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# School-based interventions for improving contraceptive use in adolescents (Review)

Lopez LM, Bernholc A, Chen M, Tolley EE

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# TABLE OF CONTENTS

HEADER
ABSTRACT
PLAIN LANGUAGE SUMMARY
SUMMARY OF FINDINGS FOR THE MAIN COMPARISON
BACKGROUND
OBJECTIVES
METHODS
RESULTS
Figure 1
Figure 2
Figure 3
DISCUSSION
AUTHORS' CONCLUSIONS
ACKNOWLEDGEMENTS
REFERENCES
CHARACTERISTICS OF STUDIES
DATA AND ANALYSES
ADDITIONAL TABLES
CONTRIBUTIONS OF AUTHORS
DECLARATIONS OF INTEREST
SOURCES OF SUPPORT
DIFFERENCES BETWEEN PROTOCOL AND REVIEW
INDEX TERMS

#### [Intervention Review]

# School-based interventions for improving contraceptive use in adolescents

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#### ABSTRACT

# Background

Young women, especially adolescents, often lack access to modern contraception. Reasons vary by geography and regional politics and culture. The projected 2015 birth rate in 'developing' regions was 56 per 1000 compared with 17 per 1000 for 'developed' regions.

#### Objectives

To identify school-based interventions that improved contraceptive use among adolescents

#### Search methods

Until 6 June 2016, we searched for eligible trials in PubMed, CENTRAL, ERIC, Web of Science, POPLINE, ClinicalTrials.gov and ICTRP.

#### Selection criteria

We considered randomized controlled trials (RCTs) that assigned individuals or clusters. The majority of participants must have been 19 years old or younger.

The educational strategy must have occurred primarily in a middle school or high school. The intervention had to emphasize one or more effective methods of contraception. Our primary outcomes were pregnancy and contraceptive use.

#### Data collection and analysis

We assessed titles and abstracts identified during the searches. One author extracted and entered the data into RevMan; a second author verified accuracy. We examined studies for methodological quality.

For unadjusted dichotomous outcomes, we calculated the Mantel-Haenszel odds ratio (OR) with 95% confidence interval (CI). For cluster randomized trials, we used adjusted measures, e.g. OR, risk ratio, or difference in proportions. For continuous outcomes, we used the adjusted mean difference (MD) or other measures from the models. We did not conduct meta-analysis due to varied interventions and outcome measures.

#### Main results

The 11 trials included 10 cluster RCTs and an individually randomized trial. The cluster RCTs had sample sizes from 816 to 10,954; the median number of clusters was 24. Most trials were conducted in the USA and UK; one was from Mexico and one from South Africa.

We focus here on the trials with moderate quality evidence and an intervention effect. Three addressed preventing pregnancy and HIV/ STI through interactive sessions. One trial provided a multifaceted two-year program. Immediately after year one and 12 months after year two, the intervention group was more likely than the standard-curriculum group to report using effective contraception during last sex (reported adjusted ORs 1.62 ± standard error (SE) 0.22) and 1.76 ± SE 0.29), condom use during last sex (reported adjusted ORs 1.91 ± SE 0.27 and 1.68 ± SE 0.25), and less frequent sex without a condom in the past three months (reported ratios of adjusted means 0.50 ± SE 0.31 and 0.63 ± SE 0.23). Another trial compared multifaceted two-year programs on sexual risk reduction and risk avoidance (abstinence-focused) versus usual health education. At 3 months, the risk reduction group was less likely than the usualeducation group to report no condom use at last intercourse (reported adjusted OR 0.67, 95% CI 0.47 to 0.96) and sex without a condom in the last three months (reported adjusted OR 0.59, 95% CI 0.36 to 0.95). At 3 and after 15 months, the risk avoidance group was also less likely than the usual-education group to report no condom use at last intercourse (reported adjusted ORs 0.70, 95% CI 0.52 to 0.93; and 0.61, 95% CI 0.45 to 0.85). At the same time points, the risk reduction group had a higher score than the usual-education group for condom knowledge. The third trial provided a peer-led program with eight interactive sessions. At 17 months, the intervention group was less likely than the teacher-led group to report oral contraceptive use during last sex (OR 0.57, 95% CI 0.36 to 0.91). This difference may not have been significant if the investigators had adjusted for the clustering. At 5 and 17 months, the peer-led group had a greater mean increase in knowledge of HIV and pregnancy prevention compared with the control group. An additional trial showed an effect on knowledge only. The group with an emergency contraception (EC) session was more likely than the group without the EC unit to know the time limits for using hormonal EC (pill) and the non-hormonal IUD as EC.

#### Authors' conclusions

Since most trials addressed preventing STI/HIV and pregnancy, they emphasized condom use. However, several studies covered a range of contraceptive methods. The overall quality of evidence was low. Main reasons for downgrading the evidence were having limited information on intervention fidelity, analyzing a subsample rather than all those randomized, and having high losses.

#### PLAIN LANGUAGE SUMMARY

#### School-based programs to improve birth control use among adolescents

#### Background

Adolescents have high rates of unplanned pregnancy. They may not have family planning services nearby or know how to get modern birth control. We wanted to find programs in schools that helped teenagers learn about birth control.

#### Methods

We did computer searches for randomized trials until 6 June 2016. Programs included in this review must have occurred in a school, such as a middle school or high school. The programs tried to improve birth control use among teenagers. They also had to emphasize one or more methods of birth control known to work well.

#### Results

We found 11 trials. One study was small, and the other 10 had 816 to 10,954 participants. Six studies were from the USA, three were from the UK, and one each came from Mexico and South Africa. We focus here on three programs that had some effect and were good quality. All three involved students in a variety of activities versus usual sex education. After a two-year program, the intervention group reported more use of birth control as well as condoms during last sex than the group with standard classes. Another study lasting two years provided two different programs. The intent was to avoid risk by not having sex until marriage or to reduce risk by delaying sex until older. The control group had usual health education. The programs for avoiding risk and reducing risk showed fewer reports of sex without using birth control or condoms. The third study had peers lead eight sessions of educational activities. The program showed less birth control use compared with teacher education but the researchers did not adjust for the study design.

Of the other eight studies, one had good quality results. The intervention group knew the time limits for using emergency contraception. Six of seven studies with low or very low quality results reported some program effect, such as more condom or contraceptive use or more knowledge of condoms.

#### Authors' conclusions

Since most trials aimed to prevent STI/HIV and pregnancy, they focused on condom use. However, several studies covered a variety of birth control methods. The overall quality of results was low. Some trials lacked information on how their programs worked. Many analyzed subsamples rather than all students in the study, and most had high losses.

# SUMMARY OF FINDINGS FOR THE MAIN COMPARISON [Explanation]

Interactive program on HIV/STI and pregnancy prevention compared with usual sex or health education for improving contraceptive use

Patient or population: middle or high school students with need for contraceptive information

Settings: school classroom

Intervention: HIV/STI and pregnancy prevention Comparison: usual sex or health education

Outcomes	Reported relative effect	Clusters; participants (study)	Quality of evidence (GRADE)	Intervention; grade level
Use of effective contraceptive during last sex: after year 1; 12 months after year 2	Adjusted OR ± SE: 1.62 ± 0.22; 1.76 ± 0.29	20 schools <sup>a</sup> ; 3869 students (Coyle 2001)	⊕⊕⊕⊝ M oderate	Multifaceted, 20-lesson program vs standard HIV prevention (5 sessions + activities) 9th and 10th grades
Condom use at last sex: after year 1; 12 months after year 2	Adjusted OR ± SE: 1.91 ± 0.27; 1.68 ± 0.25	_		
Frequency of sex without condom in last 3 months: after year 1; 12 months after year 2	Ratio of adjusted means $\pm$ SE: $0.50 \pm 0.31$ ; $0.63 \pm 0.23$			
No condom use at last vaginal sex (3 months)	OR 0.67 (0.47 to 0.96)	15 schools <sup>a</sup> ; 1742 students (Markham 2012)	⊕⊕⊕⊜ M oderate	Sexual risk reduction (abstinence until older), 24 sessions vs usual health
Vaginal sex without condom in past 3 months (3 months)	OR 0.59 (0.36 to 0.95)	_		education; 7th and 8th grades
No condom use at last vaginal sex: 3 months; 15 months	ORs: 0.70 (0.52 to 0.93); 0.61 (0.45 to 0.85)			Sexual risk avoidance (abstinence until marriage), 24 sessions vs usual health education; 7th and 8th grades

Oral contraceptive use during last sex (17 months)	OR 0.57 (0.36 to 0.91)	102 middle-school classes <sup>b</sup> ;2110 students (Kirby 1997)	-	Peer-led interactive prevention (8 sessions) vs didactic teacher-led sex education; 7th grade
				7th grade

CI: Confidence interval; MD = mean difference; OR: Odds Ratio; SE = standard error

GRADE Working Group grade of evidence

High quality: Further research is very unlikely to change our confidence in the estimate of effect.

Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low quality: We are very uncertain about the estimate.

<sup>&</sup>lt;sup>a</sup>Randomized schools

<sup>&</sup>lt;sup>b</sup>Randomized classes

#### BACKGROUND

#### **Description of the condition**

Internationally, access to modern contraceptive information and services for young women is considered a human rights issue (UNFPA 2011). Factors that limit access vary across geographic boundaries and according to regional politics and culture. Policies may prohibit young women, and especially adolescents, from obtaining certain contraceptive methods or any at all (Ross 2013; Chandra-Mouli 2014). Adolescents may lack the knowledge, skills, or resources to obtain the available contraceptive information or to reach services. Their contraceptive use may be influenced by peers, social media, or the Internet; those sources may or may not provide accurate information. Attitudes and beliefs may lead parents, teachers, or providers to discourage teens from using contraception or to withhold information or services (Biddlecom 2008; Bankole 2010; Ross 2013). Unmarried or nulliparous women may not have access to the most effective methods such as intrauterine contraception (Wilson 2012; Rubin 2013). Of the 16 million births each year to adolescents from 15 to 19 years old, 95% are in low- and middle-income countries (LMICs) (Chandra-Mouli 2014). The projected 2015 birth rate for young women in this age group was 116 per 1000 in sub-Saharan Africa and 86 per 1000 young women in Latin America and the Caribbean (UN 2015). The projected average birth rate in 2015 for girls aged 15 to 19 years in developing regions was 56 per 1000, unchanged since 2000, compared with 17 per 1000 for developed regions, down from 26 in 2000. Complications from pregnancy and childbirth are the leading cause of death in this age group. Many adolescents choose abortion, which may be unsafe due to local restrictions. Three-fourths of unsafe abortions, as well as other causes of maternal mortality, could be prevented by improved access to modern contraception (WHO 2014). In sub-Saharan Africa and South Central Asia, two-thirds of sexually active women aged 15 to 19 years want to avoid pregnancy but are not using a modern contraceptive method (Darroch 2011). In the United States of America (USA), rates for teenage pregnancies, births, and abortions have decreased markedly since 1990. The pregnancy rate for teenagers was 57 per 1000 (6%) in 2010 compared to 117 per 1000 (12%) in 1990 (Kost 2014). The rate was twice as high when based on those who were sexually experienced. In 2008, 82% of the pregnancies in this age group were unintended (Finer 2014). Of teenage women at risk of unintended pregnancy in the USA, 59% reportedly use a highly effective contraceptive method, i.e. oral contraceptives or another hormonal method (Guttmacher 2015). However, in this age group, the male condom is the most common method at first sex and at most recent sex (Martinez 2011; Guttmacher 2015). Because of incorrect and inconsistent use, condoms are considered less effective than other modern methods. In a study of urban clinics in the USA, African American adolescents reported condoms alone as

the most frequently used contraceptive method (35%) (Brown 2011a). Among never-married adolescent females, reported condom use at last sex averaged 22% in West Africa, 35% in East Africa, and 60% in Southern Africa (Doyle 2012).

#### **Description of the intervention**

Schools provide a setting to reach many adolescents and to address pregnancy prevention with adolescent males as well as females (Taylor 2014). Schools offer the opportunity for reinforcement and social support of attitudes and behaviors about contraception. School interventions may include clinic-based family planning services, as well as classroom education or school-wide activities. Clinic services generally involve counseling or education, and may increase access to contraceptive methods (Blank 2010; Chandra-Mouli 2014). Classroom-based instruction may be a single session on contraception or a multisession curriculum on sexual health promotion. Sessions may be didactic or interactive, and may utilize technology for computer-assisted assessments or instruction (Guse 2012). Program material may also be obtained from the Internet (Shegog 2014). School-wide activities may include communication campaigns involving print or digital information, as well as interpersonal communications led by peer educators or school-based clubs.

In many locations, intervention content has been focused on abstinence only, i.e. risk avoidance, due to governmental or local restrictions on contraception education for youth (Fonner 2014). Abstinence-plus programs, also known as risk reduction or comprehensive sexual education, may encourage delaying sexual intercourse but also provide information on preventing disease and unintended pregnancy (Markham 2012; Fonner 2014). In the USA, a 2006 survey indicated 65% of high schools taught students how to find valid information on pregnancy prevention and 58% taught contraception methods in a health education course (CDC 2013a). According to a 2012 survey, 78% of school districts in the USA required teaching of pregnancy prevention in high schools, and 66% of middle schools required such education (CDC 2013b).

Where abstinence education is not a limiting factor, programs for adolescents often emphasize condom use. When used correctly and consistently, condoms can provide protection against both pregnancy and disease (CDC 2015). Failure of condoms to protect against sexually transmitted infections (STIs) or unintended pregnancy is usually due to inconsistent or incorrect use rather than condom breakage (CDC 2015). For the male condom, the estimated first-year pregnancy rate with typical use is 18% and the rate for perfect use is 2% (Trussell 2011). Other contraceptive methods have lower failure rates, e.g. oral contraceptives at 9% for typical use and 0.3% with perfect use. Long-acting reversible contraception (LARC), such as intrauterine contraception or an implant, does not require regular user action, and typical-use failure rates for LARC are estimated at less than 1% (Trussell 2011).

#### Why it is important to do this review

This review examined school-based interventions to improve the use of effective contraceptive methods among sexually active adolescents. The objectives of these interventions had to include preventing unintended pregnancy. Programs could have provided information on contraceptive methods available, the relative effectiveness of methods, and appropriate method use. Such efforts can help teenagers choose an appropriate contraceptive method and continue to use their preferred type. Since some adolescents have limited access to contraception due to lack of clinic transportation or cost of a method, educational programs may be combined with service provision.

Several reviews have examined educational strategies to prevent pregnancy or improve contraceptive use among adolescents; the scope of many has differed from the review proposed here. Some include interventions for preventing HIV or STIs as well as programs for pregnancy prevention (Chin 2012). Theory-based interventions for youth may be implemented in schools or in the community (Lopez 2013a), either of which can support multifaceted programs. Reviews focused on school-based programs may include studies of varying designs (Owen 2010) or interventions in universities as well as high schools (Blank 2010).

Given the number of interventions developed for young people, and adolescents in particular, we limited this review to those tested in randomized controlled trials. We tried to identify interventions that increase knowledge of contraception among teens and improve contraceptive use among those who are sexually active. The interventions should be feasible for middle or high school settings or the equivalent.

#### **OBJECTIVES**

To identify school-based interventions that improved contraceptive use among adolescents

#### **METHODS**

#### Criteria for considering studies for this review

#### Types of studies

We considered randomized controlled trials (RCTs) that assigned individuals as well as those that assigned clusters, e.g. classrooms or schools.

#### Types of participants

We were interested in interventions developed for adolescents, i.e. aged 19 years or younger. However, school-based interventions are typically implemented in certain grades rather than provided to a specific age group. High schools or secondary schools may have students older than 19 years. For this review, the majority of participants must have been 19 years or younger. We did not set a lower age limit, as an intervention for younger adolescents may be provided to students by grade or class regardless of the students' ages.

The age range for adolescence and young adulthood varies in research and policymaking. Healthcare policy organizations may identify adolescence as ages 10 to 19 years (UN 2015; WHO 2015a). Others have considered 10 to 15 years old as the lower age cutoff for adolescence, and programs may include young people 18 to 24 years old (DHHS 2008; Gavin 2009). Contraceptive counseling for adolescents may focus on those aged 14 to 19 years old (Jaccard 2013). Peer education for sexual health among young people may include those to the age of 20 years (Tolli 2012). Contraceptive service interventions for young people in educational settings have participants up to 19 years of age (Blank 2010; Owen 2010).

#### Types of interventions

We considered educational strategies that occurred primarily in a school, such as a middle or high school, and addressed improving contraceptive use among adolescents. This did not preclude having some activities with parents or in the community, but most of the intervention must have been conducted within the school. We did not include interventions implemented in a college or university because the content and structure may differ when most the audience is older than our target group.

The behavioral strategy being tested had to address the use of one or more reversible methods of contraception. Interventions may have addressed preventing HIV and other STIs in addition to preventing pregnancy. Programs had to provide information on modern family planning methods (WHO 2015b) and include those considered more effective in preventing pregnancy. Effectiveness is 99% with correct and consistent use of the more effective methods, and typical-use effectiveness ranges from 90% to 99% (Trussell 2011; WHO 2015b). These methods include pills, injectables, the contraceptive patch, the vaginal ring, lactational amenorrhea, and emergency contraception. In addition, typicaluse effectiveness for long-acting methods such as intrauterine contraception and implants is greater than 99%. Of the fertility awareness-based methods, sometimes known as 'natural family planning,' only the sympto-thermal method may have typical-use effectiveness of greater than 90%; effectiveness is 98% with correct and consistent use (WHO 2015b).

#### Types of outcome measures

#### **Primary outcomes**

We only included trials that had one of the following measures.

- Pregnancy (six months or more after the intervention began)
- Contraceptive use (three months or more after the intervention began)
  - o initiation of a new method
  - o improved use or continuation of a method

Contraceptive use could have been assessed in various ways, e.g. consistent use or improved adherence. Where we found multiple measures within an included trial, we focused on the investigator's assessment of consistent use or use at last sex. If we did not find one of those preferred outcomes, we accepted the measure used by the investigator, e.g. use of effective pregnancy prevention at last sex or sex without effective pregnancy prevention in the last three months.

The minimum time frame for contraception use assessment was three months after the intervention began, which indicates initiation of a method. For pregnancy assessment, the minimum time was six months. For high quality evidence, we required 6 months for contraceptive use and 12 months for pregnancy. The longer time frames provide more meaningful outcome measures.

#### Secondary outcomes

These measures may supplement the primary outcomes above. The study groups may differ after the intervention in their thinking about contraception, regardless of whether behavior changed.

- Knowledge of contraceptive effectiveness or effective method use
- Attitude about contraception or a specific contraceptive method

For inclusion of these outcomes, the time frame for assessment was three months or more after the baseline. For high quality evidence, we required at least six months.

#### Search methods for identification of studies

#### **Electronic searches**

Until 6 June 2016, we searched for eligible RCTs in PubMed, the Cochrane Central Register of Controlled Trials (CENTRAL), ERIC (Educational Resources Information Center), Web of Science, and POPLINE. We also searched for recent trials via Clinical Trials.gov and the World Health Organization's International Clinical Trials Registry Platform (WHO ICTRP). Searches started from the inception of each database. Appendix 1 shows our search strategies.

#### Searching other resources

We examined reference lists of reviews and other relevant articles to find trials we may have missed in our electronic search.

#### Data collection and analysis

#### Selection of studies

We assessed for inclusion all titles and abstracts that the literature search identified. One author reviewed the search results and a second author examined the reports identified for appropriate categorization. For studies that appeared eligible for this review, we obtained and examined the full-text articles. We resolved discrepancies by discussion.

#### Data extraction and management

Two authors conducted the data extraction. One author entered the data into Review Manager (RevMan 2014), and a second author checked accuracy. These data included the study characteristics, risk of bias, and outcomes. We focused on the primary and secondary outcomes for this review, which may not include all outcomes from each included trial. The authors resolved discrepancies through discussion.

#### Assessment of risk of bias in included studies

#### Intervention fidelity

We used an existing framework to assess the quality of the educational intervention (Borrelli 2011). This framework was developed for assessing treatment fidelity in public health trials of health behavior change. The principles were relevant for this systematic review of behavior change interventions. We examined the trial reports for evidence of intervention (or treatment) fidelity. Domains of treatment fidelity are study design, training of providers, delivery of treatment, receipt of treatment, and enactment of treatment skills. We list the criteria of interest for our review below.

- Study design: had a curriculum or treatment manual
- Prior training of providers: specified providers' credentials
- Project-specific training: provided standardized training for the intervention
  - Delivery: assessed providers' adherence to the protocol
- Receipt: assessed clients' understanding and skills regarding the intervention

For the assessment of evidence quality, we downgraded the trials that met fewer than four of the five listed criteria.

#### Research design

We evaluated the included trials for methodological quality in accordance with recommended principles (Higgins 2011), and entered the information into the 'Risk of bias' tables. We considered the randomization method, allocation concealment, blinding, and losses to follow-up and early discontinuation.

#### Measures of treatment effect

For unadjusted dichotomous outcomes, we calculated the Mantel-Haenszel odds ratio (OR) with 95% confidence interval (CI). This applied to an individually randomized trial or a cluster randomized trial that did not adjust for clustering. An example is the proportion of adolescents who used a condom with the last sexual intercourse. Fixed effect and random-effects give the same result if no heterogeneity exists, as when a comparison includes only one study.

Cluster randomized trials may use a variety of strategies to account for the clustering. When available, we used adjusted measures that the investigators considered the primary effect measures. The adjusted odds ratio (OR) is commonly provided for dichotomous outcomes when analyses are obtained using cluster-adjusted logit models with or without covariates. If an appropriate adjusted OR was unavailable from the report, we considered other effect measures, e.g. adjusted risk ratio, adjusted difference in proportions, or regression coefficient (adjusted beta). For continuous outcomes, we used the adjusted mean difference (MD), the adjusted beta, or other measure obtained from cluster-adjusted linear models. Where the investigators used multivariate models, we did not analyze the treatment effect as that would usually require individual participant data. Rather we presented the results from adjusted models as reported by the investigators.

#### Unit of analysis issues

If clustering was part of the trial design, we assessed whether the investigators properly adjusted estimates to account for clustering effects. The cluster RCTs may use various methods of accounting for the clustering, such as multilevel modeling. We noted the specific methods the investigators used in the results for each trial.

#### Dealing with missing data

We wrote to trial investigators to request missing statistics, such as sample sizes for analysis and actual proportions or means for outcomes presented in figures. However, we limited our requests to studies less than 10 years old, as well as trials that had a report within the past five years. Investigators are unlikely to have access to data from older studies. In some cases, we had obtained information from investigators for earlier work that included the studies. If we could not analyze the data due to missing data, we presented the results as reported by the investigators.

#### Assessment of heterogeneity

We did not conduct meta-analyses due to varied educational interventions and outcome measures and the use of adjusted analyses. Statistical heterogeneity was irrelevant. However, we addressed heterogeneity due to differences in trial design, populations, interventions, outcome measures, and analyses. For example, some trials focus on younger adolescents, many of whom had not yet initiated sex, while other trials include older adolescents. Location may influence the design, while the specific outcome measure may affect the ability to detect an effect. In addition, we synthesized results by the focus of the intervention and the methods used, e.g. didactic versus interactive or peer-led versus teacher-led.

#### Data synthesis

To assess the quality of evidence and address confidence in the effect estimates, we applied principles from GRADE (Grades of Recommendation, Assessment, Development and Evaluation) (Higgins 2011; GRADE 2013). If meta-analysis is not viable because of varied interventions or outcome measures, a typical 'Summary of findings' table is not feasible. We do provide a 'Summary of findings' table for the main results although we did not conduct a formal GRADE assessment for all outcomes (GRADE 2013). We assessed the body of evidence based on the quality of evidence from the included trials. Evidence quality includes the design, implementation, and reporting of the intervention and of the trial. The information on intervention fidelity is part of the overall assessment. We considered RCTs to be high quality and then downgraded the evidence based on the criteria below.

- Intervention fidelity information for fewer than four criteria
- Inadequate randomization sequence generation or allocation concealment, or no information provided for either one
- Analysis for primary outcome based on non-randomized subsample, or analysis not adjusted for clustering
- Follow-up less than 6 months for contraceptive use or less than 12 months for pregnancy
  - Loss to follow-up greater than 20%

We examined the trials that provided evidence of moderate quality and had sufficient outcome data. None of the studies met the criteria for having high quality evidence.

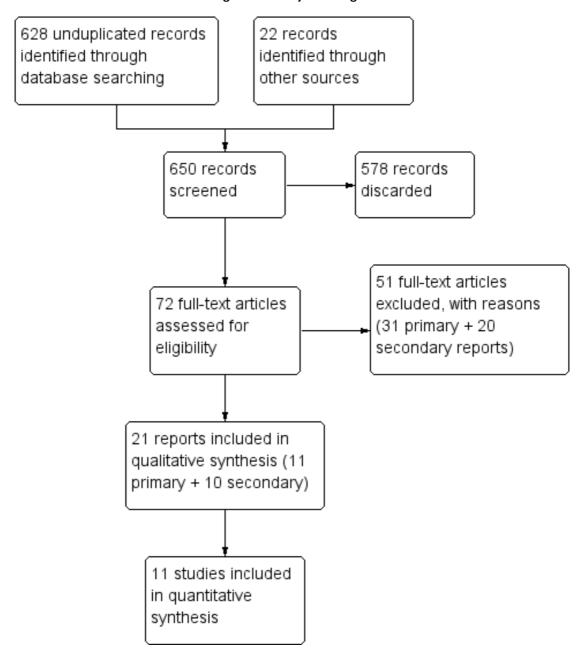
#### RESULTS

#### **Description of studies**

#### Results of the search

The database searches yielded 628 unduplicated references (Figure 1). With 22 items from other sources the total was 650. We discarded 578 references based on the title or abstract. After reviewing the full text of 72 articles or abstracts, we excluded 51 items that did not meet the eligibility criteria (31 primary reports plus 20 secondary references). We included 21 items, i.e. 11 primary reports from studies that met the eligibility criteria plus 10 secondary references. Searches of clinical trials listings produced 50 unduplicated trials. Four trials are reportedly finished but have not yet produced outcome data (Studies awaiting classification). The other trials were irrelevant or from completed studies we had already considered.

Figure I. Study flow diagram.



#### **Included studies**

Of 11 trials, 10 were cluster randomized, i.e. they assigned schools or classrooms, and one randomized individuals (Schinke 1981). Six trials were conducted in the USA, three were from the UK ( Graham 2002; Wight 2002; Stephenson 2008), and one each came from Mexico (Walker 2006) and South Africa (Taylor 2014). Some interventions were targeted to younger adolescents, i.e. seventhand eighth-grade students, several focused on students aged 13 to 15 years, and one included high school students age 14 and older. The trial reports were published from 1997 to 2014, except for a small RCT from 1981 (N = 36). Sample sizes for the cluster randomized trials ranged from 816 to 10,954 individuals with a median of 3794. The number of clusters ranged from 10 to 102; the median was 24. For the cluster RCTs, the effective sample sizes would be smaller due to the assignment of groups rather than individuals. Seven trials provided details on sample size calculations. The number of contacts or sessions varied. The shortest experimental intervention involved a single unit on emergency contraception added to a standard curriculum. In contrast, four studies involved 20 to 24 sessions over two years.

Follow-up ranged from 3 to 18 months postprogram. Two trials conducted follow-up at more than four years through record review (Wight 2002; Stephenson 2008) and by survey (Stephenson 2008).

#### **Excluded studies**

We excluded 31 trials. Some did not use random assignment while others did not have our primary outcomes. For many studies, we could not find evidence of contraception education in the intervention. For details, see Characteristics of excluded studies.

#### Risk of bias in included studies

Figure 2 summarizes our assessments of risk of bias for the overall review; Figure 3 provides our assessment for each study.

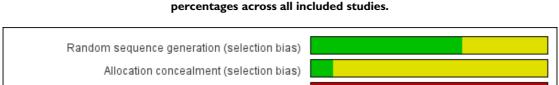


Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as

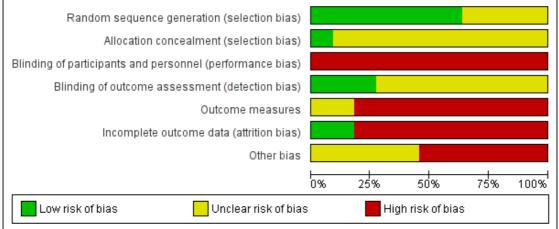


Figure 3. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Outcome measures	Incomplete outcome data (attrition bias)	Other bias
Coyle 2001	•	?	•	?	•	•	?
Coyle 2006	•	?		?			
Graham 2002	•	?	•	?	•	•	?
Kirby 1997	?	?	•	?		•	•
1	ı						
Markham 2012	•	?	•	?	•	•	?
Markham 2012 Schinke 1981	?	?	•	?	•	•	?
			•		?	•	
Schinke 1981	?	?	<ul><li>•</li><li>•</li><li>•</li></ul>	•	?	•	
Schinke 1981 Stephenson 2008	?	?	<ul><li>•</li><li>•</li><li>•</li><li>•</li></ul>	?		•	?
Schinke 1981 Stephenson 2008 Taylor 2014	?	?	<ul><li>•</li><li>•</li><li>•</li><li>•</li><li>•</li></ul>	?		•	?

We looked for evidence of intervention fidelity in the included studies (Table 1). Our assessment of evidence quality includes intervention fidelity reporting.

#### **Allocation**

Of the 11 included trials, seven provided information on the randomization process, such as restricted randomization, minimization strategy, or computer-generated. Two only mentioned stratification (Taylor 2014; Walker 2006) and two provided no information (Kirby 1997; Schinke 1981).

The cluster randomized trials identified the clusters prior to randomization; all individuals meeting the inclusion criteria were eligible. We considered allocation concealment unclear if the report did not indicate whether the recruiters of individuals or the potential participants were aware of the cluster allocation prior to the consent process.

#### **Blinding**

Seven trials mentioned blinding. Two trials stated that participants and investigators or providers were not blinded (Graham 2002; Stephenson 2008). Five trials had some blinding of the assessors or data collection process (Schinke 1981; Graham 2002; Wight 2002; Tortolero 2010; Markham 2012). Double-blinding is often not feasible for participants or providers in educational interventions. We found no mention of blinding for four trials (Coyle 2001; Coyle 2006; Walker 2006; Taylor 2014).

#### Incomplete outcome data

Loss to follow-up was 20% or greater for seven trials. High loss to follow-up threatens validity (Strauss 2005).

- Coyle 2001: 21% at 31 months after baseline (12 months after intervention)
- Coyle 2006: 27% after program; 38% at 6 months after program; 44% at 12 months after program
- Kirby 1997: 27% at 5 months after program; 23% at 17 months
- Markham 2012: 21% to 27% per group at 3 months (9th grade); 27% to 31% by 10th grade follow-up
- Stephenson 2008: 13% intervention and 24% control at 6 months after program; 23% and 37% at 18 months; 48% and 62% at 54 months
  - Walker 2006: 33% at 1 year after program
  - Wight 2002: 31% at 6 months after program

For Tortolero 2010, loss to follow-up was low but overall losses were high, i.e. 42% intervention and 34% comparison, mostly due to withdrawal from school or repeated absence. In addition, Taylor 2014 had differential losses (11% intervention and 23% control).

#### Other potential sources of bias

Of the 10 cluster RCTs, 9 used adjusted analysis to account for cluster effects. We did not have sufficient data for analysis in this review and therefore presented the results as reported by the investigators. The analysis in Kirby 1997 was the exception to that of the other cluster RCTs. The investigators planned to use hierarchical analysis to adjust for clustering if they found any positive differences in the behavioral outcomes. Some results may not have been significant if they had been adjusted for clustering. Schinke 1981 was the only trial that assigned individuals. The report did not have sufficient data for analysis here, so we presented the results as the investigators reported them.

Seven trials based the analysis of behavioral outcomes on a subsample of students who reported ever having sex or being sexually active, variables that the intervention could affect (Graham 2002; Wight 2002; Coyle 2006; Walker 2006; Stephenson 2008; Tortolero 2010; Taylor 2014). Those analyses did not include all students randomized, and therefore were not randomized comparisons. The results have a high risk of bias.

#### **Effects of interventions**

#### See: Summary of findings for the main comparison

We organized this section by intervention focus. Three studies focused on pregnancy prevention, and two more narrowly on emergency contraception (EC). Six trials covered a broad range of issues to prevent pregnancy as well as HIV/STI. Table 2 provides a summary of the interventions and the target audience for each study. In the analysis tables for 'other data,' NS refers to the study groups not being significantly different for that outcome.

#### Preventing pregnancy

Three trials focused on pregnancy prevention among high school students approximately 13 to 15 years old. A theory or model formed the basis of each experimental intervention. The programs differed in emphasis, activities, and duration.

The pregnancy prevention program of Schinke 1981 was based on cognitive and behavioral training, and used a problem-solving schema. Content included sexuality, birth control, pregnancy. This USA trial randomized 36 individuals in one school to study groups. All the other trials assigned classes or schools. Participants were high school sophomores. Contact included 14 sessions of 50 minutes each. The control group only received the assessments, in contrast to the other included trials, which provided the comparison group some type of health education. The report provided results of t-tests and did not clearly define the outcome variables. We did not request details due to the age of the publication. At the six-month follow-up, the students who received the training had a

higher mean than the control group for "more habitual contraception" (reported t (32) = 2.38; P < 0.05), "greater protection at last intercourse" (reported t (32) = 3.26; P < 0.005), and less reliance on "inadequate birth control" (reported t (32) = 4.35; P < 0.001) (Analysis 1.1). The intervention group also had better attitudes toward family planning (reported t (32) = 2.08; P < 0.05) (Analysis 1.1). At the post-test, the intervention group had higher mean scores than the control group for knowledge of human reproduction (t (34) = 3.40; P < 0.002) and of birth control (reported t (34) = 2.63; P < 0.02) (Analysis 1.2).

The intervention in Wight 2002 was based on social learning theory, and incorporated educational principles with which teachers were familiar to enhance acceptability. The 7616 participants were 13 to 15 years old, and attending 25 state schools in Scotland. The program included active learning and skill development in 20 sessions over two years. The control group received the usual sex education. To assign schools to treatment groups, the investigators selected an allocation from the set of 20,000 possible allocations, which provided the best balance of school-level measures. To analyze the outcome of unwanted pregnancy, the investigators used a random effects logistics regression. For the other outcomes, they used a randomization test, based on all the possible allocations from which they selected the final allocation. The investigators based the analysis of behavioral outcomes at six months on a subsample of those who were sexually experienced, a variable that the intervention could affect. Since they did not include all those randomized, those comparisons were not randomized comparisons. At six months postprogram (or 24 months from baseline), the study groups were not significantly different for oral contraceptive (OC) use during last intercourse or self-reported unwanted pregnancy (Analysis 2.1), first intercourse without condom use or no condom use during most recent intercourse (Analysis 2.2). By linking records from the National Health Service, the investigators examined pregnancies by age 20, approximately 4.5 years after the intervention. The termination data included live births, stillbirths, abortions, and miscarriages. The groups did not differ significantly in conceptions or terminations (Analysis 2.3).

For Taylor 2014, the pregnancy prevention intervention involved 12 weekly interactive sessions. Participants were in the first year of high school (grade eight) in KwaZulu-Natal, South Africa. The study randomized 16 schools and had 816 participants. The conceptual framework was based on the I-Change model. The special intervention addressed choice, body development, contraception, and parenthood. Both the intervention and comparison groups received the compulsory program on life skills plus media messages about teen pregnancy. The analysis corrected for cluster effect; multivariate linear and logistic regression models included covariates such as age, gender, socioeconomic status, and sexual experience. The investigators based the analysis of behavioral outcomes on a subsample that reported ever having sex, a variable that the intervention could affect. Since they did not include all those randomized, the comparisons were not randomized com-

parisons. The study groups did not differ significantly in self-reported pregnancy (Analysis 3.1), and the groups did not differ for attitudes toward teen pregnancy (Analysis 3.2). The experimental group was more likely than the control group to report having any condom use (reported adjusted beta 0.98  $\pm$  SE 0.37; reported P < 0.01) (Analysis 3.1). The two groups did not differ significantly for condom use consistency (Analysis 3.2).

#### **Emergency contraception**

Two trials added a lesson on emergency contraception (EC) to an existing curriculum on sex education or HIV prevention. Both focused on students in grade 10. In Graham 2002, both groups received the usual sex education. The trial was conducted in 24 secondary schools in Avon, England. A total of 3234 students completed the baseline survey. To account for the clustering, the investigators weighted the regression analysis for schools rather than individuals. They analyzed by gender, and adjusted for baseline score and four factors in a minimization strategy. However, for EC use, the analyzed a subsample that reported ever having sex. Since they did not include all those randomized, this was not a randomized comparison. Among the girls or the boys, the study groups did not differ significantly for EC use by six months (Analysis 4.1). Knowledge of EC at six months did differ by group, and the analyses included all those randomized. The intervention group was more likely to know the time limit for hormonal EC use among girls (reported weighted percent difference 20.4, 95% CI 10.4 to 30.4; P < 0.01) and boys (reported weighted percent difference 15.9, 95% CI 6.5 to 25.3; P < 0.01) (Analysis 4.2). The group with EC education was also more likely to know the correct time limit for use of intrauterine contraception as EC, among the girls (reported weighted percent difference 10.7, 95% CI 0.4 to 21.0; P = 0.04) and the boys (reported weighted percent difference 4.2, 95% CI 0.7 to 7.7; P = 0.02) (Analysis 4.2).

For Walker 2006, two groups received an HIV prevention program with one also having the unit on EC. A third group had the usual sex education course. The trial took place in 40 schools in Moreles, Mexico and had 10,954 participants. The report mentions improved EC access as part of the special intervention, but does not provide further information. The Discussion mentions that EC is available at pharmacies without a prescription, but young people may have trouble accessing it thus affecting their results. The analysis reportedly took the cluster sample design into account. The investigators used fixed effect for regression and adjusted the standard errors for the number of primary sampling units for the descriptive statistics. However, they analyzed the behavioral outcomes for a subsample that reported being sexually active, a variable that the intervention could affect. Since they did not include all those randomized, those comparisons were not randomized comparisons. By one year, the study groups did not differ significantly for condom use at first sex or at last sex (Analysis 5.1). The group with HIV prevention + EC was more likely to have used

EC compared with the group that had the usual sex education (reported adjusted OR 2.16, 95% CI 1.30 to 3.59) (Analysis 5.2). Analysis of knowledge outcomes included all those randomized. The HIV prevention + EC group was also more likely to have knowledge of EC at one year (reported adjusted OR 2.82, 95% CI 2.36 to 3.37) (Analysis 5.3). Those with HIV prevention alone (no EC unit) did not differ significantly from the group with usual sex education in use of EC (Analysis 5.2) or knowledge of EC (Analysis 5.3).

#### Preventing HIV/STI and pregnancy

Six trials tested curricula to prevent pregnancy and HIV or other STI. Two studies compared peer-led versus teacher-led sex education and two examined interactive programs versus usual sex education or prevention activities. The remaining two trials compared the same basic intervention for risk reduction versus usual health education, but one also had a third arm for risk avoidance. We list them by intervention focus and sessions provided.

#### Peer-led versus teacher-led sex education

- The program evaluated in Kirby 1997 provided eight interactive sessions over two weeks. The intervention group also had the same general sex education as the control group. Peer educators led the special interactive sessions. Students were in the seventh grade in Los Angeles, CA (USA). The 102 classes randomized included six middle schools and approximately 2110 students. In most schools, both the intervention and control groups received didactic sessions on reproductive health. Students were the unit of analysis. The evaluators intended to use hierarchical analysis to control for clustering if they found positive results. The study groups did not differ significantly in any of the behavioral outcomes, except for OC use being less likely for the intervention group (OR 0.57, 95% CI 0.36 to 0.91; participants = 354) (Analysis 6.1). This negative effect may not have been significant if the investigators had adjusted for the clustering. The other outcomes were reported condom use with last sex (Analysis 6.2) and ever been pregnant or gotten anyone pregnant (Analysis 6.3; Analysis 6.4). Based on a six-item knowledge scale, the intervention group had a greater mean increase in knowledge of HIV and pregnancy prevention compared with the control group at both 5 months (reported mean increase 0.59 vs 0.07; P < 0.001) and 17 months (reported mean increase 0.89 vs 0.53; P < 0.001) (Analysis 6.5). Again, these effects were not adjusted for clustering.
- The special intervention in Stephenson 2008 involved three class sessions of one hour each, led by trained peers. The 8766 participants were grade eight students, 13 to 14 years old, in 27 UK schools. The investigators used general estimating equations, accounting for correlation within schools, and based on the robust variance estimator. As with Taylor 2014, they based the

analysis of self-reported behavioral outcomes on a subsample that reported ever having sex, for which the proportion increased by the length of follow-up. Therefore, we did not consider the comparisons to be randomized comparisons. For pregnancy data, the investigators obtained self reports as well as long-term followup from national records of abortions and live births. In the 54month follow-up, self reports of ever having a pregnancy indicated a lower rate for the intervention group compared to the control (reported weighted adjusted OR 0.62, 95% CI 0.42 to 0.91) (Analysis 7.1). Other pregnancy measures were not significantly different between the groups: no unintended pregnancy, ever had unwanted pregnancy, ever had abortion. Also, the study arms were not significantly different for the trial's primary outcome of abortion by age 20 nor for live births by age 20.5 (Analysis 7.2). The comparison groups did not differ significantly at any time point for contraceptive use (Analysis 7.3; Analysis 7.4), condom use (Analysis 7.5; Analysis 7.6), knowledge of EC pill timing (Analysis 7.7), or attitude about condom use (Analysis 7.8).

# Interactive programs versus usual sex education or prevention activities

The curriculum in Coyle 2001 addressed using condoms and other contraception and included 20 sessions, divided between grades 9 and 10. The 20 randomized schools had 3869 students who completed baseline surveys. The program also included school organization activities and parent education. The comparison group received the standard five-session curriculum and some school activities. The locations were in southeast Texas and northern California (USA). This cluster randomized trial accounted for the cluster effects in the analysis by using multilevel models. The investigators conducted assessments immediately after intervention year one and year two as well as 12 months after year two. Compared to the comparison group, the intervention group participants were more likely to report

- having used an effective method of contraception (condoms, OCs, or both) at last intercourse immediately after year one (reported adjusted OR 1.62  $\pm$  standard error (SE) 0.22; P = 0.03) and 12 months after year two (reported adjusted OR 1.76  $\pm$  SE 0.29; P = 0.05) (Analysis 8.1);
- having used a condom during last intercourse, as assessed immediately after year one (reported adjusted OR 1.91  $\pm$  SE 0.27; P = 0.02) and 12 months after year two (reported adjusted OR 1.68  $\pm$  SE 0.25; P = 0.04) (Analysis 8.2);
- a lower frequency of sex without condom use in the past three months, as assessed immediately after year one (reported ratio of adjusted means  $0.50 \pm SE\ 0.31$ ; P = 0.03) and 12 months after year two (reported ratio of adjusted means  $0.63 \pm SE\ 0.23$ ; P = 0.05) (Analysis 8.2);

The intervention group in Coyle 2001 also had a higher mean for positive attitudes about condoms immediately after year one

(reported MD 0.10  $\pm$  SE 0.03; P < 0.01) and year two (reported MD 0.07; P < 0.01), as well as 12 months after year two (reported MD 0.07  $\pm$  SE 0.02; P = 0.01) (Analysis 8.3).

For Coyle 2006, the curriculum provided nine sessions of skill-based learning plus five service-learning activities in 24 alternative day schools in northern California (USA). The comparison group received the usual prevention activities for HIV, STI, and pregnancy. The schools served high school students with severe discipline issues, substance use, or chronic absenteeism. This cluster RCT accounted for the cluster effects in the analysis by using multilevel models. The study included 988 participants. The investigators based the analysis of behavioral outcomes on a subsample that reported ever having sex, a variable that the intervention could affect. Since they did not include all those randomized, we did not consider the comparisons to be randomized comparisons. The assessments at 6, 12, and 18 months after baseline were conducted about 5, 11, and 17 months postprogram.

- The study groups did not differ significantly for selfreported pregnancy or using an effective method of pregnancy prevention at last sex (Analysis 9.1; Analysis 9.2).
- At 5 months but not 11 or 17 months, the intervention group was more likely than the usual-activity group to report
- o having used a condom during last intercourse (reported OR 2.12, 95% CI 1.24 to 3.56) (Analysis 9.3);
- $\circ$  less frequent sex without a condom in the past three months (reported adjusted MD -1.09  $\pm$  0.36; P = 0.002) (Analysis 9.4).
- The intervention group had a higher mean for condom knowledge at 5 months (reported MD  $0.055 \pm 0.028$ ; P = 0.05) and at 17 months (reported MD  $0.060 \pm 0.030$ ; P = 0.04) (Analysis 9.5).
- The two groups did not differ significantly in their attitudes about condoms (Analysis 9.6).

# Risk reduction or risk avoidance versus usual health education

Two USA studies provided 24 sessions across the seventh and eighth grades and used variations of the same curriculum. In Tortolero 2010, the focus was on delaying sexual behavior, although the intervention addressed a range of contraceptive methods and the relative effectiveness (see Characteristics of included studies). The comparison group had the usual health classes, which varied by school. The study included 1307 participants across the 10 schools randomized. In the analysis, the investigators used multilevel models that included the baseline measures of the dependent variable plus covariates judged to be potential confounders. However, they based the analysis of behavioral outcomes on a subsample that reported ever having sex, so the comparisons were not randomized comparisons. The study groups did not differ significantly in reported condom use at last sex, sex without a condom in the last three months, or sex without effective pregnancy preven-

tion in the last three months (Analysis 10.1). For condom knowledge, the intervention group had a higher reported mean (2.41  $\pm$  SD 0.79) than the comparison group (2.25  $\pm$  SD 0.95) (reported P  $\leq$  0.01) (Analysis 10.2). This analysis of knowledge did include all those randomized.

Markham 2012 included the risk reduction (RR) intervention from Tortolero 2010, which encouraged abstinence until older and a comparison group with the usual health classes, which varied by school. An additional third arm for risk avoidance (RA) focused on abstinence until marriage. As in Tortolero 2010, the intervention addressed a range of contraceptive methods and their relative effectiveness (see Characteristics of included studies). The 15 randomized schools included 1742 participants. The analysis involved generalized linear models with covariates; the estimated standard errors were adjusted for intraclass correlation via random-effects models. Results came from reports in 2012 and 2014.

- At 3 months and after 15 months postprogram, the risk avoidance group was less likely than the control group to report unprotected vaginal sex at last intercourse (reported adjusted ORs 0.70, 95% CI 0.52 to 0.93; and 0.61, 95% CI 0.45 to 0.85, respectively) (Analysis 11.1). Protected sex included using a condom or abstaining from sex. The RA and control groups did not differ significantly for vaginal sex without a condom in the last three months (Analysis 11.2) or for general condom knowledge (Analysis 11.3).
- At three months postprogram, the risk reduction group was less likely than the control group to report unprotected sex at last vaginal intercourse (reported adjusted OR 0.67, 95% CI 0.47 to 0.96) (Analysis 11.1). Also at three months postprogram, the RR group was less likely to report vaginal sex without a condom in the last three months (reported adjusted OR 0.59, 95% CI 0.36 to 0.95) (Analysis 11.2). The RR group had a higher score for "general condom knowledge" at 3 months and after 15 months postprogram (reported adjusted MD 0.09 and 0.10, respectively; P < 0.01) (Analysis 11.3).

#### DISCUSSION

#### Summary of main results

Table 3 summarizes the evidence quality for each included study and the evidence of effectiveness. We focus here on studies with moderate quality evidence.

Three trials had moderate quality evidence and showed intervention effects on one of our primary outcomes. i.e. pregnancy or contraceptive use. All three compared an interactive program to prevent HIV/STI and pregnancy versus usual health or sex education (Summary of findings for the main comparison). Two were multifaceted programs provided over two years. In one trial,

the intervention group was more likely than the standard curriculum group to report use of effective contraception during last sex, as assessed immediately after year one and 12 months after year two. At the same time points, the intervention group was more likely to report having used a condom during last sex and to have a lower reported frequency of sex without a condom in the past three months. The other multifaceted intervention provided a sexual risk reduction program and a risk avoidance (abstinence) program. The comparison was usual health education. At three months postprogram, the risk reduction group was less likely to report no condom use at last vaginal sex, as well as vaginal sex without a condom in the last three months. At 3 months and after 15 months, the risk avoidance group was less likely to report no condom use at last vaginal sex. The third trial provided a peerled intervention for HIV and pregnancy prevention that had eight interactive sessions. At 17 months, the intervention group was less likely to report OC use during last sex compared with the teacherled group. This negative effect may not have been significant if the investigators had adjusted for the clustering.

Our secondary outcomes were knowledge and attitudes about contraception. Three trials with moderate quality evidence showed intervention effects on knowledge. A multifaceted program noted above addressed risk reduction and risk avoidance. The risk reduction group had a higher score than the usual education group for condom knowledge at 3 months and after 15 months. For the trial with a peer-led intervention discussed above, the experimental group had a greater mean increase in knowledge of HIV and pregnancy prevention compared with the control group at 5 and 17 months. Another trial with moderate quality evidence showed an effect on knowledge but not on a primary outcome. One group had a session on emergency contraception (EC) added to the usual sex education. The group with the EC unit was more likely than a group with usual education alone to know the time limits for using hormonal EC (pill) and for using the non-hormonal intrauterine device (IUD) as EC.

# Overall completeness and applicability of evidence

Most of the studies were conducted in higher income countries, i.e. the USA and the UK. One came from Mexico and one from South Africa. As noted earlier, the 2015 projected birth rate for girls aged 15 to 19 years in developing regions was three times that of developed regions (UN 2015). We did not have any representation from sub-Saharan Africa or South Central Asia, where two-thirds of sexually active women aged 15 to 19 years want to avoid pregnancy but are not using a modern contraceptive method (Darroch 2011). Fonner 2014 examined studies of school-based sex education for HIV prevention in low- and middle-income countries with a wide range of study designs. Using meta-analysis, they found an intervention effect for condom use. However, they

did not seek outcome data on pregnancy or contraceptive use since they were focused on HIV prevention.

The types of programs included were pregnancy prevention as well as preventing pregnancy and STI/HIV. The content regarding contraceptives often focused on condom use, perhaps in part because condoms are the most used contraceptive among adolescents. They are readily available at pharmacies in many regions. Also, condoms are the only contraceptive that can prevent transmission of HIV/STI, which was a large part of many programs. Several interventions also addressed oral contraceptives, also used by adolescents. Some programs ranked the relative effectiveness of modern and traditional contraceptive methods.

The number of sessions varied widely. Four interventions that provided 20 or more sessions over two years included a pregnancy prevention curriculum and programs to prevent pregnancy and HIV/STI. Five programs provided anywhere from 3 to 14 sessions. Two trials added a unit on EC to an existing sex education or HIV prevention curriculum.

#### Quality of the evidence

We considered the overall quality of evidence to be low. See Data synthesis for the criteria we used to grade the evidence. We rated the quality as moderate for four trials, low for four, and very low for three (Table 3). The main reasons for downgrading studies were having limited information on intervention fidelity, analyzing a subsample rather than all those randomized, and having high loss to follow-up or discontinuation.

For educational settings, some study design features are rarely feasible. One example is blinding of participants and investigators to group assignment. Also, without a clinic, few options exist for an objective outcome measure of contraceptive use such as injection records for depot medroxyprogesterone acetate (DMPA) or electronic monitoring of pill intake. Further, trials of educational interventions often assess use of a range of contraceptive methods. An objective measure would be needed for each type of contraceptive reported.

Of five trials that assessed pregnancy, all had self reports for the main assessments. Under-reporting is possible with self reports since women may not have reported an abortion. For long-term follow-up, two trials also used medical records of pregnancies and abortions, but they obtained those data at four years after the intervention.

#### Potential biases in the review process

Intervention information was limited for some older studies. We had to determine whether the trial addressed contraception sufficiently for inclusion or not. We attempted to gather related papers that addressed intervention content. However, we may have excluded trials that addressed contraceptive methods in more de-

tail than the reports indicated. Similarly, outcomes measured may not have been fully reported if not significant. We did not contact investigators for missing data from older trials (see Dealing with missing data).

# Agreements and disagreements with other studies or reviews

Some reviews of school-based programs have focused on contraceptive service interventions (Blank 2010; Owen 2010). In Blank 2010, interventions were located in universities as well as high schools. They included both RCTs and non-randomized studies, so results are not directly comparable to our review. Studies were limited in quantity and quality. The most effective interventions were reportedly intensive case management with a culturally matched social worker and school-based health centers. Owen 2010 examined rates of sexual activity, use of school-based services, and contraceptive use. The researchers found no good quality evidence of an intervention association with increased use of condoms or other contraceptives, and no evidence of effect on unplanned pregnancies.

We had searched for studies using digital media but did not find any that met our study design criteria. Guse 2012 reviewed the use of digital media for improving the sexual health of young people to age 24. They did not limit by type of study. Some programs were conducted in schools. Outcomes included STIs, HIV, and contraceptive use. They noted intervention effects for psychosocial outcomes such as condom self-efficacy and abstinence attitudes and for knowledge of HIV, STI, or pregnancy.

Two reviews included interventions focused on adolescents but were not limited to school-based programs. A review of theorybased interventions to improve contraceptive use had 11 trials focused on adolescents (Lopez 2013a). Seven of those trials with adolescents showed an intervention effect, but only four had moderate or high quality evidence. One of the four was in this review and highlighted above (Summary of main results). The other three differed in focused from this review. They studied a clinic intervention for 18 to 24-year-old women, an intensive home-based intervention for parenting teens, and a school-based intervention focused more on use of condoms than other contraceptives. Another review examined interventions to prevent adolescent pregnancy (Oringanje 2016). The programs could have been based in schools, clinics, or the community, home, or faith group. They found that multiple interventions, e.g. education and promoting contraceptives, resulted in lower risk of unintended pregnancy in individually randomized trials but not cluster RCTs. They did not see an effect on contraceptive use with these types of interventions. Educational interventions increased reported condom use but did not affect pregnancy rates. Efforts to promote contraception led to an increase in hormonal method use but not to a decrease in pregnancy.

Several ongoing studies will add to the evidence base in the near future. These cluster randomized trials are all USA-based. Shegog 2015a adapted the curriculum from Tortolero 2010 for American Indian or Alaskan Native youth. The investigators transferred the program to a web-based format and added culturally relevant components. Constantine 2015 provided a 12-session sexual 'rights-based' curriculum for ninth graders to prevent pregnancy and STIs. The intervention included parent education and access to sexual health services for pregnancy and STI testing and prescriptions for contraceptives. The investigators have yet to report on behavioral outcomes. Two trials are evaluating a teen outreach program that has a school-based curriculum and community service learning (Francis 2014; Buhi 2015).

#### AUTHORS' CONCLUSIONS

### Implications for practice

Despite the concern about reducing pregnancy rates among adolescents, the evidence base for school-based programs to improve contraceptive use is still somewhat limited. Many interventions addressed reproductive physiology or emphasized abstinence or delayed sexual initiation, and did not appear to provide information about contraceptives. Similarly, many trials assessed contraceptive use as an outcome but did not report whether the content included contraceptive methods and their relative effectiveness. Of the trials included, most compared the new programs to 'usual' sex education. Therefore, the investigators were looking for an effect greater than that of the currently used programs.

Most included trials aimed to prevent HIV/STI and pregnancy. All of the effective interventions with evidence of high or moderate quality addressed these issues. A few, mostly older trials, focused on pregnancy prevention and had limited effect. Peer-led education did not have a positive effect compared with teacher-led education. The effective strategies were generally multifaceted with multiple sessions. They were often interactive and provided a variety of activities, and therefore more likely than a didactic approach to engage adolescents in learning and to lead to behavior change.

# Implications for research

As noted above, interventions that addressed HIV/STI and pregnancy appeared to be more effective than programs focused on pregnancy prevention alone. Trials testing these multifaceted programs with multiple sessions are costly to implement. However, schools provide the environment and infrastructure for such repeated contact. Most of the included trials were large and well-designed. Some quality issues, such as blinding of participants and providers, are not feasible with educational interventions. Others, such as objective outcome assessments of contraceptive use, are not feasible in school situations, at least not without a clinic.

We considered the quality of evidence to be low. Limiting factors were information on intervention fidelity, analyzing a subsample rather all those randomized, and large loss to follow-up or discontinuation. Training of providers on the program may help with consistent intervention implementation, as would monitoring adherence to the protocol. More careful follow-up with teachers, who could then follow-up with students, may improve participation in assessments.

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# CHARACTERISTICS OF STUDIES

# Characteristics of included studies [ordered by study ID]

# **Coyle 2001**

Methods	Design: cluster randomized trial; 20 schools assigned to study groups Location: southeast Texas and northern California, USA Time frame: 1993 to 1996 Sample size calculation (and outcome of focus): no information
Participants	General with N: 20 public schools; 3869 students in grade 9 Inclusion criteria: school districts served diverse populations (ethnicity and socioeconomic status); areas with high HIV prevalence; close to research team Exclusion criteria: no information
Interventions	Study focus: prevention of HIV, STI, and pregnancy for high school youth 1) Intervention: 20 lessons (10 lessons in grade 9 and 10 lessons in grade 10); communicating about using condoms and other contraception; school organization activities; peer resource team; parent education; school-community linkages 2) Comparison: standard 5-session knowledge-based HIV prevention curriculum plus some school activities that varied by school Duration: 2-year program
Outcomes	Primary: frequency of unprotected sex; condom use during last sex; use of effective contraception during last sex (i.e., condom, birth control pills, or both)  Secondary: attitudes about sex or condom use; HIV/STD knowledge; beliefs; self efficacy; barriers to condom use; HIV/STD risk perceptions  Follow-up: 7 months (after year 1 lessons (in 9th-grade)), 19 months (after year 2 lessons (in 10th-grade)), and 31 months (12 months after year 2 lessons)
Notes	Theory or model: Social Cognitive Theory plus social influence model; models of school change
Risk of bias	

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Restricted randomization process to assign schools: schools were ranked on index of possible confounders, and adjacent schools in ranking were paired and randomly as- signed to intervention or control
Allocation concealment (selection bias)	Unclear risk	Schools were identified prior to random- ization. All students in the identified grades were eligible

# Coyle 2001 (Continued)

Blinding of participants and personnel (performance bias) All outcomes	High risk	Presume no blinding of participants or providers; not feasible due to type of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Outcome measures	High risk	No objective measure for contraceptive use
Incomplete outcome data (attrition bias) All outcomes	High risk	Loss to follow-up: 19 months 17% (immediately after year 2); 31 months 21% (12 months after year 2) Exclusions after randomization: 346 students who left in year 1 and did not enroll in fall of year 2; 95 took baseline survey but were grade 11 or 12
Other bias	Unclear risk	Results as reported by investigators; insufficient data for analysis in this review Analysis accounted for cluster effects using multilevel models (levels measurement occasion, student, and school); predictor variables i.e. baseline responses on outcomes, intervention group, geographic area, and "outcome specific covariates"

# Coyle 2006

Methods	Design: cluster randomized trial: 24 schools assigned to intervention or control Location: northern California, USA Time frame: recruited 2000 to 2001 Sample size calculation (and outcome of focus): no information
Participants	General with N: 24 alternative day schools; 988 students (ages 14 to > 18 years) Inclusion criteria: 4 counties with ethnic diversity and in close proximity to investigators; all enrolled students (generally had severe discipline issues, substance use, or chronic absenteeism) Exclusion criteria: students on extended leave (e.g. maternity or medical); suspended or incarcerated at baseline; functionally dropped out of school
Interventions	Study focus: prevention of HIV, STI, and pregnancy 1) Intervention: based on that in Coyle 2001; skills-based HIV, STD, and pregnancy prevention curriculum (9 sessions; 13.5 hours total) plus service-learning activities (5 visits to volunteer sites; 12.5 hours total); implemented 2 or 3 times per week for 5 to 7 weeks 2) Comparison: usual activities related to prevention of HIV, STI, and pregnancy (typ-

# Coyle 2006 (Continued)

	ically presenters from community-based agencies)		
Outcomes	Primary: frequency of sex without condom in past 3 months, condom use with last sex, use of effective birth control, pregnancy (self report) Secondary: attitude toward condoms (general, protecting against STDs or pregnancy); knowledge of condoms or HIV and condoms; self efficacy Follow-up: 6, 12, and 18 months after baseline (about 5, 11, and 17 months postprogram) Report provided effect estimates but not means or frequencies per study group; unable to obtain further information from investigator		
Notes	Theory or model: Social Cognitive Theory plus Theory of Planned Behavior		
Risk of bias			
Bias	Authors' judgement	Support for judgement	
Random sequence generation (selection bias)	Low risk	Restricted randomization: schools put into matched sets; matched groups formed with set from each county; matched groups randomized	
Allocation concealment (selection bias)	Unclear risk	Schools identified prior to randomization; all students in schools were eligible	
Blinding of participants and personnel (performance bias) All outcomes	High risk	Presume no blinding of participants or providers; not feasible due to type of intervention	
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information	
Outcome measures	High risk	No objective measure for contraceptive use; pregnancy by self report	
Incomplete outcome data (attrition bias) All outcomes	High risk	Loss to follow-up: after baseline, 6 months 27% (immediately postprogram); 12 months 38% (6 months postprogram); 18 months 44% (12 months postprogram); Losses by group not reported	
Other bias	High risk	Analysis: accounted for cluster effects by using multilevel models (levels student and school); psychosocial outcomes also had survey measurement occasion  Predictor variables in models: baseline responses on outcome, intervention group,	

# Coyle 2006 (Continued)

and "outcome specific covariates"
Analysis of behavioral outcomes based on
who had sex (could be affected by inter-
vention), rather than all randomized (high
risk)

# Graham 2002

Methods	Design: cluster randomized trial; 24 schools assigned to intervention and control conditions Location: county of Avon, England Time frame: 1999 to 2000 Sample size estimation and outcome of focus: Primary outcome was proportion of pupils able to identify 72-hour limit for use of hormonal emergency contraception (EC). To detect difference of 18% between intervention and control, 80% power, significance P < 0.05 (two-tailed test): 11 schools needed in each group. Assumed intention-to-treat analysis, absentee rate 15%, and intracluster correlation coefficient 0.05; and at baseline 26% girls would know 72-hour time limit for EC use (previous research)
Participants	General with N: 24 secondary schools; 3234 students completed baseline survey Inclusion criteria: mixed sex, state secondary schools; year 10 students Exclusion criteria: no information
Interventions	Study focus: emergency contraception  1) Intervention: usual sex education + 1 lesson on emergency contraception (EC)  2) Comparison: usual sex education
Outcomes	Primary: EC knowledge (72-hour limit for use) Secondary: knowledge of time for IUD use as EC (5 days); not virgin; used EC; intent to use EC Follow-up: 6 months
Notes	

# Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Minimization strategy included pupils entitled to free school meals, size of year group, whether sex education was taught by tutor or specialized team of teachers, and whether sex education was taught mainly in year 9 or year 10. Allocation of schools to groups, after recruiting schools, determined by sequential minimization protocol. Order for minimizing schools determined by computer-generated random numbers

# Graham 2002 (Continued)

Allocation concealment (selection bias)	Unclear risk	Schools identified prior to randomization. All students in year 10 in the schools were eligible
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Investigator blind to allocation assessed whether questionnaires were "spoilt" (presumably incomplete or unusable); 44 such questionnaires were removed from further analysis
Outcome measures	High risk	No objective measure for contraceptive use
Incomplete outcome data (attrition bias) All outcomes	Low risk	Loss to follow-up (questionnaires): 18% (691/3794); 16% intervention and 20% control
Other bias	Unclear risk	Analysis: regression analysis, weighted for schools rather than individuals; analyzed outcomes separately for boys and girls; ad- justed for baseline score and four factors in minimization strategy

# **Kirby 1997**

Methods	Design: cluster RCTs with 102 classrooms randomly assigned to intervention or control Location: 2 areas of Los Angeles, CA (USA)  Time frame: no information  Sample size estimation and outcome of focus: no information
Participants	General with N: 102 7th-grade classes; approximately 1600 students Inclusion criteria: all students within 7th-grade classes in 6 middle schools Exclusion criteria: no mention
Interventions	Study focus: HIV (AIDS) and pregnancy prevention program for middle schools  1) SNAPP: peer-led HIV (AIDS) and pregnancy prevention with interactive activities; 8 sessions over 2 weeks; goals of delaying intercourse and increasing condom use; included contraceptive methods displayed and discussed; also had general education as per control  2) Control: instruction on reproduction, pregnancy prevention, HIV, STD; usually didactic
Outcomes	Primary: delay sexual initiation Secondary: condom use at last sex; use of OCs at last sex; self report of ever pregnant or ever gotten anyone pregnant; change in knowledge, attitudes, beliefs (scales) Follow-up: 5-month post-test and 17-month follow-up

# Kirby 1997 (Continued)

Notes	Children's hospital developed program; another organization designed and conducted evaluation  Theory or model: based on social learning theory and principles of health belief model	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No information
Allocation concealment (selection bias)	Unclear risk	Schools identified prior to randomization. All students in grade 7 were eligible
Blinding of participants and personnel (performance bias) All outcomes	High risk	Presume no blinding of participants or providers; not feasible due to type of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Outcome measures	High risk	No objective measure for contraceptive use; pregnancy self report
Incomplete outcome data (attrition bias) All outcomes	High risk	Loss to follow-up: 5 months 27% (1549/2110); 17 months 23% (1616/2110)
Other bias	High risk	Analysis: individual as unit of analysis; if investigators found positive results for behavioral outcomes, they planned to use hierarchical analysis to control for clustering Some results may not have been important if adjusted for clustering (high risk)
Markham 2012		
Methods	Design: cluster randomized trial; 15 urban middle schools assigned, 5 to each condition Location: south-central USA (most authors based in Houston) Time frame: trial conducted 2006 to 2010 Sample size estimation and outcome of focus: Assumed 15% controls would initiate sex by grade 9, 25% attrition, intra-school correlations = 0.005, and alpha = 0.05 (two-tailed); initial sample size 1500 grade 7 students estimated, 80% power to detect 10% pair-wise differences in sexual initiation between intervention and control conditions at grade 9 follow-up; recruited to reach quota of 100 students per school	

# Markham 2012 (Continued)

Participants	General with N: 15 schools; 1742 students Inclusion criteria: grade 7 students in study schools Exclusion criteria: no information
Interventions	Study focus: sexual risk avoidance and risk reduction; 24 sessions of 50 minutes each (12 session grade 7; 12 sessions grade 8); based on middle-school program (Tortolero 2010) 1) Risk avoidance (RA): focused on abstinence until marriage 2) Risk reduction (RR): addressed abstinence until older; had activities regarding condom use and contraception use and on advantages and limitations of various contraceptive methods  Investigator communicated contraceptive methods in intervention: condoms, birth control pills, injectable (DMPA), vaginal ring, transdermal patch, abstinence or choosing to wait to have sex, spermicides, EC, condom with other method, as well as rhythm method, withdrawal, and hope. Ranked each method by effectiveness and noted whether method was considered effective or ineffective 3) Comparison (C): usual health classes that varied by school
Outcomes	Primary: delayed sexual initiation for those with no sexual experience Secondary: delayed oral, vaginal, and anal sex specifically; reduced sexual risk (no sex without condom; fewer partners); general condom knowledge; belief about condoms; intent to use condoms Audio-computer-assisted self-interview Follow-up: 9th grade (2012 report), about 3 months postprogram; October to July of 10th grade (2014 report), > 15 months postprogram
Notes	Investigator provided information about contraceptive methods addressed in curriculum (see Tortolero 2010).

# Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Multi-attribute randomization protocol accounting for school size, racial and ethnic composition, and geographic location
Allocation concealment (selection bias)	Unclear risk	Schools assigned and randomized; all 7th-grade students were eligible
Blinding of participants and personnel (performance bias) All outcomes	High risk	Presume no blinding of participants or providers; not feasible due to type of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information Audio-computer-assisted self interview
Outcome measures	High risk	No objective measure for contraceptive use

# Markham 2012 (Continued)

Incomplete outcome data (attrition bias) All outcomes	High risk	Loss to follow-up: 3 months (9th grade) RA 27%, RR 26%, C 21%; 10th grade follow-up RA 27%, RR 31%, C 30%
Other bias	Unclear risk	Analysis: non-response weighting due to nonrandom attrition; generalized linear models with covariates (gender, race or ethnicity, age at baseline, family structure, time between measures, school-level sexual experience at baseline, and baseline measure for psychosocial outcomes); estimated standard errors adjusted for intraclass correlation via random-effects models

# Schinke 1981

Methods	Design: RCT; individuals assigned Location: not specified; investigators based in Seattle, WA (USA) Time frame: no information Sample size calculation (and outcome of focus): no information
Participants	General with N: 36 students in public high school Inclusion criteria: sophomore class students Exclusion criteria: no information
Interventions	Study focus: preventing adolescent pregnancy  1) Intervention: cognitive and behavioral training (14 sessions of 50-min each); reproductive biology and contraceptive methods; guest speakers, audiovisual aids, Socratic discussion  • pretest, training, and post-test  • training and post-test  2) Control: 2 groups, no training for either  • pretest and post-test  • post-test only  Duration: 14 group sessions of 50 minutes each
Outcomes	Primary: "habitual contraception"; "greater protection at last intercourse"; "less reliance on inadequate birth control" (no definitions)  Secondary: knowledge of pregnancy prevention (post-test only); attitudes toward family planning  Follow-up: 6 months
Notes	Theory or model: cognitive and behavioral training; problem-solving schema Analysis: data not available for analysis in this review; did not request data from investigator due to age of study. Investigator did communicate that contraceptive outcomes were based on reported behavior

# Schinke 1981 (Continued)

Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No information
Allocation concealment (selection bias)	Unclear risk	No information
Blinding of participants and personnel (performance bias) All outcomes	High risk	Presume no blinding of participants or providers; not feasible due to type of intervention
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Measures were scored by 2 assistants who were not aware of study conditions or hypotheses
Outcome measures	High risk	No objective measure for contraceptive use
Incomplete outcome data (attrition bias) All outcomes	Low risk	Loss to follow-up: 6% (2/36) at 6 months
Other bias	Unclear risk	Results as reported by investigators; insufficient data for analysis in this review

# Stephenson 2008

Methods	Design: cluster randomized trial; 29 schools randomized (2 withdrew before knowing allocation), 3 strata based on sum of standardized criteria including socioeconomic factors and services (low, medium, high risk)  Location: central and southern England (UK)  Time frame: enrollment 1998 to 1999  Sample size calculation (and outcome of interest): 14 schools per arm with 150 girls each to detect 33% reduction in abortion by age 20 (from 9% to 6%); 80% power
Participants	General with N: 27 secondary schools; 8766 participants at baseline Inclusion criteria:  • schools: comprehensive, mixed sex, nonselective; admitted students until age 18  • individuals: in grade 8; aged 13 to 14 years  • peer educators: students in grade 11  Exclusion criteria: schools already implementing peer-led sex education
Interventions	Study focus: prevent pregnancy and STI; improve quality of sexual relationships 1) Intervention: school-based peer-led sex education during summer term (3 sessions); peer training included 3 pre-training meetings, 2 days of training, and follow-up meeting; sessions included sexual communication, condom use, HIV/STI, types of contraception including EC, local sexual health services 2) Comparison: teacher-led sex education (usual method)

# Stephenson 2008 (Continued)

	Duration of peer-led education: 3 class sessions at 1 hour each	
Outcomes	Primary: 2008 report had data on pregnancy from records of abortion by age 20 and live births by age 20.5 (statutory abortion notification and birth registration of National Health Service) and follow-up at 54 months after baseline; 2004 report had 6- and 18-month follow-up data  Secondary: ever pregnant (self report); no unintended pregnancy (self report); contraception use by first sex; STI (self report); knowledge of EC timing; attitude toward condom use  Follow-up: 6 and 18 months after intervention (in classroom); about 54 months after baseline (in school; if no longer in school, by mail or home visit; lastly, via their general practitioner)	
Notes	Theory or model: none	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated sequence; block size 10 Randomized 29 schools; 2 withdrew before knowing allocation due to staff changes
Allocation concealment (selection bias)	Unclear risk	No information
Blinding of participants and personnel (performance bias) All outcomes	High risk	No blinding
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No blinding for self-reported outcomes (2004); implementation and evaluation teams reportedly independent Data for long-term follow-up (2008) of pregnancy and abortion came from National Health Service (NHS) records. NHS staff blind to allocation did the matching; data de-identified
Outcome measures	Unclear risk	Shorter-term follow-up: no objective measure for contraceptive use; pregnancy self report (high risk) Long-term follow-up: pregnancy and abortion records (low risk)
Incomplete outcome data (attrition bias) All outcomes	High risk	Loss to follow-up: 6 months, 13% intervention and 24% control; 18 months, 23% intervention and 37%

# **Stephenson 2008** (Continued)

		control; 54-months, 48% intervention and 62% control (missing postal codes for 25% (21% intervention and 28% control) Exclusions after randomization: where outcome referred to time until present, excluded questionnaires returned via general practitioner because that occurred much later than other responses
Other bias	High risk	Results as reported by investigators; insufficient data for analysis in this review Analysis: generalized estimating equations, including correlation within schools and based on robust variance estimator; CI reportedly account for clustering by school Analysis of behavioral outcomes based on who had sex (could be affected by intervention), rather than all randomized (high risk)

# Taylor 2014

Methods	Design: cluster randomized trial; 16 high schools (urban and rural) allocated to conditions Location: KwaZulu-Natal, South Africa Time frame: 2009 Sample size estimation and outcome of focus: no information
Participants	General with N: 16 high schools; 816 students Inclusion criteria: 2 of 11 districts (1 urban and 1 rural); 16 of 1580 high schools on Department of Education list; randomly selected grade 8 classes (1st year high school) Exclusion criteria: no information
Interventions	Study focus: teenage pregnancy prevention  1) Intervention: interactive program with 12 weekly sessions addressing choice, body development, contraception (role play included visiting clinic for contraception), parenthood; compulsory program (below)  2) Control: compulsory Lifeskills program and media messages regarding teen pregnancy; had experimental program at trial end
Outcomes	Primary: attitudes to teen pregnancy (pro and con scales); intent to prevent pregnancy and to use condoms  Secondary: ever had sex; been pregnant or caused pregnancy; condom use (any); condom use consistency as 4-point scale from 1 (never) to 4 (always)  Follow-up: 4 months postprogram (8 months after baseline)

# Taylor 2014 (Continued)

Notes	Theory or model: intervention development based on Bandura's social cognitive theory; final report states conceptual framework was I-Change model of de Vries	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No specifics on sequence generation: 16 of 1580 schools selected; geographical strat- ification; randomly allocated schools to groups
Allocation concealment (selection bias)	Unclear risk	Students invited from 1 randomly selected grade 8 class
Blinding of participants and personnel (performance bias) All outcomes	High risk	Presume no blinding of participants or providers; not feasible due to type of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Outcome measures	High risk	No objective measure for contraceptive use; pregnancy self report
Incomplete outcome data (attrition bias) All outcomes	High risk	Loss to follow-up: intervention 11% (48/431); control 23% (89/385); differential losses
Other bias	High risk	Analysis corrected for cluster effect; multi- variate linear and logistic regression mod- els included covariates of age, gender, so- cioeconomic status, sexual experience, and baseline scores Analysis of behavioral outcomes based on who had sex (could be affected by inter- vention), rather than all randomized (high risk)

#### **Tortolero 2010**

Methods	Design: cluster randomized trial; 10 urban middle schools, 5 to each condition Location: Texas, USA Time frame: Fall 2004 to Spring 2006 Sample size estimation and outcome of focus: no information; investigators state small sample of sexually active youth in grade 7 left little power
Participants	General with N: 10 middle schools; 1307 students completed baseline survey Inclusion criteria: middle schools selected within urban school district (served low-income population); students in grade 7 Exclusion criteria: no mention
Interventions	Study focus: HIV, STI, and pregnancy prevention  1) Intervention: 'It's Your Game' curriculum (12 lessons in 7th grade; 12 lessons in 8th grade); grade 8 addressed pregnancy testing and skills regarding condom and contraceptive use; 6 parent-child homework activities at each grade level  Investigator communicated contraceptives in intervention: condoms, birth control pills, injectable (DMPA), vaginal ring, transdermal patch, abstinence or choosing to wait to have sex, spermicides, EC, condom with other method, as well rhythm method, withdrawal, and hope. Ranked each method by effectiveness and noted whether method was considered effective or ineffective  2) Comparison: regular health classes that varied by school
Outcomes	Primary: delayed sexual initiation Secondary: condom use; sex without pregnancy prevention Audio-computer-assisted self-interview Investigator communicated survey listed effective prevention as condoms (male or female), birth control pills, spermicides, IUD, injectable (DMPA), transdermal patch, vaginal ring, tubal ligation, and EC Follow-up: grade 9 (24 months after baseline or > 3 months postprogram)
Notes	Theory or model: curriculum reportedly based in social cognitive theory, social influence models, and theory of 'triadic influence'

# Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Multi-attribute randomization protocol; took into account size and racial or ethnic composition and geographic location
Allocation concealment (selection bias)	Unclear risk	Schools identified prior to randomization; all 7th-grade students presumably eligible
Blinding of participants and personnel (performance bias) All outcomes	High risk	Presume no blinding of participants or providers; not feasible due to type of intervention

#### Tortolero 2010 (Continued)

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Data collectors unaware of study condition
Outcome measures	High risk	No objective measure for contraceptive use
Incomplete outcome data (attrition bias) All outcomes	High risk	Loss to follow-up: 7% intervention; 5% comparison Loss overall: 42% intervention; 34% comparison; most withdrew from school or were repeatedly absent
Other bias	High risk	Analysis: multilevel models (intraclass correlation from 0 to .03); baseline measures of dependent variable plus covariates judged to be potential confounders  Analysis of behavioral outcomes based on who had sex (could be affected by intervention), rather than all randomized (high risk)

# Walker 2006

Methods	Design: cluster randomized trials: 40 schools assigned (15 HIV prevention; 15 HIV prevention + emergency contraception (EC) module; 10 control)  Location: Morelos, Mexico  Time frame: 2001 to 2002  Sample size estimation and outcome of focus: based on expected intra-cluster (school) correlation, expected difference in outcome variables, average of expected observations by school, and feasible number of schools per arm (total); intra-cluster correlation 0. 001 based on previous studies. Sample size based on detecting improvement of 10% in proportion, using most restrictive proportion of 50%
Participants	General with N: 40 public high schools with 10,954 students in grade 10 Inclusion criteria: public high schools in state of Morelos; all grade 10 students Exclusion criteria: no information
Interventions	Study focus: HIV prevention with emergency contraception as back-up 1) Intervention A: HIV prevention promoted condom use; 30 hours over 15 weeks; based on guidelines of United Nations program 2) Intervention B: HIV prevention with emergency contraception (EC) as back-up (HIV prevention A + 2 hours on EC and improved access to EC ( <i>no information on access</i> ) 3) Control: usual sex education course
Outcomes	Primary: condom use; EC use Secondary: knowledge of EC Follow-up: 1 year postprogram (16 months after baseline)

# Walker 2006 (Continued)

Notes		
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Did not specify how randomized; stated random sampling stratified by degree of urbanization
Allocation concealment (selection bias)	Unclear risk	Schools randomized; all students in grade 10 were eligible.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Presume no blinding of participants or providers; not feasible due to type of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Outcome measures	High risk	No objective measure for contraceptive use
Incomplete outcome data (attrition bias) All outcomes	High risk	Loss to follow-up: 33% (3646/10,954)
Other bias	Unclear risk	Analyses reportedly took cluster sample design into account (fixed effects for regression and standard errors adjusted for number of primary sampling units for descriptive statistics)
Wight 2002		
Methods	Design: cluster randomized trial; 25 schools assigned to intervention or control Location: Tayside and Lothian regions, Scotland Time frame: recruited 1996 and 1997 Sample size calculation (and outcome of focus): based on 80% power to detect 33% decrease in abortion rate by age 20 and 28% decrease in sex without condom use for each gender at 6 months; for latter, assumed 27% would have first sex between 14 and 16 years old (survey data) and 60% events with no condom use for overall rate of 16% no condom use at first sex; assumed design effect 1.5	
Participants	General with N: 25 schools; 8430 participants, 13 to 15 years old Inclusion criteria: non-Catholic state schools within 24 km of main cities in region; students in 3rd year of secondary school Exclusion criteria: pilot schools; teachers excluded 3 students due to learning difficulties	

# Wight 2002 (Continued)

Interventions	1) Intervention: reduce unsafe sex behavior and unwanted pregnancies, and improve quality of sexual relationships; 5-day teacher training; 20 sessions for students (10 in year 3 and 10 in year 4) combining active learning, information provision, and skill development 2) Comparison: usual sex education Duration: 2 school years
Outcomes	Primary: first sex without condom; condom use with last sex; oral contraception with last sex; unwanted pregnancy (self report)  Outcomes at age 20 (4.5 years after intervention) from linked National Health Service records (Henderson 2006): overall termination (abortion) and conception (live births, stillbirths, miscarriages, and terminations; 'any' abortion or conception due to some women having > 1 event.  Secondary: no mention  Follow-up: 6 months after program completion
Notes	Theory or model: primarily Social Cognitive Theory plus 'orthodox' health education principles

# Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Balanced randomization; assigned schools by selecting allocation from set of 20,000 possible allocations, which provided best balance of school-level measures
Allocation concealment (selection bias)	Low risk	Two groups determined by comparability of school baseline data. One randomization assigned all schools. All students meeting inclusion criteria were eligible
Blinding of participants and personnel (performance bias) All outcomes	High risk	Presume no blinding of participants or providers; not feasible due to type of intervention
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Data analysis and checking blinded to study arm
Outcome measures	Unclear risk	Shorter-term follow-up: no objective measure for contraceptive use; pregnancy self report ( <b>high risk</b> ) Long-term follow-up: pregnancy and abortion records ( <b>low risk</b> )

# Wight 2002 (Continued)

Incomplete outcome data (attrition bias) All outcomes	High risk	Loss to follow-up: 32% intervention; 29% comparison
Other bias	High risk	Results as reported by investigators; insufficient data for analysis in this review Analysis accounted for cluster effects 6-month outcomes: for pregnancy, used random effects logistic regression; for other outcomes, used randomization test based on all possible allocations from which final allocation selected Analysis of behavioral outcomes at 6 months based on sexually experienced (could be affected by intervention), rather than all randomized (high risk) 4.5-year outcomes: adjusted for school socioeconomic measure and individual measures of school leaver and social class

CI: confidence interval

DMPA: depot medroxyprogesterone acetate

EC: emergency contraception IUD: intrauterine device OC: oral contraceptive

RCT: randomized controlled trial STD: sexually transmitted disease STI: sexually transmitted infection

# Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Agha 2004	Emphasis on HIV prevention; abstinence for pregnancy prevention; no identified contraceptive education
Ajuwon 2007	Investigator communicated that intervention broadly addressed various contraceptives (other than condoms) but focused on those adolescents could obtain without prescription (spermicides and condoms) Outcomes included condom use but no other contraceptive methods or pregnancy Study described as quasi-experimental; 4 schools assigned to 1 of 4 arms
Amin 2004	Assignment not random; retrospective study with teens who attended the program and teens who attended other schools without the program
Atwood 2012	Emphasis on reducing risk of STDs, HIV, and pregnancy by abstaining from sex or using condoms if choose to have sex. No mention of contraception

#### (Continued)

Bannink 2014	Intervention addresses multiple health issues, including safe sex (measured by 2 items on condom use. No mention of pregnancy prevention or contraception					
Barth 1992	Not all classes assigned randomly in this cluster RCT; in some schools with classes of unequal size, larger classes assigned to treatment group					
Borawski 2009	Emphasis on HIV prevention; abstinence for pregnancy prevention; no identified contraceptive education					
Brown 2011b	Investigator communicated that study was not randomized. Materials for each condition were distributed ad hoc within each classroom or data collection setting Full text indicated allocation was not 'true randomization.'					
Cabezon 2005	Intervention was abstinence-only sexual education; mentioned contraception but did not recommend use					
Caron 2004	No relevant outcome data					
Cowan 2010	Interim survey showed nearly half the cohort migrated out of area. Investigators and data and safety monitoring board changed design to cross-sectional survey					
Eisen 1990	Comparison programs differed in duration, format, content across sites (community agencies and 1 school district)					
Flay 2004	No mention of contraception; condom use assessed regarding safe sex					
Gilchrist 1983	Outcomes were cognitive, not behavioral; no contraception use					
Lederman 2003	No relevant outcome data; behavioral data not reported					
Mbizvo 1997	Emphasized knowledge and attitudes					
Mitchell-DiCenso 1997	Intended for preventing pregnancy but does not appear to address contraception; focuses on problem- solving and decision-making					
Moberg 1998	Report mentions birth control information as included in lessons (54 lessons during 16 class periods; no detail). Target behaviors regarding sexuality included condom use but no other contraceptive use. No measure of other contraceptive use, pregnancy, or knowledge or attitudes regarding contraceptive use					
Peskin 2015	'It's Your Game (IYG)-Tech': computer-based, middle school sexual health education program No outcome data for condom use (assessed) Report states no intervention effect on delay of sexual activity (primary outcome) or "in any other sexual behavior" (secondary outcomes)					
Roberto 2007	Risk reduction for HIV prevention; condom use outcome; no contraception in intervention (or outcomes) Two schools assigned to 1 of 2 conditions. Analysis could not be adjusted for cluster assignment with 2 units (schools)					
Rokicki 2015	Intervention based on text messages via mobile phone. Activities did not take place in school, although participants were students in secondary schools assigned to treatment conditions					

#### (Continued)

Ross 2007	No mention of contraception other than condoms even in background article; cross-sectional survey (several years later) included use of modern contraception as outcome					
Smith 1994	No information about what types of contraceptive methods, if any, the intervention addressed					
Somers 2001	Full text indicated no random or systematic assignment to groups Teen pregnancy prevention used baby 'simulator'; contraception as outcome but not part of intervention					
Thato 2008	Described as quasi-experimental; random selection of classes, no random or systematic assignment					
Tortolero 2008	Baseline data only; no mention of contraception in curriculum or study measure; program basis included communicating about contraception other than condoms					
Vincent 1987	Non-randomized study; pregnancy rates conducted county-wide rather than limited to program participants					
Wang 2014	Experimental condition focused on parent-adolescent risk communication for HIV prevention; did not include pregnancy prevention except for control (usual curriculum)					
Weeks 1997	Focus on AIDS prevention; use of condoms and foam or film Random assignment by group; analysis did not appear to account for cluster effects					
Ybarra 2013	Intervention focused on HIV prevention; no mention of contraception or pregnancy					
Zabin 1986	Assignment not random Program in junior high school serving all-black population and senior high school that was magnet and community school in same general area; control group from schools with racially-mixed populations but only African American students included as comparison					

RCT: randomized controlled trial STD: sexually transmitted disease

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

# **Buhi 2015**

Methods	Design: cluster randomized trial with schools assigned to intervention groups; double blind (participant and provider) Location: non-metropolitan communities in Florida (USA) Time frame: August 2012 to June 2015 Sample size estimation and outcome of focus: no information
Participants	General with N: 8161 students, 13 to 22 years old; 26 high schools Inclusion criteria: enrolled in class selected for evaluation; had parental consent; proficient in English; capable of independently taking paper and pencil survey Exclusion criteria: joined participating class after completion of parental consent process

# Buhi 2015 (Continued)

Interventions	1) Intervention: Teen Outreach Program + usual class listed below 2) Control: usual class (Health, HOPE, Critical Thinking, Career Research, or Leadership)					
Outcomes	Primary: ever pregnant or gotten someone pregnant; ever had sex Secondary: positive youth development by survey (character, competence, caring, connection, and confidence) Follow-up: 10 months					
Notes	Information from ClinicalTrials.gov and ISCTRN, which has intervention information but no indication of contraception education; reportedly completed June 2012  Abstracts from APHA 2015  Unable to obtain information from investigator regarding protocol or manuscript in progress for intervention information					

#### Constantine 2015

Methods	Design: cluster randomized trial; schools assigned to study conditions; single blind (participant) Location: Los Angeles, CA (USA) Time frame: 2011 to 2013 Sample size estimation and outcome of focus: no information
Participants	General with N: 2379 students, 13 to 16 years old; 10 high schools Inclusion criteria: 9th grade student at participating high school in East or South Los Angeles; written parent or guardian consent and student assent to participate Exclusion criteria: none
Interventions	1) Sexuality Education Initiative (SEI): 12-session 'rights-based' (sexual rights) curriculum for 9th graders to reduce risk of pregnancy and sexually transmitted infections (STI); included parent education, peer advocate program, and access to sexual health services (pregnancy and STI testing, counseling, prescriptions for contraceptives, referrals) 2) Basic sex education (control)
Outcomes	Primary: recent sex but not using contraception or condoms; recent vaginal, anal, or oral sex but no condom use Secondary: ever had sex; recent sex; condom use at last sex; contraceptive use at last sex Follow-up: 1 year
Notes	2015 report had short-term outcome, e.g. knowledge. Consider for inclusion when results for our primary outcomes are available

# Francis 2014

Methods	Design: Cluster randomized trial; teachers randomized within schools to treatment or control condition; open label Location: Hennepin County, MN (USA)  Time frame: July 2011 to November 2014  Sample size estimation and outcome of focus: no information
Participants	General with N: 1644 students, 12 to 19 years old; 61 teachers in 24 urban schools Inclusion criteria: enrolled in study teacher's class at baseline survey; active parental consent and youth assent Exclusion Criteria: inability to complete survey in languages provided; prior participation in Teen Outreach Program (TOP)

# Francis 2014 (Continued)

Interventions	1) Teen Outreach Program included weekly curriculum sessions, community service learning, and adult guidance and support; curriculum had 4 levels (age 12 or 13 through age 17) 2) Control: usual activities Intervention: 9 months Follow-up: 12 and 24 months after baseline survey
Outcomes	Primary: sex in past 90 days; ever had sex Secondary: sex without contraception in past 90 days Follow-up: 90 days; 12 and 24 months
Notes	Reportedly completed November 2014; no outcome data yet Information from ClinicalTrials.gov and abstract that described program

# Shegog 2015

Methods	Design: cluster randomized trial with middle schools and Boys and Girls Clubs assigned to condition; open label Location: 4 USA states (Alaska, Arizona, Oregon, Texas) Time frame: September 2010 to January 2015 Sample size estimation and outcome of focus: no information
Participants	General with N: 574 youth 12 to 14 years old; middle schools and Boys and Girls clubs Inclusion criteria: American Indian or Alaska Native (AI/AN) descent or tribal affiliation; attending regular classes in regional middle schools or youth attending after-school programs or Boys and Girls Clubs Exclusion criteria: not AI/AN; physical or mental condition inhibits ability to complete surveys and use computer programs, such as cognitive impairment, motor disorders (e.g. quadriplegia), learning difficulties or psychiatric or behavioral problems (e.g. autism, attention deficit disorder); surveys and intervention materials will be in English and students will be asked to consider comfort level with participating in study
Interventions	1) It's Your GameKeep It Real (IYG) curriculum (Tortolero 2010) adapted for AI/AN youth; transferred to web-based format; modified to include culturally relevant components 2) Standard science education (no sexual health elements), web-based
Outcomes	Primary: delayed onset of sexual activity Secondary: condom use during sex; contraception use during sex; other Follow-up: 5 and 16 months
Notes	Reportedly completed January 2015; information from Clinical Trials.gov

#### DATA AND ANALYSES

#### Comparison 1. Pregnancy prevention education versus no education

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Contraceptive use and attitudes at 6 months			Other data	No numeric data
2 Contraception knowledge at post-test			Other data	No numeric data

#### Comparison 2. Pregnancy prevention curriculum versus usual sex education

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pregnancy and oral contraceptive use at 6 months postprogram (24 months)			Other data	No numeric data
2 Condom use at 6 months postprogram (24 months)			Other data	No numeric data
3 Outcomes by age 20 (women, 4. 5 years postprogram)			Other data	No numeric data

#### Comparison 3. Pregnancy prevention program versus usual life skills program

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Dichotomous outcomes at 4- month follow-up			Other data	No numeric data
2 Scale outcomes at 4-month follow-up			Other data	No numeric data

#### Comparison 4. Sex education: EC unit versus no EC unit

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Used EC by 6 months			Other data	No numeric data
2 EC knowledge at 6 months			Other data	No numeric data

# Comparison 5. HIV prevention ± EC unit versus usual sex education

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Condom use by 1 year			Other data	No numeric data
2 Used EC by 1 year			Other data	No numeric data
3 Knowlege of EC at 1 year			Other data	No numeric data

#### Comparison 6. Curriculum for HIV and pregnancy prevention versus usual sex education

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 OC use with last sex	1		Odds Ratio (M-H, Fixed, 95% CI)	Subtotals only
1.1 5-month post-test	1	229	Odds Ratio (M-H, Fixed, 95% CI)	0.73 [0.42, 1.27]
1.2 17-month follow-up	1	354	Odds Ratio (M-H, Fixed, 95% CI)	0.57 [0.36, 0.91]
2 Condom use with last sex	1		Odds Ratio (M-H, Fixed, 95% CI)	Subtotals only
2.1 5-month post-test	1	233	Odds Ratio (M-H, Fixed, 95% CI)	0.78 [0.46, 1.34]
2.2 17-month follow-up	1	353	Odds Ratio (M-H, Fixed, 95% CI)	0.76 [0.49, 1.18]
3 Ever pregnant or caused pregnancy (reported no pregnancy at pretest)	1		Odds Ratio (M-H, Fixed, 95% CI)	Subtotals only
3.1 5-month post-test	1	1402	Odds Ratio (M-H, Fixed, 95% CI)	1.53 [0.66, 3.55]
3.2 17-month follow-up	1	1482	Odds Ratio (M-H, Fixed, 95% CI)	0.82 [0.34, 1.99]
4 Ever pregnant or caused pregnancy (sexually experienced)	1		Odds Ratio (M-H, Fixed, 95% CI)	Subtotals only
4.1 5-month post-test	1	201	Odds Ratio (M-H, Fixed, 95% CI)	1.25 [0.46, 3.36]
4.2 17-month follow-up	1	312	Odds Ratio (M-H, Fixed, 95% CI)	0.85 [0.33, 2.14]
5 Knowledge of HIV and pregnancy prevention			Other data	No numeric data

Comparison 7. Pregnancy and STI prevention education: peer-led versus teacher-led education

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pregnancy self-reported (females)			Other data	No numeric data
2 Abortion or live birth records by age 20			Other data	No numeric data
3 Contraception use for girls			Other data	No numeric data
4 Contraception use for boys			Other data	No numeric data
5 Condom use for girls			Other data	No numeric data
6 Condom use for boys			Other data	No numeric data
7 Knowledge of EC pill timing			Other data	No numeric data
8 Positive attitude about condom use			Other data	No numeric data

# Comparison 8. Curriculum to prevent pregnancy, HIV, and STI versus standard sex education

Outcome or subgroup title	No. of studies	No. of participants	Statistical mo	ethod	Effect size
1 Effective protection against			Other data	N	lo numeric data
pregnancy					
2 Condom use			Other data	N	Io numeric data
3 Attitudes toward condoms			Other data	N	lo numeric data

# Comparison 9. Curriculum to prevent HIV, STI, and pregnancy versus usual prevention activities (in alternative schools)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pregnancy (self report)			Other data	No numeric data
2 Effective pregnancy prevention at last sex			Other data	No numeric data
3 Condom use at last sex			Other data	No numeric data
4 Frequency of sex without condom use in past 3 months			Other data	No numeric data
5 Condom knowledge			Other data	No numeric data
6 General attitudes toward condoms			Other data	No numeric data

#### Comparison 10. HIV, STI, and pregnancy prevention versus usual health classes

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Contraception use			Other data	No numeric data
2 Condom knowledge			Other data	No numeric data

# Comparison 11. Education for sexual risk avoidance versus risk reduction versus usual health education

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Unprotected sex (no condom) at last vaginal sex			Other data	No numeric data
2 Vaginal sex without condom in last 3 months			Other data	No numeric data
3 General condom knowledge			Other data	No numeric data

#### **ADDITIONAL TABLES**

Table 1. Intervention fidelity

Study	Curriculum or manual	Provider credentials	Training for intervention		Assessed intervention receipt	•
Pregnancy preve	ention					
Schinke 1981	0	Graduate students, 3 to 4 years counseling experience; not with teens re- garding sex	-	-	Sessions involved problem solving, role play, rehearsal	3
Wight 2002	Resource pack of 20 lessons, pi- loted twice and revised; pilot- test had evalua- tion with teach- ers and students		5 days	ation: lesson ob- servation	Interaction on video with dis- cussion; how to obtain condoms, practice use	5
Taylor 2014	lessons with top-	2 pairs, young, male and female trained facilita-	_	-	Lessons were interactive (role	3

Table 1. Intervention fidelity (Continued)

	de- veloped with for- mative research	tors			play, discussions, debates, videos)	
Emergency cont	raception					
Graham 2002	1 EC lesson from resource for schools	Teachers	2-hour training for teachers to improve skill and knowledge; trainer was investigator training in family planning	r	Lesson had scenario activity and quiz on EC (latter replaced role play after pilot; students had difficulty engaging)	4
Walker 2006	15-week course based on UN guidelines for school programs; 2 hours on EC	Teachers chosen by school	hour) training + 2 hours on EC	Investigators monitored via phone calls and visits with teachers and direct class observation	Classes included practice in communication, negotiation, and refusal skills; study assessed knowledge of HIV and of EC	5
Preventing HIV	STI and pregnanc	y				
Kirby 1997	Curriculum of 8 sessions over 2 weeks; specific topics and activities for each session	Peer educators hired and trained	50 hours training to implement	Practiced delivering; had ongoing training and clinical supervision during implementation	Participants practiced skills and applied knowledge in program activities; assessed knowledge and attitudes	5
Stephenson 2008	3 sessions with identified topics and activities; peer-educators prepared lessons; intervention "standardized as far as possible"	Peer educators: 11th-grade stu- dents Trainers: expertise in sex- ual health pro- motion		Observation for process data (not		4

Table 1. Intervention fidelity (Continued)

Coyle 2001	U	School teachers; in-class peer leaders for selected activities	U	_	In- class peer leaders for some activi- ties, role playing; homework (stu- dent-parent, lo- cal resources)	4
Coyle 2006	14-session curriculum; 9 class lessons and 5 units of ser- vice-learning; pi- lot-tested twice	Experienced health educators	Trained to implement; practiced during pilot	-	Curriculum had experiential activities, e.g., creating posters, role playing, group discussion, guided skill practice	4
Tortolero 2010	24 lessons (45-minute) developed with qualitative work and participatory methods	Trained facilitators	-	-	Sessions had computer-based activities with quizzes, serials with on-line student feedback, discussion	3
Markham 2012	per year) of 50 min each; based on existing mid-	Hired for pro- gram; most were African Ameri- can or Hispanic with college de- grees; expe- rienced working with adolescents	training; skilled trainers modeled	ing implementa-	Assessed knowledge and self efficacy about sex and condom use	5

Table 2. Intervention summary

Study	Interventions	Special intervention sessions	Participants	Sample size	Location			
Pregnancy prevention								
Schinke 1981	Cognitive and be- havioral training vs assessment only	14; 50 minutes each	Sophomores (2nd year high school)	1 school; 36 students	USA			

Table 2. Intervention summary (Continued)

Wight 2002	skill development vs	20; 10 in each of 2 years	13 to 15 years old	25 schools; 7616 students completed	Scotland				
	usual sex education			baseline surveys					
Taylor 2014	Interactive program + usual life skills + media messages vs usual life skills and media messages	12; weekly	Grade 8 (1st year high school)	16 schools; 816 students completed baseline surveys	South Africa				
Emergency contraception									
Graham 2002	Usual sex education + EC unit vs usual sex education	1 on EC	Year 10	24 secondary schools; 3234 students com- pleted baseline sur- vey	England				
Walker 2006	HIV prevention ed- ucation + EC unit or HIV prevention ed- ucation vs usual sex education	-	Grade 10	40 schools; 10,954 students at baseline	Mexico				
Preventing HIV/S	TI and pregnancy								
Kirby 1997	Peer-led interactive curriculum + didac- tic sex education vs didactic sex educa- tion	8; over 2 weeks	Grade 7	102 classes (6 mid- dle schools); approx- imately 2110 students com- pleted baseline sur- veys	USA				
Stephenson 2008	Peer-led vs teacher- led sex education	3; 1 hour each	Grade 8 (age 13 to 14 years)	27 schools; 8766 students at baseline	UK				
Coyle 2001	Multicomponent program vs standard HIV prevention cur- riculum	20; 10 in each of 2 years	Grades 9 & 10	20 schools; 3869 students completed baseline surveys	USA				
Coyle 2006	Skills-based curricu- lum + service learn- ing vs usual preven- tion activities	14 (9 + 5 service); over 5 to 7 weeks	Alternative day school (age 14 to 18+ years)	24 schools; 988 students completed baseline surveys	USA				
Tortolero 2010	Risk reduction vs usual health educa- tion	24; 12 in each of 2 years	Grades 7 & 8	10 schools; 1307 students completed	USA				

Table 2. Intervention summary (Continued)

				baseline surveys	
Markham 2012	Risk avoidance or risk reduction vs usual health educa- tion	24; 12 in each of 2 years	Grades 7 & 8	15 schools; 1742 students completed baseline survey	USA

EC: emergency contraception

OC: oral contraceptive

Table 3. Summary of evidence quality and outcomes

Study	Interven- tion fidelity < 4 items	Randomiza- tion; alloca- tion conceal- ment	Follow-up period	Analysis	Loss > 20%	Evidence quality	Evidence of effectiveness	
Pregnancy prevention								
Wight 2002	-	_	-	-1	-1	Low	None	
Schinke 1981	-1	-1	-	-	-	Low	Contraception use (6 months); unclear definitions	
Taylor 2014	-1	-	-	-1	-1	Very low	Condom use, any (4 months)	
Emergency co	ntraception							
Graham 2002	-	-	-	-1	-	Moderate	Knew time limits for hormonal EC and for IUC as EC (6 months)	
Walker 2006	-	-	-	-1	-1	Low	HIV + EC group: used EC and had EC knowledge (1 year)	
Preventing HIV/STI and pregnancy								
Kirby 1997	-	-	-	-1	-	Moderate	OC use with last sex (17 months) <sup>b</sup> ; mean knowledge increase (5 & 17 months)	

Table 3. Summary of evidence quality and outcomes (Continued)

Stephenson 2008	-1	-	-	-1	-1	Very low	Ever pregnant, self re- port (54 months)
Coyle 2001	-	-	-	-	-1	Moderate	After year 1 & 12 months after year 2: less frequent sex without condom in past 3 months; condom use at last sex; use of effective contraceptive at last sex
Coyle 2006	-	-	-	-1	-1	Low	5 months after program: less frequent sex without condom in past 3 months; condom use at last sex 5 & 17 months: greater condom knowledge
Tortolero 2010	-1	-	-	-1	-1	Very low	Condom knowledge (24 months after baseline)
Markham 2012	-	-	-		-1	Moderate	Risk avoidance group: no condom use at last sex (3 months); Risk reduction group: no condom use at last sex (3 months); sex without condom in last 3 months (3 months); greater condom knowledge (3 months & > 15 months)

EC: emergency contraception

IUC: intrauterine contraception

OC: oral contraceptive

<sup>a</sup> Downgraded (-1) for the following: (1) intervention fidelity < 4 criteria; (2) inadequate randomization sequence generation or allocation concealment, or no information on either; (3) analysis for primary outcome based on non-randomized subsample, or analysis not adjusted for clustering; (4) follow-up < 6 months for contraceptive use or < 12 months for pregnancy; (5) loss to follow-up > 20% <sup>b</sup>OC result favors control group; other differences favor experimental group. May not have been significant if investigators had adjusted for clustering.

#### **CONTRIBUTIONS OF AUTHORS**

LM Lopez developed the idea and the search strategies, conducted the primary data extraction, developed the summary tables, and drafted the review. A Bernholc helped conceptualize the project, reviewed the draft search results, conducted part of the second data extraction, and helped interpret the analyses and results. M Chen contributed to the Methods, especially the data analysis sections, and reviewed the quality of evidence assessment. EE Tolley contributed to the Background section. All authors reviewed and commented on the manuscript.

#### **DECLARATIONS OF INTEREST**

No known conflict of interest for Laureen Lopez, Alissa Bernholc, Mario Chen, or Elizabeth Tolley

#### **SOURCES OF SUPPORT**

#### Internal sources

• No sources of support supplied

#### **External sources**

• National Institute of Child Health and Human Development, USA. Support for developing the protocol and conducting the review at FHI 360

#### DIFFERENCES BETWEEN PROTOCOL AND REVIEW

We revised the criteria for downgrading the evidence (Data synthesis). We removed the criterion for 'no objective measure for outcome assessment, e.g. pregnancy (test or record) or contraceptive use.' No trial met this criterion for a primary outcome. A school setting without a clinic has few options for an objective measure of contraceptive use. For pregnancy data, two studies used records for long-term follow-up, i.e. at four years after the intervention.

We added a criterion for 'analysis for primary outcome based on non-randomized subsample, or analysis not adjusted for clustering.' Many trials based the analysis of behavioral outcomes on a subsample of students who reported ever having sex or being sexually active, variables that the intervention could affect. The analyses did not include all students randomized, and therefore were not randomized comparisons. We also included in this criteria not adjusting the analysis for clustering, which can lead to imprecise results.

#### INDEX TERMS

#### **Medical Subject Headings (MeSH)**

\*Contraception Behavior; \*School Health Services; Condoms [utilization]; Contraception [methods]; Contraception, Postcoital [utilization]; Pregnancy in Adolescence [\*prevention & control]; Program Evaluation; Randomized Controlled Trials as Topic; Schools; Sex Education [methods]; Sexually Transmitted Diseases [\*prevention & control]

#### MeSH check words

Adolescent; Female; Humans; Male; Pregnancy; Young Adult