE: Overall 35.6% did not complete follow up surveys UNIT OF DATA ANALYSIS: Individuals SAMPLE SIZE CALCULATION: No information provided EQUIVALENT STUDY GROUPS AT BASELINE: Difficult to judge because baseline characteristics are reported only for selected outcomes and do not distinguish between the interventions. PROCESS EVALUATION: Attendance at workshops was recorded: Completed at least 1 workshop: Chicago 90%; Newark 39%; Camden 58%. Attended all workshops: Chicago 79%; Newark 10%; Camden 24%. Participation in family planning workshop ranged from 21% in Newark to 85% in Chicago. Authors noted that case managers were trained in parenting skills but in reality had few opportunities to offer individual counselling in this area
Participants	NUMBER RANDOMISED: 5297 randomised but the study focuses on 3412 who completed follow up (1691 from Group 1 and 1721 from Group 2). Stated that these were representative of the full sample (no data provided) AGE: mean 18.4 years GENDER: All women SOCIO-ECONOMIC STATUS: Received welfare as child occasionally or always: 63% Grew up in single-parent household: 42% Living with employed mother: 15.8% Living with unemployed mother: 31.6% Not living with mother: 52.7% Completed high school or GED: 33.3% In high school or GED: 34.7% Dropped out: 32.0% ETHINCITY/RACE (data for 3412 participants): black 2580 (76%); Hispanic 562 (17%); white 236 (7%) LOCATION: USA; Chicago, Camden, Newark; assumed urban PREVIOUS STI: Not reported SEXUAL RISK BEHAVIOUR: Had never used contraception: 27.2% Did not use contraception at last intercourse: 54.3% Average age at first contraception use: 15.9 years (sexually active on average for 3 years at enrolment) OTHER: Participants (in Group 1) were required to participate or be subject to a substantial reduction in benefits ($160 per month).
Interventions	NAME OF STUDY: Not stated **GROUP 1: Education and parenting skills programme for teenage mothers** (n = **1721**) YEAR STARTED: 1987 to 1990 PROVIDER(S): Trained case managers (50 to 60 cases each) SETTING(S): Stated only that conducted in 3 cities, each of which had high rates of unemployment, poverty and crime TYPE: Information/Education; practical skill development (personal skills; parenting skills; awareness of contraception methods and STIs); increased self-sufficiency

	DURATION (note inter-site variability): Overall duration: 3 days to 12 weeks Chicago: 6 workshops; total 9 hours over 3 consecutive days Camden, Newark: total number of workshops not stated; total 80 to 100 hours over 5 to 12 weeks Illustration of variability of duration for specific workshops: Family planning: ranged from 1.5 hours (Chicago) to 54 hours (Newark) Parenting: ranged from 1.5 hours (Chicago) to ~20 hours (Newark) Life skills: only offered as needed in Chicago; ~20 hours in Newark THEORETICAL BASIS: Not stated STIs COVERED: None specified: primarily a pregnancy management programme but did mention STIs in workshops **GROUP 2: Usual local welfare services provision for teenage mothers** (n = **1691**) Standard welfare provision: participants received Aid to Families with Dependent Children (AFDC) benefits and the limited support and services normally available under that programme OTHER: Benefits penalties (see participants section above) appear to be relevant only to Group 1, although this was not stated explicitly
Outcomes	PRIMARY/SECONDARY: Not stated which outcomes were primary or secondary. Behaviour (contraceptive use; choice of contraception) Health state (repeat pregnancy; pregnancy outcome)
Notes	COST DATA: none reported. Note that the outcomes were reported only as relative effects in the enhanced services intervention compared to regular services; they were only reported for location and ethnicity groups, with no overall intervention effect given.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Adequate sequence generation?	Unclear risk	No information provided
Allocation concealment?	Unclear risk	No information provided
Blinding? All outcomes	Unclear risk	No information provided
Incomplete outcome data addressed? All outcomes	Unclear risk	The study only analysed data for 3412 participants who completed follow up (of the 5297 randomised) Attrition rates were not reported separately by trial group. No reasons were given for attrition and it is therefore not clear whether reasons for attrition differed between trial groups
Free of selective reporting?	Unclear risk	Difficult to judge because several outcomes were stated in the methods but it was not explained whether these would be included in a predictive model and/or reported separately. Probably more outcome data would have been available than were reported as the results given are only an overall summary. All 4 outcomes were reported but only according to ethnicity and site (not overall)

Free of other bias?	Unclear risk	Unclear whether trial groups were equivalent at baseline, due to limited information

Morrison-Beedy 2005

Methods	DESIGN: Single-centre RCT (pilot study) LENGTH OF FOLLOW-UP: 3 months (after last intervention group session) DATA ANALYSIS: Stated that although only 48 of 62 randomised participants had completed the post-treatment assessment, data from all 62 were used in the analyses to provide estimates of effect. Also stated that generalised estimating equations (GEE) were used to handle missing data, so that all available data can be used in the analyses. But did not explain the method for imputing missing data ATTRITION RATE: Not reported separately by study group. Overall, 62/62 participants (100%) completed all intervention sessions and 48/62 participants (77.4%) (reported as 78%) completed the 3-month follow up UNIT OF DATA ANALYSIS: Individuals; same as the unit of randomisation SAMPLE SIZE CALCULATION: Not reported. Stated that sample size was intentionally small (pilot study) and that because sample size was small, effect sizes were calculated using post-treatment data (effect sizes calculated with post-treatment data from randomised trials are unbiased, even in the presence of significant baseline differences; reference cited) EQUIVALENT STUDY GROUPS AT BASELINE: Stated there were no observed pre-intervention differences between the study groups with respect to demographics, HIV-related knowledge or motivation. However, girls in the HIV intervention had higher levels of confidence in condom use (mean (SD) score from 5-item confidence scale: Group 1=4.0 (1.0); Group 2=3.2 (1.1); $P < 0.01$) PROCESS EVALUATION: None reported.
Participants	NUMBER RANDOMISED: 62 AGE: Not reported separately by study group. Overall: mean =17.3 years (SD 1.4; range 15 to 19) SOCIO-ECONOMIC STATUS: Not reported separately by study group. Overall: low income (received free school lunch programme)=28%; worked outside their home=53% (mean 15.6 hours/week; SD 9.1) ETHINCITY/RACE: Not reported separately by study group. Overall: White=59%; Black=29%; Hispanic=10%; Asian = 2% LOCATION: USA; Central New York State; urban. PREVIOUS STI: Not reported separately by study group. Overall: Reported a history of STIs=15% SEXUAL RISK BEHAVIOUR: Not reported separately by study group. Overall: Sexually active with male partner in past 3 months=62/62 (100%) (an inclusion criterion) Had ≥ 2 sex partners in past year=53% Reported previous pregnancy=21% Reported having a sex partner who injected drugs= 11% Reported having drunk alcohol before sex in past 3 months=39% Reported having taken drugs before sex in past 3 months=15% Reported anal sex=<5% (therefore anal sex data not considered further in the study report)

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Interventions	**GROUP 1: HIV risk reduction group** (n = **33**) YEAR STARTED: Not reported. PROVIDER(S): Two trained female interventionists who were nurses; one aged mid-20s and African-American; the other aged mid-40s and Caucasian. Trained research assistants also helped with some administrative tasks (participant recruitment and assistance if required with participants' self-report survey questionnaires) SETTING: Urban family planning clinic that provided services to economically disadvantaged teens. Sessions were held in the community education rooms of the clinic TYPE: Information/education: provision of information about HIV, transmission, risk reduction and prevention; increasing motivation to reduce risky behaviour. Practical skills development: provision of behavioural skills training that is ultimately necessary to reduce HIV risk, comprising: sexual assertiveness skills; negotiating condom use or other safer sex practices with partner; identifying high-risk situations. Delivered to groups of 6 to 8 participants. Each session included (unspecified) take-home activities for participants to complete for the following session. Refreshments (unspecified) were provided to participants DURATION: Four 2-hour sessions (interval not stated) held after school hours THEORETICAL BASIS: Information-Motivation-Behavioural Skills (IMB) Model STIs COVERED: HIV **GROUP 2: Health promotion control group** (n = **29**) YEAR STARTED: Not reported. PROVIDER(S): As Group 1 (the same personnel delivered both). SETTING(S): As Group 1. TYPE: Followed the same structure as Group 1 (i.e. participants had equivalent professional attention, time and group support), but did not target sexual or HIV-related behaviours. Instead, addressed anger management, caffeine use and nutrition (topics not addressed in Group 1). Comprised information/education, but unclear whether also practical skills development (not explicitly stated) DURATION: As Group 1. THEORETICAL BASIS: None reported. STIs COVERED: None (not applicable).
Outcomes	Not stated whether primary or secondary outcomes: Knowledge about HIV Risk perception (beliefs) Readiness to change risky behaviours (motivation) Behavioural intentions to reduce risk Pros and cons of condom use (perceptions/beliefs) Confidence in condom use (self-efficacy) Self-reported sexual risk behaviours in past 3 months: frequency of protected vaginal or anal sex; frequency of unprotected vaginal or anal sex; frequency of giving oral sex; frequency of receiving oral sex; number of male and female sex partners; communication frequency with partner about safer sex; frequency of drug use before sex; frequency of alcohol use before sex
Notes	COST DATA: Mentioned only that participants received the following financial incentives: $10 for completion of the pre-randomisation survey; $15 per intervention session attended to offset travel, babysitting and lost wages; and $15 for attending the follow-up assessment

Risk of bias

Bias	Authors' judgement	Support for judgement

Adequate sequence generation?	Unclear risk	No information provided.
Allocation concealment?	Unclear risk	No information provided.
Blinding? All outcomes	Unclear risk	No information provided.
Incomplete outcome data addressed? All outcomes	Unclear risk	The description of analysis implies that data for all randomised participants were included in the analyses but the method used in the generalised estimating equations was not explained Attrition rates were not reported separately by trial group. No reasons were given for attrition and it is therefore not clear whether reasons for attrition differed between trial groups
Free of selective reporting?	Low risk	The outcomes listed in the methods section are all reported in the results section
Free of other bias?	Unclear risk	Unclear

Orr 1996

Methods	DESIGN: Cluster RCT (appears to be equivalent to single-centre, involving one clinic each per intervention arm) LENGTH OF FOLLOW-UP: 5 to 7 months after intervention DATA ANALYSIS: Not explicitly stated but appears to be based on intervention received (attrition, although characterised separately, was excluded from analysis and reporting of the results) ATTRITION RATE: Overall attrition (not reported separately by intervention group): 97/209 (46%) (Table 2 shows sample size at follow up: 50 in Group 1; 55 in Group 2) UNIT OF DATA ANALYSIS: Individuals (not clinics). No intra-class correlation coefficient reported SAMPLE SIZE CALCULATION: No information provided EQUIVALENT STUDY GROUPS AT BASELINE: The authors stated that the two groups did not differ significantly in SES, race/ethnicity, number of recent sexual partners, sexual practices, condom use or history of pregnancy or STD. However, they also reported that the control group had a significantly higher percentage of White participants (50% versus 23%; P = 0.001) and was slightly older (18.0 versus 17.4 years; P = 0.06) PROCESS EVALUATION: Not reported
Participants	NUMBER RANDOMISED: 209 AGE: Mean 17.9 (SD 1.7; range 14 to 19) years GENDER: All female SOCIO-ECONOMIC STATUS: Median SES score 4 (lower class) ETHINCITY/RACE: Black: 55% (other not stated) LOCATION: USA; urban; no other details reported PREVIOUS STI: Treatment for chlamydia trachomatis was a study inclusion criterion; 21% had had a gonococcal infection SEXUAL RISK BEHAVIOUR:

	Had been pregnant: 49% Had never used a condom: nearly 49% Had never used a condom for STI protection: 38% Had never used a condom for contraception: 39% Used condom at last sexual encounter: 22% Reported an average of 4.9 (range 1 to 32) lifetime sexual partners Reported an average of 2.2 (range 1 to 12) sexual partners in the past year Had partners who had probably or definitely used injectable drugs: 5%
Interventions	NAME OF STUDY: Not stated **GROUP 1: Brief clinic-based condom use education and practical skills development session** (n = **58 after attrition; randomised number not stated**) YEAR STARTED: Not reported PROVIDER(S): Research assistant SETTING(S): Urban family planning clinics (2) and STI clinic (1) TYPE: Information/Education; practical skill development (correct condom use; negotiation skills for condom use with a partner) DURATION: 10 to 20 minutes THEORETICAL BASIS: Health Belief Model STIs COVERED: chlamydia **GROUP 2: Brief clinic-based condom use education session** (n = **54 after attrition; randomised number not stated**) Usual clinic procedure comprising an individual discussion with clinic nurse about STI (including the importance of partner treatment and condom use) and printed information on chlamydia infection. Differed primarily from Group 1 in not having a practical skills development (condom use practice) component
Outcomes	PRIMARY: SECONDARY: Not stated which outcomes primary or secondary Attitudes (towards the use of condoms and to STIs) Awareness/Beliefs (perception of being at risk) Behaviour (condom use) Knowledge (HIV and STI risk activities) Health problem or state (infection with Chlamydia trachomatis)
Notes	COST DATA: None reported. OTHER: The attitudes, awareness/beliefs and knowledge outcomes were included in a univariate risk model but not presented separately by intervention arm

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Adequate sequence generation?	Low risk	Two clinics were allocated to experimental or control intervention by coin toss. Authors stated there was an inability to achieve randomization within each of the family planning clinics
Allocation concealment?	Unclear risk	No information provided
Blinding? All outcomes	Unclear risk	No information provided

Incomplete outcome data addressed? All outcomes	Unclear risk	Dropouts were analysed and it was reported that they were more likely to have been sexually active for a shorter period before enrolment. However, analysis appears to have ignored the attrition; also, the attrition rates per intervention arm were not stated or the reasons for any differences between arms in attrition
Free of selective reporting?	Unclear risk	The principal outcomes described in the methods section are reported in the results. However, selective reporting is difficult to judge because the different outcomes were not all reported in the same way (some were presented only in a univariate risk model whereas others were presented separately by intervention arm)
Free of other bias?	High risk	This was a cluster RCT involving only one cluster (clinic) each per intervention arm, raising the possibility of chance imbalance in group characteristics. There were significant differences at baseline between the trial groups in a couple of demographic variables. Outcomes were analysed at the level of the individual not the cluster

Peipert 2008

Methods	DESIGN: Two-centre RCT LENGTH OF FOLLOW-UP: 24 months (also 6, 12 and 18 months but data not reported) DATA ANALYSIS: Stated that all comparisons among the primary outcomes were made according to the intention to treat principle (no definition of intention to treat was provided). Different methods for analysing missing data were evaluated for applicability, but not whether any were actually used ATTRITION RATE: Completed 24 month follow up: Group 1 = 166/272 (61%); Group 2=180/270 (67%) UNIT OF DATA ANALYSIS: Individuals (as randomised). SAMPLE SIZE CALCULATION: Based on 3 assumptions: that the baseline event rate for either an unintended pregnancy or an incident STI was at least 30% over 12 months in the high-risk sample; the intervention would reduce these to 15% or less; and the attrition rate would be 25% over 2 years. Approximately 250 participants would need to be enrolled in each arm to detect a 2-fold change in dual method use from approximately 15% to 30% (intervention RR=2.0) or a 50% difference in incidence of an STI or unintended pregnancy (intervention RR=0.5), with 90% power and type I error rate 2. 5% The authors stated that despite using an *a priori* sample size calculation and recruiting more than 500 participants, the statistical power to address some outcomes was limited. Approximately 28 to 31 % of participants reported male condom use before intervention, which increased to more than 40% after intervention in both groups. According to the authors, this increase in condom use in Group 2 limited the power to assess differences EQUIVALENT STUDY GROUPS AT BASELINE: Stated that, overall, randomisation achieved similar characteristics in the two study groups, but there were some slight imbalances: Participants in Group 2 were more likely to have had less than a high school education (29% versus 21%; P = 0.03), a history of STI (51% versus 43%; P = 0.07) and were more likely to have had 2 or more sexual partners in the past month (20% versus 11%; P = 0.02) PROCESS EVALUATION: Not reported.
Participants	NUMBER RANDOMISED: 542

	(Asterisks indicate minor differences in reported and correct percentages; the correct percentages are reported here) AGE, n (%): <20 years: Group 1= 82 (30); Group 2 =73 (27); 20 to 24 years: Group 1 = 140 (51); Group 2 = 133 (49); ≥25 years: Group 1 = 50 (18); Group 2 = 64 (24). SOCIO-ECONOMIC STATUS: Marital status, n (%): Single, never married: Group 1 = 240 (88*): Group 2=n 245 (91*) Married: Group 1 = 17 (6); Group 2 = 12 (4); Separated/divorced/widowed: Group 1 = 12 (4); Group 2 = 15 (6) Education, n (%): Less than high school: Group 1 = 56 (21); Group 2 = 77 (29); High school/GED: Group 1 = 105 (39); Group 2 = 95 (35); 2 year degree or some college: Group 1 = 87 (32); Group 2 = 76 (28); 4 year degree or more: Group 1 = 24 (9); Group 2 = 21 (8). ETHINCITY/RACE, n (%): White, non-Hispanic: Group 1 = 125 (46); Group 2 = 118 (44); Black, non-Hispanic: Group 1 = 70 (26); Group 2 = 71 (26); Hispanic: Group 1 = 43 (16); Group 2 = 50 (19); Other: Group 1 = 34 (13); Group 2 = 31 (11). LOCATION: USA; Providence, Rhode Island (urban). PREVIOUS STI, n (%): Group 1 = 116 (43); Group 2 = 137 (51). SEXUAL RISK BEHAVIOUR: History of unplanned pregnancy, n (%): Group 1 = 127 (47); Group 2 = 136 (50*) Contraceptive use, n (%): None: Group 1 = 88 (32); Group 2 = 96 (36) Hormonal: Group 1 = 95 (35); Group 2 = 82 (30); Male condoms: Group 1 = 75 (28); Group 2 = 84 (31). Lifetime sexual partners, n (%): 1 to 2: Group 1 = 34 (13); Group 2 = 36 (13); 3 to 5: Group 1 = 99 (36); Group 2 = 90 (33); 6 to 10: Group 1 = 69 (25); Group 2 = 60 (22); ≥11: Group 1 = 70 (26); Group 2 = 83 (31). Sexual partners in past month, n (%): 0: Group 1 = 40 (15); Group 2 = 33 (12); 1: Group 1 = 203 (75); 183 (68); ≥2: Group 1 = 28 (10*); Group 2 = 53 (20). New main partner in past 6 months, n (%): Group 1 = 71 (26); Group 2 = 68 (25) Inclusion criteria stated that women were sexually active with a male partner in the past 6 months and at high risk for unintended pregnancy or STI OTHER: All participants were negative for STIs and pregnancy at baseline (or were treated with direct observed treatment with a highly active antimicrobial). The authors reported the diagnostic criteria for PID and duration of infection with herpes simplex virus (HSV). Only participants with new-onset HSV infection after randomisation were eligible for this STI outcome
Interventions	**GROUP 1: Individual-tailored dual contraception interactive computer intervention** (n = **272**) YEAR STARTED: October 1999 to October 2003.

	PROVIDER(S): None reported; intervention was self-administered using an interactive computer system SETTING(S): Secondary care (hospital focusing on women and infants) TYPE: Information on dual contraception delivered by interactive computer system that gave on-screen and printed dual contraception feedback; tailored to an individual's readiness to change their condom and contraceptive behaviours, according to the stages of change in the Transtheoretical Model. The intervention comprised three different sessions, at baseline, 1 month and 2 months. Participants were also given a packet of information about dual methods and a sample condom DURATION: Stated that participants were scheduled to receive the 3 sessions over period of 80 days; however, also stated that sessions were delivered up to 2 months, which would approximate to 60 days. Duration of individual sessions not reported THEORETICAL BASIS: Transtheoretical Model. STIs COVERED: STIs in general (HIV not mentioned). **GROUP 2: Enhanced standard care computer intervention** (n = **270**) YEAR STARTED: As Group 1. PROVIDER(S): As Group 1. SETTING(S): As Group 1. TYPE: Standard contraceptive and STI prevention information delivered by interactive computer system that gave on-screen and printed standard care feedback; not tailored to individual participants. Included information about dual contraception method use. Comprised one session at baseline. Participants were also given a packet of information about dual methods and a sample condom DURATION: Not reported. THEORETICAL BASIS: Not reported. STIs COVERED: STIs in general, including HIV.
Outcomes	PRIMARY BEHAVIOURAL: Self-reported use ofdual methods ofcontraception (hormonal contraception plus barrier method; male condoms plus female condoms; condoms plus spermicide; or intrauterine device or sterilisation plus a barrier method) PRIMARY BIOLOGICAL: Incidence or recurrence of STI (gonorrhoea, chlamydia, Herpes simplex, trichomoniasis or acute PID) and/or unintended pregnancy SECONDARY (PROCESS MEDIATING): Stages of change for condom and contraceptive use; pros and cons of condom and contraceptive use; self-efficacy for condom and contraceptive use; processes of condom use; sexual assertiveness; anticipated partner reaction; victimisation history; and substance use
Notes	COST DATA: Reported only that recruited women received $25 at the time of randomisation and $20 at each annual examination to reimburse for child care and transportation. Participants in the intervention group also received an additional $10 for returning for 30-day and 60-day components of the computer intervention

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Adequate sequence generation?	Low risk	Stated that participants were assigned by a computer-generated random sequence into the intervention or control groups. Randomisation was stratified by study site and baseline contraceptive group
Allocation concealment?	Low risk	Stated that random assignment was separated from the executor of assignment (phone interviewer and nurse practitioner

		doing examinations) and that randomisation, allocation and concealment were all done by the computer at the participant's baseline assessment ensuring that assignment was free from bias
Blinding? All outcomes	Unclear risk	Stated that although true masking was difficult in this setting, every effort was made to mask the follow-up evaluators to the treatment allocation (but no details were provided)
Incomplete outcome data addressed? All outcomes	Unclear risk	The sample sizes (n, N and %) given for the primary outcomes suggest that all randomised participants were analysed in the groups to which they were randomised. However, it is unclear how the missing data were handled to achieve this. The choice of imputation method used was not reported. Attrition rates were balanced between trial groups, but no reasons were given for attrition and it is therefore not clear whether reasons for attrition differed between trial groups
Free of selective reporting?	Unclear risk	Most aspects of the outcomes described in the methods were also reported in the results section. Some specific aspects of outcomes described in the methods (e.g. the type and combination of dual use method) were subsumed within more general outcomes presented in the results (e.g. reported as any dual method use). Also, certainty of STI diagnosis (e.g. possible, probable) were not presented in the results section so it is not fully clear how the diagnosis classes relate to the results presented
Free of other bias?	High risk	Imbalance between trial groups on three relevant variables at baseline (see 'Methods' above)

Ploem 1997

Methods	DESIGN: Single-centre RCT LENGTH OF FOLLOW-UP: One month DATA ANALYSIS: Unclear. Appears to be based on participants who completed follow-up but stated that as dropout was random, missing data were imputed based on group means ATTRITION RATE: 14.3% for overall study population. Attrition rates not given for randomised groups but stated to not to differ between groups UNIT OF DATA ANALYSIS: Individual SAMPLE SIZE CALCULATION: Not reported. It is stated that the size of the control group was limited in order to maximize the size of the experimental groups EQUIVALENT STUDY GROUPS AT BASELINE: Authors report no statistically significant differences betwen groups on the basis of pre-test scores or social/sexual behaviour characteristics, using discriminant function analysis PROCESS EVALUATION: Not reported.
Participants	NUMBER RANDOMISED: 112

	AGE: 18 to 32 years (mode =18 years) SOCIO-ECONOMIC STATUS: Not reported, though all were University undergraduates ETHINCITY/RACE: described as largely Caucasian and native to the unspecified Canadian province in which this study was conducted LOCATION: Canada (exact location not specified, though possibly New Brunswick) PREVIOUS STI: Almost 5% had been tested for HIV, but none reported a positive result. 9% of the coitally experienced participants reported having had one or more STD SEXUAL RISK BEHAVIOUR: 80% had engaged in vaginal intercourse. On average they had been coitally experienced for 2.5 years. Coitally experienced women reported a mean of 3.7 partners (range 1 to 30 partners). 48% of coitally experienced participants reported never having used condoms consistently with any of their partners; 84% of those coitally active in past year had engaged in unprotected intercourse OTHER: The majority of participants were enrolled in a Faculty of Arts (59.8%) and were in their first year of University (79.5%). The sample was described as heterosexual
Interventions	NAME OF STUDY: Not reported **GROUP 1 Information, condom eroticisation/normalization and communication skills combination intervention** (n = **49**) YEAR STARTED: Not stated PROVIDER(S): Researcher SETTING(S): University TYPE: Information/Education. Information about AIDS disseminated through a 15 minute videotape as well as through several information-orientated pamphlets and handouts. Information was provided on the definition, etiology, epidemiology, transmission, prevention and ‘treatment’ of AIDS, as well as on effective condom use. Practical skill development. Fifteen minute segment of the audiotape ‘How to talk with your partner about smart sex’. This audiotape models the communication skills required for negotiating safer sex and condom use with a partner Condom eroticisation, condom normalisation.Ten minute audiotape erotic account of a heterosexual college couple integrating condom use into their sexual script. Addresses a a number of negative beliefs about condoms DURATION: 40 minutes THEORETICAL BASIS: Social Learning Theory. The Theory of Reasoned Action. Sexual Behaviour Sequence Theory (theories or erotophobia-erotophilia) STIs COVERED: HIV/AIDS **GROUP 2 Information only intervention** (n = **44**) YEAR STARTED: Not stated PROVIDER(S): As Group 1 SETTING(S): As Group 1 TYPE: As Group 1 but only the Information/Education component DURATION: 15 minutes THEORETICAL BASIS: As Group 1 STIs COVERED: As Group 1 **GROUP 3 No-intervention control group** (n = **19**) No information provided
Outcomes	Knowledge of AIDS Perceived social norms

	Attitudes towards condoms
	Behaviour (condom use)
	Not stated which outcomes were primary/secondary
Notes	COST DATA: None reported.

Risk of bias

Bias	Authors' judgement	Support for judgement
Adequate sequence generation?	Unclear risk	No information given on randomisation procedure.
Allocation concealment?	Unclear risk	Not reported
Blinding? All outcomes	Unclear risk	Not reported
Incomplete outcome data addressed? All outcomes	Unclear risk	States that the attrition rates did not differ between randomised groups (though does not give reasons). No mention of whether an ITI analysis was done though they do report using the respective group means for knowledge, attitudes and norms (though not behaviour) for the missing cases
Free of selective reporting?	Low risk	Results for all outcomes specified in the methods section of the trial publication are reported
Free of other bias?	Unclear risk	Unclear

Roye 2007

Methods	DESIGN: RCT; number of centres not reported.
	LENGTH OF FOLLOW-UP: 3 and 12 months.
	DATA ANALYSIS: Not reported in detail. Appears to be based only on the participants who completed each follow up
	ATTRITION RATE: Attrition reported in Table 2 is based on 337 participants at baseline; attrition reported in the text is based on 400 participants at baseline. The attrition data given here were extracted from Table 2:
	Completed 3 month follow up: Group 1=49/84 (58%); Group 2=59/81 (73%); Group 3=56/88 (64%); Group 4=49/84 (58%)
	Completed 12 month followup: Group 1 = 50/84 (60%); Group 2=50/81 (62%); Group 3=36/88 (41%); Group 4=51/84 (61%)
	UNIT OF DATA ANALYSIS: Individuals.
	SAMPLE SIZE CALCULATION: Not reported.
	EQUIVALENT STUDY GROUPS AT BASELINE: Reported only that the study groups did not differ significantly on ethnicity (P = 0.42), age (P = 0.22) and condom use at last vaginal intercourse with main partner (P = 0.92)
	PROCESS EVALUATION: Not reported.

Participants	NUMBER RANDOMISED: Not reported. Stated that 400 participants were recruited; however, the data presented indicate that there were 337 participants in total in the study groups at baseline AGE: Not reported separately by study group. Overall mean =18 years (range 15 to 21) SOCIO-ECONOMIC STATUS: Not reported. ETHINCITY/RACE: Not reported separately by study group. Overall, Latina=55%; Black=45% LOCATION: USA; New York City. PREVIOUS STI: Not reported separately by study group. Overall, 25% had had an STI SEXUAL RISK BEHAVIOUR: Not reported separately by study group. Overall, 58% had used a condom at last vaginal intercourse with a casual partner; 47% had used a condom at last vaginal intercourse with their main partner; 35% had engaged in anal intercourse; 47% had a history of pregnancy
Interventions	**GROUP 1: HIV risk-reduction counselling and video (n randomised not stated;** n = **84 at baseline)** YEAR STARTED: Not reported. PROVIDER(S): Trained clinic staff (health care assistants). SETTING(S): Not explicitly stated; appears to be family planning clinic(s) TYPE: Information/education and practical skills development: Participants received the Group 3 intervention (video) followed by the Group 2 intervention (counselling) DURATION: Not reported. Minimum duration would be 36 to 41 minutes (i.e 21 minutes of video and 15 to 20 minutes of counselling) THEORETICAL BASIS: The interventions were informed by Social Cognitive Theory; the Theory of Reasoned Action; and the Health Belief Model (not stated explicitly whether these three theoretical models were all applicable to all the interventions) STIs COVERED: Mainly about HIV but appears to cover STIs in general **GROUP 2: HIV risk reduction counselling (n randomised not stated;** n = **81 at baseline)** YEAR STARTED: Not reported. PROVIDER(S): Not stated; appears to be as Group 1. SETTING(S): As Group 1. TYPE: Information/education (details not reported) and practical skills development for sexual risk reduction (few details given). One-to-one counselling based on the protocol of project RESPECT but omitting the HIV testing component DURATION: Single session, 15 to 20 minutes. THEORETICAL BASIS: As Group 1. STIs COVERED: As Group 1. **GROUP 3: HIV risk reduction video (n randomised not stated;** n = **88 at baseline)** YEAR STARTED: Not reported. PROVIDER(S): Mainly self-directed by participants (watching a video) with some contact with a research assistant SETTING(S): As Group 1. TYPE: Video watched by participants individually, providing information/education about HIV and condom use. Appears to involve some practical skills development, as encourages cognitive restructuring or rehearsal DURATION: 21 minutes. THEORETICAL BASIS: As Group 1. STIs COVERED: AS Group 1.

	GROUP 4: Usual care (n randomised not stated; n = **84 at baseline)** YEAR STARTED: Not reported. PROVIDER(S): Not reported. SETTING(S): Not reported (assumed to be family planning clinics) TYPE: Reported only as usual care, with no details provided; unclear what 'usual care' refers to, e.g. whether STI prevention or family planning DURATION: Not reported (usual care). THEORETICAL BASIS: Not applicable (usual care). STIs COVERED: Not reported.
Outcomes	PRIMARY (stated as the 'main' outcome): Condom use at last vaginal intercourse with main partner. SECONDARY (stated as 'other' outcomes but results not reported): Self-reported recurrent STIs; positive chlamydia tests; Number of casual sex partners; HIV risk beliefs; self-efficacy for condom use (6-point scale); The following were included in follow up questionnaires (not formally stated as outcomes): Types of intercourse (vaginal, oral, anal); types of main partners (main, casual, new); number of unprotected sex acts with each partner type
Notes	COST DATA: Stated only that the Group 1 intervention is inexpensive (cost of video = approximately $30); and that participants were paid $30 for their participation, $40 for the 3-month follow up and $50 for the 12-month follow up As baseline assessment may affect outcomes, to evaluate the independent and joint contributions of baseline assessment and intervention on the outcomes being measured, 70% of the participants were randomised to receive the baseline questionnaire and 30% were randomised to get no baseline questionnaire. Reported in the results that having had a baseline assessment did not affect outcomes

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Adequate sequence generation?	Unclear risk	No information provided.
Allocation concealment?	Unclear risk	No information provided.
Blinding? All outcomes	Unclear risk	No information provided.
Incomplete outcome data addressed? All outcomes	High risk	A 12 month follow up, Group 3 lost more participants than the other groups (based on findings of a Chi-square test; not reported). No reasons given for attrition
Free of selective reporting?	Unclear risk	Most outcomes were only introduced in the results section. The outcomes alluded to in follow up questionnaires (types of intercourse; types of main partners; number of sex acts with each partner type) were not reported except for main partners). Quantitative data were only reported consistently for the main outcome. For other outcomes, data were either not reported at all or were described narratively, with some illustrative reporting of p-values
Free of other bias?	Unclear risk	Unclear

Scholes 2003

Methods	DESIGN: multi-centre RCT (number of centres not stated)
	LENGTH OF FOLLOW-UP: 3 and 6 months.
	DATA ANALYSIS: Stated that study outcomes were analysed using an intent-to-treat approach but no definition of intent-to-treat was provided
	ATTRITION RATE:
	Completed 3 month follow up: Group 1 = 543/596 (91%); Group 2=537/614 (87%)
	Completed 6 month follow up: Group 1 = 522/596 (88%); Group 2=524/614 (85%)
	UNIT OF DATA ANALYSIS: Individuals (as randomised).
	SAMPLE SIZE CALCULATION: Not reported. Stated that the target sample size was 1200 participants
	EQUIVALENT STUDY GROUPS AT BASELINE: Stated that the intervention and usual care groups did not differ significantly with respect to a wide variety of baseline variables. The data presented (Table 1) support this
	PROCESS EVALUATION: The receipt and use of intervention components (booklet, newsletter, condoms) by participants was reported (Table 2; data not extracted). Stated that 96% of participants randomised to Group 1 recalled receiving one or both tailored packets, of which 60% reported reading the booklet and/or newsletter. 66% reported that they found the materials personally relevant and 59% of sexually active respondents had used condoms provided in the intervention
Participants	NUMBER RANDOMISED: 1210
	AGE, mean: Group 1=21 years; Group 2=21 years.
	In each age class (%): 18 to 20 years: Group 1=47; Group 2=49; 21 to 25 years: Group 1 = 53; Group 2=51
	SOCIO-ECONOMIC STATUS: (NB: stated that participants were from socio-demo-graphically distinct communities, but these community differences were not reported quantitatively)
	Full time student education (%): Group 1=37; Group 2=39.
	Education beyond high school (%): Group 1=69; Group 2=70.
	Employed full time (%): Group 1=43; Group 2=42.
	With Medicaid insurance (%): Group 1 = 16%; Group 2=15%.
	Living with own child (%): Group 1 = 17; Group 2=16.
	ETHINCITY/RACE (%):
	White: Group 1=69; Group 2=69; Black: Group 1 = 19; Group 2=19; Other: Group 1 = 12; Group 2=12
	LOCATION: USA; Washington State and Durham, North Carolina.
	PREVIOUS STI (%): Group 1=27; Group 2=26.
	SEXUAL RISK BEHAVIOUR:
	Ever used condoms (%): Group 1=97; Group 2=99.
	Used condoms with any partner in past 3 months (%): Group 1=71 Group 2=73
	Used condoms with primary partner in past 3 months (%): Group 1=67; Group 2=68
	Used condoms with non-primary partner in past 3 months (%): Group 1=79; Group 2=73
	Used condoms at least once (not reported separately by study group): Overall 72%
	Consistent condom use (not reported separately by study group): Overall 41%
	Intercourse with any partner in past 3 months (%): Group 1=90; Group 2=92
	Intercourse with primary partner in past 3 months (%): Group 1=79; Group 2=81
	Intercourse with non-primary partner in past 3 months (%): Group 1=21; Group 2=18

	Mean (median) number of intercourse episodes with any partner in past 3 months:
	Group 1=21 (10); Group 2=19 (10)
	Mean (median) number of intercourse episodes with primary partner in past 3 months: Group 1=23 (15); Group 2=23 (13)
	Mean (median) number of intercourse episodes with non-primary partner in past 3 months: Group 1= 5 (2); Group 2=5 (3)
	Mean proportion of intercourse episodes where condom was used with any partner in past 3 months: Group 1=54; Group 2=55
	Mean proportion of intercourse episodes where condom was used with primary partner in past 3 months: Group 1 = 50; Group 2=51
	Mean proportion of intercourse episodes where condom was used with non-primary partner in past 3 months: Group 1=69; Group 2=66
	Carried condoms in past 3 months (%): Group 1=51; Group 2=54
	Had ≥2 sex partners in past 12 months (not stated, assumed %): Group 1 = 17; Group 2=19
	Ever pregnant (%): Group 1=31; Group 2=33.
	Inclusion criteria were: sexual intercourse with a male partner in the prior 6 months; not in a monogamous relationship of >12 months' duration; not pregnant
Interventions	**GROUP 1: Self-help intervention** (n = **614**)
	YEAR STARTED: June 1999 to April 2000.
	PROVIDER(S): Not reported (self-help materials mailed to participants)
	SETTING(S): Managed care networks (the Group Health Cooperative, a mixed model health care system in Washington State; and the Duke Health System, a network of affiliated practices, clinics and hospitals in Durham, North Carolina)
	TYPE: Information/education comprising a 12-page individual-tailored self-help booklet; and resource provision comprising male and female condoms, condom carrying case and instructions. These were reinforced after 3 months with a tailored booster feedback newsletter (a single folded sheet that focused on removing barriers/enhancing facilitators to condom use) and a condom packet. The tailored intervention was defined as a combination of strategies and information intended to reach one specific person, based on characteristics that are unique to that person, related to the outcome of interest and derived from an individual assessment. Four sections of the booklet were generic and seven incorporated varying degrees of tailoring. Tailoring of the booklet was based on a range of the participant's baseline characteristics, including ethnicity, STI history and number of partners; tailoring of the newsletter was partly based on information obtained at the 3 month follow up
	DURATION: Not reported (self-help materials mailed to participants)
	THEORETICAL BASIS: Social Science Theory.
	STIs COVERED: STIs in general, including HIV.
	GROUP 2: Usual care (n = **596**)
	YEAR STARTED: As Group 1.
	PROVIDER(S): Not reported.
	SETTING(S): As Group 1.
	TYPE: Usual care but no details provided.
	DURATION: Not reported.
	THEORETICAL BASIS: Not applicable (usual care).
	STIs COVERED: Not reported.
Outcomes	PRIMARY (stated as *a priori* main outcomes):
	Percentage of sexually active women using condoms with any partner during the previous 3 months;
	Percentage of sexually active women using condoms with a primary partner during the previous 3 months;

	Percentage of sexually active women using condoms with a non-primary partner during the previous 3 months; Proportion of total episodes of intercourse during which condoms were used in the previous 3 months SECONDARY (stated as additional information that was collected): Consistent condom use (using condoms for 100% of intercourse episodes); Purchased or carried condoms; Discussed of condoms with partners; Self-efficacy to use condoms (by partner type).
Notes	COST DATA: Reported only that some incentives were provided: A 30-minute telephone calling card was included in each contact letter for the 3 month follow up; and $10 was sent after completion of the 6 month follow up survey

Risk of bias

Bias	Authors' judgement	Support for judgement
Adequate sequence generation?	Unclear risk	Stated that participants were randomly assigned to either intervention or usual care groups, blocking by study site, but no details of the randomisation method were provided
Allocation concealment?	Unclear risk	No information provided.
Blinding? All outcomes	High risk	Stated that survey interviewers were not blinded to participants' status and were not part of the project staff. No information provided on whether outcome assessors were blinded
Incomplete outcome data addressed? All outcomes	Unclear risk	Stated that analysis was by intention to treat but no information provided on whether or how missing data were accounted for in analyses. Attrition rates were similar between groups, but no reasons were given
Free of selective reporting?	Low risk	Results were presented for all outcomes that were stated in the methods section
Free of other bias?	Unclear risk	Unclear

Shain 1999

Methods	DESIGN: RCT (not specifically stated, but appears to be single-centre) LENGTH OF FOLLOW-UP: 6 and 12 months post-intervention DATA ANALYSIS: States intention to treat (not defined), however participants were excluded from analysis if laboratory data were missing ATTRITION RATE: Overall at 6 months 18% (n = 508); 18 % for Group 1 (56/313) and 20% for Group 2 (61/304).Overall at 12 months 11% (n = 549); 9% for Group 1 (28/313) and 13% for Group 2 (49/313). While 26 women present at 6 months follow up were lost by 12 months, another 67 women who missed the 6 months follow up visit returned for the 12 months follow up visit UNIT OF DATA ANALYSIS: Individuals.

	SAMPLE SIZE CALCULATION: Not reported. EQUIVALENT STUDY GROUPS AT BASELINE: States no significant differences between groups but no p values are reported. Multiple logistic-regression analysis was used to control for differences at baseline in number of previous partners during the 3 months preceding the study, which was higher in Group 1. Baseline data only reported for 285/313 for Group 1 and 264/304 for Group 2. Eligibility was limited to English speakers and 8% of otherwise eligible Hispanic women were therefore excluded PROCESS EVALUATION: none reported.
Participants	NUMBER RANDOMISED: 617 AGE: range 14 to 45 years; mean 21.8 (SE 0.33) years Group 1; 21.3 (SE 0.36) years Group 2. Overall 71% <24 years; 32.6% <19 years in Group 1; 39% <19 years in Group 2 Gender: 100% female SOCIO-ECONOMIC STATUS: Population characterised by low levels of income. Monthly income per capita $243 for Group 1 and $267 for Group 2 ETHINCITY/RACE: 70% Mexican-American (Group 1 69.8%, Group 2 68.2%) and 30% African-American (Group 1 30.2%, Group 2 31.8%) LOCATION: USA (San Antonio, Texas) PREVIOUS STI: Current STIs for Group 1 - gonorrhoea 21.4%, chlamydia 67.0%, trichomonal infection 26.3%, syphilis 6.0%. Current STIs for Group 2 Gonorrhea 20. 8%, chlamydia 70.5%, trichomonal infection 20.8%, Syphilis 6.1% SEXUAL RISK BEHAVIOUR: To be included in the study, women had to be of high-risk status and therefore have a current non-viral sexually transmitted disease (gonorrhoea, chlamydia, trichomonal infection or syphilis) OTHER: $25 incentive for first 2 sessions and £50 for third session. All participants were informed that they could be observed by one-way mirror to ensure uniformity of procedure
Interventions	NAME OF STUDY: none reported **GROUP 1: Behavioural-cognitive intervention** (n = **313**) YEAR STARTED: January 1993 to end of July 1994 PROVIDER(S): Female facilitator of same race or ethnic group SETTING(S): Public health clinic (research clinic) TYPE: Information/education (e.g. increase awareness of AIDS and sexually transmitted diseases, including personal risk, prevention and treatment). Practical skill development (correct and consistent use of condoms, decision making skills for negotiating safer sex) . Content for African-American and Mexican-American women was largely the same, but emphases and cultural cues varied NUMBER OF SESSIONS: 3 sessions (one per week) of 3 to 4 hours each with 5 or 6 participants (range 3 to 12) DURATION: 3 weeks THEORETICAL BASIS: AIDS Risk Reduction Model (adapted to include findings from focus-group and individual interviews) Integrated elements of social and psychological theories, including Health Belief Model, self-efficacy theory, decision-making models and diffusion theory. Three stages: recognition of one's risk, commitment to reducing that risk and following though with that commitment by seeking solution STIs COVERED: gonorrhoea, chlamydia, trichomonal infection, syphilis and HIV/AIDS **Group 2: Control group** (n = **304**) PROVIDER(S): nurse practitioner. SETTING(S): Public health care unit/specialist clinic TYPE: individualised HIV standard counselling according to the patient's sexual history and her responses to a test of knowledge, following guidelines issued by the

	'Centers for Disease Control and Prevention'. Participants were invited to receive behavioural-cognitive intervention after completion of study NUMBER OF SESSIONS: 1 DURATION: 15 minutes
Outcomes	PRIMARY: Subsequent infection with Chlamydia trachomatis or Neisseria gonorrhoea SECONDARY: Behaviour: compliance, number of sexual partners, number of unprotected sexual acts. Health problem: number of episodes of infection during the 12-month study period, association between study group assignment and infection during the follow-up period HIV was excluded as an outcome, due to low prevalence in the heterosexual community
Notes	COST DATA: none reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Adequate sequence generation?	Unclear risk	Randomly assigned after stratification according to race and ethnic group, treatment allocation for each participant entered into a log book. Participants selected starting times from several dates within three weeks of enrolment. Starting times for both the Group 1 and Group 2 were pre-assigned to dates randomised and balanced during the enrolment period across times of day, days of the week, weeks of the month and months of the year. No detail given on the actual method of random sequence generation
Allocation concealment?	Unclear risk	No information given.
Blinding? All outcomes	Unclear risk	Study was not conducted in a blinded manner, but group assignments did not appear on interview documents or clinic records. Participants were asked their group assignment only at the end of follow-up interviews, to ascertain the benefits of the intervention.
Incomplete outcome data addressed? All outcomes	Unclear risk	Authors assert that intention to treat was conducted, but women with missing laboratory data were excluded from analysis, if results were indeterminate and if any treatments were missed. Attrition rates were similar between groups, but no reasons were given and it is therefore not clear whether reasons for attrition differed between trial groups
Free of selective reporting?	Unclear risk	For behavioural outcomes, data only reported for women that attended both follow-up visits (6 and 12 months) at 12 months. Selective reporting difficult to evaluate as not all reported outcomes were in the methods section
Free of other bias?	Unclear risk	Multiple logistic-regression analysis was used to control for differences in one variable where there was reported to be a significant difference at baseline. However, baseline data not provided for all randomised participants (see 'Methods' above)

Shrier 2001

Methods	DESIGN: RCT (not specifically stated, but appears to be single-centre)

	LENGTH OF FOLLOW-UP: 1, 3, 6 and 12 months DATA ANALYSIS: not reported ATTRITION RATE: 34% for month 1, 41% for months 3 and 48% for 12 months (33% attended all 4 follow up visits, 11% participants did not return for any follow ups) . Attrition rates generally balanced between the study groups. No reasons for attrition specified UNIT OF DATA ANALYSIS: Individuals. SAMPLE SIZE CALCULATION: Not stated if statistically powered for primary outcome, but states that study had limited power (35%) to detect a significant difference in condom use between groups, as only 35% of adolescents at 1 month follow-up reported a non-main partner in the previous 6 months. Also states that low participation rates threatened the external validity of results EQUIVALENT STUDY GROUPS AT BASELINE: States no significant difference between groups at baseline (no p values reported) and that percentage reported may not add up to 100% due to missing values. Group 1 had a 10% higher rate of motherhood than Group 2 (23% versus 13%) and the same higher rate for 'another partner in the last 6 months' (40% versus 30%), as well as 9% higher in condom used with last sexual encounter (47% versus 38%). Cervicitis participants had higher baseline knowledge (P = 0.03) and negotiation (P = 0.008) than PID patients PROCESS EVALUATION: not reported
Participants	NUMBER RANDOMISED: 123 AGE: median 17.2 years (Group1 17.0 median years, range 14.1 to 22.0; Group 2 17. 5 median years, range 13.9 to 21.9) Gender: female SOCIO-ECONOMIC STATUS: not reported ETHINCITY/RACE: Non-Hispanic black 49% (Group 1 48%, Group 2 49%); Hispanic 18% (Group 1 20%, Group 2 16%); Non-Hispanic white 14% (Group 1 17%, Group 2 11%); Other 17% (Group 1 13%, Group 2 21%) LOCATION: USA (Boston, Massachusetts - urban) PREVIOUS STI: history of previous STI/ PID 44% (Group 1 42%, Group 2 46%) SEXUAL RISK BEHAVIOUR: <50% reported using condom at last intercourse and sexual risk behaviours described as prevalent, with 48% young women needing treatment for cervicitis (n = 59) or 52% for PID (n = 64) OTHER: 3 randomised participants with cervicitis did not receive intervention or return for any follow up visits. Participants were paid $10 for each follow up visit. Group 1 received free condoms and written material about safer sex, condoms and spermicide and an opportunity to view 'Time Out: The Truth About AIDS, HIV and You' videotape again. Group 2 were offered free condoms at the end of the visit. States that 82 eligible adolescent were not included in the study as no research assistant was available to approach them for study participation at the time of treatment and this might have introduced a bias
Interventions	NAME OF INTERVENTION: none reported **GROUP 1: Safer sex education** (n = **60**) YEAR STARTED: 1996 to 1998 PROVIDER(S): female health educators SETTING(S): children's hospital adolescent clinic and inpatient service TYPE: Information/Education (increased awareness of sexual risk behaviour,dangers of unsafe sex, STI transmission, abstinence, correct condom use and use of female condom) and practical skill development (correct condom use and condom-use negotiating skills if appropriate) DURATION: 1 individual session lasting approximately 37 minutes (7 minutes videotape and around 30 minutes on intervention topics), with 3 booster sessions (month 1, 3 and 6) THEORETICAL BASIS: Social cognitive theory, the Transtheoretical Model of behaviour change and Motivational interviewing

	STIs COVERED: AIDS/HIV and STIs (no specific STIs reported) **Group 2: Standard care/STD education** (n = **63**) NAME OF INTERVENTION: PROVIDER(S): STD education provided at the discretion of the treating clinician SETTING(S): children's hospital adolescent clinic and inpatient service TYPE: Information/education (e.g. increased awareness of STD transmission, importance of consistent condom use) DURATION: not reported. THEORETICAL BASIS: none reported.
Outcomes	PRIMARY: not specifically stated but would appear to be self-reported condom use and recurrence of STD SECONDARY: Attitudes (attitudes toward condoms) Behaviour (self-reported behaviours) Knowledge (sexual risk knowledge) Practical skill (condom use negotiation skills)
Notes	COST DATA: none reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Adequate sequence generation?	Low risk	Randomisation was stratified by presenting diagnosis (cervicitis or PID) using 2 separate random numbers lists
Allocation concealment?	Unclear risk	No details reported.
Blinding? All outcomes	Unclear risk	Not reported
Incomplete outcome data addressed? All outcomes	Unclear risk	Not reported, but follow-up data appears to be based only on those who received the intervention. Attrition rates were similar between groups, but no reasons were given and it is therefore not clear whether reasons for attrition differed between trial groups
Free of selective reporting?	Unclear risk	The baseline stage of change scale could not be scored due to 73% of responders not following instructions. No results for 3 months follow-up reported. Selective reporting difficult to evaluate as not all reported outcome measures are explained in the methods section
Free of other bias?	Unclear risk	Uncertain

Smith 1993

Methods	DESIGN: Cluster RCT (single centre).

	LENGTH OF FOLLOW-UP: Up to 3 months, Time 1 (immediately post intervention) and Time 2 (2 months) later for Group 1 (intervention) and Time 3 only for Group 2 (control) DATA ANALYSIS: Analysis is at a different level to randomisation and is based on intervention received ATTRITION RATE: Overall 56% based on number randomised (42% group 1; 74% group 2). Full compliers had more previous condom use (Time 0 - baseline) than those who dropped out (52.38 versus 11.11%, P < 0.05) UNIT OF DATA ANALYSIS: randomised by floors, but analysis by individuals SAMPLE SIZE CALCULATION: none reported. EQUIVALENT STUDY GROUPS AT BASELINE: Baseline questionnaire completed by 80.9% of Group 1 and 72.8% of Group 2. Baseline data only reported for participants completing follow-up at 2 months (34% Group 1; 54% Group 2). No difference in age, age at menarche, dating status, percent experienced sexual intercourse ever, age at first sexual intercourse, number of sexual partners ever, percent ever used condoms and percent condom use in last month. Group 2 had more sexual partners in the last year (1. 36 versus 1.00, P < 0.01). The rate of condom use in the two months prior to baseline was higher in Group 2 (control) (61.29) than Group 1 (intervention) (49.75) but stated not statistically significant PROCESS EVALUATION: none reported.
Participants	NUMBER RANDOMISED: 380 AGE: Group 1 - intervention 18.80 years, Group 2 - control 18.82 years Gender: 100% female. SOCIO-ECONOMIC STATUS: not reported (university students) ETHINCITY/RACE: not reported. LOCATION: Canada (Ontariouniversity) PREVIOUS STI: not reported. SEXUAL RISK BEHAVIOUR: Only just under a third in the intervention group and around half of the control group were sexually active. STI history not reported OTHER: the number offloors used for randomisation could be insufficient in number to ensure even distribution of socio-demographic and outcome related characteristics (and unknown mediating factors) of participants, however, participants were randomised to floors upon entry to the University. This may have ensured balanced distribution
Interventions	NAME OF INTERVENTION: none reported **GROUP 1: Condom desensitisation and AIDS education** (n = **199**) YEAR STARTED: not reported. PROVIDER(S): Two female programme providers, approximately five years older than participating students SETTING(S): Educational Institution - tertiary education (University dormitory meetings, site could be considered to be ‘home’) TYPE: Information/education (e.g. relevance of AIDS to the female university population, risk factors and transmission of AIDS, misconceptions about condoms, desensi-tisation to condoms, increasing positive attitudes towards condom use, increasing condom use); practical skill development (e.g. correct condom use, communication skills in negotiating condom use, strategies of preventing condom failure) NUMBER OF SESSIONS: 1 DURATION: Approximately 45 minutes THEORETICAL BASIS: Theory of Reasoned Action and its extension the Theory of Planned Behaviour STIs COVERED: HIV/AIDS **Group 2: Control group** (n = **181**)

	TYPE: no intervention NUMBER OF SESSIONS: 0
Outcomes	PRIMARY: None explicitly stated, but would appear to be behaviour (i.e. condom use) SECONDARY: Awareness/Beliefs: subjective norms towards safer sex Behaviour: condoms use Self-efficacy/self-esteem/self-confidence: perceived control over safer sex behaviours, motivation to comply with safer sex
Notes	COST DATA: none reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Adequate sequence generation?	Unclear risk	Researchers randomised by dormitory quadrant (dormitory had 6 floors, each quadrant 2 floors). 4 quadrants used to receive an experimental session or no session (control) by floor (4 floors assigned to experimental group and 4 to control group)
Allocation concealment?	Unclear risk	No details reported.
Blinding? All outcomes	Unclear risk	Not stated. Data collected by trained female data collectors, remaining with participant during completion of questionnaire (to answer questions and collect completed questionnaires)
Incomplete outcome data addressed? All outcomes	High risk	Participants with more previous condom use at baseline were less likely to drop out before completing the programme session ($P < 0.05$) the authors acknowledge that the fully compliant sample may have been biased through self selection. Attrition was higher in Group 2 (control) (74%) compared to Group 1 (intervention) (42%).No reaons were given for attrition
Free of selective reporting?	Unclear risk	In order to avoid re-test bias, not all planned behaviour questions were used at baseline for the intervention group, only at Time 1 (immediate post intervention)
Free of other bias?	High risk	Cluster RCT with analysis at the level of the individual. Baseline data only reported for those completing 2 month follow-up (see 'Methods' above). Statistically significant trial group differences at baseline on at least one relevant variable

* Slight disagreement between reported and actual percentages

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

Study	Reason for exclusion

Amaro 2002	Design: study not an RCT
Anderson 2006	Population: mixed sex or females aged over 25 years
Anon 2002	Population: mixed sex or females aged over 25 years
Anon 2004	Design: study not an RCT
Anon 2005	Design: study not an RCT
Anon 2005a	Design: study not an RCT
Anon 2005b	Population: mixed sex or females aged over 25 years
Artz 2000	Design: study not an RCT
Artz 2005	Population: mixed sex or females aged over 25 years
Asamoah Adu 1994	Population: mixed sex or females aged over 25 years
Ashery 1997	Population: mixed sex or females aged over 25 years
Askin 2004	Design: study not an RCT
Barnet 2009	Outcomes: no relevant sexual behavioural outcomes or biological outcomes (STI or cervical cancer) reported
Beadnell 2006	Population: mixed sex or females aged over 25 years
Bearss 1995	Design: study not an RCT
Belcher 1998	Population: mixed sex or females aged over 25 years
Belgrave 2008	Design: study not an RCT
Bender 2004	Population: mixed sex or females aged over 25 years
Benner 2008	Design: study not an RCT
Benner 2008a	Design: study not an RCT
Benner 2008b	Design: study not an RCT
Bennett 2005	Population: mixed sex or females aged over 25 years
Bhave 1995	Design: study not an RCT
Black 2006	Outcomes: no relevant sexual behavioural outcomes or biological outcomes (STI or cervical cancer) reported
Bluespruce 2001	Population: mixed sex or females aged over 25 years
Boyle 2007	Design: study not an RCT
Callegari 2008	Population: mixed sex or females aged over 25 years
Carey 1997	Population: mixed sex or females aged over 25 years
Carey 2000	Population: mixed sex or females aged over 25 years
Caron 2004	Population: mixed sex or females aged over 25 years
Cartagena 2006	Population: mixed sex or females aged over 25 years
Champion 2007	Outcomes: no relevant sexual behavioural outcomes or biological outcomes (STI or cervical cancer) reported
Chen 2009	Population: mixed sex or females aged over 25 years
Chhabra 2008	Population: mixed sex or females aged over 25 years
Chung-Park 2008	Outcomes: no relevant sexual behavioural outcomes or biological outcomes (STI or cervical cancer) reported
Clark 2005	Population: mixed sex or females aged over 25 years
Cohen 2006	Population: mixed sex or females aged over 25 years
Corby 1996	Population: mixed sex or females aged over 25 years

Cowan 2008	Population: mixed sex or females aged over 25 years
Coyle 2001	Population: mixed sex or females aged over 25 years
Coyle 2004	Population: mixed sex or females aged over 25 years
Coyle 2006	Population: mixed sex or females aged over 25 years
Crepaz 2007	Design: study not an RCT
Dancy 2000	Population: mixed sex or females aged over 25 years
Darbes 2008	Design: study not an RCT
Deas 2000	Population: mixed sex or females aged over 25 years
Di Noia 2007	Outcomes: no relevant sexual behavioural outcomes or biological outcomes (STI or cervical cancer) reported
DiCenso 2002	Design: study not an RCT
DiClemente 1995	Population: mixed sex or females aged over 25 years
Dorfman 1992	Population: mixed sex or females aged over 25 years
Dupas 2009	Population: mixed sex or females aged over 25 years
Ehrhardt 2002	Population: mixed sex or females aged over 25 years
El-Bassel 2003	Population: mixed sex or females aged over 25 years
El-Bassel 2005	Population: mixed sex or females aged over 25 years
Eldridge 1997	Population: mixed sex or females aged over 25 years
Esere 2008	Population: mixed sex or females aged over 25 years
Fagen 2009	Population: mixed sex or females aged over 25 years
Farr 1996	Population: mixed sex or females aged over 25 years
Feldblum 2001	Population: mixed sex or females aged over 25 years
Feldblum 2007	Population: mixed sex or females aged over 25 years
Flaskerud 1997	Population: mixed sex or females aged over 25 years
Flay 2004	Population: mixed sex or females aged over 25 years
Flisher 2005	Design: study not an RCT
Fogarty 2001	Population: mixed sex or females aged over 25 years
Ford 1996	Population: mixed sex or females aged over 25 years
Ford 2000	Population: mixed sex or females aged over 25 years
Forehand 2007	Population: mixed sex or females aged over 25 years
Fox 1993	Population: mixed sex or females aged over 25 years
French 2003	Population: mixed sex or females aged over 25 years
Getty 2008	Design: study not an RCT
Ghys 2001	Intervention: Not a behavioural intervention to prevent STIs or cervical cancer
Gilliam 2004	Intervention: Not a behavioural intervention to prevent STIs or cervical cancer
Gold 2004	Intervention: Not a behavioural intervention to prevent STIs or cervical cancer
Goldberg 2009	Population: mixed sex or females aged over 25 years
Gollub 2001	Population: mixed sex or females aged over 25 years
Graham 2002	Population: mixed sex or females aged over 25 years
Greenberg 2000	Population: mixed sex or females aged over 25 years

Harrington 2001	Outcomes: no relevant sexual behavioural outcomes or biological outcomes (STI or cervical cancer) reported
Harris 1998	Population: mixed sex or females aged over 25 years
Hobfoll 1994	Population: mixed sex or females aged over 25 years
Hobfoll 2002	Population: mixed sex or females aged over 25 years
Hoffman 2003	Population: mixed sex or females aged over 25 years
Holden 2008	Design: study not an RCT
Ickovics 1994	Population: mixed sex or females aged over 25 years
Ingersoll 2005	Intervention: Not a behavioural intervention to prevent STIs or cervical cancer
Ito 2008	Outcomes: no relevant sexual behavioural outcomes or biological outcomes (STI or cervical cancer) reported
Jahanfar 2009	Population: mixed sex or females aged over 25 years
Jemmott 2007	Population: mixed sex or females aged over 25 years
Jewkes 2006	Outcomes: no relevant sexual behavioural outcomes or biological outcomes (STI or cervical cancer) reported
Jewkes 2008	Population: mixed sex or females aged over 25 years
Johnson-Mallard 2005	Population: mixed sex or females aged over 25 years
Kalichman 1996	Population: mixed sex or females aged over 25 years
Kaplan 2009	Design: study not an RCT
Kaul 2002	Population: mixed sex or females aged over 25 years
Kelly 1994	Population: mixed sex or females aged over 25 years
Kim 2008	Design: study not an RCT
Kirby 2004	Population: mixed sex or females aged over 25 years
Kirby 2005	Design: study not an RCT
Kirby 2007	Design: study not an RCT
Kirby 2009	Design: study not an RCT
Koniak-Griffin 2008	Population: mixed sex or females aged over 25 years
Korte 2004	Design: study not an RCT
Krauss 2000	Population: mixed sex or females aged over 25 years
Laga 1994	Design: study not an RCT
Lang 2009	Outcomes: no relevant sexual behavioural outcomes or biological outcomes (STI or cervical cancer) reported
Lauby 2000	Population: mixed sex or females aged over 25 years
LeCroy 2004	Intervention: Not a behavioural intervention to prevent STIs or cervical cancer
Legardy 2005	Population: study population aged over 25 years
Lin 2008	Design: study not an RCT
Lopez 2009	Design: study not an RCT
Lopez 2009a	Design: study not an RCT
Lyles 2007	Design: study not an RCT
Magnussen 2004	Design: study not an RCT
Magura 1995	Population: mixed sex or females aged over 25 years
Malow 2000	Population: mixed sex or females aged over 25 years

Manhart 2005	Design: study not an RCT
Marion 2009	Population: mixed sex or females aged over 25 years
Marsh 1991	Design: study not an RCT
McCoy 1998	Design: study not an RCT
McKay 2004	Design: study not an RCT
Meade 2005	Design: study not an RCT
Medley 2009	Design: study not an RCT
Merakou 2006	Design: study not an RCT
Miller 2004	Outcomes: no relevant sexual behavioural outcomes or biological outcomes (STI or cervical cancer) reported
Morrison-Beedy 2004	Design: study not an RCT
Morrison-Beedy 2009	Outcomes: no relevant sexual behavioural outcomes or biological outcomes (STI or cervical cancer) reported
Ngugi 2007	Population: mixed sex or females aged over 25 years
NIMH 1998	Population: mixed sex or females aged over 25 years
Noar 2008	Design: study not an RCT
Noar 2009	Design: study not an RCT
Nyamathi 1993	Population: mixed sex or females aged over 25 years
Nyamathi 1994	Population: mixed sex or females aged over 25 years
Nyamathi 1997	Population: mixed sex or females aged over 25 years
Nyamathi 1998	Population: mixed sex or females aged over 25 years
Nyamathi 2001	Population: mixed sex or females aged over 25 years
O'Neill 1996	Population: mixed sex or females aged over 25 years
Oakeshott 2000	Population: mixed sex or females aged over 25 years
Oringanje 2009	Design: study not an RCT
Pals 2009	Outcomes: no relevant sexual behavioural outcomes or biological outcomes (STI or cervical cancer) reported
Patterson 2006	Population: mixed sex or females aged over 25 years
Patterson 2008	Population: mixed sex or females aged over 25 years
Peragallo 2005	Population: mixed sex or females aged over 25 years
Petersen 2007	Population: mixed sex or females aged over 25 years
Postrado 1992	Design: study not an RCT
Pronyk 2008	Population: mixed sex or females aged over 25 years
Quirk 1993	Design: study not an RCT
Rew 2003	Design: study not an RCT
Rhodes 1992	Design: study not an RCT
Rhodes 2007	Population: mixed sex or females aged over 25 years
Robin 2004	Population: mixed sex or females aged over 25 years
Ross 2006	Design: study not an RCT
Rye 2008	Outcomes: no relevant sexual behavioural outcomes or biological outcomes (STI or cervical cancer) reported
Schilling 1991	Population: mixed sex or females aged over 25 years

Schmiege 2009	Population: mixed sex or females aged over 25 years
Schunmann 2006	Intervention: Not a behavioural intervention to prevent STIs or cervical cancer
Seitz 1991	Design: study not an RCT
Semaan 2002	Design: study not an RCT
Sikkema 1995	Population: mixed sex or females aged over 25 years
Sikkema 2000	Population: mixed sex or females aged over 25 years
Sikkema 2005	Population: mixed sex or females aged over 25 years
Silva 2002	Design: study not an RCT
Simbayi 2004	Population: mixed sex or females aged over 25 years
Singh 1994	Design: study not an RCT
Slap 1991	Design: study not an RCT
Sly 1997	Population: mixed sex or females aged over 25 years
Smith 1997	Design: study not an RCT
Smoak 2006	Design: study not an RCT
Speizer 2003	Population: mixed sex or females aged over 25 years
St Lawrence 2001	Population: mixed sex or females aged over 25 years
St. Lawrence 1997	Design: study not an RCT
Stein 1999	Design: study not an RCT
Stephenson 2004	Population: mixed sex or females aged over 25 years
Stephenson 2008	Population: mixed sex or females aged over 25 years
Strathdee 2009	Population: mixed sex or females aged over 25 years
Swaddiwudhipong 1990	Design: study not an RCT
Thurman 2008	Design: study not an RCT
Tyden 1996	Design: study not an RCT
Underhill 2007	Design: study not an RCT
Underhill 2007a	Design: study not an RCT
Underhill 2007b	Design: study not an RCT
Underhill 2008	Design: study not an RCT
van Devanter 2002	Population: mixed sex or females aged over 25 years
Vicinanza 2008	Design: study not an RCT
Visrutaratna 1995	Design: study not an RCT
Wechsberg 2004	Population: mixed sex or females aged over 25 years
Wingood 2006	Outcomes: no relevant sexual behavioural outcomes or biological outcomes (STI or cervical cancer) reported
Witte 2006	Population: mixed sex or females aged over 25 years
Wong 1996	Population: mixed sex or females aged over 25 years
Yimin 2002	Outcomes: no relevant sexual behavioural outcomes or biological outcomes (STI or cervical cancer) reported
Yimin 2003	Outcomes: no relevant sexual behavioural outcomes or biological outcomes (STI or cervical cancer) reported

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

Ergene 2005

Methods	Controlled trial, possibly randomised
Participants	Male and females, mean age 20 years
Interventions	(i) Peer education, (ii) single-session lecture, (iii) wait-list control
Outcomes	Personal behaviour, knowledge, attitudes
Notes	

Horowitz 2003

Methods	Systematic review of effectiveness studies
Participants	US populations of a broad demographic range
Interventions	Interventions applying the transtheoretical model to pregnancy and STD prevention
Outcomes	Safer sex behaviours
Notes	

Knecht 2002

Methods	RCT (described as ‘quasi-experimental design’)
Participants	Women (no age given)
Interventions	Condom promotion intervention, with 25 free condoms, a carrying pouch and instructions
Outcomes	Condom use at last sex
Notes	

Lindenberg 2002

Methods	RCT (described as a pilot study)
Participants	Mexican-American low income young women
Interventions	Either a resilience workshop or a health information correspondence course
Outcomes	Condom use, attitudes, sexual self-efficacy, resilience
Notes	

Shaughnessy 2002

Methods	No information currently available (title only)
Participants	No information currently available (title only)

Interventions	No information currently available (title only)
Outcomes	No information currently available (title only)
Notes	

DATA AND ANALYSES

This review has no analyses.

ADDITIONAL TABLES

Table 1
Overview of intervention characteristics

Study	Intervention group 1	Intervention group 2	Intervention group 3
Boyer 2005	Cognitive-behavioural intervention (n = 1062) PROVIDER: Trained civilian research assistants TYPE: Information/ education; practical skills development SETTING: US female Marine training academy	Health promotion control (n = 1095) Identical to Group 1 but focused on healthier food choices, sports or physical training injuries and risk of cancer	N/A
Bryan 1996	Education and skills development intervention: condom use (n = 100) PROVIDER: Researcher TYPE: Information/ education; practical skills development SETTING: University	Education and skills development control: stress management (n = 98) Comparable in format to experimental programme	N/A
Bull 2008	POWER for Reproductive Health social marketing campaign (n = 6 neighbourhoods) PROVIDER: None (materials self-accessed by participants) TYPE: Information/ Education; Resource provision SETTING: Urban community venues (unspecified)	Comparison group (n = 6 neighbourhoods) PROVIDER: None (no intervention) TYPE: None (no intervention) SETTING: As Group 1.	N/A
Choi 2008	Female condom skills training intervention (n = 213) PROVIDER: Health Educators TYPE: Information/ education; practical skills development; resource provision SETTING: Family planning clinics	GROUP 2: General health promotion intervention (n = 196) Identical to Group 1 except that it ex-cluded practical skills development and focused on general health issues such as cancer and heart disease	N/A
Dancy 2009	GROUP 1: Mother/ Daughter HIV Risk	GROUP 2: Health Expert Risk Reduction	GROUP 3: Mother/ Daughter Health

Study	Intervention group 1	Intervention group 2	Intervention group 3
	Reduction intervention (MDRR) n = 135 PROVIDER: Mothers (to their daughters) TYPE: Information/ education; practical skills development (HIV risk reduction content) SETTING: Not stated	intervention (HERR) n = 127 PROVIDER: Female health professionals TYPE: Information/ education; practical skills development (HIV risk reduction content) SETTING: Not stated	Promotion intervention (MDHP) n = 141 PROVIDER: Mothers (to their daughters) TYPE: Not stated (nutrition and exercise content) SETTING: Not stated
DiClemente 2004;	HIV prevention intervention (n = 251) PROVIDERS: A trained female health educator and 2 female peer educators, all African American TYPE: Information/ education about HIV risk and prevention; practical skills development for safer sex negotiation and condom use SETTING: Family medicine clinic.	General health promotion group (n = 271) PROVIDERS: As Group 1 (assumed). TYPE: Information/ education about nutrition and exercise. SETTING: As Group 1 (assumed).	N/A
DiClemente 2009	GROUP 1: STI/HIV risk reduction intervention (Horizons) (n = 348) PROVIDER: African American women health educators TYPE: Information/ education; practical skills development; resource provision SETTING: Sexual health clinic	GROUP 2: Enhanced usual care comparison (n = 367) PROVIDER: As Group 1 TYPE: Information/ education SETTING: As Group 1	N/A
Downs 2004	GROUP 1: Interactive video intervention (n: not reported) PROVIDER: Not reported (stand alone intervention for participant self use) TYPE: Information/ Education (video); Practical skills development (cognitive rehearsal) SETTING: Primary care sites (unspecified)	GROUP 2: Content-matched control (n: not reported) PROVIDER: As group 1 TYPE: Information/ Education (book); Practical skills development (cognitive rehearsal) SETTING: As Group 1	GROUP 3: Topic-matched control (n: not reported) PROVIDER: As group 1 TYPE: Information/ Education (brochures); unclear whether also a practical skills component SETTING: As Group 1
Ferguson 1998	Culturally specific peer-led education and skills based pregnancy prevention programme (n = 33) PROVIDER: Peer counselors (aged 12 to 16 years) TYPE: Information/ education; practical skills development SETTING: Community site	Individual-led pregnancy prevention programme (n = 30) Similar to group 1, but taught by author alone; type appears to be information/ education - unclear whether skills development included	N/A
Jaworski 2001	Intervention-Motivation-Behavioural skills group (IMB) with	Information-only group (INFO) (n not reported)	Waiting list control (WLC) (n not reported)

Study	Intervention group 1	Intervention group 2	Intervention group 3
	motivational enhancement (n not reported) PROVIDERS: Two facilitators who were advanced grade students in clinical psychology with training in sexual health TYPE: Information/ education about STI transmission, consequences, prevention and treatment; Motivation enhancement; Practical skills development about sexual communication and assertiveness SETTING: Appears to be a university department.	PROVIDERS: As Group 1. TYPE: Information/ education about STI transmission, consequences, prevention and treatment. Structured and timed as Group 1 SETTING: As Group 1.	PROVIDERS: None reported. TYPE: Non-intervention group. SETTING: None reported.
Jemmott 2005	Skills-based HIV/STD risk reduction intervention (n = 235) PROVIDERS: African-American women with at least a degree and experience working with inner city youth TYPE: Information/ education about HIV/STI risks and transmission, risk reduction responsibilities and condom use; practical skills development for condom use and condom negotiation SETTING: Hospital-based adolescent medicine clinic that provided family planning services for low income inner city youth	Information-based HIV/STD risk reduction intervention (n = 228) PROVIDERS: As Group 1. TYPE: As Group 1 but without practical skills component. SETTING: As Group 1.	Health promotion control (n = 219) PROVIDERS: As Group 1. TYPE: Structure and timing as Group 1 but comprised information/ education and practical skills development relevant to prevention of cardiovascular disease, cancer and stroke; no STI content SETTING: As Group 1.
Kershaw 2009	Group prenatal care with an integrated HIV component (Centering Pregnancy Plus) (n = 318) PROVIDER(S): A trained practitioner (e.g. midwife or obstetrician) (unclear whether one or more) TYPE: Group based prenatal care programme with information/education about HIV and sexual communication practical skills development SETTING: Hospital-based obstetrics clinics.	Group prenatal care (Centering Pregnancy) (n = 335) PROVIDER(S): As Group 1. TYPE: Group based prenatal care programme similar to Group 1 but without HIV and skills components SETTING: As Group 1.	Individual standard prenatal care (n = 394) PROVIDER(S): As Group 1. TYPE: Individual based standard prenatal care programme. SETTING: As Group 1.

Study	Intervention group 1	Intervention group 2	Intervention group 3
Koniak-Griffin 2003	HIV prevention programme (CHARM 1) (n = 347 after attrition) PROVIDER: Trained nurse facilitators delivered content. Specially trained research staff de-livered questionnaires TYPE: Information/ Education, Practical Skills development, Resource provision (condoms); about HIV and AIDS SETTING: Schools with pregnant minor or young parents' programmes	Healthy living parenting programme (CHARM 2) (n = 150 after attrition) PROVIDER: A nurse facilitator who was not involved in group 1 TYPE: Information/ education, practical skills development and resource provision but not specifically about HIV and AIDS (resource provision was the same as group 1) SETTING: As Group 1.	N/A
Maynard 1994	Education and parenting skills programme for teenage mothers (n = 1721) PROVIDER: Trained case managers TYPE: Information/ education; practical skills development SETTING: 3 cities; no other details given.	Usual local welfare services provision for teenage mothers (n = 1691) Standard welfare provision (aid benefits and limited support and services - unclear whether information/education component)	N/A
Morrison-Beedy 2005	HIV risk reduction group (n = 33) PROVIDERS: Delivered by two trained interventionists who were nurses. Some administrative assistance was provided by trained research assistants TYPE: Information/ education about HIV risk reduction and practical skills development for sexual negotiation and assertiveness SETTING: An urban family planning clinic	Health promotion control group (n = 29) PROVIDERS: The same individuals who delivered Group 1. TYPE: Structured as Group 1 but content did not target sexual or HIV-related behaviours. Instead, it addressed anger management, caffeine use and nutrition, which were not included in the Group 1 intervention. Comprised information/ education but unclear whether also included practical skills development SETTING: As Group 1	N/A
Orr 1996	Brief clinic-based condom use education and practical skills develop-ment session (n = 58 after attrition) PROVIDER: Research assistant TYPE: Information/ education; practical skills development SETTING: Urban family planning and STI clinics	Brief clinic-based condom use education session (n = 54 after attrition) Similar to group 1, but excludes practical skills development component (condom use practice)	N/A
Peipert 2008	Individual-tailored dual contraception	Enhanced standard care interactive	N/A

Study	Intervention group 1	Intervention group 2	Intervention group 3	
	interactive computer intervention (n = 272) PROVIDER: None (computer delivery self-accessed by participants) TYPE: Participant-tailored information/ education on STIs and contraception delivered by interactive computer program SETTING: Secondary care (hospital for women and infants).	computer intervention (n = 270) PROVIDER: As Group 1. TYPE: Standard care information/education on STIs delivered by interactive computer program SETTING: As Group 1.		
Ploem 1997	Information, condom eroticisation/nor-malization and communication skills combination intervention (n = 49) PROVIDER: Researcher TYPE: Information/ Education about AIDS (video); Practical communication skills development (au-diotape); Condom eroti-cisation (audiotape) SETTING: University	Information only intervention (n = 44) PROVIDER: As Group 1 TYPE: Information/ Education about AIDS (video) only. SETTING: University	No-intervention control group (n = 19)	N/A
Roye 2007 (4 study groups)	HIV risk-reduction counselling and video (n randomised not stated; n = 84 at baseline) PROVIDERS: Trained clinic staff (health care assistants). TYPE: Information/ education and practical skills development: Participants received the Group 3 intervention (video) followed by the Group 2 intervention (counselling) SETTING: Not explicitly stated; appears to be family planning clinic(s)	HIV risk reduction counselling (n randomised not stated; n = 81 at baseline) PROVIDERS: Not stated; appears to be as Group 1. TYPE: Information/ education (details not reported) and practical skills development for sexual risk reduction (few details given) SETTING: As Group 1.	HIV risk reduction video (n randomised not stated; n = 88 at baseline) PROVIDER(S): Mainly self-directed by participants (watching a video) with some contact with a research assistant TYPE: Information/ education video about HIV and condom use. Appears also to involve some practical skills development SETTING: As Group 1.	Usual care (n randomised not stated; n = 84 at baseline) PROVIDER(S): Not re-ported. TYPE: Reported only as usual care, but unclear what this means SETTING: Not reported.
Scholes 2003	Self-help intervention (n = 614) PROVIDER(S): Not reported (self-help materials mailed to participants) TYPE: Information/ education (details not specified) delivered by booklet and newsletter; resource provision comprising male and female condoms, condom carrying case and instructions	Usual care (n = 596) PROVIDER(S): Not reported. TYPE: Usual care but no details provided. SETTING: As Group 1.	N/A	

Study	Intervention group 1	Intervention group 2	Intervention group 3
	SETTING: Managed care networks (details not reported).		
Shain 1999	Behavioural-cognitive intervention (n = 313) PROVIDER: Female facilitator (same race/ethnic group) TYPE: Information/education; practical skills development SETTING: Possibily public health care unit or specialist clinic	Nurse practitioner-led counselling (n = 304) Individualised HIV standard counselling according to the patient's sexual history and responses to a knowledge test; type and setting as Group 1 except excluded practical skills development	N/A
Shrier 2001	Safer sex education (n = 60) PROVIDER: female health educators TYPE: Information/education; practical skills development SETTING(S): children's hospital adolescent clinic and inpatient service	Standard care/STD education (n = 63) STD education provided at the discretion of the treating clinician; excluded practical skills development	N/A
Smith 1993	Condom desensitisation and AIDS education (n = 199) PROVIDER: Female programme providers (slightly older than students) TYPE: Information/education; practical skills development SETTING: Educational Institution (tertiary education)	No-intervention (n = 181)	N/A

NA = Not applicable

NR = Not reported

Table 2
Outcome data: engaged in sex

Study	Intervention group 1	Intervention group 2	Intervention group 3	Statistical significance	Other
Dancy 2009	*Mother/ Daughter HIV Risk Reduction intervention (MDRR)*	*Health Expert Risk Reduction intervention (HERR)*	*Mother/Daughter Health Promotion intervention (MDHP)*	*Statistical significance*	*Other*
Engaged in sex (at T3, 6 months follow-up) 1= yes	−0.46		N/A	NS	Mean difference Group 1 versus Group 2
	−0.71			NS	Mean difference Group 1 and Group 2 combined versus Group 3
DiClemente 2004;	*HIV prevention intervention*	*General health promotion group*	*N/A*	*Statistical significance*	*Adjusted odds ratio or mean difference*
Mean number of vaginal sex acts in past 6 months. 6 month follow-up	unadjusted 12.62 adjusted 14.23	unadjusted 13.80 adjusted 17.08		p-value reported only for % relative change Group 1 versus Group 2 (data not extracted)	NR
Mean number of vaginal sex acts in past 6 months. 12 month follow-up	unadjusted 14.32 adjusted 16.67	unadjusted 15.60 adjusted 17.94		p-value reported only for % relative change Group 1 versus Group 2 (data not extracted)	NR

Study	Intervention group 1	Intervention group 2	Intervention group 3	Statistical significance	Other
Mean number of vaginal sex acts in past 6 months. For full 0 to 12 month period	unadjusted 13.44 adjusted 15.82	unadjusted 14.72 adjusted 18.86		p-value reported only for % relative change Group 1 versus Group 2 (data not extracted)	NR
Downs 2004	*Interactive video intervention*	*Content-matched control*	*Topic-matched control*	*Statistical significance*	*Other*
% self-reporting sexual abstinence during previous 3 months (3 month follow-up)	20.0[a]	Data for groups 2 & 3 pooled for analysis 8.0[a]		OR2.50 P = 0.027	(Stated frequency of abstinence higher in interactive video intervention)
% self-reporting sexual abstinence during previous 3 months (6 month follow-up)	18.8[a]	Data for groups 2 & 3 pooled for analysis 11.1[a]		OR 1.45 P = 0.344	(No difference between groups)
Ferguson 1998	*Culturally specific peer-led education and skills based pregnancy prevention programme*	*Individual-led pregnancy prevention programme*	*N/A*	*Statistical significance*	*Other*
Frequency of sexual intercourse in past 4 weeks (baseline)[b] n (%) 0 1 to 2 3 to 5	7 (88) 1 (12) 0 (0)	6(50) 3 (25) 3 (25)		NR	
Frequency of sexual intercourse in past 4 weeks (3 month follow-up)[b] n (%) 0 1 to 2 3 to 5	7 (88) 0(0) 1 (12)	9(75) 2(16) 1 (08)		NR	
Never being sexually active n (%) (baseline)	25 (76)	18 (60)			
Never being sexually active n (%) (post-intervention)	25 (76)	18 (60)			
Never being sexually active n (%) (3 month follow-up)	22 (73)	10 (45)			
Jaworski 2001	*Intervention-Motivation-Behavioural skills group (1MB) (n not reported)*	*Information-only group (INFO) (n not reported)*	*Waiting list control (WLC) (n not reported)*	*Statistical significance*	*Other*
Proportion who became sexually abstinent from baseline to 2 months follow-up	22%	16%	11%	P = 0.10	
Shain 1999	*Behavioural-cognitive intervention*	*Nurse practitioner-led counselling*	*N/A*	*Statistical significance*	*Other*
Percentage who had sex with an untreated or incompletely STI treated partner 0 to 6 months follow up	10.0	16.7	N/A	P = 0.03	Unadjusted Chi-square analysis
Percentage who had sex with an un-treated or incompletely STI treated partner (data not collected for women who returned for 6-month follow up) 0 to 12 months follow up	10.0	16.7	N/A	P = 0.03	Unadjusted Chi-square analysis

NR = Not reported

NS = Not statistically significant

[a] Data estimated from a graph using a graphical measurement computer programme (Engauge); not reported whether this is a mean value

[b] Restricted to those sexually active at the start of the study (24% intervention group, 40% comparator group)

Table 3

Outcome data: condom use for vaginal sexual intercourse

Study	Intervention group 1	Intervention group 2	Intervention group 3	Statistical significance	Other
Boyer 2005 post-intervention (mean 14 months from baseline)	*Cognitive-behavioural intervention*	*Health promotion control*	*N/A*	*Statistical significance*	*Other*
Inconsistent use of condoms during full post-intervention period	474 (36.6%)[a]	495 (38.1%)[a]		NR	
Bryan 1996 (at 6 months)	*Education and skills development intervention: condom use*	*Education and skills development control: stress management*	*N/A*	*Statistical significance*	*Other*
Used condom at last intercourse (%)[b]	68	49		P < 0.05 (one tailed)	
Bull 2008	*POWER for Reproductive Health social marketing campaign*	*Comparison group*	*N/A*	*Statistical significance*	*Other*
Total number of participants in each neighbourhood and (%) ever using a female condom for vaginal or anal sex (from separate pre- and post-intervention cross-sectional surveys)[c]	SF-Mission: Pre: 284 (7.3); Post: 244 (12.7) SF-Lake- view: Pre: 282 (13.4); Post: 246 (12.2) Inglewood: Pre: 270 (8.1); Post: 255 (9. 0) E Los Angeles: Pre: 301 (4.6); Post: 250 (9.2) Cambridge: Pre: 285 (7.7); Post: 248 (6.5) Oceanside: Pre: 293 (3.4); Post: 248 (2. 8)	E Oakland: Pre: 229 (15.7); Post 244 (10.2) W Oakland Pre: 272 (11.4) ; Post 255 (4.7) E Long Beach: Pre: 296 (9.4); Post: 243 (8.2) N Long Beach: Pre: 298 (7.3); Post: 258 (4.7) N Las Vegas: Pre: 292 (6.1); Post: 254 (6.0) San Diego: Pre: 289 (9.6); Post: 244 (13. 1	)	Effect size 0.01941; P = 0.34722 (2-tailed)	(Stated null effect, i. e. no difference between groups)
Choi 2008	*Female condom skills training intervention*	*General health promotion intervention*	*N/A*	*Statistical significance*	*Other*
Using female condom at least once (%) (baseline)	1.41	0.51		P = 0.362	
Using female condom at least once (%) (3 month post-intervention)	45.31	19.11		P < 0.001	
Using female condom at least once (%) (6 month post-intervention)	30.80	7.65		p<0.001	
Using male condom at least once (%) (baseline)	68.45	64.39		P = 0.388	
Using male condom at least once (%) (3 month post-intervention)	70.75	65.46		P = 0.289	
Using male condom at least once (%) (6 month post-intervention)	63.99	59.77		P = 0.417	
% of vaginal or anal intercourse protected by female condom (baseline)	3.82	7.62		P = 0.095	
% of vaginal or anal intercourse protected by female condom (3 month post-intervention)	11.57	11.30		P = 0.918	

Study	Intervention group 1	Intervention group 2	Intervention group 3	Statistical significance	Other
% of vaginal or anal intercourse protected by female condom (6 month post-intervention)	18.87	14.40		P = 0.198	
% of vaginal or anal intercourse protected by male condom (baseline)	38.05	39.66		P = 0.681	
% of vaginal or anal intercourse protected by male condom (3 month post-intervention)	37.00	39.60		P = 0.511	
% of vaginal or anal intercourse protected by male condom (6 month post-intervention)	44.30	40.49		P = 0.371	
% of vaginal or anal intercourse protected by any condom (baseline)	38.10	39.66		P = 0.692	
% of vaginal or anal intercourse protected by any condom (3 month post-intervention)	45.06	41.86		P = 0.426	
% of vaginal or anal intercourse protected by any condom (6 month post-intervention)	50.42	40.97		P = 0.028	
DiClemente 2004	*HIV prevention intervention*	*General health promotion group*	*N/A*	*p-value for OR or MD*	*Adjusted odds ratio (OR) or mean difference (MD), 95% CI)*
Unadjusted percentage with consistent condom use in preceding 30 days At 6 month follow up	75.3	58.2		P = 0.06	OR 1.77 (0.97, 3.20)
Unadjusted percentage with consistent condom use in preceding 30 days At 12 month follow up	73.3	56.5		P = 0.02	OR 2.23 (1.17, 4.27)
Unadjusted percentage with consistent condom use in preceding 30 days For full 0 to 12 month period	NR	NR		P = 0.003	OR 2.01 (1.28, 3.17) (from GEE regression model)
Unadjusted percentage with consistent condom use in preceding 6 months At 6 month follow up	61.3	42.6		P = 0.001	OR 2.48 (1.44, 4.26)
Unadjusted percentage with consistent condom use in preceding 6 months At 12 month follow up	58.1	45.3		P = 0.01	OR 2.14 (1.20, 3.84)
Unadjusted percentage with consistent condom use in preceding 6 months For full 0 to 12 month period	NR	NR		P < 0.001	OR 2.30 (1.51, 3.50) (from GEE regression model)
Unadjusted percentage with condom use during	80.7	54.1		P < 0.001	OR 5.08 (2.83, 9.14)

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Study	Intervention group 1	Intervention group 2	Intervention group 3	Statistical significance	Other
last vaginal sex At 6 month follow up					
Unadjusted percentage with condom use during last vaginal sex At 12 month follow up	72.3	53.9		P < 0.001	OR 3.32 (1.86, 5.92)
Unadjusted percentage with condom use during last vaginal sex For full 0 to 12 month period	NR	NR		P < 0.001	OR 3.94 (2.58, 6.03) (from GEE regression model)
Unadjusted mean (SD) percentage condom use in preceding 30 days At 6 month follow up	84.93 (30.80)	65.12 (44.30)		P < 0.001	MD 18.38 (10.47, 25.45)
Unadjusted mean (SD) percentage condom use in preceding 30 days At 12 month follow up	79.97 (36.64)	62.82 (45.28)		P < 0.001	MD 21.09 (10.73, 32.20)
Mean (SD) percentage condom use in preceding 30 days. For full 0 to 12 month period	NR	NR		P < 0.001	MD 21.09 (13.70, 28.48) (from GEE regression model)
Unadjusted mean (SD) percentage condom use in preceding 6 months At 6 month follow up	82.29 (30.24)	61.65 (40.70)		P < 0.001	MD 17.33 (10.26, 24.39)
Unadjusted mean (SD) percentage condom use in preceding 6 months At 12 month follow up	73.49 (37.86)	57.58 (43.21)		P = 0.001	MD 18.33 (9.46, 29.86)
Mean (SD) percentage condom use in preceding 6 months. For full 0 to 12 month period	NR	NR		P < 0.001	MD 25.07 (19.89, 30.25) (from GEE regression model)
Unadjusted mean (SD) frequency score of applying condoms on sex partners in preceding 6 months (rated 1 =never to 5= every time on 5-point scale) At 6 month follow up	2.18 (1.38)	1.51 (1.09)		P < 0.001	MD 0.69 (0.42, 0.92)
Unadjusted mean (SD) frequency score of applying condoms on sex partners in preceding 6 months (scale as above) At 12 month follow up	1.97 (1.28)	1.59 (1.09)		P = 0.003	MD 0.44 (0.19, 0.77)
Mean (SD) frequency score of applying condoms on sex partners in pre-ceding 6 months (scale as above) For full 0 to 12 month period	NR	NR		P < 0.001	MD 0.58 (0.37, 0.78) (from GEE regression model)
Unadjusted mean (SD) number of episodes of unprotected vaginal sex in preceding 30	1.02 (3.37)	2.02 (4.06)		P = 0.046	MD -1.06 (-1.82, 0.27)

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Study	Intervention group 1	Intervention group 2	Intervention group 3	Statistical significance	Other
days 6 month follow up					
Unadjusted mean (SD) number of episodes of unprotected vaginal sex in preceding 30 days 12 month follow up	1.15 (3.03)	2.04 (4.47)		P = 0.002	MD -1.06 (-1.86, 0.44)
Mean (SD) number of episodes of unprotected vaginal sex in preceding 30 days For full 0 to 12 month period	NR	NR		P = 0.001	MD -1.17 (-1.88, -0.45) (from GEE regression model)
Unadjusted mean (SD) number of episodes of unprotected vaginal sex in preceding 6 months 6 month follow up	3.77 (11.68)	9.24 (23.08)		P = 0.006	MD -6.51 (-10.97, -2.90)
Unadjusted mean (SD) number of episodes of unprotected vaginal sex in preceding 6 months 12 month follow up	5.77 (16.41)	10.25 (24.66)		P = 0.02	MD -5.51 (-11.18, -0.34)
Mean (SD) number of episodes of unprotected vaginal sex in preceding 6 months For full 0 to 12 month period	NR	NR		P = 0.001	MD -7.15 (-11.38, -2.93) (from GEE regression model)
DiClemente 2009	*STI/HIV risk reduction intervention (Horizons)*	*Enhanced usual care comparison*	*N/A*	*Statistical significance*	*Adjusted mean difference or RR, 95% CI)*
Proportion of condom protected sex acts in the past 14 days At 6 months follow up	0.60 (unadjusted)	0.48 (unadjusted)		P = 0.057 for adjusted mean difference	Adjusted mean difference = 5.49 (-1. 87 to 12.86)
Proportion of condom protected sex acts in the past 14 days At 12 months follow up	0.61 (unadjusted)	0.47 (unadjusted)		P = 0.001 for adjusted mean difference	Adjusted mean difference = 12.79 (3. 06 to 22.52)
Proportion of condom protected sex acts in the past 14 days For 0 to 12 months follow up	NR	NR		P = 0.004 for adjusted mean difference	Adjusted mean difference = 8.17 (1.22 to 15.12)
Proportion of condom protected sex acts in the past 60 days At 6 months follow up	0.63 (unadjusted)	0.47 (unadjusted)		P < 0.001 for adjusted mean difference	Adjusted mean difference = 12.09 (5. 64 to 18.55)
Proportion of condom protected sex acts in the past 60 days At 12 months follow up	0.61 (unadjusted)	0.48 (unadjusted)		P = 0.002 for adjusted mean difference	Adjusted mean difference = 10.78 (3. 61 to 17.95)
Proportion of condom protected sex acts in the past 60 days For 0 to 12 months follow up	NR	NR		P < 0.001 for adjusted mean difference	Adjusted mean difference = 10.84 (5. 27 to 16.42)
Adjusted consistent condom use in past 14 days, % At 6 months follow up	40.2	39.0		P = 0.33 for adjusted RR	Adjusted RR 1.22 (0.84 to 1.57)
Adjusted consistent condom use in past 14 days, % At 12 months follow up	49.7	39.0		P = 0.01 for adjusted RR	Adjusted RR 1.70 (1.09 to 1.95)

Study	Intervention group 1	Intervention group 2	Intervention group 3	Statistical significance	Other
Adjusted consistent condom use in past 14 days, % For 0 to 12 months follow up	NR	NR		P = 0.04 for adjusted RR	Adjusted RR 1.29 (1.01 to 1.59)
Adjusted consistent condom use in past 60 days, % At 6 months follow up	31.9	28.2		P = 0.14 for adjusted RR	Adjusted RR 1.37 (0.91 to 1.81)
Adjusted consistent condom use in past 60 days, % At 12 months follow up	40.5	30.1		P = 0.007 for adjusted RR	Adjusted RR 1.75 (CI 1.13 to 2.09)
Adjusted consistent condom use in past 60 days, % For 0 to 12 months follow up	NR	NR		P = 0.01 for adjusted RR	Adjusted RR 1.41 (1.09 to 1.80)
Adjusted condom use at last sexual intercourse, % At 6 months follow up	51.9	43.5		P = 0.06 for adjusted RR	Adjusted RR 1.36 (0.98 to 1.58)
Adjusted condom use at last sexual intercourse, % At 12 months follow up	53.3	42.7		P = 0.01 for adjusted RR	Adjusted RR 1.51 (1.06 to 1.68)
Adjusted condom use at last sexual intercourse, % For 0 to 12 months follow up	NR	NR		P = 0.005 for adjusted RR	Adjusted RR 1.30 (1.09 to 1.54)
Downs 2004	*Interactive video intervention*	*Content-matched control*	*Topic-matched control*	*Statistical significance*	*Other*
Adjusted frequency of condom use during previous 3 months (6-point scale)[d] (3 month follow up)	Not reported	Data for groups 2 & 3 pooled for analysis but not reported		P = 0.57 for comparison group 1 versus (groups 2+3 pooled)	(Stated no difference between groups)
Adjusted frequency of condom use during previous 3 months (6-point scale)[d] (6 month follow up)	Not reported	Data for groups 2 & 3 pooled for analysis but not reported		P = 0.15 for comparison group 1 versus (groups 2+3 pooled)	(Stated no difference between groups)
Number of self-reported condom failures during previous 3 months6 (3 month follow up)	0.630[f]	Data for groups 2 & 3 pooled for analysis 0.659[f]		P = 0.92 for comparison group 1 versus (groups 2+3 pooled)	(Stated no difference between groups)
Number of self-reported condom failures during previous 3 months[e] (6 month follow up)	0.369[f]	Data for groups 2 & 3 pooled for analysis 0.709f		P = 0.02 for comparison group 1 versus (groups 2+3 pooled)	(Stated fewer condom failures in video intervention group)
Ferguson 1998	*Culturally specific peer-led education and skills based pregnancy prevention programme*	*Individual-led pregnancy prevention programme*	*N/A*	*Statistical significance*	*Other*
Use of effective contraceptives at most recent sexual intercourse n (%)[g] (baseline)	5(63)	10 (83)		NR	
Use ofeffective contraceptives at most recent sexual intercourse n (%)[g] (post-intervention)	3 (38)	7(58)		NR	
Use ofeffective contraceptives at most recent sexual intercourse n (%)[g] (three month follow-up)	2(25)	4(33)		NR	

Study	Intervention group 1	Intervention group 2	Intervention group 3	Statistical significance	Other
Jaworski 2001	*Intervention-Motivation-Behavioural skills group (IMB)*	*Information-only group (INFO)*	*Waiting list control (WLC)*	*Statistical significance*	*Other*
Mean (SD) number of vaginal sex acts without a condom in past 2 months. Baseline[h]	4.7 (6.3)	3.9 (3.9)	5.6 (9.1)	Stated no difference between groups based on log odds	
Mean (SD) number of vaginal sex acts without a condom in past 2 months. 2 month follow up[h,I]	4.4 (8.6)	3.7 (6.3)	4.6 (8.6)	Stated no difference between groups based on log odds	
Mean (SD) number of vaginal sex acts with a condom in past 2 months. Baseline[h]	5.0 (6.5)	3.0 (4.1)	3.3 (3.9)	Stated no difference between groups based on log odds	
Mean (SD) number of vaginal sex acts with a condom in past 2 months. 2 month follow up[h,I]	3.2 (5.0)	7.8 (22.9)	4.0 (7.2)	Stated no difference between groups based on log odds	
Jemmott 2005	*Skills-based HIV/ STD risk reduction intervention*	*Information-based HIV/ STD risk reduction intervention*	*Health promotion control*	*p-value for difference based on adjusted means; effect size, d (p-value for d)*	*Other*
Mean (SE) number of days of sex without condom in past 3 months. 3 month follow up with corresponding baseline data for 3-month completers	Baseline, unadjusted: 2.58 (0. 54) 3 months, unadjusted: 3.66 (0.76) 3 months, adjusted: 3.71 (0.75)	3.06 (0.47) 3.83 (0.79) 3.56 (0.75)	2.71 (0.43) 3.52 (0.60) 3.46 (0.78)	Group 1 versus Group 2: P = 0.83; d=NR Group 1 versus Group 3: P = 0.95; d=NR Group 2 versus Group 3: P = 0.89; d=NR	
Mean (SE) number of days of sex without condom in past 3 months. 6 month follow up with corresponding baseline data for 6-month completers	Baseline, unadjusted: 2.13 (0. 38) 6 months, unadjusted: 2.99 (0.63) 6 months, adjusted: 2.98 (0.69)	3.32 (0.50) 3.17 (0.66) 2.60 (0.68)	2.69 (0.42) 3.47 (0.71) 3.26 (0.70)	Group 1 versus Group 2: P = 0.74; d=NR Group 1 versus Group 3: P = 0.66; d=NR Group 2 versus Group 3: P = 0.43; d=NR	
Mean (SE) number of days of sex without condom in past 3 months. 12 month follow up with corresponding baseline data for 12-month completers	Baseline, unadjusted: 2.23 (0. 40) 12 months, unadjusted: 2.80 (0.44) 12 months, adjusted: 2.27 (0.81)	3.45 (0.55) 5.04 (0.81) 4.04 (0.80)	2.82 (0.44) 5.73 (0.99) 5.05 (0.81)	Group 1 versus Group 2: P = 0.03; d=0.19 (P = 0.033) Group 1 versus Group 3: P = 0.002; d=0.28 (P = 0.002) Group 2 versus Group 3: P = 0.32; d=NR	
Kershaw 2009	*Group prenatal care with an integrated HIV component (n = 318)*	*Group prenatal care (n = 335)*	*Individual prenatal care (n = 394)*	*p-value for difference [Group 1] versus [Groups 2 & 3 combined]; effect size (d) (if reported) ; analyses adjusted for baseline variables*	*Other*
Mean (SE) % self-estimated condom use in past 6 months Baseline	39.29 (37.7)	35.54 (37.0)	35.93 (38.1)	NR	Meaning of % condom use unclear
Mean (SE) % self-estimated condom use in past 6 months[J,K] At 3rd trimester (ca 17 weeks after baseline)	34.67 (39.2)	31.35 (37.9)	29.01 (39.3)	P = 0.30	Meaning of % condom use unclear; p-value based on F statistic
Mean (SE) % self-estimated condom use in past 6 months[J,K] At 6 months post-partum (ca 49 weeks after baseline)	51.03 (40.6)	42.74 (39.5)	40.67 (40.1)	P = 0.007 Group 1 versus 2: d= 0.16 1 Group 1 versus 3: d= 0.2 1	Meaning of % condom use unclear; p-value based on F statistic

Study	Intervention group 1	Intervention group 2	Intervention group 3	Statistical significance	Other
Mean (SE) % self-estimated condom use in past 6 months[j,k] At 12 months post-partum (ca 75 weeks after baseline)	49.76 (41.4)	41.88 (41.3)	44.11 (40.8)	P = 0.04	Meaning of % condom use unclear; p-value based on F statistic
% reporting that condom use was for STI protection (rather than pregnancy prevention)[k] At 12 months post-partum (ca 75 weeks after baseline)	64	55 (Groups 2 and 3 combined)		P = 0.028	Statistical test NR
Mean (SE) number of unprotected sex acts in past 30 days Baseline	5.26 (6.8)	6.45 (8.3)	5.66 (7.6)	NR	
Mean (SE) number of unprotected sex acts in past 30 days[m] At 3rd trimester (ca 17 weeks after baseline)	4.47 (6.9)	5.05 (7.2)	4.14 (6.6)	P = 0.49	p-value based on F statistic
Mean (SE) number of unprotected sex acts in past 30 days[m] At 6 months post-partum (ca 49 weeks after baseline)	3.81 (6.5)	4.84 (7.2)	4.72 (7.0)	P = 0.18	p-value based on F statistic
Mean (SE) number of unprotected sex acts in past 30 days[m] At 12 months post-partum (ca 75 weeks after baseline)	3.89 (6.5)	5.69 (7.9)	5.26 (7.8)	P = 0.04 (table) P = 0.05 (text) Group 1 versus 2: d= 0.16 1 Group 1 versus 3: d= 0.15 1	p-value based on F statistic (discrepancy in the paper)
Koniak-Griffin 2003	*HIV prevention programme (CHARM 1)*	*Healthy living parenting programme (CHARM 2)*	*N/A*	*Difference between groups in change through time*	*Other*
Number of unprotected sex episodes, mean (SD) in past 3 months. Baseline	14.10 (21.92)	12.73 (20.03)		P= 0.634 from repeated measures ANCOVA adjusted for baseline behavioural intentions and hedonism	
Number of unprotected sex episodes, mean (SD) in past 3 months.[n] 3 months follow up	5.41 (10.26)	6.54 (12.54)			
Number of unprotected sex episodes, mean (SD) in past 3 months.[n] 6 months follow up	7.94 (12.22)	7.93 (14.74)			
Number of unprotected sex episodes, mean (SD) in past 3 months.[n] 12 months follow up	10.75 (20.03)	9.28 (16.49)			
Condom use during last sex episode, n (%) of participants. Baseline	51 (16)	31 (23)	N/A	NR	
Condom use during last sex episode, n (%) of participants. 12 months follow up	165 (48)	75 (50)		NR	

Study	Intervention group 1	Intervention group 2	Intervention group 3	Statistical significance	Other
Proportion engaging in risky (= unprotected) sex in past 3 months. Baseline	0.688	0.632		N/A	
Proportion engaging in risky (= unprotected) sex in past 3 months. 6 months follow up	0.596	0.576		0.096 (0.059); P > 0.05	
Proportion engaging in risky (= unprotected) sex in past 3 months. 12 months follow up	0.617	0.612		NR	
Maynard 1994	*Education and parenting skills programme for teenage mothers*	*Usual local welfare services provision for teenage mothers*	*N/A*	*Statistical significance*	*Other*
% Contraceptive (condom) use at last intercourse (at follow-up)	23.1% (for study sample as a whole)		N/A	NR	
Morrison-Beedy 2005	*HIV risk reduction group*	*Health promotion control group*	*N/A*	*Difference between groups: p-value from Chi square test; effect size from mean difference & pooled variance*	*Other*
Frequency (mean) of vaginal sex with condom during past 3 months. Baseline	5.8	8.1		P = 0.43 Effect size=NR	
Frequency (mean) of vaginal sex with condom during past 3 months 3-month follow up	6.3	13.2		P = 0.50 Effect size=0.16	
Frequency (mean) of vaginal sex without condom during past 3 months. Baseline	5.4	7.6		P = 0.55 Effect size=NR	
Frequency (mean) of vaginal sex without condom during past 3 months 3-month follow up	4.3	6.0		P = 0.38 Effect size=0.26	
Orr 1996	*Brief clinic-based condom use education and practical skills development session*	*Brief clinic-based condom use education session*	*N/A*	*Statistical significance*	*Other*
Probability of having used condoms for protection against STIs	OR 2.4, 95% CI 1.2,5.2)			P = 0.02	
Probability of having used condoms for contraception	NR			NR	
Probability of having used condoms for vaginal intercourse	OR 3.1, 95% CI 1.4 to 6.8)			P = 0.005	
Probability of having used condoms at last coitus	NR			NR	
Frequency of condom use for contraception	OR 7.5, 95% CI 2.9 to 10.72)			P = 0.0001	
Frequency of condom use for STD protection	OR 13.2, 95% CI 4.2 to 41.8)			P = 0.0001	

Study	Intervention group 1	Intervention group 2	Intervention group 3	Statistical significance	Other
Frequency of condom use for vaginal intercourse	OR 11.8, 95% CI 3.3 to 41.9)			P = 0.0002	
Condom use at last described as "no effect" coitus				NS	
Peipert 2008	I*ndividual-tailored dual contraception computer intervention*	*Enhanced standard care computer intervention*	*N/A*	Relative risk, 95% CI) for Group 1 **a.** unadjusted **b.** adjusted for baseline covariates	*Other*
Any dual method use (time period not stated) at 24-month follow up, n/N (%)	86/272 (32)	71/270 (26)		**a.** 1.38 (1.00,1.89) **b.** 1.70 (1.09,2.66)	
Consistent condom use (time period not stated) at 24-month follow up, n/N (%)	124/272 (46)	124/270 (46)		**a.** 1.14 (0.89,1.47) **b.** 1.26 (0.88,1.79)	
Ploem 1997	*Information, condom eroticisation/ normalization and communication skills combination intervention*	*Information only intervention*	*No-intervention control group*	*Statistical significance*	*Other*
Consistent condom use[o]	1	2	2	NR	
Proportion of intercourse occasions protected by con-dom[o] n (%)	Increase = 7 (58)[p] No change = 3 (25) Decrease = 2 (17)	Increase = 0 (0)[p] No change =13 (81)[p] Decrease = 3 (19)	Increase = 4 (50) No change = 3 (37. 5) Decrease = 1 (12.5)	P < 0.05	
Roye 2007	*1: Video + counselling; 2: Counselling only; 3: Video only; 4: Usual care*			*Group differences*	*Other*
Percentage who used condoms at last vaginal intercourse with main partner 3 month follow up	NR (quantitative data reported only for ethnic and age sub groups)			Group 2 versus Group 4: stated NS (p-value NR). Group 3 versus Group 4: stated NS (p-value NR). Group 1 versus Group 4: stated 'significant at 0.06 level' (exact p-value NR)	Stated that Group 1 were 2.5 times as likely as Group 4 to have used a condom at last intercourse with their main partner
Percentage who used condoms at last vaginal intercourse with main partner 12 month follow up	NR (quantitative data reported only for ethnic and age sub groups)			Stated no significant differences for any group comparisons (p-values NR)	
Condom use during anal intercourse 3 and 12 month follow up	NR			Stated no significant effect (for any group comparisons) (p-values NR)	
Scholes 2003 (Group x site interactions were not statistically significant unless stated)	*Self-help intervention*	*Usual care*	*N/A*	*Unadjusted Odds ratio (OR) or mean difference (MD), 95% CI)*	*Adjusted odds ratio (OR) or mean differ-ence(MD), 95% CI) ; p-value*
Percentage sexually active who reported condom use with any partner in past 3 months At 6 month follow up (total both groups n = 849)	72.8	63.0		OR 1.57 (1.18, 2. 10) p-value NR	OR 1.86 (1.32, 2. 65) P = 0.0005
Percentage sexually active who reported condom use with a primary partner in past 3 months At 6 month follow up (total both groups n = 756)	69.1	57.9		OR 1.63 (1.21, 2. 19) p-value NR	OR 1.97 (1.37, 2. 86) P = 0.0003

Study	Intervention group 1	Intervention group 2	Intervention group 3	Statistical significance	Other
Percentage sexually active who reported condom use with a non-primary partner in past 3 months At 6 month follow up (total both groups n = 155)	87.5	76.9		OR 2.10 (0.87, 5. 10) p-value NR	OR 2.25 (0.91, 6. 07) P = 0.09
Percentage sexually active who reported condom use with any partner in past 3 months Combined 3 and 6 month follow up (repeated measures analysis) (total both groups n = 1707)	71.7	64.0		OR 1.42 (1.11, 1. 83) p-value NR	OR 1.65 (1.24, 2. 19) P = 0.0005
Percentage sexually active who reported condom use with a primary partner in past 3 months Combined 3 and 6 month follow up (repeated measures analysis) (total both groups n = 1540)	68.9	58.5		OR 1.57 (1.22, 2. 03) p-value NR	OR 1.96 (1.46, 2. 65) P = 0.0001
Percentage sexually active who reported condom use with a non-primary partner in past 3 months Combined 3 and 6 month follow up (repeated measures analysis) (total both groups n = 322)	82.1	80.2		OR 1.13 (0.63, 2. 03) p-value NR	OR 1.09 (0.61, 2. 41) P = 0.77
Mean percent of inter- course episodes condoms were used by sexually active participants with any male partner in past 3 months 6 month follow up (Total both groups n = 842)	52.7	47.9		MD 4.8% (-1.2,10. 7) p-value NR	MD 5.2% (0.4, 10. 4) P = 0.05 Stated significant Group x site interaction (P = 0.01)[q]: Site 1: stated mean % in both groups very similar (data not reported) Site 2: MD 15.0% (6.3, 23.8); P = 0. 001
Mean percent of inter-course episodes condoms were used by sexually active participants with any male partner in past 3 months Combined 3 and 6 month follow up (repeated measures analysis) (Total both groups n = 1692)	52.0	49.2		MD 2.8% (-2.4, 8. 0) p-value NR	MD 4.5% (-0.3, 9. 3) P = 0.07
Percentage sexually active who reported consistent condom use with all partners in past 3 months 6 month follow up (total both groups n = 849)	36.8	33.5		OR 1.16 (0.87, 1. 54) p-value NR	OR 1.24 (0.89, 1. 73) P = 0.21 Stated significant Group x site interaction (P = 0.01): Site 1: OR 0.92 (0. 61, 1.38); P = 0.68 Site 2: OR 2.94 (1. 51, 5.92); P = 0.002
Shain 1999	*Behavioural-cognitive intervention*	*Nurse practitioner-led counselling*	*N/A*	*Statistical significance*	*Other*
Percentage of unprotected sexual acts from study entry through to follow-up at 12 months Fewer than 5	29.7	20.2	N/A	P = 0.03	

Study	Intervention group 1	Intervention group 2	Intervention group 3	Statistical significance	Other
Percentage of unprotected sexual acts from study entry through to follow-up at 12 months 5 or more	70.3	79.8	N/A		
Percentage practising unsafe sex (never using condoms with at least one casual partner in the past 3 months OR both ≥5 unprotected sex acts in the past 3 months AND incorrect or problematic condom use) Baseline	41.8	38.2	N/A	P = 0.42	Logistic regression adjusting for base-line values
Percentage practising unsafe sex (never using condoms with at least one casual partner in the past 3 months OR both ≥5 unprotected sex acts in the past 3 months AND incorrect or problematic condom use) 0 to 6 months follow up	20.1	28.5	N/A	P = 0.02	Logistic regression adjusting for baseline values
Percentage practising unsafe sex (never using condoms with at least one casual partner in the past 3 months OR both ≥ 5 unprotected sex acts in the past 3 months AND incorrect or problematic condom use) 6 to 12 months follow up	21.3	31.6	N/A	P = 0.007	Logistic regression adjusting for baseline values
Percentage practising unsafe sex (never using condoms with at least one casual partner in the past 3 months OR both ≥ 5 unprotected sex acts in the past 3 months AND incorrect or problematic condom use) 0 to 12 months follow up	29.7	43.0	N/A	P < 0.001	Logistic regression adjusting for baseline values
Shrier 2001	*Safer sex education*	*Standard care/STD education*	*N/A*	*Statistical significance*	*Other*
At last sexual encounter, n (%) At baseline	29 (47)	24 (38)		NR	
At last sexual encounter, n (%) At 1 month follow up	22 (55)	24 (59)		NR	
At last sexual encounter, n (%) At 6 months follow up	25 (60)	26 (54)		P < 0.10 for difference in change from baseline	
At last sexual encounter, n (%) At 12 months follow up	18 (60)	18 (53)		NR	
Frequency of use with main partner (mean frequency (of 5 *r*)). At baseline	3.2	3.3		NR	
Frequency of use with main partner (mean frequency (of	3.7	3.5	N/A	NR	

Study	Intervention group 1	Intervention group 2	Intervention group 3	Statistical significance	Other
5[f])). At 1 month follow up					
Frequency of use with main partner (mean frequency (of 5[f])). At 6 months follow up	3.7	3.4		NR	
Frequency of use with main partner (mean frequency (of 5[f])). At 12 months follow up	3.6	3.5		NR	
Consistent use with main partner (every time)[s] n (%). At baseline	12 (26)	14 (30)		NR	
Consistent use with main partner (every time)[s] n (%). At 1 month follow up	12(40)	9 (29)		NR	
Consistent use with main partner (every time)[s] n (%). At 6 months follow up	17 (50)	12 (32)		NR	
Consistent use with main partner (every time)[s] n(%).At 12 months follow up	12(52)	11 (36)	N/A	NR	
Frequency of use with another partner in past 6 months (mean frequency (of 5[f])) At baseline	4.3	4.1	N/A	NR	
Frequency of use with another partner in past 6 months (mean frequency (of 5[f])) At 1 month follow up	4.7	4.2	N/A	P < 0.10 for difference in change from baseline	
Frequency of use with another partner in past 6 months (mean frequency (of 5[f])) At 6 months follow up	4.2	4.5	N/A	NR	
Frequency of use with another partner in past 6 months (mean frequency (of 5[f])) At 12 months follow up	4.5	4.1	N/A	NR	
Consistent use with another partner in past 6 months (every time)[t] n (%). At baseline	12(50)	10 (53)	N/A	NR	
Consistent use with another partner in past 6 months (every time)[t] n (%). At 1 month follow up	11 (69)	4 (33)	N/A	P < 0.10 for difference in change from baseline	
Consistent use with another partner in past 6 months (every time)[t] n (%). At 6 months follow up	6 (60)	17 (68)	N/A	NR	
Consistent use with another partner in past 6 months (every time)[t]	5(71)	5(42)		NR	

Study	Intervention group 1	Intervention group 2	Intervention group 3	Statistical significance	Other
n(%).At 12 months follow up					
Smith 1993	*Condom desensitisation and AIDS education*	*No intervention*	*N/A*	*Statistical significance*	*Other*
Self-reported condom use[u,v] 2 months follow-up	52.04	55.68[w]		P = 0.19 (t test)	

NR = Not reported

[a] Denominator for both groups is 1,298 (which is less than the 1381 who completed the study). It is not clear what the denominator is for each of the randomised study groups.

[b] Limited to young women who had had intercourse at least once during the follow-up period (n = 83 of 198 randomised).

[c] Paper states that only young women who heard of female condoms were asked to answer questions related to female condoms. At follow-up 1,912 (64%) of the total study sample (3,003) had heard of the female condom. Furthermore, questions on condom use appear to be limited to those who had ever had sex (2,005 of the total 3,003 follow-up sample). The sub-group of young women in each study group who therefore answered questions on condom use is therefore unclear.

[d] Participants who were sexually abstinent were omitted from this analysis (up to 20%).

[e] Abstinent participants and those who never used condoms in the past three months were omitted from this analysis.

[f] Estimated from a graph using a computer graphics measurement programme (Engauge); not reported whether this is a mean value.

[g] Restricted to those who were sexually active at the start of the study (25% in the intervention group; 40% in the comparator group).

[h] Reported as mean (SD) without explanation and as log odds. Appears to refer to the mean (SD) number of acts, according to information in a related publication.

[i] not explicitly stated, but it appears that these data exclude the sub-group of up to 20% who became sexually abstinent from baseline to follow-up.

[j] Reported recall period exceeds the interval between follow up assessments.

[k] Data presented for sexually active participants in the past six months (though number of such participants not reported).

[l] Assumed by review author and that this is an effect size; however, described in the text as both an effect size and a difference (no details of calculation method provided).

[m] Individuals who did not have any sexual partners were coded as having zero unprotected sex acts. The number of such individuals is not reported.

[n] Those abstinent over the past three months were assigned a zero score (though the number of abstainers was not reported).

[o] sub-set of 36 (of 112 randomised) who had been coitally active in the month prior to and subsequent to the intervention.

[p] Statistically significant between study groups

[q] Not stated whether this group x site interaction was for the analysis of 6 month follow up or of the combined 3 and 6 month follow up.

[r] 5-point response scale, from "every time" to "never".

[s] For a sub-set of participants reporting a main partner at the time of assessment (54 of 123 randomised).

[t] For a sub-set of participants reporting another partner at the time of assessment (19 of 123 randomised).

[u] Computed as index reflecting frequency of condom use over previous 2 months divided by the frequency of intercourse occasions, multiplied by 100

[v] Based on a sub-set of 58 of 380 randomised participants. It is not clear whether this sub-set is limited to those who were sexually active during the study period (notwithstanding attrition).

[w] Reported as 54.28 in the text of the paper and 55.68 in a table.

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Table 4
Outcome data: incidence of STIs

Study	Intervention group 1	Intervention group 2	Intervention group 3	Statistical significance	Other
Boyer 2005 (mean 14 months from baseline)	*Cognitive-behavioural intervention*	*Health promotion control*	*N/A*	*Statistical significance*	*Other*
Any of three STIs	47 (5.7%)[a]	73 (8.8%)[a]	N/A	NR	
DiClemente 2004	*HIV prevention intervention*	*General health promotion group*	*N/A*	*p-value for OR*	*Adjusted odds ratio (OR), 95% CI) for the 12 month period after baseline (from GEE regression model)*
Crude laboratory-determined chlamydia incidence per 100 person-months For full 0 to12 month period	2.1	2.0		P = 0.04	OR 0.17 (0.03, 0.92)
Crude laboratory-determined Trichomonas incidence per 100 person-months For full 0 to 12 month period	0.9	1.2		P = 0.16	OR 0.37 (0.09, 1.46)
Crude laboratory-determined gonorrhoea incidence per 100 person-months For full 0 to 12 month period	0.9	0.7		P = 0.21	OR 0.14 (0.01, 3.02)
DiClemente 2009	*STI/HIV risk reduction intervention (Horizons)*	*Enhanced usual care comparison*	*N/A*	*Statistical significance*	*Generalised estimating equations regression models (GEE) Risk ratio (95% CI)*
chlamydia incidence baseline to 12 months, n	42	67		crude RR 0. 71, 95% CI 0.50 to 1.02) P = 0.059	0.65 (0.42 to 0.98) P = 0.04
Gonorrhoea incidence baseline to 12 months, n	23	25		P = 0.62	0.85 (0.44 to 1.63)
Trichomoniasis incidence baseline to 12 months, n	52	57		P = 0.87	0.96 (0.59 to 1.54)
Downs 2004	*Interactive video intervention*	*Content-matched control*	*Topic-matched control*	*Statistically significant*	*Other*
% with self-reported diagnosis with any of 9 STIs (including chlamydia) during previous 3 months (6 month follow- up)	11.8[b]	Data for groups 2 & 3 pooled for analysis 22.1[b]		OR 2.79 P = 0.05	(Stated frequency lower in interactive video intervention group; same direction of difference applied to all 9 STIs;

Study	Intervention group 1	Intervention group 2	Intervention group 3	Statistical significance	Other
					sign test P = 0.004)
% with self-reported diagnosis with chlamydia during previous 3 months (6 month follow-up)	5.8[b]	Data for groups 2 & 3 pooled for analysis 7.8[b]		OR 7.75 P = 0.05	(Stated frequency lower in interactive video intervention group)
% with clinically-determined chlamydia at 6 month follow-up	Not reported	Data for groups 2 & but not reported	3 pooled for analysis	OR 2.79 P = 0.56 (underpowered)[c]	(Frequency lower in interactive video intervention)
Jemmott 2005	*Skills-based HIV/ STD risk reduction intervention*	*Information-based HIV/ STD risk reduction intervention*	*Health promotion control*	*p-value for difference based on adjusted means; effect size, d (p-value for d)*	
Mean (SE) % testing positive for chlamydia, gonorrhoea and/or trichomoniasis 6 month follow-up with corresponding baseline data for 6-month completers	Baseline, unadjusted: 21.3 (3. 1) 3 months, unadjusted: 15.5 (2.8) 3 months, adjusted: 15.8 (2.7)	27.2 (3.4) 16.0 (2.8) 15.5 (2.8)	17.5 (2.9) 14.6 (2.7) 14.8 (2.8)	Group 1 versus Group 2: P = 0.91; d=NR Group 1 versus Group 3: P = 0.80; d=NR Group 2 versus Group 3: P = 0.89; d=NR	
Mean (SE) % testing positive for chlamydia, gonorrhoea and/or trichomoniasis 12 month follow-up with corresponding baseline data for 12-month completers	Baseline, unadjusted: 23.6 (3. 5) 12 months, unadjusted: 10.8 (2.6) 12 months, adjusted: 10.5 (2.9)	24.7 (3.5) 16.0 (3.0) 15.4 (2.9)	14.3 (2.8) 17.4 (3.0) 18.2 (2.8)	Group 1 versus Group 2: P = 0.23; d=NR Group 1 versus Group 3: P = 0.05; d=0.18 (P = 0.05) Group 2 versus Group 3: P = 0.44; d=NR	
Kershaw 2009	*Group prenatal care with an integrated HIV component*	*Group prenatal care*	*Individual prenatal care*	*OR, 95% CI) for difference [Group 1] versus/Groups 2 & 3 combined] adjusted for baseline variables*	
% testing positive for chlamydia and/ or gonorrhoea At 3rd trimester (ca 17 weeks after baseline)	6.9	7.2	7.1	OR 0.88 (0.53 - 1. 47); P = 0.63	
% testing positive for chlamydia and/ or gonorrhoea At 6 months postpartum (ca 49 weeks after baseline)	6.9	6.6	5.8	OR 0.95 (0.55 - 1. 64); P = 0.86	
% testing positive for chlamydia and/ or gonorrhoea At 12 months postpartum (ca 75 weeks after baseline)	8.8	8.1	10.2	OR 0.72 (0.38 - 1. 36); P = 0.32	
Orr 1996	*Brief clinic-based condom use education and practical skills development session*	*Brief clinic-based condom use education session*	*N/A*	Difference between groups	
% reinfected with chlamydia at 6 month follow-up	26	17		P = 0.3	
Peipert 2008	*Individual-tailored dual contraception computer intervention*	*Enhanced standard care computer intervention*	*N/A*	Hazard Rate Ratio, 95% CI) for Group 1	

a. unadjusted

Study	Intervention group 1	Intervention group 2	Intervention group 3	Statistical significance	Other
				b. adjusted for baseline covariates	
Any STI (chlamydia, gonorrhoea, trichomonas, HSV, PID) at 24 month follow-up n/N (%)	43/272 (16)	44/270 (16)		**a.** 1.06 (0.69,1.61) **b.** 1.29 (0.70,2.36)	
chlamydia at 24 month follow-up n/N (%)	27/272 (10)	26/270 (10)		**a.** 1.13 (0.66,1.94) **b.** 1.31 (0.61,2.82)	
Gonorrhoea at 24 month follow-up n/N (%)	12/272 (4)	13/270 (5)		**a.** 0.96 (0.44,2.11) **b.** 1.83 (0.61, 5.50)	
Trichomonas at 24 month follow-up n/N (%)	13/272 (5)	9/270 (3)		**a.** 1.52 (0.65, 3.55) **b.** 2.41 (0.72,8.02)	
Pelvic inflammatory disease (PID) at 24 month follow-up n/N (%)	8/272 (3)	4/270 (1)		**a.** 2.13 (0.64,7.07) **b.** 1.03 (0.20, 5.19)	
Roye 2007	*1: Video + counselling; 2: Counselling only; 3: Video only; 4: Usual care*			*Group differences*	
Self-reported recurrent STIs at 3 months follow-up	NR			Not explicitly reported but implied that there was no statistically signifi-cant difference between groups for this outcome (P > 0. 05)	
Postitive chlamydia tests at 3 months follow-up	NR				
Scholes 2003	*Self-help intervention*	*Usual care*	*N/A*	*Unadjusted OR, 95% CI)*	*Adjusted OR, 95% CI); p-value*
Percentage sexually active who reported STI diagnosis in past 3 months At 6 month follow-up (total both groups n = 849)	3.5	3.6		0.95 (0.49, 1.83) p-value NR	0.97 (0.48, 1.96) P = 0.93
Shain 1999	*Behavioural-cognitive intervention*	*Nurse practitioner-led counselling*	*N/A*	*Difference Group 1 versusGroup 2 (OR or Chi square test; p-value)*	
No (%) of episodes of chlamydia and/ or gonorrhoea infection during the 12 month study period 1) Zero 2) One 3) Two or more	n = 285 1) 237 (83.2) 2) 32 (11.2) 3) 16 (5.6)	n = 264 1) 193 (73.1) 2) 51 (19.3) 3) 20 (7.6)		P = 0.01	Chi-square test for the association ofgroup assignment with the number ofepisodes ofin-fection
No (%) of participants infected with chlamydia and/or gonorrhoea 0 to 6 months	n = 265 30 (11.3)	n = 244 42 (17.2)		OR0.58,95%CI0. 34 to 0.99) P = 0.05	OR, 95% CI) from multiple logistic regression
No (%) of participants infected with chlamydia and/or gonorrhoea 6 to 12 months	n = 285 26 (9.1)	n = 260 46 (17.7)		OR0.49,95%CI0. 29 to 0.83) P = 0.008	OR, 95% CI) from multiple logistic regression

Study	Intervention group 1	Intervention group 2	Intervention group 3	Statistical significance	Other
No (%) of participants infected with chlamydia and/or gonorrhoea 0 to 12 months	n = 285 48 (16.8)	n = 264 71 (26.9)		OR0.52,95%CI0. 34 to 0.81) P = 0.004	OR, 95% CI) from multiple logistic regression
Shrier 2001 (at 12 months)	*Safer sex education*	*Standard care/STD education*	*N/A*	*Difference*	
% reported having an STD since enrolment	17	32		P = 0.17	

NR=not reported

[a] Denominator for both groups is 826 (which is less than the 1381 who completed the study, notwithstanding the fact that 486 women were not screened for STIs at 2nd post-intervention follow-up because of limited study resources). It is not clear what the denominator is for each of the randomised study groups.

[b] Data estimated from a graph using a graphical measurement computer programme (Engauge); not reported whether this is a mean value

[c] This test has only 12% power at alpha=0.05

Table 5
Outcome data: Sexual partners

Study	Intervention group 1	Intervention group 2	Intervention group 3	Statistical significance	other
Boyer 2005 post-intervention (mean 14 months from baseline)	*Cognitive-behavioural intervention*	*Health promotion control*	*N/A*	*Statistical significance*	*Other*
Sexual intercourse with multiple sexual partners	377 (28.8%)[a]	361 (27.6%)		NR	
DiClemente 2004	*HIV prevention intervention*	*General health promotion group*	*N/A*	*p-value for OR*	*Adjusted odds ratio (OR), 95% CI)*
Unadjusted percentage with new vaginal sex partner in past 30 days At 6 month follow-up	2.7	7.4		P = 0.01	OR 0.29 (0.11 to 0.77)
Unadjusted percentage with new vaginal sex partner in past 30 days At 12 month follow-up	3.6	5.6		P = 0.36	OR 0.59 (0.19 to 1.84)
Percentage with new vaginal sex partner in past 30 days. For full 0 to 12 month period	NR	NR		P = 0.01	OR 0.40 (0.19 to 0.82) (from GEE regression model)
Jaworski 2001	*Intervention-Motivation-Behavioural skills group (1MB)*	*Information-only group (INFO)*	*Waiting list control (WLC)*	*Statistical significance*	*Other*
Mean (SD) number of sex partners in the past 2 months. Baseline	1.3 (0.54)	1.2(0.37)	1.1 (0.40)	NR	
Mean (SD) number of sex partners in the past 2 months[b] 2 month follow-up	0.83 (0.49)	0.89 (0.46)	1.1 (0.53)	NR	
Proportion with a decrease in number of sexual partners from baseline to 2 month follow-up[b]	35%	21%	16%	Group 1 versus Group 3: P = 0.04 Group 2 versus Group 1: P = 0.33	
Jemmott 2005	*Skills-based HIV/ STD risk reduction intervention*	*Information-based HIV/ STD risk reduction intervention*	*Health promotion control*	*p-value for difference based on adjusted*	*Other*

Study	Intervention group 1	Intervention group 2	Intervention group 3	Statistical significance	other
				means; effect size, d (p-value for d)	
Mean (SE) number of sexual partners in past 3 months. 3 month follow-up with corresponding baseline data for 3-month completers	Baseline, unadjusted: 1.06 (0. 05) 3 months, unad-justed: 0.98 (0.06) 3 months, adjusted: 0.97 (0.06)	1.11 (0.06) 1.06 (0.07) 1.04 (0.06)	1.10 (0.05) 1.10 (0.07) 1.07 (0.07)	Group 1 versus Group 2: P = 0.41; d=NR Group 1 versus Group 3: P = 0.13; d=NR Group 2 versus Group 3: P = 0.49; d=NR	
Mean (SE) number of sexual partners in past 3 months. 6 month follow-up with corresponding baseline data for 6-month completers	Baseline, unadjusted: 1.02 (0. 05) 6 months, unadjusted: 0.93 (0.04) 6 months, adjusted: 0.92 (0.06)	1.09 (0.06) 1.01 (0.07) 0.98 (0.06)	1.11 (0.05) 1.04 (0.06) 1.00 (0.06)	Group 1 versus Group 2: P = 0.53; d=NR Group 1 versus Group 3: P = 0.22; d=NR Group 2 versus Group 3: P = 0.56; d=NR	
Mean (SE) number of sexual partners in past 3 months. 12 month follow-up with corresponding baseline data for 12-month completers	Baseline, unadjusted: 1.04 (0. 05) 12 months, unadjusted: 0.93 (0.04) 12 months, adjusted: 0.91 (0.05)	1.06 (0.05) 1.02 (0.05) 1.00 (0.05)	1.10 (0.05) 1.06 (0.06) 1.04 (0.05)	Group 1 versus Group 2: P = 0.17; d=NR Group 1 versus Group 3: P = 0.04; d=0.17 (P = 0.04) Group 2 versus Group 3: P = 0.51; d=NR	
Mean (SE) % reporting multiple partners in past 3 months. 3 month follow-up with corresponding baseline data for 3-month completers	Baseline, unadjusted: 12.6 (2. 3) 3 months, unadjusted: 10.7 (2.1) 3 months, adjusted: 10.9 (2.4)	17.2 (2.7) 15.8 (2.6) 15.1 (2.4)	15.4 (2.6) 14.9 (2.6) 14.2 (2.5)	Group 1 versus Group 2: P = 0.17; d=NR Group 1 versus Group 3: P = 0.29; d=NR Group 2 versus Group 3: P = 0.76; d=NR	
Mean (SE) % reporting multiple partners in past 3 months. 6 month follow-up with corresponding baseline data for 6-month completers	Baseline, unadjusted: 11.9 (2. 2) 6 months, unadjusted: 9.5 (2.0) 6 months, adjusted: 9.7 (2.5)	16.8 (2.7) 13.2 (2.4) 12.5 (2.5)	16.6 (2.6) 15.1 (2.5) 14.3 (2.4)	Group 1 versus Group 2: P = 0.36; d=NR Group 1 versus Group 3: P = 0.12; d=NR Group 2 versus Group 3: P = 0.54; d=NR	
Mean (SE) % reporting multiple partners in past 3 months. 12 month follow-up with corresponding baseline data for 12-month completers	Baseline, unadjusted: 12.4 (2. 3) 12 months, unadjusted: 7.4 (1.8) 12 months, adjusted: 6.9 (2.5)	15.1 (2.6) 11.4 (2.3) 10.7 (2.5)	15.3 (2.6) 17.5 (2.8) 16.6 (2.5)	Group 1 versus Group 2: P = 0.20; d=NR Group 1 versus Group 3: P = 0.002; d=0.25 (P = 0.002) Group 2 versus Group 3: P = 0.09; d=NR	
Koniak-Griffin 2003	*HIV prevention programme (CHARM 1)*	*Healthy living parenting programme (CHARM 2)*	*N/A*	*Difference between groups in change through time*	*Other*
Number of sex partners in past 3 months, mean (SD) [mean adjusted for baseline behavioural intentions]. Baseline	0.84 (0.46) [0.84]	0.79 (0.46) [0.79]		P= 0.042 from repeated measures ANCOVA adjusted for baseline behavioural intentions	
Number of sex partners in past 3 months, mean (SD) [mean adjusted for baseline behavioural intentions] 6 months follow-up[c]	0.84 (0.50) [0.84]	0.95 (0.47) [0.96]			Stated significantly fewer sex partners in group 1 at 6 months (n and p NR)
Number of sex partners in past 3 months, mean (SD) [mean adjusted for baseline behavioural intentions] 12 months follow- up[c]	0.95 (0.53) [0.95]	0.99 (0.48) [0.98]			
Morrison-Beedy 2005	*HIV risk reduction group*	*Health promotion control group*	*N/A*	Difference between groups: p-value from Chi square test; effect size from mean difference & pooled variance	*Other*
Frequency (mean) of male sex partners in past 3 months.	1.5	2.0		P = 0.13 Effect size=NR	

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Study	Intervention group 1	Intervention group 2	Intervention group 3	Statistical significance	other
Baseline					
Frequency (mean) of male sex partners in past 3 months. 3-month follow-up	1.3	1.6		P = 0.46 Effect size=0.11	
Shain 1999	*Behavioural-cognitive intervention*	*Nurse practitioner-led counselling*	*N/A*	*Statistical significance*	*Other*
Percentage not mutually monogamous (where mutually monogamous is defined as having the same steady, faithful, partner (or no sex partner) in the past 6 months Baseline	69.1	63.6		P = 0.21	Logistic regression adjusting for baseline values
Percentage not mutually monogamous (where mutually monogamous is defined as having the same steady, faithful, partner (or no sex partner) in the past 6 months 0 to 6 months follow up	36.9	48.2		P = 0.003	Logistic regression adjusting for baseline values
Percentage not mutually monogamous (where mutually monogamous is defined as having the same steady, faithful, partner (or no sex partner) in the past 6 months 6 to 12 months follow up	35.7	45.2		P = 0.01	Logistic regression adjusting for baseline values
Percentage not mutually monogamous (where mutually monogamous is de-fined as having the same steady, faithful, partner (or no sex partner) in the past 12 months 0 to 12 months follow up	53.0	62.3		P = 0.008	Logistic regression adjusting for baseline values
Percentage with rapid partner turnover (having a new sex partner within 3 months of another sex partner) in the past 6 months 0 to 6 months follow up (baseline data not reported)	20.1	22.8		P = 0.47 (n = 228)	Unadjusted Chi- square analysis
Percentage with rapid partner turnover (having a new sex partner within 3 months of another sex partner) in the past 6 months 6 to 12 months follow up	10.4	22.8		P < 0.001	Unadjusted Chi- square analysis
Percentage with rapid partner turnover (having a new sex partner within 3 months of another sex partner) in the past 12 months 0 to 12 months follow up	26.5	32.5		P = 0.15	Unadjusted Chi- square analysis
Shrier 2001	*Safer sex education*	*Standard care/STD education*	*N/A*	*Difference*	
With main partner now, n (%) At baseline	46 (77)	47 (75)		NR	

Study	Intervention group 1	Intervention group 2	Intervention group 3	Statistical significance	other
With main partner now, n (%) At 1 month follow up	30 (75)	31 (76)		NR	
With main partner now, n (%) At 6 months follow up	34 (81)	38 (79)		NR	
With main partner now, n (%) At 12 months follow up	23 (77)	31 (91)		P < 0.10 for difference in change from baseline	
With another partner in the past 6 months, n (%) At baseline	24 (40)	19 (30)		NR	
With another partner in the past 6 months, n (%) At 1 month follow up	16 (40)	12 (29)		NR	
With another partner in the past 6 months, n (%) At 6 months follow up	10 (24)	25 (52)		P < 0.05 for difference in change from baseline	
With another partner in the past 6 months, n (%) At 12 months follow up	7 (23)	12 (35)		NR	

NR: not reported

[a]Denominator for both groups is 1,307 (which is less than the 1381 who completed the study). It is not clear what the denominator is for each of the randomised study groups.

[b]not explicitly stated, but it appears that these data exclude the sub-group of up to 20% who became sexually abstinent from baseline to follow-up.

Table 6
Outcome data: casual sexual partners

Study	Intervention group 1	Intervention group 2	Intervention group 3	Statistical significance	Other
Boyer 2005 post-intervention (mean 14 months from baseline)	Cognitive-behavioural intervention	*Health promotion control*	*N/A*	*Statistical significance*	*Other*
Sexual intercourse with a casual partner	285 (21.8%)[a]	276 (21.1%)[a]		NR	
Roye 2007	*1: Video + counselling; 2: Counselling only; 3: Video only; 4: Usual care*			*Group differences*	*Other*
Number of causal sex partners (3 months follow-up)	NR			Not explicitly reported but implied that there was no statistically significant difference between groups for this outcome (P > 0. 05)	

[a]Denominator for both groups is 1,307 (which is less than the 1381 who completed the study). It is not clear what the denominator is for each of the randomised study groups.

Table 7
Behavioural aims of the studies

Study	Delaying initiation of sex/ promoting abstinence/ reducing sexual activity	Promoting condom use to prevent STIs	Reduction in number of partners	Increase in protective behaviours/ decrease in risk behaviours	Prevent/reduce unintended pregnancy	Uptake of STI services
Boyer 2005		✓		✓	✓	
Bryan 1996		✓				
Bull 2008		✓				
Choi 2008		✓				
Dancy 2009	✓	✓				
DiClemente 2004	✓	✓	✓	✓	✓	
DiClemente 2009		✓		✓		✓
Downs 2004	✓	✓	✓	✓		
Ferguson 1998	✓	✓			✓	
Jaworski 2001		✓	✓			
Jemmott 2005		✓				
Kershaw 2009		✓		✓		
Koniak-Griffin 2003		✓	✓			
Maynard 1994		✓			✓	
Morrison-Beedy 2005		✓	✓			
Orr 1996		✓				
Peipert 2008		✓			✓	
Ploem 1997		✓				
Roye 2007		✓		✓		
Scholes 2003		✓		✓		
Shain 1999	✓	✓	✓	✓		
Shrier 2001	✓	✓		✓	✓	
Smith 1993		✓				

WHAT'S NEW

Last assessed as up-to-date: 11 March 2011.

Date	Event	Description
27 March 2014	Amended	Contact details updated.

HISTORY

Protocol first published: Issue 1, 1998

Review first published: Issue 3, 1999

Date	Event	Description
11 March 2011	New search has been performed	Review updated
11 March 2011	New citation required and conclusions have changed	The review has undergone major revisions to reflect a change in scope. The searches were updated to reflect this change and conclusions were modified
9 June 1999	New citation required and conclusions have changed	Substantive amendment

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* . Indicates the major publication for the study

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PLAIN LANGUAGE SUMMARY

Interventions for encouraging sexual behaviours intended to prevent cervical cancer

Young women are at high risk of contracting sexually transmitted infections (STIs), including types of human papillomavirus (HPV) that can cause cervical cancer. High rates of STIs among young people highlight a need for effective strategies to prevent the spread of infections. Although behavioural approaches (e.g. using condoms consistently) could protect against STIs and cervical cancer, there is a lack of evidence on which strategies would be most effective in practice. This systematic literature review was conducted to identify which types of behavioural strategy have been tested and to assess their effectiveness.

Eight electronic bibliographic databases were searched up to the end of 2009. To be considered relevant, studies had to use a randomised controlled trial (RCTs) design; include young women up to the age of 25 years; report one or more behavioural interventions that aimed to prevent STIs or cervical cancer; and record outcomes which were either behavioural (e.g. condom use) or biological (incidence of STIs or cervical cancer).

Searches identified 5271 bibliographic records. Screening the records independently by two review authors identified 23 relevant randomised controlled trials (RCTs). The trials were mostly conducted in the USA (21 trials) and in health-care (e.g. family planning) clinics (14 trials), with only four in educational settings. Trial participants had mixed socio-economic and demographic characteristics and most were sexually experienced. The interventions mostly provided information about STIs and taught safer sex skills (e.g. communication with partners), occasionally supplemented with provision of resources (e.g. free sexual health services). Interventions varied considerably in duration, contact time, provider, behavioural aims and outcomes. A variety of STIs were addressed including HIV and chlamydia, but not explicitly HPV.

The most common behavioural outcome (measured in 19 trials) was condom use for vaginal intercourse. Sexual partners, sexual abstinence and STIs were reported in four, two and 12 trials respectively. In terms of statistically significant effects, some interventions improved condom-related behaviour and reduced the number of sexual partners, but none affected the frequency of sexual episodes. Effects of interventions on STIs were limited. None of the interventions appeared to be harmful. The methods used in the trials were not always well described making it difficult to tell whether their results may have been biased. In conclusion, although some behavioural interventions improve condom-related behaviour, trials have been predominantly in USA healthcare settings, did not specifically address HPV and were too different to enable a most effective type of intervention to be identified.

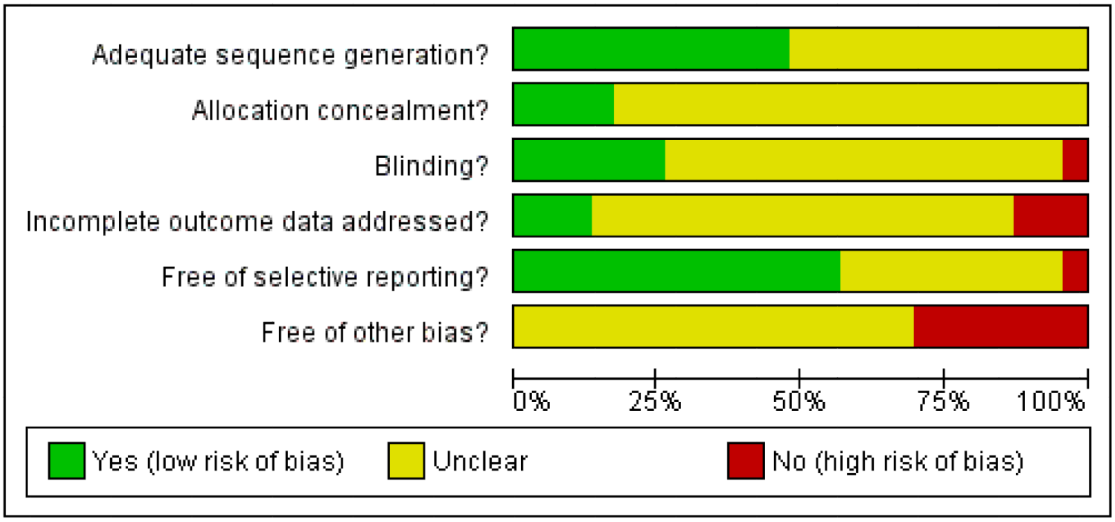

Figure 1. Methodological quality graph: review authors' judgements about each methodological quality item presented as percentages across all included studies

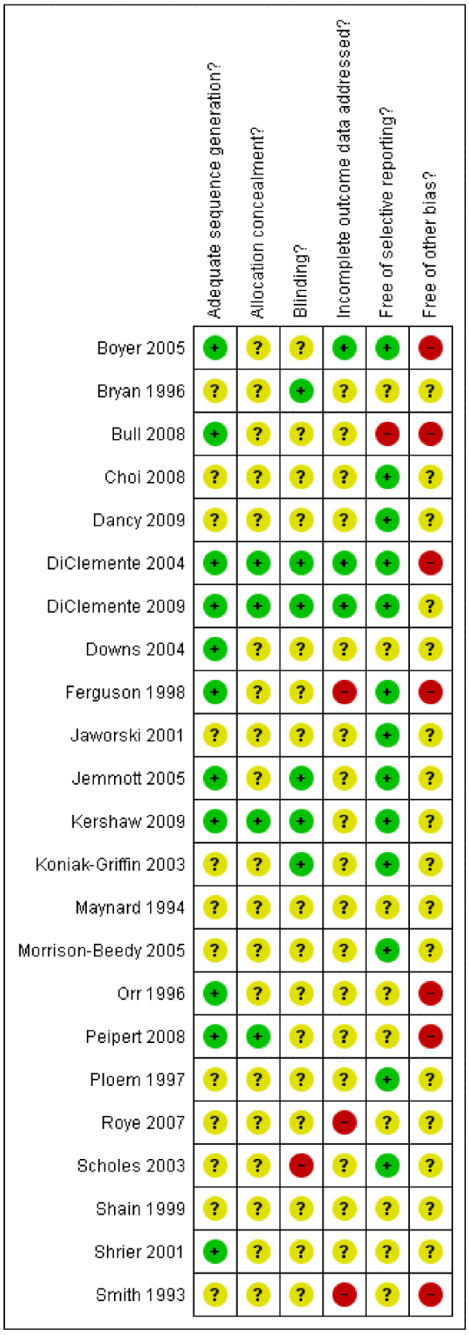

Figure 2. Methodological quality summary: review authors' judgements about each methodological quality item for each included study