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RESEARCH

Sexual abstinence only programmes to prevent HIV infection in high income countries: systematic review

Kristen Underhill, research officer,[1] Paul Montgomery, lecturer,[1] Don Operario, lecturer[1]

Centre for Evidence-Based Intervention, University of Oxford, Oxford OX1 2ER

Correspondence to: K Underhill
kristen.underhill@socres.ox.ac.uk

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ABSTRACT

Objective To assess the effects of sexual abstinence only programmes for HIV prevention among participants in high income countries.

Design Systematic review.

Data sources 30 electronic databases without linguistic or geographical restrictions to February 2007, contacts with experts, hand searching, and cross referencing.

Review methods Two reviewers independently applied inclusion criteria and extracted data, resolving disagreements by consensus and referral to a third reviewer. Randomised and quasirandomised controlled trials of abstinence only programmes in any high income country were included. Programmes aimed to prevent HIV only or both pregnancy and HIV. Trials evaluated biological outcomes (incidence of HIV, sexually transmitted infection, pregnancy) or behavioural outcomes (incidence or frequency of unprotected vaginal, anal, or oral sex; incidence or frequency of any vaginal, anal, or oral sex; number of partners; condom use; sexual initiation).

Results The search identified 13 trials enrolling about 15 940 US youths. All outcomes were self reported. Compared with various controls, no programme affected incidence of unprotected vaginal sex, number of partners, condom use, or sexual initiation. One trial observed adverse effects at short term follow-up (sexually transmitted infections, frequency of sex) and long term follow-up (sexually transmitted infections, pregnancy) compared with usual care, but findings were offset by trials with non-significant results. Another trial observed a protective effect on incidence of vaginal sex compared with usual care, but this was limited to short term follow-up and countered by trials with non-significant findings. Heterogeneity prevented meta-analysis.

Conclusion Programmes that exclusively encourage abstinence from sex do not seem to affect the risk of HIV infection in high income countries, as measured by self reported biological and behavioural outcomes.

INTRODUCTION

Although AIDS was first diagnosed in the 1980s an effective and accessible vaccine against HIV is still awaited. In 2005 more than 7600 people died daily from AIDS related causes, and about 38.6 million people worldwide are infected with HIV.[1] Behavioural interventions for preventing sexually acquired HIV remain essential, particularly for vulnerable groups.

Programmes that exclusively encourage sexual abstinence are one such strategy. These interventions are designed to teach the social, health related, and psychological benefits of abstaining from sexual activity; most also emphasise the harms of sexual activity outside marriage.[2 3] Abstinence only interventions encourage both primary abstinence (delaying sexual debut) and secondary abstinence (returning to abstinence after sexual activity). Theoretical underpinnings include social cognitive theory, social inoculation (participants rehearse how they will resist peer pressure or sexual advances), the health belief model, and cognitive behavioural theory.[2 4 5] Programme participants are typically adolescents. Settings include schools, community centres, family homes, and faith based organisations. Although the programmes' definitions of "sex" are variable and often unclear,[6] abstinence only interventions can encourage abstinence from oral, anal, and vaginal intercourse.

Abstinence only programmes differ from abstinence plus programmes. Both interventions present abstinence from sex as the most effective option for HIV prevention, but abstinence plus programmes also promote safer sex strategies such as condom use. In contrast, abstinence only programmes present abstinence as the exclusive option for HIV prevention, without promoting safer sex.[7]

Abstinence only programmes that aim to prevent HIV (or HIV and pregnancy) may differ from programmes that aim to prevent pregnancy only. Programmes with an HIV prevention component are more likely to acknowledge the HIV related risks of oral sex, anal sex, same sex sexual behaviours, and non-sexual means of transmission. In contrast, programmes that focus entirely on pregnancy prevention may only emphasise abstinence from vaginal sex, without acknowledging other risk behaviours. We systematically reviewed trials of programmes that aim to prevent HIV infection only or to prevent HIV and pregnancy.

This review complements a systematic review of abstinence based programmes in developing countries, which found only one trial of an abstinence only programme. This trial did not find significant effects on sexual behaviour.[8] No review has focused

on trials of abstinence only programmes for HIV prevention in all high income countries. It is productive to review this evidence for several reasons. The implementation and effectiveness of abstinence only programmes may vary with contextual differences (for example, prevalence of HIV, resources enabling the programme, government policy, structures for delivering the programme), and the same trial evidence may not apply to high income settings and those with limited resources.[9] A recent analysis also indicates that HIV related evaluations carried out in low income countries may differ methodologically from trials carried out in high income countries,[10] and combining heterogeneous evidence from the two settings may produce misleading conclusions.

We hypothesised that some high income settings may present optimal conditions for showing the effectiveness of abstinence only programmes. Many high income populations face fewer structural risk factors for HIV (for example, poverty), possibly giving people more opportunities to choose whether, when, and how they have sex.[11] Because abstinence only programmes encourage abstinence as an individual choice,[4] these opportunities may influence the effectiveness of programmes. High income countries, however, encompass inequalities in income and health,[1] and the residents of high income countries at highest risk for HIV infection—for example, youths, men who have sex with men, migrants, and ethnic minority groups—are more vulnerable to poverty, discrimination, and other structural risks.[12-14]

Abstinence only interventions have received considerable political attention, particularly in the United States and countries receiving funding through the President's Emergency Plan for AIDS Relief. The programmes' exclusion of safer sex strategies and condom instruction continues to ignite controversy on the basis of human rights, politics, morality, and public health.[15-25] Methodologically rigorous evidence has been largely overlooked, however, prompting the need for an apolitical, up to date systematic review.

In the context of high income countries, existing reviews of abstinence only programmes for risky sexual behaviour often focus exclusively on US youths, include studies with varying methods, and draw divergent conclusions. Many reviews incorporate abstinence only programmes alongside other types of interventions to reduce sexual risk, making it difficult to isolate programme effects.[26-34] Additionally, reviews often focus on general sexual health or pregnancy instead of HIV prevention.[32 35-37] With these caveats, past reviews of abstinence only programmes summarise effects ranging from significant benefit[7] to possible harm.[27] The most methodologically rigorous reviews have consistently documented no evidence that abstinence only programmes can reduce risky sexual behaviour[27 37-39]; these reviews were limited to youths and did not exclusively examine abstinence only programmes for HIV prevention.

We identified, appraised, and synthesised the trials of abstinence only programmes for HIV prevention among the residents of high income countries. This is a version of a Cochrane review; a more detailed report will be published and updated in the Cochrane Library.

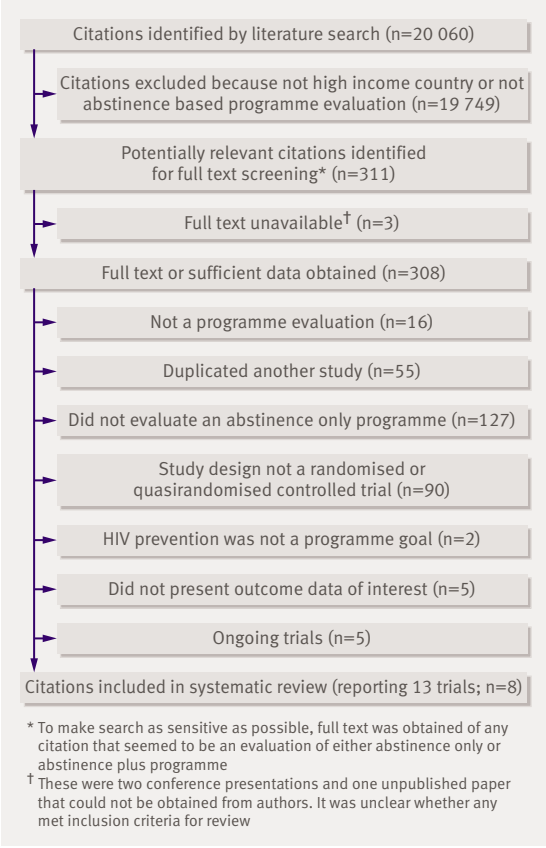

Fig 1 | Included and excluded citations in systematic review

METHODS

We included randomised and quasirandomised controlled trials of sexual abstinence only interventions for HIV prevention in high income economies, as agreed with the Cochrane HIV/AIDS Group on the basis of methodological guidelines and previous reviews.[40-42] High income economies were defined by the World Bank as those with a gross national income per capita of at least $10 726 (£5450; €8035).[43] Including only randomised and quasirandomised controlled trials ensured that the evidence was of the highest level of methodological rigour for evaluating programme effectiveness.[44-46] Quasirandomised controlled trials approximated randomisation by using a method of allocation that was unlikely to lead to consistent bias, such as alternating participants.[40] We made no exclusions by type of control group.

Interventions were any efforts to encourage sexual abstinence as the exclusive means of HIV prevention. We included trials of programmes to prevent pregnancy and HIV as well as those to prevent HIV only. We made no exclusions by specific definitions of abstinence, as definitions for abstinence and sex are

often not specified.[6-47] We also made no exclusions by the type of organisation delivering the programme.

We extracted outcome data for biological outcomes (for example, HIV incidence) and behavioural outcomes (for example, unprotected vaginal sex), as these are most directly related to the sexual acquisition of HIV. Outcomes for same sex sexual behaviour were included.

Exclusion criteria

Because we were interested in the primary prevention of HIV infection we excluded trials limited to participants who were HIV positive; no other exclusions were made by participant characteristics, including age. We excluded trials of programmes that explicitly promoted condom use or safer sex as these programmes did not fall under our classification of abstinence only.

We also excluded trials of abstinence only programmes that did not list HIV prevention as a goal —these programmes focused exclusively on pregnancy prevention, without aiming to prevent HIV. Including these trials might have increased statistical heterogeneity or obscured the effects of HIV focused interventions.

Trials that did not report a biological or behavioural outcome were excluded; although knowledge, intentions, and attitudes are important mediators of effects,[28 48] these outcomes may not necessarily correspond to sexual behaviour or actual risk of HIV infection.[49-54]

Search strategy

We searched 30 electronic databases from January 1980 to February 2007: ADOLEC, AIDSLINE, AMED, ASSIA, BiblioMap, BIOSIS, BNI, Catalog of US Government Publications, CENTRAL, CHID, CINAHL, DARE, Dissertation Abstracts International, Embase, ERIC, EurasiaHealth Knowledge Multilingual Library, Global Health Abstracts, HealthPromis, HMIC, PAIS, Political Science Abstracts, PsycINFO, PubMed, RCN, SCISEARCH, SERFILE, SIGLE, Social Services Abstracts, Sociological Abstracts, and TRoPHI. We applied no restrictions by country, geography, economic characteristics, participant group, outcome measure, or language of publication. We also searched the libraries of agencies involved with HIV prevention (for example, the joint United Nations programme on HIV/AIDS, WHO, Centers for Disease Control and Prevention) and hand searched relevant conference proceedings (for example, International AIDS Conference) from 2000 onwards. We searched for unpublished and ongoing trials by contacting more than 130 experts and cross referencing papers on pregnancy prevention and HIV prevention.

Because our search contained no restrictions or search terms on the basis of outcome measure, it was designed to identify programme trials measuring any biological, behavioural, cognitive, attitudinal, or other outcome, not just HIV incidence. To heighten sensitivity our search was also designed to identify trials of both abstinence only and abstinence plus programmes; we excluded trials of abstinence plus programmes after retrieving a full description of the intervention. Similarly, we excluded trials of abstinence only programmes without an HIV prevention goal after reviewing the full text description of the programme. Trialists were contacted for clarification as needed.

Two reviewers independently assessed abstracts and full papers for inclusion, resolving disagreements by discussion and referral to the third reviewer. Reviewers were not blind to any aspect of the studies; previous investigations report inconsistent findings on what effect blinding reviewers may have on systematic reviews,[55-57] although some analyses suggest that blinding has "neither a clinically nor a statistically significant effect" on results.[56 57]

Data extraction and assessment of trial quality

Using standard forms, two reviewers independently extracted data and assessed trials for methodological quality. When several reports of a single trial existed, data were extracted from all available reports. Disagreements were resolved by discussion and referral to the third reviewer or to the Cochrane HIV/AIDS Group. Trialists were contacted by email for missing data.

We assessed methodological quality according to the Cochrane handbook[40] and we highlighted attrition as a limitation of any trials with a total dropout exceeding 33% of baseline enrolment. When possible we assessed data on programme implementation—that is, programme design, delivery by trial staff, uptake by trial participants (for example, attendance), and trial context.[58] These data informed our assessment of heterogeneity across trials. Our methods are further detailed in the upcoming Cochrane review.[59]

Presentation of results

All trials were summarised in RevMan 4.2.8 to the fullest extent possible. Data were entered by one reviewer and independently checked by another reviewer. As a result of data unavailability, lack of intention to treat analyses, and heterogeneity in programme and trial designs, we determined that a statistical meta-analysis would be inappropriate. Instead we present individual trial results using RevMan and provide a narrative synthesis. When we were unable to reanalyse data, we report analyses from the primary trials. We were unable to test for publication bias owing to limitations on data.

When trials used cluster randomisation we followed procedures outlined by the Cochrane handbook[40] and Johnson et al[60] to adjust for intraclass correlation. We follow the precedent[60] of reporting results using an intraclass correlation coefficient of 0.015 for school based trials and 0.005 for community based trials, as data for individual participants were not available. Unadjusted results can be found in the Cochrane review. Calculation of average cluster size was impossible for one trial.[w1]

Table 1 | Characteristics of included trials

Trial	Setting (US state or region)	Baseline characteristics of participants*	Intervention, theoretical basis	Control	Units of assignment, analysis	Months of follow-up (attrition)	Attrition analyses
Anderson[w1]	Schools and community centres (CA)	n=405 (10.6); 40% male; 21% African-American, 46% Hispanic, 13% white; socioeconomic status unclear; no baseline differences	8 sessions led by health educators; 2 sessions involved parents; cognitive behavioural theory or social learning theory	No treatment	"Natural groupings," individual	Immediate post-intervention (0%); 12 (38%)	Dropouts older, more likely to be male, less likely to report skipping school
Blake[w2]	Middle school (NY)	n=389 (13.5); 52% male; 85% white; socioeconomic status middle class; baseline difference controlled in analyses	5 sessions led by peer educators, 5 parent-child homework assignments; social cognitive theory or social learning theory	Same as intervention, without parent-child homework	Classroom, multilevel	1.5 (10%)	Non-completion of homework higher if male, African-American, or Hispanic, reporting recent sex, or not receiving mostly "A" grades
Clark[w3]	Middle school (south east)	n=248 (12.6); 55% male; 98% African-American; socioeconomic status low; baseline difference controlled in analyses	10 sessions led by adults; theory of possible selves	Usual care defined by school	Classroom, multilevel	4.4 (15%); 12 (37%)	No differences by group or any other characteristic
Goldfarb[w4]	Middle school (NJ)	Baseline number unclear (n=839) at follow-up (age 12.5); 48% male; "high minority"; socioeconomic status low; no baseline differences	23 sessions led by health educator; social learning theory	Usual care defined by school	School, individual	2 (unclear)	At post-test, intervention group more likely to be older and to live in house rather than apartment
Hernandez[w5]	University (NC)	n=410 (19.3); 55% male; 85% white; socioeconomic status unclear; no baseline differences	1×45 minute session, with video and pamphlet; theory unclear	Abstinence plus programme using same format; safer sex programme using same format; no treatment	Individual, individual	1.5 (5%)	Not reported
Kirby[w6]	Middle school (CA)	n=4652 (12.8); youth led comparison—44% male; 48% Hispanic, 21% white; adult led—42% male; 45% Hispanic, 28% white; socioeconomic status diverse; no baseline differences	5 sessions led by peer educators; social inoculation. Same, led by adult health educators	Usual care defined by school	Classroom, multilevel	3 (18%); 17 (34%)	1% more lost from intervention group; no interaction between dropout and age, gender, family, grades, or other risk factors
Kirby[w6]	Middle school (CA)	n=5244 (12.8); 42% male; 6% native American, 12% Asian or Pacific Islander, 10% African-American, 21% Hispanic, 49% white; socioeconomic status diverse; baseline difference controlled in analyses	5 sessions led by adult health educators; social inoculation	Usual care defined by school	School, multilevel	17 (26%)	
Kirby[w6]	Community centres (CA)	n=704 (12.8); 45% male; 2% native American, 49% Asian or Pacific Islander, 2% African-American, 20% Hispanic, 8% white; socioeconomic status diverse; no baseline differences	5 sessions led by adult health educators; social inoculation	Usual care defined by community centre	Individual, individual	17 (45%)	
Miller[w7]	Family homes (UT)	n=548 (12.9%); male unclear; 93% mothers and 97% fathers white; socioeconomic status unclear; unclear baseline equivalence.	6×20 minute videos, with newsletters; theory unclear	Same as intervention, without newsletters; no treatment	Family, individual	3 (unclear); 12 (8%)	Not reported
Trenholm[w8]	Middle and high schools (VA)	n=551 (13.3); 49% male, 11% African-American, 3% Hispanic, 83% white; socioeconomic status middle or working class; baseline differences controlled in analyses	52 sessions over 3 years, led by adults; theory unclear	Usual care defined by school	Individual, individual	About 62.5 (19%)	Not reported. Higher for controls
Trenholm[w8]	Middle schools (FL)	n=597 (12.8), 0% male; 63% African-American, 23% Hispanic, 3% white; socioeconomic status low; baseline differences controlled in analyses	About 180 sessions over 1 year, led by adults; theory unclear	Usual care defined by school	Individual, individual	About 65 (20%)	Not reported. Higher for controls
Trenholm[w8]	Elementary and middle schools (WI)	n=504 (10.3); 38% male; 77% African-American, 8% Hispanic, 2% white; socioeconomic status low; baseline differences controlled in analyses	About 720 sessions over 4 years, led by adults; theory unclear	Usual care defined by school	Individual, individual	About 62.5 (18%)	Not reported. Higher for controls
Trenholm[w8]	Elementary schools (MS)	n=849 (10.7); 48% male; 87% African-American, 8% Hispanic, 0% white; socioeconomic status low; baseline differences controlled in analyses	About 72 sessions over 2 years, led by adults; social inoculation, social learning theory	Usual care defined by school	Individual, individual	About 59 (16%)	Not reported. Higher for experimental group

Elementary school=ages 5-11; middle school=ages 11-14; high school=ages 14-18. Theory of possible selves=By envisioning their future lives, participants will realise how current risky behaviours might threaten their future goals, thereby motivating safer behaviour.
*Mean age in brackets.

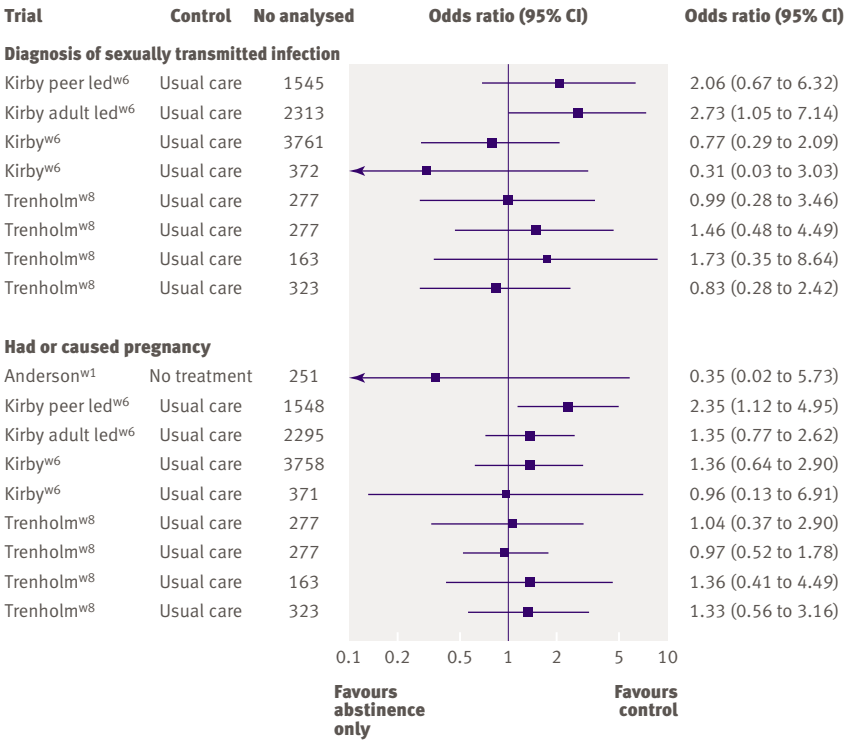

Fig 2 | **Biological effects of sexual abstinence only programmes at each trial's longest follow-up (months)**

RESULTS

The search retrieved 20 060 records (fig 1), of which 311 were deemed potentially relevant citations by any reviewer. Full text or sufficiently complete versions were obtained for 308 citations; remaining citations were unpublished studies of unclear relevance, for which further data could not be obtained from the authors. After excluding reports on the basis of study design, intervention description, and outcomes of interest, 13 randomised controlled trials from eight papers were included.[w1-w8] When available, data were also extracted from supplementary papers.[2 w9-w11] One trial was included on the basis of correspondence with the trialist (Goldfarb).[w4] No quasirandomised controlled trials met the inclusion criteria. Two papers reported multiple trials: one contained three trials that differed by unit of randomisation[w6] and the other contained four trials that differed by intervention site and experimental programme.[w8] Results for one trial[w6] are further categorised by whether the participants in the intervention group were randomly assigned to receive the intervention from peer leaders or from adult health educators.

Description of trials

Despite an international search without restrictions by participants' age, all 13 included trials enrolled adolescents and young adults in the United States. About 15 940 (median 551) participants were enrolled at baseline; one trial did not report baseline sample size.[w4] Participants were mainly from minority ethnic groups in eight trials[w1 w3 w4 w6 w8] and were mixed or primarily white in five[w2 w5-w8]; when reported, participants' socioeconomic status varied across trials. No trial assessed or reported outcomes by sexual orientation.

Programme exposure ranged from one[w5] to 720 sessions,[w4] with a median of eight sessions across trials. Ten programmes were school based,[w2-w6 w8] one was community based,[w6] one was delivered in both schools and community centres,[w1] and one was delivered in the family home.[w7] Twelve programmes[w1-w4 w6-w8] were designed for adolescents and delivered to elementary aged and middle-school aged youths (grades 5-8, approximate ages 10-14); these programmes included multiple sessions, targeted pregnancy prevention along with HIV risk reduction, and, with one exception,[w3] seemed to emphasise parent-child communication. The remaining programme[w5] targeted young adults (aged 18-21), included one session, and focused on HIV prevention only. Programme facilitators for most interventions were adults,[w1 w3 w4 w6 w8] including teachers and public health staff; two interventions were delivered by peer leaders[w2 w6] and two were primarily media based.[w5 w7]

Control groups varied (table 1) and included no treatment[w1 w5 w7]; a non-enhanced programme version (no parent-child homework,[w2] no posted newsletters[w7]); usual care, defined by schools[w3 w4 w6 w8] or community centres[w6]; a time matched abstinence plus programme[w5]; and a time matched safer sex programme.[w5] "Usual care" was rarely defined and could have included any programme type (for example, safer sex, abstinence plus, abstinence only, no treatment); this ambiguity prevented a quantitative synthesis of trials with usual care controls.

Missing information made the assessment of methodological quality difficult. Only four trials reported procedures for generating the allocation sequence (by random number generator[w8]) and no trial reported procedures for concealing the randomisation process. Blinding of participants and staff was generally impossible, potentially allowing performance bias. When sexual behaviours were reported they were limited to vaginal sex; no trial assessed oral or anal sex. No trial reported outcomes for same sex sexual behaviour. All outcomes were assessed through written self report questionnaires (sometimes administered by telephone in four trials[w8]) without confirmation from medical records or biological assessments, making results vulnerable to recall and self report biases. Attempts to minimise self report bias included reading survey questions aloud,[w1 w5] using anonymised surveys,[w1 w4 w5] emphasising confidentiality during assessments,[w2] separating participants for surveys,[w5 w6] identifying participants by numbers rather than by names,[w6] and concealing participants' responses using cover sheets[w6] or unmarked envelopes.[w7]

When reported, final attrition rates ranged from 5%[w5] to 45%[w6] (median 20%). Attrition in four trials[w1 w3 w6] exceeded 33%, which must be considered

when judging internal and external validity. Seven trials[w2 w3 w6 w8] found at least one significant difference between groups at baseline but controlled for these in analyses; one trial[w7] did not provide an explicit statement of baseline equivalence. Instead of using intention to treat analyses, the trials carried out complete case analyses, in which participants were analysed in their original groups, regardless of programme attendance, without imputing data for dropouts. Eleven trials[w2 w3 w5-w8] specified analyses that accommodated the unit of randomisation; two trials[w1 w4] randomised clusters of participants but seemed to carry out analyses on an individual basis, which may increase type I errors.

Biological outcomes

No trial evaluated HIV incidence, therefore the biological outcomes of interest were self reported incidence of sexually transmitted infection and pregnancy (table 2 and fig 2). Odds ratios less than 1 for these results indicate a protective effect of the abstinence only programme—results favoured the abstinence only programme over controls. Odds ratios greater than 1 favour controls over abstinence only programmes. Results were significant at $P<0.05$.

Seven trials[w6 w8] (n=9779) assessed participants' reports of having been diagnosed as having a sexually transmitted infection by a doctor or nurse. Every trial compared an abstinence only programme with usual care by schools or community centres. No trial found a significant short term or long term benefit, and one trial[w6] found significant adverse effects of the adult led programme at three months' follow-up (n=2711; odds ratio 4.16, 95% confidence interval 1.16 to 14.94) and 17 months' follow-up (n=2313; 2.73, 1.05 to 7.14). It was unclear whether the higher incidence of diagnosed infection reported by participants resulted from differences in reporting, frequency of testing, or actual risk; long term adverse effects did not correspond to significant changes in sexual behaviour.

Of the eight trials[w1 w6 w8] that assessed self reported pregnancy (n=9417) none found a significant benefit compared with usual care[w6 w8] or no treatment.[w1] One trial[w6] found evidence of significant harm when the peer led programme was compared with usual care at 17 months' follow-up (n=1548; odds ratio 2.35, 1.12 to 4.95). This effect was not mirrored by significant long term change in self reported sexual behaviour, and further analyses found that the effect was isolated among seventh grade males at one school.

Behavioural outcomes

For behavioural outcomes, odds ratios less than 1 continue to favour the abstinence only programme over controls. When trial specific odds ratios for behavioural outcomes could be calculated, the results are displayed with 95% confidence intervals and significance (table 3 and fig 3). When odds ratios could not be calculated, results are shown as reported by the trialists (table 3). Across trials the behavioural outcomes most indicative of HIV risk—namely, unprotected vaginal, oral, or anal sex—were underutilised.

Five trials[w4 w8] provided sufficient data to extract the recent incidence of unprotected vaginal sex among all participants (n=2892) and compared an abstinence only programme with usual care. No trial found a significant effect on unprotected sex in the past month (n=839)[w4] or unprotected sex in the past year (n=2053).[w8]

Seven trials[w2-w4 w8] reported incidence of any vaginal sex (n=3454). One trial[w4] found a significant protective

Table 2 | Trials of sexual abstinence only programmes reporting biological outcomes

Outcome and trial	Control	No analysed	Time (months)*	Odds ratio (95% CI)	P value
Sexually transmitted infection†:					
Kirby, peer led[w6]	Usual care	1895; 1545	3; 17	3.04 (0.59 to 15.73); 2.06 (0.67 to 6.32)	0.18; 0.21
Kirby, adult led[w6]	Usual care	2711; 2313	3; 17	4.16 (1.16 to 14.94); 2.73 (1.05 to 7.14)	0.03‡; 0.04‡
Kirby[w6]	Usual care	3761; 372	17; 17	0.77 (0.29 to 2.09); 0.31 (0.03 to 3.03)	0.61; 0.32
Trenholm[w8]	Usual care	277; 277; 163; 323	62.5; 65; 62.5; 59	0.99 (0.28 to 3.46); 1.46 (0.48 to 4.49); 1.73 (0.35 to 8.64); 0.83 (0.28 to 2.42)	0.99; 0.50; 0.50; 0.73
Pregnancy§:					
Anderson[w1]	No treatment	405; 251	Immediate post-intervention¶; 12	No events observed; 0.35 (0.02 to 5.73)	0.46
Kirby, peer led[w6]	Usual care	1548	17	2.35 (1.12 to 4.95)	0.02‡
Kirby, adult led[w6]	Usual care	2295	17	1.35 (0.73 to 2.52)	0.34
Kirby[w6]	Usual care	3758; 371	17; 17	1.36 (0.64 to 2.90); 0.96 (0.13 to 6.91)	0.43; 0.97
Trenholm[w8]	Usual care	277; 277; 163; 323	62.5; 65; 62.5; 59	1.04 (0.37 to 2.90); 0.97 (0.52 to 1.78); 1.36 (0.41 to 4.49); 1.33 (0.56 to 3.16)	0.94; 0.91; 0.61; 0.52

*Time from baseline.
†Ever been diagnosed with sexually transmitted infection by doctor or nurse. In Kirby,[w6] analyses included participants who reported never having had a diagnosed sexually transmitted infection at baseline. In Trenholm,[w8] analyses included participants who reported ever having had sex.
‡Findings significant at P<0.05. Odds ratio <1 indicates a protective intervention effect. Odds ratios were calculated in RevMan with controls for clustering where needed, except where otherwise indicated.
§In Anderson,[w1] became pregnant or partner became pregnant since baseline, among all participants. Results do not control for clustering but represent one pregnancy in each group at 12 months' follow-up. In Kirby,[w8] ever pregnant or partner ever pregnant, among participants who reported never having had a pregnancy at baseline. Trenholm,[w8] ever pregnant or partner ever pregnant, among participants who reported ever having had sex.
¶Unclear time from baseline.

effect at two months' follow-up compared with usual care (n=839; odds ratio 0.53, 95% confidence interval 0.29 to 0.97). This finding may be limited by measurement error, as a larger proportion of control participants reported having sex in the past month than reported having sex ever. The remaining trials found no significant effects at short term or long term follow-up compared with a non-enhanced programme version (no parent-child homework, n=351)[w2] or usual care (n=2264).[w3 w8]

Four trials[w5 w6] assessed frequency of vaginal sex (n=2376). Three trials compared an abstinence only programme with usual care (n=1988)[w6] and the fourth compared an abstinence only programme with an abstinence plus programme, a safer sex programme, and no treatment (n=388).[w5] No trial observed a protective effect at short term or long term follow-up. One trial[w6] found evidence of harm for frequency of vaginal sex when the peer led programme was compared with usual care at three months' follow-up (n=338); this was not sustained at 17 months' follow-up.

Eight trials[w5 w6 w8] assessed number of sex partners (n=4483). No trial found a significant effect compared with usual care (n=4095)[w6 w8] or with an abstinence plus programme, a safer sex programme, or no treatment (n=388).[w5]

Although no intervention promoted condoms, nine trials[w4-w6 w8] assessed condom use (n=3642). For consistency with other outcomes, the results in table 3 and figure 3 are transformed to indicate lack of condom use. No trial found a significant short term or long term effect compared with usual care (n=3254)[w4 w6 w8] or with a safer sex programme, an abstinence plus programme, or no treatment (n=388).[w5] One of these trials[w5] assessed the absolute number of times participants used condoms in the past six weeks but did not present these data relative to the number of times participants had sex.

Ten trials[w2-w4 w6 w8] assessed incidence of sexual initiation (ever had vaginal sex; n=11 298). None observed a significant effect at short term or long term follow-up compared with a non-enhanced programme version (no parent-child homework, n=351)[w2] or usual care (n=10 947).[w3 w4 w6 w8]

One trial[w7] used a sexual behaviour index, in which participants reported behaviours ranging from "holding hands" to "the sexual act by which pregnancy can occur" (not shown in table 3). According to a three (group) by three (time) repeated measures analysis of variance, the abstinence only programme had no significant effect compared with a non-enhanced programme version (no posted newsletters) and no treatment at 12 months' follow-up (n=503, P=0.66 from a group by time interaction).

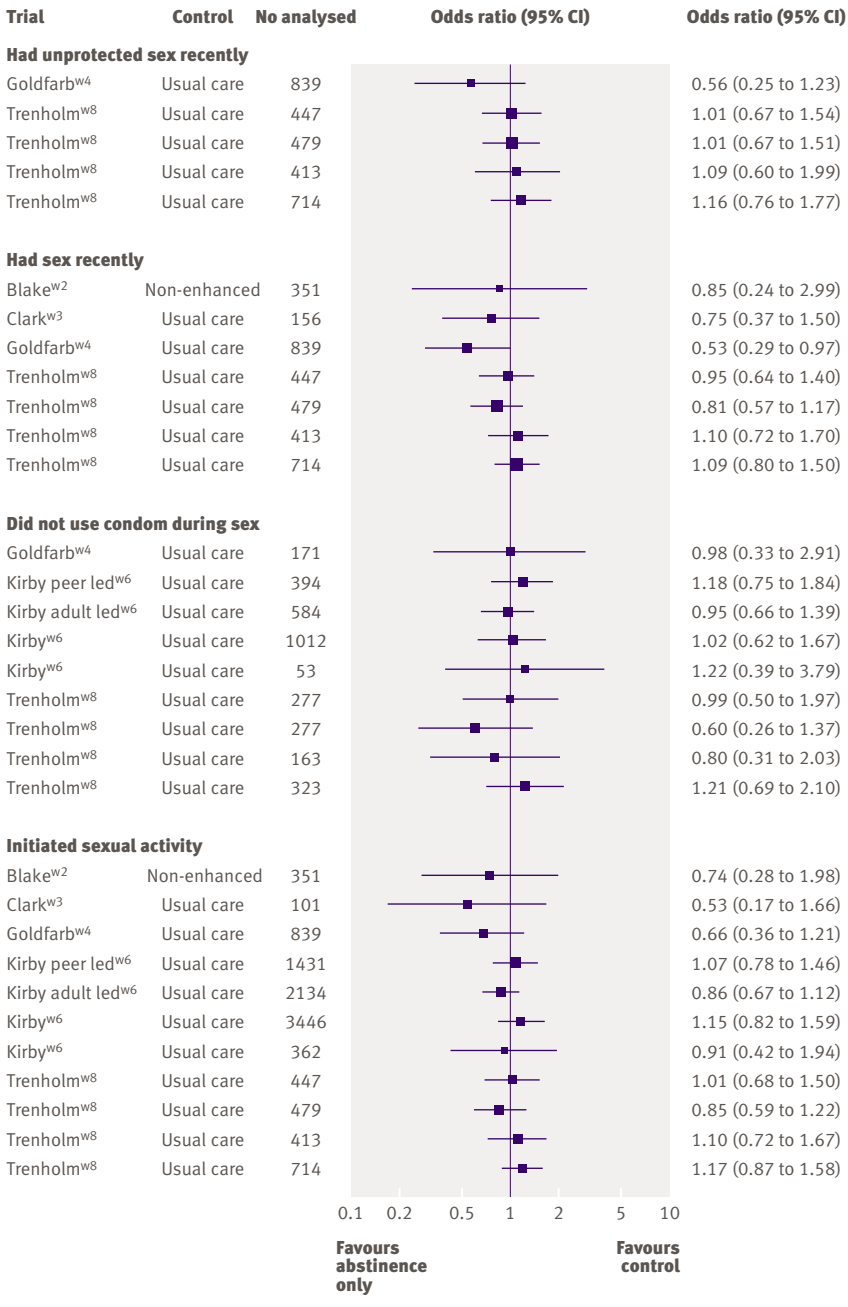

Fig 3 | Behavioural effects of sexual abstinence only programmes at each trial's longest follow-up (months)

DISCUSSION

In this systematic review the 13 included trials totalling more than 15 900 participants indicate that sexual abstinence only programmes for prevention of HIV infection do not decrease or exacerbate sexual risk among youths in high income countries, as measured by self reported biological and behavioural outcomes. When trials found significant results in either direction[w4 w6] these were offset by other evaluations reporting non-significant findings. Evidence from this review suggests that abstinence only programmes that aim to prevent HIV infection are ineffective but that the generalisability of results may be limited to US youths. Although this assessment focused specifically on HIV prevention these results may also be relevant for the prevention of other sexually transmitted infections.

The trial results also suggest that abstinence only programmes do not effectively encourage abstinent

behaviour but instead are ineffective for preventing or decreasing sexual activity among most participants. This was true for both primary abstinence and secondary abstinence. One trial found a protective effect from the programme compared with usual care for incidence of recent sex (n=839),[w4] but this was limited to short term follow-up and offset by non-significant findings in six other trials (n=2615).[w2 w3 w8] An adverse effect observed for frequency of sex (n=338) compared with usual care[w6] was not sustained at long term follow-up and this was also offset by non-significant findings in four other trial comparisons (n=2038).[w5 w6]

Additional findings of ongoing trials

Beyond the included results our search discovered mid-term findings of two ongoing trials[w12 w13] and long term findings of a recently completed trial,[w14] but full reports were not available. (No results were available for another two ongoing trials.[w15 w16]) All trials enrolled US adolescents and are classified as "ongoing" in figure 1. On the basis of preliminary results we do not believe that including full reports of these three trials would have changed the conclusions of our review.

One ongoing cluster randomised trial[w12 w17] is based in Toledo, Ohio, and randomised 510 adolescents to a school based abstinence only programme of eight sessions or to no treatment. χ^2 analyses at immediate post-test found no significant difference in participants' reports of vaginal sex in the past two months. No other behavioural outcomes were presented. These findings reinforce the non-significant results of six included trials from our review (n=2615)[w2 w3 w8] compared with one included trial with significant findings (n=839).[w4]

A multisite ongoing trial[w13 w18 w19] randomised the families of 189 adolescents in Denver and Montezuma County, Colorado, to a 22 hour community based abstinence only programme or to no treatment. At six months' follow-up (n=132) no significant difference was found in whether participants had ever had sex (P=0.15 from a group by time interaction, using a repeated measures analysis of variance). This aligns with the non-significant findings of 10 included trials from our review (n=11 298).[w2-w4 w6 w8] Results of the ongoing trial at 12 months' follow-up favoured the intervention group for this outcome but significance was not stated.

A recently completed trial[w14] allocated 662 adolescents to 10 arms spanning four interventions: abstinence only (two arms), abstinence plus (four arms), safer sex (two arms), and attention control (two arms). At 24 months' follow-up (n=559) logistic regression found that participants in the abstinence only groups were less likely to report ever having had sex than participants in the attention control (P=0.02), abstinence plus (P=0.05), or safer sex (P=0.007) groups. With analyses limited to participants who reported never having had sex at baseline (n<559), effects remained significant compared with the attention control (P=0.01) and the safer sex programme (P=0.007) but not with the abstinence plus programme (P=0.07). These findings are offset by the non-significant results of 10 included trials in this review (n=11 298).[w2-w4 w6 w8] The trial also found no significant differences between the abstinence only programme and the attention control in consistent condom use or condom use at last sex at 24 months' follow-up (n<224, P value not reported), which aligns with non-significant findings in nine trials in this review (n=3642).[w4-w6] Comparisons for condom use outcomes between the abstinence only, abstinence plus, and safer sex arms were not reported and could not be obtained; however, previous trials evaluating variants of the abstinence plus programme found significantly protective effects for condom use and unprotected sex compared with attention controls.[w20-w23]

Strengths of the review

Our review adds to previous assessments because of several strengths: its international scope; the pre-specified, systematic, and highly sensitive search for trial evidence; the inclusion of published and unpublished literature; the exclusive focus on behavioural and biological outcomes related to the prevention of HIV infection; the prereviewed Cochrane protocol; and acceptance of only the most methodologically rigorous trial evidence. Our review adds to individual trials by providing up to date, consistent trial evidence from a variety of abstinence only programmes across the United States, with a total sample size exceeding that of any individual study.

Our conclusions are consistent with previous reviews that found no evidence of an effect of abstinence only programmes in developing countries[8] or in the United States.[27 37 39] We concur with reviews suggesting that general interventions for reduction of HIV risk have low rates of behaviour change for sexual abstinence[28 30] and that general interventions for the reduction of HIV risk do not significantly increase risky sexual behaviour.[61] Our findings also dovetail with a recent analysis by Santelli et al,[62] which suggested that the recent decline in the US rate of adolescent pregnancies was mainly a result of the improved use of contraception rather than decreases in sexual activity.

As with previous reviews, our analysis is based on findings of trials that enrolled US youths, despite a systematic search for methodologically rigorous evaluations of abstinence only programmes from all high income countries. That we did not find trials outside the United States might indicate that such evaluations are inaccessible by existing search methods or that abstinence only programmes are not popular HIV prevention strategies in other high income countries. The second possibility seems likely, given the sensitivity of our search and previous reviews suggesting that abstinence based approaches are rare outside the United States.[63 64]

Limitations of the review

Our review process had several limitations. As with all reviews this assessment is vulnerable to publication

Table 3 | **Trials of sexual abstinence only programmes to prevent HIV infection reporting behavioural outcomes. Effects of intervention are odds ratios (95% confidence intervals) unless stated otherwise**

Outcome	Trial	Control	No analysed	Time (months)	Effect of intervention	P value
Incidence of unprotected vaginal sex						
In past month	Goldfarb	Usual care	839	2	0.56 (0.25 to 1.23)	0.15
In past year	Trenholm[w8]		447; 479; 413; 714	62.5; 65; 62.5; 59	1.01 (0.67 to 1.54); 1.01 (0.67 to 1.51); 1.09 (0.60 to 1.99); 1.16 (0.76 to 1.77)	0.96; 0.96; 0.78; 0.50
Incidence of vaginal sex						
In past 3 months	Blake[w2]	Non-enhanced	351	1.5	0.85 (0.24 to 2.99)	0.79
From baseline	Clark[w3]	Usual care	211	4.4	0.69 (0.36 to 1.32)	0.26
In past 7.6 months			156	12	0.75 (0.37 to 1.50)	0.42
In past month	Goldfarb[w4]	Usual care	839	2	0.53 (0.29 to 0.97)	0.04*
In past 12 months	Trenholm[w8]	Usual care	447; 479; 413; 714	62.5; 65; 62.5; 59	0.95 (0.64 to 1.40); 0.81 (0.57 to 1.17); 1.10 (0.72 to 1.70); 1.09 (0.80 to 1.50)	0.79; 0.27; 0.66; 0.57
Frequency of vaginal sex						
No of sex occasions since baseline	Hernandez[w5]	A+, SS, no treatment	388	1.5	No significant effect	—
Mean increase since baseline in No of acts of intercourse in past 3 months†	Kirby, peer led[w6]	Usual care	338	3	0.9 *v* 0.3	0.02*
			338	17	1.8 *v* 1.6	0.62
	Kirby, adult led[w6]	Usual care	464	3	0.8 *v* 0.4	0.11
			586	17	2.0 *v*. 1.6	0.16
	Kirby[w6]	Usual care	1012; 52	17; 17	1.7 *v* 1.9; 2.0 *v* 1.9	0.53; 0.96
No of sex partners						
No of partners since baseline	Hernandez[w5]	A+, SS, no treatment	388	1.5	No significant effect	—
Mean increase since baseline in No of lifetime sexual partners†	Kirby, peer led[w6]	Usual care	342	3	1.1 *v* 0.7	0.07
			393	17	2.3 *v* 2.0	0.28
	Kirby, adult led[w6]	Usual care	470	3	1.0 *v* 0.8	0.12
			584	17	1.9 *v* 1.8	0.64
	Kirby[w6]	Usual care	1012; 53	17; 17	1.9 *v* 2.0; 1.0 *v* 1.4	0.42; 0.60
No of sexual partners ever‡	Trenholm[w8]	Usual care	447; 479; 413; 714	62.5; 65; 62.5; 59	No significant effect	0.20; 0.80; 0.90; 0.49
Lack of condom use						
Did not use condom in past month§	Goldfarb[w4]	Usual care	171	2	0.98 (0.33 to 2.91)	0.97
No of times participants used condoms since baseline	Hernandez[w5]	A+, SS, no treatment	388	1.5	$F_{2,354}$=1.48	0.22
Did not use condom at last vaginal sex†	Kirby, peer led[w6]	Usual care	339	3	0.88 (0.55 to 1.43)	0.62
			394	17	1.18 (0.75 to 1.84)	0.48
	Kirby, adult led[w6]	Usual care	471	3	0.67 (0.44 to 1.01)	0.06
			584	17	0.95 (0.66 to 1.39)	0.80
	Kirby[w6]	Usual care	1012; 53	17; 17	1.02 (0.62 to 1.67); 1.22 (0.39 to 3.79)	0.93; 0.73
Did not use condom at first vaginal sex†	Trenholm[w8]	Usual care	277; 277; 163; 323	62.5; 65; 62.5; 59	0.99 (0.50 to 1.97); 0.60 (0.26 to 1.37); 0.80 (0.31 to 2.03); 1.21 (0.69 to 2.10)	0.97; 0.22; 0.63; 0.50
Sexual initiation						
Ever had vaginal sex	Blake[w2]	Non-enhanced	351	1.5	0.74 (0.28 to 1.98)	0.55
	Goldfarb[w4]	Usual care	839	2	0.66 (0.36 to 1.21)	0.18
	Trenholm[w8]	Usual care	447; 479; 413; 714	62.5; 65; 62.5; 59	1.01 (0.68 to 1.50); 0.85 (0.59 to 1.22); 1.10 (0.72 to 1.67); 1.17 (0.87 to 1.58)	0.97; 0.38; 0.65; 0.29
Initiated sexual intercourse since baseline¶	Clark[w3]	Usual care	134	4.4	0.28 (0.07 to 1.10)	0.07
			101	12	0.53 (0.17 to 1.66)	0.28
	Kirby, peer led[w6]	Usual care	1678	3	1.10 (0.69 to 1.75)	0.70
			1431	17	1.07 (0.78 to 1.46)	0.68
	Kirby, adult led[w6]	Usual care	2435	3	1.04 (0.70 to 1.52)	0.86
			2134	17	0.86 (0.67 to 1.12)	0.27
	Kirby[w6]	Usual care	3446; 362	17; 17	1.15 (0.82 to 1.59); 0.91 (0.42 to 1.94)	0.42; 0.80

A+=Abstinence plus programme; SS=safer sex programme. Findings for Hernandez are based on 4(group)×2(time)×2(gender)×2(baseline sexual experience) analysis of variances. Calculation of odds ratios was impossible because of missing data. Test statistics were given only for condom use. *Significant at P<0.05. Odds ratios were calculated in RevMan with controls for clustering where needed. Odds ratio <1 indicates protective intervention effect. Time=Months since baseline. Analyses include all participants with follow-up data (both sexually experienced and sexually inexperienced), except where otherwise indicated. †Analyses represent participants who reported ever having had sexual intercourse. In Kirby,[w6] means for frequency of sex and number of partners are listed for intervention group and then control group; P values reported with these means are from two tailed *t* tests on basis of change scores.
‡P values are from F tests of distributional differences. §Paper did not clearly state whether results referred to (lack of) condom use in past month among participants reporting intercourse in past month, or to (lack of) condom use ever among participants reporting intercourse ever. We carried out analyses according to first assumption. In second case, results would have been n=167, odds ratio 0.75 (95% confidence interval 0.26 to 2.23), P=0.61. ¶Analyses represent participants who reported never having had sexual intercourse at baseline.

WHAT IS ALREADY KNOWN ON THIS TOPIC

Abstinence only programmes present sexual abstinence as the exclusive means of preventing HIV infection, without promoting safer sex behaviours

Reviews have reached divergent conclusions on the effectiveness of abstinence only interventions in high income settings

WHAT THIS STUDY ADDS

Abstinence only programmes do not seem to affect HIV risk in high income countries compared with usual care, no treatment, non-enhanced programme versions, a safer sex programme, and an abstinence plus programme

Despite an international search for published and unpublished trials, generalisability may be limited to US youths

bias despite our extensive search for unpublished and ongoing trials. Although our search for unpublished literature extended to April 2007 we could not include trials indexed electronically after February 2007. Because we only included trials of abstinence only programmes with an HIV prevention component, results may not apply to abstinence only programmes focusing exclusively on pregnancy prevention. We did not use a Bonferroni or other correction to control for multiple statistical tests. Our reanalysed results differed slightly from results published in original trials by Clark (short term results for both outcomes),[w3] Kirby (condom use at three months' follow-up for the adult led arm),[w6] and Goldfarb (sexual initiation)[w4]; this may be a result of differences in software, analytical procedures, or methods to control for clustering. All differences were in the direction of non-significance in our reanalysed results.

The generalisability of this review may extend only to the United States. External validity is also limited by homogeneity in settings and participants: participants were adolescents or young adults and all but one programme took place in a school or community setting. It was impossible to carry out subgroup analyses by age, ethnicity, sexual orientation, socioeconomic status, gender, family structure, religion, baseline sexual experience, or other variables. No trial assessed same sex behaviours, resulting in findings being less relevant to youths who engage in same sex sexual activity.

External and internal validity are further restricted by limitations in the primary trials. Strengths of the trials included relatively large samples at baseline, long term follow-up assessments, and efforts to improve the validity of self reported data. Results were consistent across trials. These strengths were, however, countered by under-reporting of methodological and statistical data, attrition rates exceeding 33% in four trials,[w1 w3 w6] lack of intention to treat analyses, and incomplete reporting of programme implementation. Non-response and data loss by some trialists hindered our search for missing information. Key outcomes of interest, such as medical evaluation of HIV, were underutilised. Self reported data are an inevitable source of bias,[65-68] which may be compounded by the variety of definitions for terms such as "sex."[69-71] Furthermore, there are limits to the use of sexual behaviour as a proxy for HIV risk,[48 72] and floor effects or lack of diagnosis may impede the measurement of biological outcomes.

CLINICAL RELEVANCE AND FUTURE RESEARCH

Notwithstanding these limitations the evidence from this systematic review is clear. When compared with a variety of control groups, the participants in these 13 abstinence only programme trials did not report differences in risky sexual behaviours or biological outcomes. We hypothesised that conditions in high income countries may offer abstinence only programmes favourable chances of reducing risk behaviour. As an editorial in the *Lancet* suggested in 2004, it seemed possible that "abstinence only works where women have the means to make it work."[20] We could not carry out subgroup analyses by socioeconomic status within high income countries, but our findings suggest that this statement does not apply to high income countries as a whole.

Evidence from this review might inform ongoing assessments of US policy on abstinence only interventions, which have received federal funding since 1981. The 2007 budget outlined by the White House allocated $204m[73] in federal funds to domestic abstinence only approaches meeting federal guidelines,[74] with the goal of increasing annual funding to $270m by 2009.[73] This estimate does not include state funding ($3 for every $4 in federal contributions[3]), private and charitable contributions, or abstinence only funds from the President's Emergency Fund for AIDS Relief.

Should the funding of abstinence only interventions continue at its current levels, policy makers and practitioners might consider allocating more resources to methodologically rigorous evaluations with outcomes that directly indicate HIV risk. Ongoing school based and community based trials[w12-w16] will help remedy some gaps in knowledge but additional trials may be necessary, particularly to assess interventions run by faith based organisations. Another salient deficit in research is the direct comparison of abstinence only programmes with abstinence plus programmes, programmes that promote condoms, or safer sex programmes. According to our criteria only one included trial explicitly made this type of comparison.[w5] (Additionally, a 1998 evaluation[w19] compared two abstinence plus programmes that emphasised abstinence to differing extents; however, each programme openly stated that condoms can prevent HIV infection.) In future evaluations of abstinence only programmes we urge more complete reporting of methodological and statistical data (according to guidelines from the consolidated standards of reporting trials[75]), as well as more information on programme design and implementation.[76]

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