

economic evaluations.⁸ The trials simply totalled the monetary cost of the dressings and did not examine their cost effectiveness.

Clinical implications

Although a wide variety of dressings are available, and used on venous leg ulcers, we found insufficient evidence to justify the use of a particular dressing or dressing type in preference to any other. In particular, the use of hydrocolloid dressings rather than simple, low adherent dressings should be questioned. Cost effectiveness studies examining dressings for venous leg ulcers are urgently needed, as dressing frequency drives costs by influencing the amount of time taken by clinicians to treat ulcers.

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

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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

Programmes aimed at sexual abstinence only are one strategy for preventing sexually acquired HIV. These interventions encourage primary abstinence (delaying sexual debut) and secondary abstinence (returning to abstinence after sexual activity) whereas abstinence plus programmes promote abstinence along with safer sex strategies.

Abstinence only programmes to prevent HIV are more likely to acknowledge the HIV related risks of oral sex, anal sex, same sex sexual behaviours, and non-sexual means of transmission, whereas programmes to prevent pregnancy only may just mention vaginal sex. To complement a systematic review of abstinence based programmes in developing countries we systematically reviewed trials of abstinence only programmes to prevent HIV infection or HIV and pregnancy in high income countries.

METHODS

We included randomised and quasirandomised controlled trials of sexual abstinence only interventions for HIV prevention in high income economies (see

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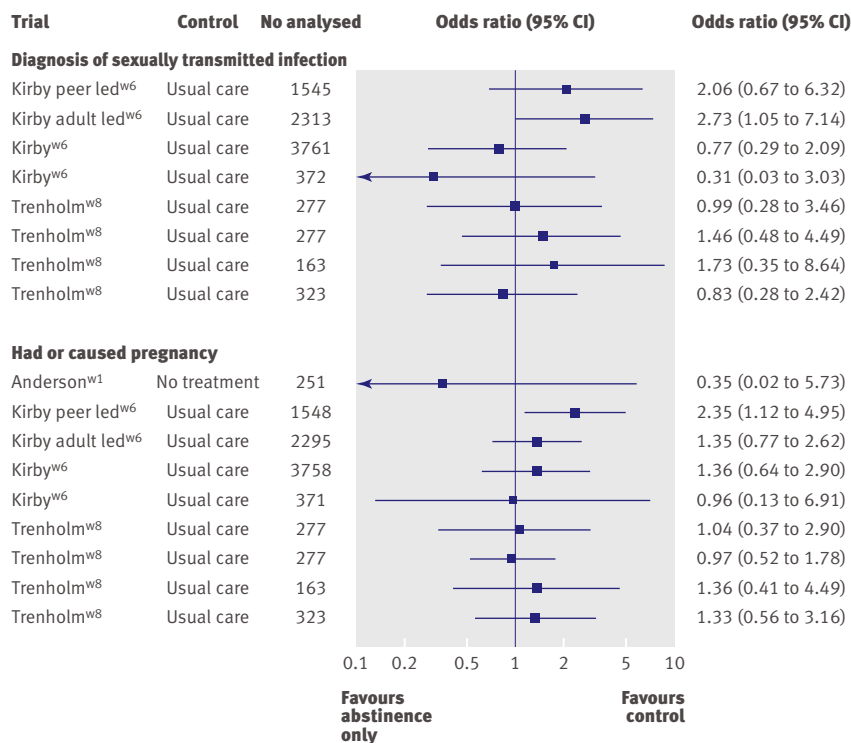


Fig 1 | Biological effects of sexual abstinence only programmes at each trial's longest follow-up (months)

definition on bmj.com). 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 extracted data for biological and behavioural outcomes as these are directly related to the sexual acquisition of HIV. Outcomes for same sex sexual behaviour were included. (See bmj.com for exclusions.)

We searched 30 electronic databases from January 1980 to February 2007 (see bmj.com) and conference proceedings from 2000; we also searched libraries of HIV agencies, and contacted experts for unpublished and ongoing trials.

We assessed methodological quality according to the Cochrane handbook¹ and we highlighted attrition as a limitation of trials with a dropout exceeding 33% of baseline enrolment.

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. When trials used cluster randomisation, we adjusted for intraclass correlation where possible.¹² We used an intraclass correlation coefficient of 0.015 for school based trials and 0.005 for community based trials.

RESULTS

Sufficient information was obtained to assess 308 of 311 potentially relevant trials. Thirteen randomised controlled trials from eight papers were included.^{w1-w8} No quasirandomised controlled trials met the inclusion

criteria. Two papers reported multiple trials.^{w6 w8} Results for one trial^{w6} are categorised by whether the intervention group received the intervention from peer leaders or from adult health educators.

Despite an international search without age restrictions, the 13 trials enrolled young people (about 15 940 participants, median 551) in the United States. No trial assessed outcomes by sexual orientation.

Programme exposure ranged from one^{w5} to 720 sessions^{w4} (median eight). 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 at home.^{w7} Twelve programmes^{w1-w4 w6-w8} were delivered to youths aged 10-14; all but one^{w3} emphasised parent-child communication. The remaining programme^{w5} targeted youths aged 18-21 and included one session. Programme facilitators were mostly adults^{w1 w3 w4 w6 w8}; two interventions were delivered by peer leaders^{w2 w6} and two were primarily media based.^{w5 w7}

Control groups varied (see bmj.com) 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.

Missing information made the assessment of methodological quality difficult. Only four trials reported procedures for generating the allocation sequence and no trial reported on concealment of randomisation. Blinding of participants and staff was generally impossible. When sexual behaviours were reported they were limited to vaginal sex; no trial assessed oral or anal sex or reported outcomes for same sex sexual behaviour. All outcomes were assessed through self report questionnaires. Attempts to minimise bias included reading questions aloud,^{w1 w5} using anonymised surveys,^{w1 w4 w5} emphasising confidentiality,^{w2} separating participants,^{w5 w6} identifying participants by numbers,^{w6} and physically concealing responses.^{w6 w7}

When reported, attrition rates ranged from 5%^{w5} to 45%.^{w6} Attrition in four trials^{w1 w3 w6} exceeded 33%. 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 a statement of baseline equivalence. The trials carried out complete case, instead of intention to treat, analyses, with participants analysed in original groups regardless of attendance and 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.

Biological outcomes

No trial evaluated HIV incidence, therefore the biological outcomes of interest were self reported incidence of sexually transmitted infection and pregnancy (fig 1).

Seven trials^{w6 w8} (n=9779) assessed self reports of a sexually transmitted infection diagnosed 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 benefit and one^{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).

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^{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).

Behavioural outcomes

When odds ratios for behavioural outcomes could be calculated, the results are displayed with 95% confidence intervals and significance (see bmj.com and fig 2). Across trials the behavioural outcomes most indicative of HIV risk (for example, unprotected vaginal 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 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 (see bmj.com). The remaining trials found no significant effects 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 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. One trial^{w6} found evidence of harm at three months' follow-up (n=338) when the peer led programme was compared with usual care.

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}

Nine trials^{w4-w6 w8} assessed condom use (n=3642). For consistency with other outcomes, the results are transformed to indicate lack of condom use (see bmj.com and fig 2). No trial found a significant effect compared with usual care (n=3254),^{w4 w6 w8} a safer sex programme, an abstinence plus programme, or no treatment (n=388).^{w5}

Ten trials^{w2-w4 w6 w8} assessed incidence of sexual initiation (ever had vaginal sex; n=11 298). None observed a significant effect 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 from holding hands to vaginal sex. According to a 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).

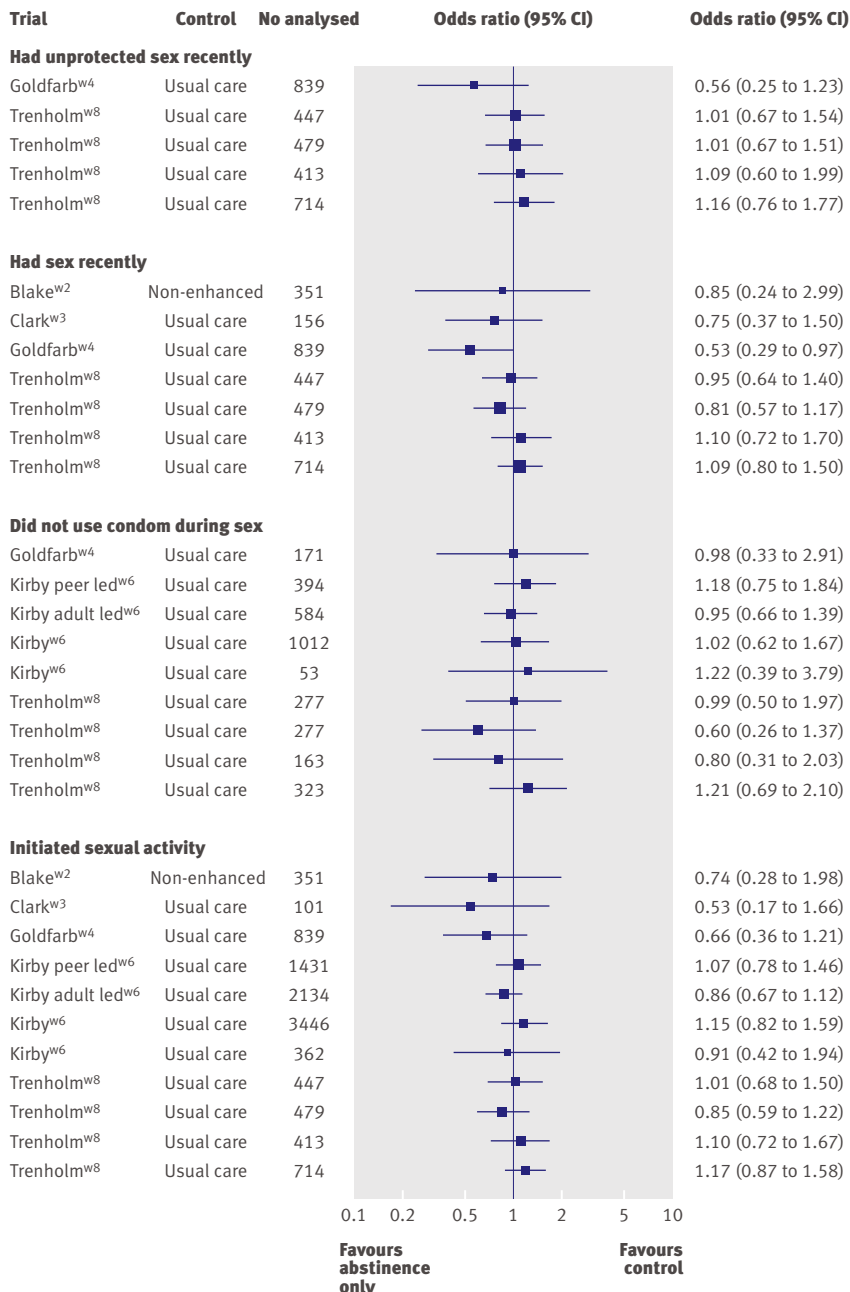


Fig 2 | Behavioural effects of sexual abstinence only programmes at each trial's longest follow-up (months)

DISCUSSION

In this systematic review the 13 included trials (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. Although evidence from this review suggests that abstinence only programmes to prevent HIV infection are ineffective the generalisability of results may be limited to US youths.

The trial results also suggest that abstinence only programmes do not effectively encourage abstinent behaviour for either primary abstinence or 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 trials (n=2038).^{w5 w6}

Additional findings of ongoing trials

A recently completed trial^{w14} allocated 662 adolescents to 10 arms for four interventions: abstinence only (two arms), abstinence plus (four), safer sex (two), and attention control (two). At 24 months' follow-up (n=559) logistic regression found that participants in abstinence only programmes were less likely to report ever having had sex than participants in the other arms. With analyses limited to participants who reported never having had sex at baseline (n<559) effects remained significant compared with the attention control and the safer sex programmes but not with the abstinence plus programme. 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), which aligns with non-significant findings in nine trials (n=3642).^{w4-w6} Comparisons for condom use outcomes between the abstinence only, abstinence plus, and safer sex arms 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 its international scope; the sensitive search for evidence; the inclusion of published and unpublished literature; the focus on behavioural and biological outcomes related to HIV prevention; the prereviewed Cochrane protocol; and acceptance of only the most methodologically rigorous trial evidence.

Our conclusions are consistent with previous reviews that found no evidence of an effect of abstinence only programmes in developing countries³ or the United States.⁴⁻⁶ We concur with reviews suggesting that general interventions for reduction of HIV risk have low rates of behaviour change for sexual abstinence^{7,8} and that general interventions for HIV risk reduction do not significantly increase risky sexual behaviour.⁹ Our findings also dovetail with another analysis,¹⁰ 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 abstinence only programmes from all high income countries. That we did not find trials elsewhere might indicate that evaluations are inaccessible by search methods or that abstinence only programmes are not popular HIV prevention strategies in other high income countries.

Limitations of the review

Our review is vulnerable to publication bias despite our search for unpublished and ongoing trials. Because we only included trials of abstinence only programmes with an HIV prevention component, results may not apply to abstinence only programmes focusing just 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,^{w3} Kirby^{w6} and Goldfarb^{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

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

inevitable source of bias,¹¹⁻¹⁴ which may be compounded by the variety of definitions for terms such as “sex.”¹⁵⁻¹⁷ Furthermore, there are limits to the use of sexual behaviour as a proxy for HIV risk,^{18,19} 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.

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. In future evaluations of abstinence only programmes we urge more complete reporting of methodological and statistical data, as well as more information on programme design and implementation.²⁰

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