PREVENTION

Reducing the risk of sexually transmitted infections in genitourinary medicine clinic patients: a systematic review and meta-analysis of behavioural interventions

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Accepted for publication
4 February 2005
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Objectives: Are behavioural interventions effective in reducing the rate of sexually transmitted infections (STIs) among genitourinary medicine (GUM) clinic patients?
Design: Systematic review and meta-analysis of published articles.
Data sources: Medline, CINAHL, Embase, PsychINFO, Applied Social Sciences Index and Abstracts, Cochrane Library Controlled Clinical Trials Register, National Research Register (1966 to January 2004).
Review methods: Randomised controlled trials of behavioural interventions in sexual health clinic patients were included if they reported change to STI rates or self reported sexual behaviour. Trial quality was assessed using the Jadad score and results pooled using random effects meta-analyses where outcomes were consistent across studies.
Results: 14 trials were included; 12 based in the United States. Experimental interventions were heterogeneous and most control interventions were more structured than typical UK care. Eight trials reported data on laboratory confirmed infections, of which four observed a greater reduction in their intervention groups (in two cases this result was statistically significant, p<0.05). Seven trials reported consistent condom use, of which six observed a greater increase among their intervention subjects. Results for other measures of sexual behaviour were inconsistent. Success in reducing STIs was related to trial quality, use of social cognition models, and formative research in the target population. However, effectiveness was not related to intervention format or length.
Conclusions: While results were heterogeneous, several trials observed reductions in STI rates. The most effective interventions were developed through extensive formative research. These findings should encourage further research in the United Kingdom where new approaches to preventing STIs are urgently required.

Recent reports highlight dramatic increases in sexually transmitted infections (STIs) in the United Kingdom[1 2] alongside substantial increases in sexual risk behaviour.[3] The government has responded with a national strategy for sexual health and HIV, which aims to improve the evidence base for prevention and sets targets for reducing new infections.[4 5] Increased infection rates have placed considerable pressure on genitourinary medicine (GUM) clinics,[3 6] which recorded over 1.5 million clinical episodes in England and Wales during 2002.[1] Re-infection and re-attendance are thought to be common, but are not identified in routine data. A survey in England estimated that 44% of those diagnosed with gonorrhoea during 1996 had previously attended a GUM clinic.[7] Reducing rates of re-infection among clinic patients by promoting behaviour change could contribute to current policy goals and improve public health.

We aimed to systematically review the evidence that behavioural interventions could reduce STIs in GUM clinic patients. A recent publication by the Health Development Agency[8] identified two high quality systematic reviews that considered randomised controlled trials (RCTs) of behavioural interventions in clinical settings that reported changes to STI rates.[9 10] Both observed considerable heterogeneity between trials and concluded that the effectiveness of interventions was related to their development through formative research. We sought to build upon this previous work using a systematic approach to identify trials, an explicit approach to appraising trial validity, and quantitative methods to explore possible sources of heterogeneity.[11 12] We also sought to broaden the scope of existing reviews by

considering measures of sexual behaviour change, relating these to infection risk.

METHODS

Identification of trials

We searched seven databases of completed and ongoing research during January 2004 with no date or language restrictions (Medline, CINAHL, Embase, PsychINFO, Applied Social Sciences Index and Abstracts, Cochrane Library Controlled Clinical Trials Register, and the National Research Register). Searches used terms describing sexually transmitted infections or sexual behaviour combined (AND) with terms for prevention, health promotion, behavioural interventions, counselling, and psychological therapies. A full version of this report is available online.[12]

Inclusion and exclusion criteria

We included RCTs of behavioural interventions that aimed to reduce the risk of STIs in patients attending GUM or equivalent clinics.[12] Infection rates were the primary outcome of interest, but we also included trials describing changes to self reported sexual behaviour. We excluded trials that provided educational materials alone, or reported only knowledge, attitudes, or behavioural intentions. Two reviewers independently assessed trials for inclusion using a standardised form.[12]

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Abbreviations: GUM, genitourinary medicine; ITT, intention to treat; MD, mean difference; RCTs, randomised controlled trials; RR, relative risk

Trial quality

Two reviewers independently assessed trial quality using a standardised form based on the Jadad scoring system.[12 13] This considers the adequacy of randomisation, concealment, masking, completeness of follow up, and the use of intention to treat (ITT) analyses.

Data abstraction and analysis

All data were abstracted using a standardised form.[12] STI diagnoses were ascertained from laboratory or clinic records, or the results of screening visits. Sexual behaviour change was ascertained from self completed questionnaires or interviews. Dichotomous outcomes were expressed as relative risks (RR) while results for continuous outcomes were expressed as the differences between intervention and control groups' mean within-subject change from baseline (mean difference, MD).[12 14] For infection related outcomes and sexual risk behaviours, a RR less than 1 or a negative MD indicates a lower rate of infections or risk taking in the intervention group relative to control. In contrast, for protective behaviours a RR greater than 1 or a positive MD indicates greater adoption of the protective behaviour in the intervention group relative to control. Infection related outcomes were analysed as ITT while behavioural outcomes represent on-treatment analyses (in many cases no information was reported on those lost to follow up).

Where outcome data were consistently available across studies, results were pooled using random effects meta-analyses (Review Manager, version 4.2, Cochrane Collaboration, 2003). Heterogeneity was explored with stratified meta-analyses using covariates defined a priori

(study population, intervention characteristics, and trial quality).[12]

RESULTS
Search for trials

We included 31 papers reporting 14 trials (identified by principal citation, fig 1).[12] Most rejected RCTs did not recruit patients from a relevant setting. Initial agreement on inclusion was good ($\kappa = 0.70$) with disagreements resolved by discussion.

Study characteristics
Population and setting

Most trials were conducted in the United States (table 1). Two trials recruited over 60% of all participants.[15 16] Four trials recruited only males[17–20] and three only females.[21–23] Three trials focused on adolescents or young women.[21 23 26] Most trials restricted entry to those with a recently diagnosed STI,[17 18 20–25 27] and/or reporting high risk sexual behaviours.[16 18 26] The largest trial did not restrict entry on these grounds and reported a 32% baseline STI rate.[15]

Trial quality

Jadad scores were low ($\leqslant 3$ out of 5) reflecting an expected lack of masking and limited descriptions of trial methods.[17 21 26–28] Recruitment, adherence, and follow up rates were low (weighted mean 45% n = 12, 66% n = 10, and 69% n = 12), especially for interventions lasting over two sessions. Recruitment was greatest for small group interventions. Five trials reported differential follow up rates,[17 18 23 24 26] though
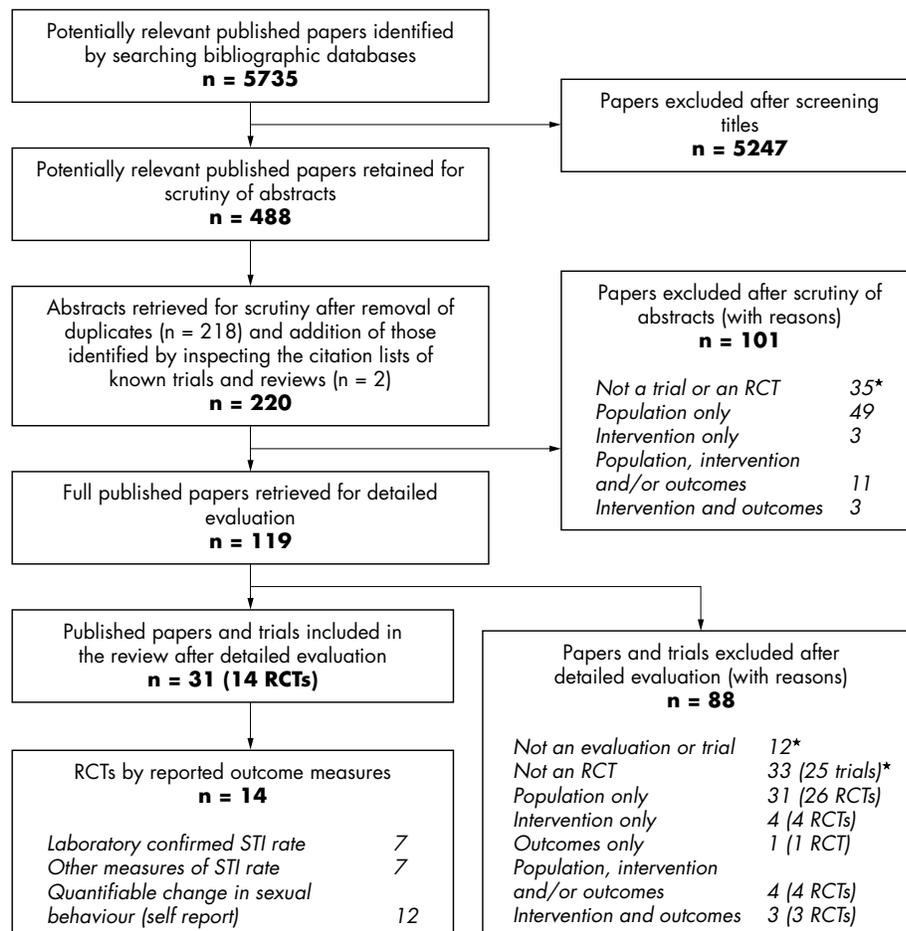
Figure 1 Flow of trials included and excluded from this review. (*No further details reported on those papers or trials not reporting evaluations or RCTs.)

Table 1 Characteristics of included trials

Trial location and dates	Population*	Number recruited (% female)	Age of participants (years)	Follow up	Intervention length and format	Trial quality Jadad score	Recruitment rate	Adherence rate	Follow up rate (at end point)
Balmer, 1998[17] Nairobi, Kenya (trial dates not stated)	Men with current STI	240 (0%)	Not reported	6 months	26×60 minutes weekly small group sessions	0	Not stated	Not stated	93% intervention 44% control
Boyer, 1997[24] San Francisco, USA, Jan 1992 to Jan 1993	Heterosexual men and women (46% African American, 15% Hispanic) with current (39%) or previous STI (61%)	399 (49%)	42% <25	5 months	4×60 minutes weekly individual sessions	3	38%	48%	66% intervention 49% control
Branson, 1998[25] Houston, USA, March 1992 to June 1993	Heterosexual men and women (90% black) with history of STI (48% current STI)	964 (43%)	35% >29 19% <20	12 months	4 small group sessions in 2 weeks plus 1 at 2 months	3	59%	47%	73% any, and 22% complete follow up
Imrie, 2001[18] London, UK, Sept 1995 to Nov 1997	Homosexual men (91% white) with acute STI and/or history of unprotected intercourse and/or concerns about sexual practices	343 (0%)	23% >34 Median 29 (range 18–58)	12 months	One 7 hour group workshop	3	72%	71%	66% intervention 78% control
Kalichman, 1999[19] Atlanta, USA (trial dates not stated)	African American heterosexual men	117 (0%)	Mean 33 (range 18–50)	6 months	2×180 minutes small group sessions	2	Approx. 70%	85%	69% (reportedly similar between groups)
Kamb, 1998[15] Five US clinics, July 1993 to Sept 1996	Heterosexual men and women (32% current STI)	5758 (43%)	Not reported (all >14)	12 months	1×20 minutes and 3×60 minutes (enhanced) or 2×20 minute (brief) individual sessions	2	43%	72%	66% (reportedly similar between groups)
Maher, 2003[20] Miami, USA, Sept 1994 to Dec 1995	Black men with confirmed/probable STI	581 (0%)	Mean 24 (range 16–29)	12 months	1×60 min and 2×40–50 minutes sessions in 30 days	2	92%	46% attended ≥2 sessions	Not applicable
Metzler, 2000[26] Oregon, USA (trial dates not stated)	Male and female adolescents (68% white) reporting recent high-risk sexual activity	339 (68%)	Mean 18 (males) 17 (females)	6 months	5×60–90 minute individual sessions	1	37%	68% attended ≥4 sessions	53% intervention 39% control
National Institute of Mental Health (NIMH), 1998[16] 37 US clinics, Jan 1994 to Sept 1996	Men and women (74% African American, 25% Hispanic) reporting recent high risk sexual activity	2426† (42%)	(32% <17) 25% <25	12 months	7 group sessions, initially twice weekly (1×60 minutes and 6×90–120 minutes)	3	33%	63% attended ≥6 sessions	76% intervention 74% control
O'Leary, 1998[28] Seven US clinics (trial dates not stated)	Men and women (91% Black)	659 (41%)	Mean 30	3 months	7 group sessions totalling 10 hours	1	24%	Not stated	70% intervention 83% control
Orr, 1996[21] Indiana, USA (trial dates not stated)	Female adolescents (55% black) with Chlamydia trachomatis infection	209 (100%)	Mean 18 (range 14–19)	6 months	1×10–20 minutes Individual session	0	Not stated	Not applicable	54% (reportedly similar between groups)
Shain, 1999[22] San Antonio, USA, Jan 1993 to July 1994	Heterosexual women with non-viral STI (68% Hispanic, 31% African American)	617 (100%)	Mean 22 (36% <19)	12 months	3×3–4 hour group sessions over 3 weeks	2	65%	82% attended ≥2 sessions	91% intervention 87% control
Shrier, 2001[23] Boston, USA, July 1996 to July 1998	Young women (49% black, 18% Hispanic) with cervicitis or pelvic inflammatory disease	123 (100%)	Median 17.5 (range 13–22)	12 months	1×30 minutes individual session	2	51%	95%	50% intervention 87% control
Solomon, 1989[27] Boston, USA, 1986 (trial dates not stated)	Men and women (8.5% black) returning for "test of cure"	182 (20%)	Median 24 (range 18–73)	Not stated	One group session	1	73%	Not applicable	46% control Not applicable

*The terms used to describe sexuality and ethnic groups reflect those used in the original papers.
†Results reported for the NIMH trial relate only to those recruited from sexual health clinics. This study also recruited women from community Health Service Organisations (total n = 3706).[16]

Study	Intervention (n/N)	Control (n/N)	RR (95% CI)	RR (95% CI)
Laboratory confirmed STIs				
Boyer 1997[24]	14/199	9/200		1.56 [0.69 to 3.53]
Branson 1998[25]	91/509	86/455		0.95 [0.72 to 1.23]
Imrie 2001[18]	21/175	11/168		1.83 [0.91 to 3.68]
Kamb 1998[15]	165/1438	211/1443		0.78 [0.65 to 0.95]
Maher 2003[20]	45/288	35/293		1.31 [0.87 to 1.97]
NIMH 1998[16]	84/1222	85/1204		0.97 [0.73 to 1.30]
Orr 1996[21]	15/54	10/58		1.61 [0.79 to 3.27]
Shain 1999[22]	48/313	71/304		0.66 [0.47 to 0.91]
Total (95% CI)	4198	4125		1.00 [0.81 to 1.23]

Total events: 483 (intervention), 518 (control)
Test for heterogeneity: $\chi^2 = 17.42$, df = 7 (p = 0.01, $I^2 = 59.8\%$)
Test for overall effect: Z = 0.01 (p = 1.00)

Clinically diagnosed or probable STIs				
Boyer 1997[24]	25/199	21/200		1.20 [0.69 to 2.07]
Imrie 2001[18]	53/175	35/168		1.45 [1.00 to 2.11]
Maher 2003[20]	90/288	80/293		1.14 [0.89 to 1.47]
Total (95% CI)	662	661		1.23 [1.01 to 1.50]

Total events: 168 (intervention), 136 (control)
Test for heterogeneity: $\chi^2 = 1.10$, df = 2 (p = 0.28, $I^2 = 0\%$
Test for overall effect: Z = 2.08 (p = 0.04)

Self reported STI diagnoses				
Shrier 2001[23]	5/60	11/63		0.48 [0.18 to 1.29]
Total (95% CI)				

Self reported STI symptoms				
NIMH 1998[16]	252/1222	319/1204		0.78 [0.67 to 0.90]
Total (95% CI)				

0.2   0.5   1   2   5

Favours intervention   Favours control

Figure 2 Results for laboratory confirmed STIs, clinically diagnosed STIs, self reported STIs, and self reported symptoms at trial end points. CI, confidence interval; n, number of events; N, number of participants; RR, relative risk. Laboratory confirmed STI includes gonorrhoea, chlamydia, syphilis, HIV, trichomonas (two trials[14 22]), non-specific urethritis (one trial[14]), chancroid and lymphogranuloma venereum (one trial[18]). Clinically diagnosed STIs also includes non-specific urethritis[16 18 22 23] or mucopurulent cervicitis,[22] pelvic inflammatory disease,[22 23] trichomonas, first presentations of genital warts, herpes simplex, or hepatitis B infection,[16 23] scabies, or pediculosis pubis,[23] and presumptive treatment of either gonorrhoea or chlamydia on clinical grounds.[18 22] Results for the trial by Kamb relate to the enhanced intervention.[13] Equivalent results for the brief intervention are RR 0.82 (95% CI 0.68 to 0.99).

the group with greatest attrition was inconsistent. We labelled five trials as higher quality using a post hoc definition that required a Jadad score of two or three, masking of outcome assessors (seven trials), and non-differential follow up.[15 16 19 20 22]

Experimental and control interventions

Intervention format and length varied considerably (see table A on *STI* website www.stijournal.com/supplemental). One trial also compared an enhanced intervention with a brief one based on US best practice guidelines for individualised risk reduction counselling.[15 29 30] Most other US trials adapted these guidelines for their control interventions, which are more structured and detailed than usual care currently provided in UK GUM clinics.[12]

Experimental interventions explored many similar themes, including risk perception, barriers to safer sex, and triggers to unsafe sex. Individually based interventions concentrated on accepting and negotiating condom use[21 23] and personal goal setting,[15 20 24 26] using roleplay to develop skills.[20 24 26] In addition, group interventions explored self esteem in the context of social expectations[16 18 25] and increasing self efficacy.[16 22 28] Modelling behaviours and skills was an important aspect of many interventions.[16 17 19 22 25 28]

The two largest trials cited the theory of reasoned action and, less specifically, social cognition theory as the basis for

their interventions.[15 16] Social cognition theory asserts that attitudes to a behaviour, perceived support for that behaviour, and self efficacy determine intentions and subsequent actions.[31] Other investigators also cited cognitive models such as the health belief model[21] and AIDS risk reduction model,[22 24] which encourage participants to label themselves as vulnerable, commit to change, take action, and maintain change.[32] Three trials cited the information motivation behavioural skills model,[19 25 26] which asserts that personalised information, motivation, and behavioural skills are prerequisites of adopting protective behaviours.[31] Finally, two trials cited the transtheoretical model of behaviour change.[18 22] This represents change in terms of ordered stages allowing health promotion messages to be tailored to an individual's readiness to change.

Trial results and quantitative data synthesis
Laboratory confirmed STIs

Four out of nine trials considering this outcome observed a greater reduction in their intervention groups relative to controls,[15 16 22 25] a result that was statistically significant (p<0.05) for two.[15 22] Pooled results do not indicate an overall effect (RR 1.00 (95% confidence interval 0.81 to 1.23)). However, visual examination of the forest plot and statistical testing suggests heterogeneity between trials that prevents over-reliance on summary measures of effect (fig 2,
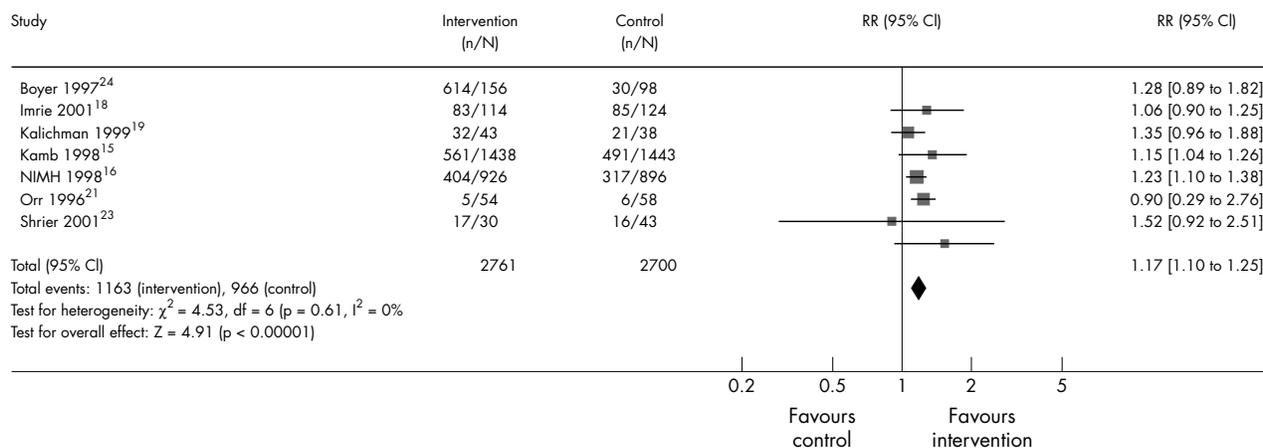
Figure 3 Results for consistent condom use (condoms used (nearly) always or no unprotected sex) at trial end points. CI, confidence interval; n, number of events; N, number of participants; RR, relative risk. Outcomes refer to self reported sexual behaviour for the previous 1–12 months. Results for Imrie relate to the previous 1 month.[16] Equivalent results for 12 months were RR 1.23 (95% CI 0.93 to 1.62).

p = 0.001). In addition, a funnel plot of these results suggests evidence of publication bias (see fig A on *STI* website www.stijournal.com/supplemental, p = 0.003 Egger test). One further trial also reported a statistically significant effect on reducing gonorrhoea and urethral discharge, but did not present the original data (reported RRs 0.39 and 0.36).[17]

Trials reporting significant effects had among the greatest adherence and follow up rates.[15 22] Generally, high quality trials were more likely to report a protective effect, though pooled results were not significantly different (high quality RR 0.89 (0.70 to 1.12), low quality RR 1.29 (0.89 to 1.87)).[15 16 20 22] Pooled results for trials enrolling both sexes[15 16 24 25] (RR 0.90 (0.78 to 1.04)) or young women[21 22] (RR 0.97 (0.41 to 2.32)) were greater than results for the remaining trials.[18 20]

Intervention format or length was not associated with trial results (group based RR 0.94 (0.70 to 1.25) versus individually based RR 1.16 (0.76 to 1.75)). Similarly, Kamb found that both brief and enhanced interventions were equally effective when compared to a short information session.[15] We did find evidence that the theoretical basis of interventions was related to effectiveness, though differences in pooled results were not statistically significant (social cognition models RR 0.91 (0.71 to 1.16) versus other trials RR 1.19 (0.84 to 1.68)). In addition, extensive formative research, including interviews, focus groups, input from community representatives, and pilot testing, was reported by the four most effective trials.[15 16 22 25]

Clinically diagnosed STIs

Four studies considered clinically diagnosed STIs (fig 2). One trial found no reduction in any individual diagnosis[25] while others observed greater STI rates in their intervention groups compared to controls.[18 20 24] Pooling of these results suggests an overall effect (RR 1.23 (1.01 to 1.50)) and there was no evidence of statistical heterogeneity (p = 0.58).

Self reported STIs

Two trials considered self reported diagnoses and found no significant effects.[23 26] However, one trial observed an effect on self reported symptoms that was greater than that for laboratory confirmed infections.[16]

Self reported condom use

Six out of seven trials reporting consistent condom use (condoms always used or used at every sexual encounter)

observed a greater increase in their intervention groups than controls.[15 16 18 19 23 24] Examination of the forest plot and statistical testing do not indicate heterogeneity between trials (fig 3, p = 0.61) and the pooled result suggests an overall effect (RR 1.17 (1.10 to 1.25)). In contrast with laboratory confirmed infections, there is no evidence of publication bias (see fig B on *STI* website www.stijournal.com/supplemental, p = 0.98 Egger test).

Pooled results do not suggest that effects were related to trial quality (high quality RR 1.19 (1.11 to 1.28) v low quality RR 1.12 (0.97 to 1.29)), intervention format (group based RR 1.18 (1.05 to 1.33) v individually based RR 1.16 (1.06 to 1.28)), intervention length, the use of theory, or formative research. Results for trials recruiting females (RR 1.40 (0.88 to 2.20)) were greater than for trials recruiting mixed populations (RR 1.19 (1.10 to 1.27)) or males alone (RR 1.14 (0.92 to 1.42)).

Five trials considered the proportion of sexual encounters protected by condoms.[16 19 22 24 28] Two found increased rates in intervention subjects relative to controls (table 2). Other trials reported inconsistent effects on refusing unsafe sex[19 28] and using condoms with recent partners.[23 24]

Sexual partners

Five out of seven trials reported fewer sexual partners among their intervention groups relative to controls (table 2),[17 22 24 26 28] while two reported fewer partners among controls.[19 25] Two of these trials also reported a reduction in sexual encounters with strangers or non-monogamous partners,[26] and more avoidance of sex with partners suffering from known STIs.[22] However, another intervention had no effect on homosexual men reporting unprotected sex with a partner of different or unknown HIV status.[18]

DISCUSSION

Several trials of behavioural interventions in sexual health clinic patients observed a greater reduction in laboratory confirmed STIs among their intervention groups relative to controls despite using different intervention formats in different populations. Successful trials were larger and of higher quality than those reporting no reduction in infection rates, and the most effective interventions were based on social cognition or related theoretical models and developed through extensive periods of formative research. We also found evidence that behavioural interventions increase consistent condom use, though effects on other aspects of sexual behaviour were inconsistent. There was no evidence

Table 2 Results for behavioural outcomes at trial end points (excludes consistent condom use, fig 3)

Trial	Outcome	Time period	Intervention group n/N or mean difference (SD)	Control group n/N or mean difference (SD)	Effect size (95% CI)
Balmer, 1998[17]	Number of new sexual partners	Not stated	Paper reports NS reduction (absolute risk difference −0.6 per 100 person months), however data not shown		
Boyer, 1997[24]	Proportion of sex acts protected by condoms	Entire study period (5 months)	−14.1% (47.7) N=121	−10.1% (47.3) N=133	MD −4.0% (−15.7 to 7.7)
	Sexual partners engaging in unprotected sex		−0.6 (SD not reported)	−0.4 (SD not reported)	MD −0.2 (paper reports p<0.05)
Branson, 1998[25]	Used condom with most recent sexual partner	Last 3 months	60/124	52/107	RR 1.00 (0.76 to 1.30)
	More than one sexual partner per month		32/124	24/107	RR 1.15 (0.73 to 1.83)
Imrie, 2001[18]	Most recent act of unprotected sex with partner of different/unknown HIV status	Entire study period (12 months)	15/31	18/39	RR 1.05 (0.64 to 1.72)
Kalichman, 1999[19]	Refused unsafe sex	Last 3 months	32/43	23/38	RR 1.23 (0.90 to 1.68)
	Acts of unprotected intercourse		−3.6 (12.1) N=43	−5.9 (29.2) N=38	MD −2.3 (−7.7 to 12.3)
	Proportion of sex acts protected by condoms		23.8% (32.2) N=43	21.3% (39.9) N=38	MD 2.5% (−12.1 to 17.1)
	Number of sexual partners		−0.8 (4.1) N=43	−2.8 (7.3) N=38	MD 2.0 (−0.1 to 4.1)
Metzler, 2000[26]	Frequency of intercourse and condom use Number of sexual partners and non-monogamous partners Sexual contacts with strangers	Entire study period (6 months)	Paper reports significant (p<0.05) decrease in sexual partners, non-monogamous partners, and contacts with strangers in intervention group relative to control, however data and effect size not shown		
NIMH, 1998[16]	Acts of unprotected intercourse	Last 3 months	−12.9 (47.6) N=926	−8.1 (58.8) N=896	MD −4.8 (−8.2 to −1.5)
	Proportion of sex acts protected by condoms		37.1% (34.4) N=926	26.1% (34.1) N=896	MD 11.0% (7.9 to 14.2)
O'Leary, 1998[28]	"Risky" sex acts	Entire study period (3 months)	−0.8 (11.1) N=292	−0.7 (9.3) N=180	MD −0.1 (−1.5 to 1.3)
	Proportion of sex acts protected by condoms		16.0% (44.0) N=292	17.0% (45.0) N=180	MD −1.0% (−9.3 to 7.3)
	Number of sexual partners		−1.1 (5.0) N=292	−0.5 (3.7) N=180	MD −0.6 (−1.2 to 0.0)
Orr, 1996[21]	Never uses condoms	Entire study period (6 months)	15/54	32/58	RR 0.50 (0.31 to 0.82)
	More than five acts of unprotected sex	Last 3 months	175/249	182/228	RR 0.88 (0.79 to 0.98)
Shain, 1999[22]	More than one sexual partner	Last 3 months	81/249	100/228	RR 0.74 (0.59 to 0.93)
	Avoiding sex with partner incompletely treated for STI or with STI symptoms		210/249	163/228	RR 1.18 (1.07 to 1.30)
Shrier, 2001[23]	Used a condom with most recent sexual partner	Entire study period (12 months)	18/30	18/34	RR 1.13 (0.74 to 1.74)
	Frequency of condom use		0.4 (SD not reported)	0.4 (SD not reported)	MD 0.1 (paper reports NS)
Solomon, 1989[27]	Redemption of condom coupons	Not stated	1.0 (0.6) N=89	0.8 (0.6) N=93	MD 0.2 (0.0 to 0.4)

CI, confidence interval; MD, mean difference; n, number of events; N, number of participants; NS, not statistically significant (p≥0.05); RR, relative risk; SD, standard deviation.

Key messages

- Interventions that could modify behaviour in GUM clinic patients (a high risk group) could play an important part in reducing recurrent STIs and thereby improve public health
- Two large high quality trials of behavioural interventions have demonstrated statistically significant reductions in STI rates despite using different intervention formats and targeting different populations
- Most trials also demonstrate an increase in self reported condom use, though effects on other aspects of sexual behaviour are inconsistent
- The most successful interventions were based on social cognition models and underwent careful development through extensive formative research. These results should be used to direct future research in a UK setting

that an intervention's success in reducing infections or increasing consistent condom use was related to its format or length.

One trial observed no difference in effect between a multiple session enhanced intervention and a two session brief one.[15] This brief intervention was similar to the control intervention used by many trials,[20–22 24 25] including one that successfully reduced infection rates.[22] In effect, the control groups in these trials received an intervention that goes beyond current UK practice, making it difficult to generalise results or transfer effect estimates to a UK settings.

The quality of identified studies was frequently poor. Masking is difficult to achieve in trials of behavioural interventions, but we did consider masking of outcome assessors in our quality assessment as this may reduce bias.[33] We included only RCTs in this review, which could have resulted in the omission of potentially relevant information. However, a suitable unbiased control group is essential to avoid ascribing sexual behaviour change to the effects of the intervention rather than the diagnosis of an STI itself.[32 33] In addition, we found evidence of publication bias for the primary outcome (laboratory confirmed infections), though we attempted to identify all publicly funded research in the United Kingdom.

Two previous reviews also reported inconsistent results, though they suggest that adherence rates and the development of an intervention through formative research were predictors of success.[9 10] We identified five trials not included in these reviews,[17 20 23 26 28] four of which report infection related outcomes, yet our findings suggest similar factors are important to an intervention's effectiveness. Formative research seeks to identify the behaviours, motivations, and beliefs within the target population that lead to increased risk, and link these to the key elements of an intervention.[10 32] The format, setting, delivery, and acceptability of the intervention can then be explored through pilot testing.[32] Theory may provide a framework for this process, though models do not specify the inclusion of particular elements within an intervention, and we also found evidence that effective interventions were more likely to be based on theoretical models relating behaviour to individual cognitions.

Trials appeared more effective at increasing (consistent) condom use than reducing infections. This could represent a chance event, or bias resulting from the different methods of ascertainment. Alternatively, small changes in condom use may be an insensitive marker of overall STI risk, which is the sum of many behavioural factors.[10 32] At the population level, increased condom use has been accompanied by increases in other risky sexual activities and a marked rise in infections.[3] Further analysis of the NIMH trial data also suggests that the number of sexual partners remains an important risk factor for gonorrhoea infection regardless of changes to condom use.[34] However, too few trials reported both behavioural outcomes alongside infection rates to explore this issue further.

This review highlights a need for research on behavioural interventions in a UK setting, where new approaches to reducing infection rates are urgently required. Heterogeneity between trials for the primary outcome of interest means that we cannot rely on simple summary measures of effect, but there is evidence that interventions can successfully change sexual behaviour and reduce infection rates if appropriately developed and targeted to a population. The success of interventions appears unrelated to their intensity. This is important, as the number of sessions is likely to be a major factor in determining cost. However, even the briefest intervention shown to be effective could not be introduced into routine GUM practice without further investment in premises, staff, and training. Information on the likely effect size, acceptability, and cost effectiveness of introducing behavioural interventions into the United Kingdom will be critical to those developing new services. However, this information cannot be simply extrapolated from existing evidence, which mainly derives from the United States. We propose that future studies should develop their experimental interventions by tailoring the approaches shown to be most effective in US settings, and crucially inform this process by a period of formative research that incorporates qualitative approaches. While this is likely to be time consuming and costly, without such an approach any proposed intervention is unlikely to be successful.

CONTRIBUTORS

The idea for the review was proposed by KWR, and the review was planned by DJW and RST with assistance from all authors; DJW developed the search strategy and together with BR undertook the searches, appraised the articles, and extracted the data; DJW analysed the data with the help of RST and HP; writing up the report was principally done by DJW with input from all members of the review team; in particular, RST advised on systematic review methods; HP advised on behavioural interventions, their theoretical basis and application, and KWR advised on sexual health and GUM clinic practice.

One supplementary table and two figures are on the STI website (www.stijournal.com/supplemental)

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REFERENCES

1 **Health Protection Agency,** SCIEH, ISD, National Public Health Service for Wales CDSC Northern Ireland, and the UASSG. *Renewing the focus. HIV and other sexually transmitted infections in the United Kingdom in 2002.* London: Health Protection Agency, 2003.
2 **PHLS,** DHSS&PS, and the Scottish ISD(D)5 Collaborative Group. *Sexually transmitted infections in the UK: new episodes seen at genitourinary medicine clinics, 1991 to 2001.* London: Public Health Laboratory Service, 2002.
3 **Johnson AM,** Mercer CH, Erens B, *et al.* Sexual behaviour in Britain: partnerships, practices, and HIV risk behaviours. *Lancet* 2001;**358**:1835–42.
4 **Department of Health.** *The national strategy for sexual health and HIV.* London: Department of Health, 2001.
5 **Department of Health.** *The national strategy for sexual health and HIV— implementation action plan.* London: Department of Health, 2002.
6 **House of Commons Health Committee.** Sexual Health. Volume I: report, together with formal minutes. Third report of session 2002–03 (HC69-I). London: House of Commons, 2003.
7 **Hughes G,** Andrews N, Catchpole M, *et al.* Investigation of the increased incidence of gonorrhoea diagnosed in genitourinary medicine clinics in England, 1994–6. *Sex Transm Infect* 2000;**76**:18–24.
8 **Ellis S,** Grey A. Prevention of sexually transmitted infections (STIs): a review of reviews into the effectiveness of non-clinical interventions. *Evidence briefing.* 1st ed. London: Health Development Agency, 2004.
9 **Elwy AR,** Hart GJ, Hawkes S, *et al.* Effectiveness of interventions to prevent sexually transmitted infections and human immunodeficiency virus in heterosexual men. *Arch Intern Med* 2002;**162**:1818–30.
10 **Stephenson JM,** Imrie J, Sutton SR. Rigorous trials of sexual behaviour interventions in STD/HIV prevention: what can we learn from them? *AIDS* 2000;**14**:s115–24.
11 **NHS Centre for Reviews and Dissemination, University of York.** *Undertaking systematic reviews of research on effectiveness. CRD Report Number 4.* 2nd ed. York: NHS Centre for Reviews and Dissemination, University of York, 2001.
12 **Ward DJ,** Rowe B, Pattison H, *et al.* Behavioural interventions to reduce the risk of sexually transmitted infections in genitourinary medicine clinic patients: a systematic review (www.pcpoh.bham.ac.uk/publichealth/wmhtac/reports.htm) Birmingham: West Midlands Health Technology Assessment Collaboration, University of Birmingham, 2004.
13 **Jadad AR,** Moore RA, Carroll D, *et al.* Assessing the quality of reports of randomized clinical trials: is blinding necessary? *Control Clin Trials* 1996;**17**:1–12.
14 **Follmann D,** Elliot P, Suh I, *et al.* Variance imputation for overviews of clinical trials with continuous response. *J Clin Epidemiol* 1992;**45**:769–73.
15 **Kamb ML,** Fishbein M, Douglas JMJ, *et al.* Efficacy of risk-reduction counseling to prevent human immunodeficiency virus and sexually transmitted diseases. A randomized controlled trial. *JAMA* 1998;**280**:1161–7.
16 **National Institute of Mental Health (NIMH) Multisite HIV Prevention Trial Group.** The NIMH Multisite HIV Prevention Trial: reducing HIV sexual risk behavior. *Science* 1998;**280**:1889–94.
17 **Balmer DH,** Gikundi E, Nasio J, *et al.* A clinical trial of group counselling for changing high-risk sexual behavior in men. *Counselling Psychology Quarterly* 1998;**11**:33–43.
18 **Imrie JM,** Stephenson JM, Cowan FM, *et al.* A cognitive behavioural intervention to reduce sexually transmitted infections among gay men: randomised trial. *BMJ* 2001;**322**:1451–6.
19 **Kalichman SC,** Cherry C, Browne-Sperling F. Effectiveness of a video-based motivational skills-building HIV risk-reduction intervention for inner-city African American men. *J Consult Clin Psychol* 1999;**67**:959–66.
20 **Maher JE,** Peterman TA, Osewe PL, *et al.* Evaluation of a community-based organization's intervention to reduce the incidence of sexually transmitted diseases: a randomized controlled trial. *Sex Transm Dis* 2003;**96**:248–53.
21 **Orr DP,** Langefeld CD, Katz BP, *et al.* Behavioral intervention to increase condom use among high-risk female adolescents. *J Pediatr* 1996;**128**:288–95.
22 **Shain RN,** Piper JM, Newton ER, *et al.* A randomized, controlled trial of a behavioral intervention to prevent sexually transmitted disease among minority women. *N Engl J Med* 1999;**340**:93–100.
23 **Shrier LA,** Ancheta R, Goodman E, *et al.* Randomized controlled trial of a safer sex intervention for high-risk adolescent girls. *Arch Pediatr Adolesc Med* 2001;**155**:73–9.
24 **Boyer CB,** Barrett DC, Peterman TA, *et al.* Sexually transmitted disease (STD) and HIV risk in heterosexual adults attending a public STD clinic: evaluation of a randomized controlled behavioral risk-reduction intervention trial. *AIDS* 1997;**11**:359–67.
25 **Branson BM,** Peterman TA, Cannon RO, *et al.* Group counseling to prevent sexually transmitted disease and HIV: a randomized controlled trial. *Sex Transm Dis* 1998;**25**:553–60.
26 **Metzler CW,** Biglan A, Noell J, *et al.* A randomized controlled trial of a behavioral intervention to reduce high-risk sexual behavior among adolescents in STD clinics. *Behavior Therapy* 2000;**31**:27–54.
27 **Solomon MZ,** DeJong W. Preventing AIDS and other STDs through condom promotion: a patient education intervention. *Am J Public Health* 1989;**79**:453–8.
28 **O'Leary A,** Ambrose TK, Raffaelli M, *et al.* Effects of an HIV risk reduction project in sexual risk behavior of low-income STD patients. *AIDS Educ Prev* 1998;**10**:483–92.
29 **Centers for Disease Control and Prevention.** Technical guidance on HIV counseling. *MMWR Recomm Rep* 1993;**42(RR-02)**.
30 **Centers for Disease Control and Prevention.** Sexually transmitted diseases treatment guidelines 2002. *MMWR Recomm Rep* 2002;**51(RR-06)**.
31 **Fisher WA.** A theory-based framework for intervention and evaluation in STD/HIV prevention. *Canadian Journal of Human Sexuality* 1997;**6**:105–11.
32 **Bonnell C,** Imrie J. Behavioural interventions to prevent HIV infection: rapid evolution, increasing rigour, moderate success. *Br Med Bull* 2001;**58**:155–70.
33 **Stephenson J,** Imrie J. Why do we need randomised controlled trials to assess behavioural interventions? *BMJ* 1998;**316**:611–13.
34 **Pinkerton SD,** Layde PMDW, Chesson HW, *et al.* All STDs are not created equal: an analysis of the differential effects of sexual behaviour changes on different STDs. *Int J STD AIDS* 2003;**14**:320–8.

Figure 4. Funnel plot for trials reporting change in laboratory confirmed STI rates (RR <1 indicates that infection rates were lower in the intervention group relative to controls).
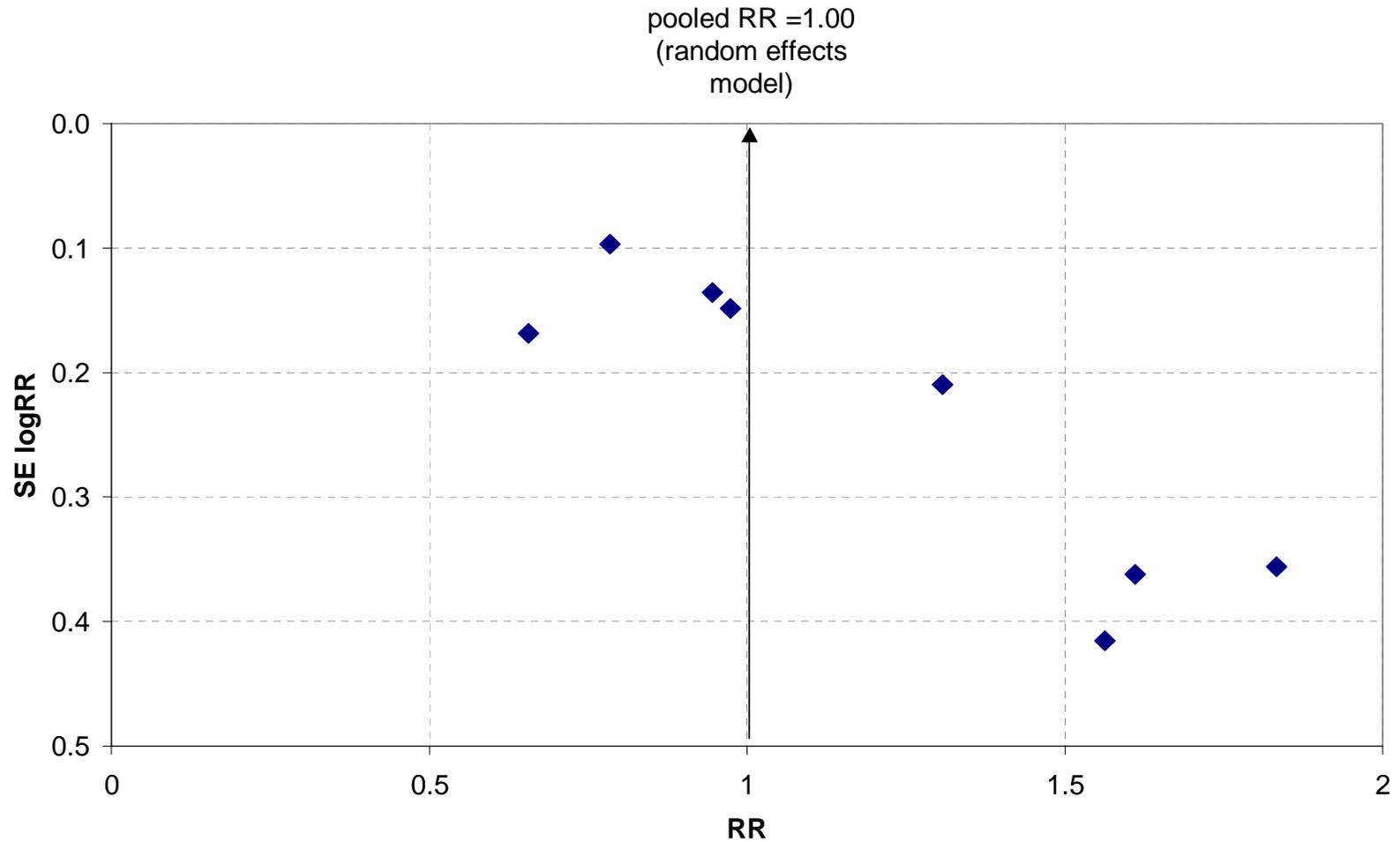
RR – relative risk, SE – standard error, logRR – natural logarithm of the relative risk

Figure 5. Funnel plot for trials reporting the proportion of participants reporting consistent condom use (RR >1 indicates that a greater proportion of the intervention group reported consistent use relative to controls).

pooled RR =1.17
(random effects
model)
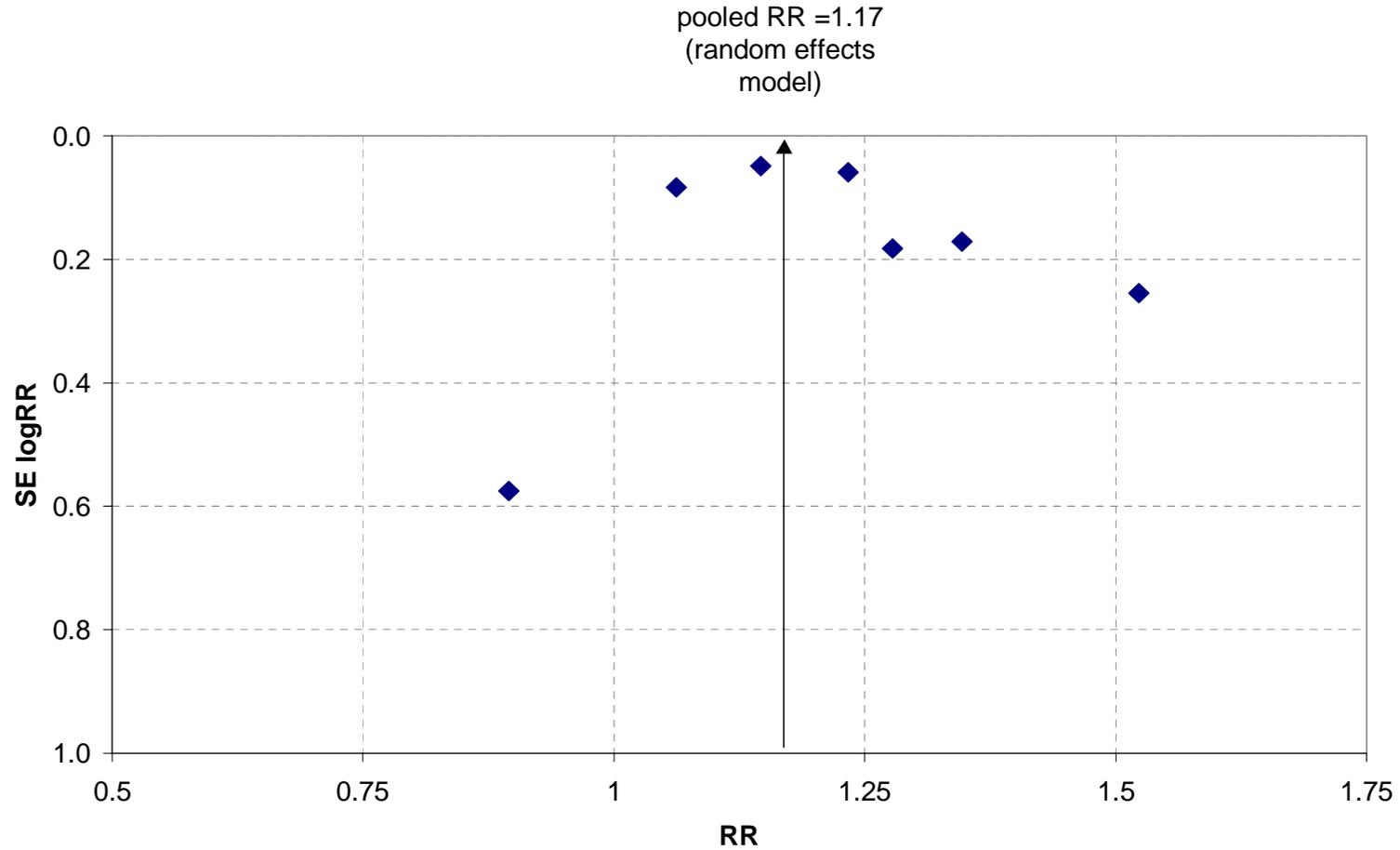
RR – relative risk, SE – standard error, logRR – natural logarithm of the relative risk

Supplemental table. Experimental and control interventions employed by trials.

Trial	Experimental intervention				Control intervention
	Theoretical basis and formative research	Format and length of intervention	Major elements or issues addressed	Adherence rate	
Balmer 1998[1]	Not stated	Small group format 26 weekly sessions (60mins each)	Motivation for behaviour, barriers to condom use and their solutions. Negotiation and condom use skills practiced using role-play	Not stated	Information & advice (usual care) plus free condoms
Boyer 1997[2]	AIDS Risk Reduction Model[3]	Individual format 4 weekly sessions (60mins each) including written information and video material	Information provision, assessing personal risk and triggers to unsafe sex and alternative approaches (partner choice, communication, reasons for refusal, self-efficacy and sources of support) and personal risk reduction plan. Skills practiced using scenarios and anatomical models	48%	One session of standardised counselling (usual care, 15mins)
Branson 1998[4]	Information Motivation Behavioral Skills Model.[5] Extensive formative research and pilot testing described	Mixed sex group format 4 sessions in 2 weeks, plus additional session at 2 months	Information provision, personal risk perception, responsibility and self-esteem, decision-making skills. Skills practiced using role-play and games	47%	Two sessions of standardised counselling (usual care, 2x20mins)

				71%	One session of standardised counselling (usual care, ≥20mins)
Imrie 2001[6]	Transtheoretical model of behaviour change and elements of other models.[3;6] Pilot study described	Single one-day group workshop (7 hours)	Information provision, goal setting, personal motivation, coping with anxiety and stress, dealing with high-risk situations and impulsive actions, body image, self-esteem, lifestyle balance and 'moving forward'. Issues addressed in exercises between pairs	71%	One session of standardised counselling (usual care, ≥20mins)
Kalichman 1999[7]	Information Motivation Behavioral Skills Model.[5] Extensive formative research described	Small group format 2 sessions (180mins each) including video material	HIV and AIDS information, condoms (attitudes and use) decision making, problem solving and risk triggers or barriers to safer sex. Skills practised using scenarios taken from popular film clips	85%	Two sessions of information provision including video material as for experimental group (180mins each)
Kamb 1998[8]	Theory of Reasoned Action, Social cognition theory.[3] Extensive formative research and pilot testing described	Individual format **Enhanced intervention** 4 sessions (1x20min and 3x60mins) **Brief intervention** 2 sessions (20mins each)	**Enhanced intervention** – sought to change key elements underlying condom use (self-efficacy, attitudes, perceived norms). Sessions included behavioural goal setting exercise **Brief intervention** – concentrated on actual vs. perceived risk, recognising barriers to safer sex, negotiate achievable plan, support self-initiated change. Sessions included behavioural goal setting exercise	72%	Two sessions of didactic information giving (5mins each)

Note: The first row header cell (Imrie 2001) merges with the content shown below it.

Maher 2003[9]	Theoretical basis not stated, but formative research and development of intervention described	Individual format 3 sessions within 30 days (1x60min plus 2x40-50mins)	Information provision, attitudes to and perception of risk, encourage STI screening and condom use, identify barriers to safer sex and strategies to overcome these and alternatives to intercourse. Identify support for behaviour change and community norms, and determine employment/educational plans. Practice negotiation skills	46% attended ≥2 sessions	Routine clinic counselling (usual care)
Metzler 2000[10]	Social cognition theory[3] and Information Motivation Behavioral Skills Model.[5] Reported to follow pilot work	Individual format 5 sessions (60-90mins each)	Review current behaviour, perceived risk, and personal goals. Work through individualised scenarios and identify effective ways of reducing risk. Reframe individual's avoidance of 'unpleasant feelings' accompanying change leading to acceptance. Practice and develop social skills including assertion, self-management, active listening, condom use, using behaviour modelling or role-play	68% attended ≥4 sessions	Brief counselling and advice (usual care)
NIMH 1998[11]	Theory of Reasoned Action, social cognition theory.[3] Extensive formative research and pilot testing described	Small group format 7 sessions, initially twice weekly (1x60mins plus 6x90-120mins), and including video material	Sought to influence factors critical to behaviour change, i.e. perceived risk of individual behaviours, perceived personal vulnerability, expectation of personal/social approval of adopting safer sex, acceptance of condoms. Develop skills and self-efficacy through behaviour modelling and personalised role-play (condom use, assertive, negotiation, identify and manage antecedents to unsafe sex). Sessions included goal setting and review	63% attended ≥6 sessions	Group education session as for initial experimental group session (1x60min)

O'Leary 1998[12]	Social cognition theory.[3] Reported as based on successful intervention in adolescents	Small group format 7 sessions totalling 10 hours	Information giving, perceived and actual risks, identifying and managing antecedents to risk behaviour, self-efficacy, condom use, negotiation, and maintenance strategies. Upbeat messages, fun games, behaviour modelling, scenarios and role-play used to develop skills and self-efficacy	Not stated	Brief counselling and information video (usual care)
Orr 1996[13]	Health Belief Model.[3]	Individual format Single session (10-20mins)	Information giving to increase perceived personal vulnerability and seriousness. Reduce barriers to condom use by practicing condom use, promoting positive attitudes and developing negotiation skills through rehearsing scenario	Not applicable	Personalised brief discussion and written information (usual care)
Shain 1999[14]	AIDS Risk Reduction Model.[3] Extensive formative research and pilot testing described	Small group format Three sessions over 3 weeks (3-4 hours each)	Recognise risk, commit to reducing risk, and identify strategies/skills to achieve this. Requires knowledge of STIs, risk behaviours, personal vulnerability, sources of support, perception of benefits and costs in making change. Develop social skills and self-efficacy through games, videos, behaviour modelling and role-play. Practice condom skills	82% attended ≥2 sessions	One session of brief individual counselling (15mins)
Shrier 2001[15]	Social cognition theory and Transtheoretical model of behaviour change.[3] Pilot study reported	Individual format Single session (30mins) following 7min video illustrating condoms as normative behaviour and negotiating their use	Self assess stage of change, then tailor discussion of condom use (pros and cons), STI information and personalised discussion of other sexual health topics. Practice condom skills and develop negotiation skills using role-play	95%	Brief session giving information and advice (usual care) plus free condoms

Solomon 1989[16]	Not theory based, but formative research and pilot study described	Small group format Single session viewing video. Condom coupons issued on leaving	Culturally specific video portraying condoms as socially acceptable normative behaviour. Focussing on interpersonal, negotiation and communications skills and attempts to make condoms more sexually appealing	Not applicable	Condom coupons given as for experimental group

1. Balmer DH, Gikundi E, Nasio J, Kihumo F, Plummer FA. A clinical trial of group counselling for changing high-risk sexual behavior in men. *Counselling Psychology Quarterly* 1998;**11**:33-43.

2. Boyer CB, Barrett DC, Peterman TA, Bolan G. Sexually transmitted disease (STD) and HIV risk in heterosexual adults attending a public STD clinic: evaluation of a randomized controlled behavioral risk-reduction intervention trial. *AIDS* 1997;**11**:359-67.

3. Bonnell C,.Imrie J. Behavioural interventions to prevent HIV infection: rapid evolution, increasing rigour, moderate success. *Br Med Bull* 2001;**58**:155-70.

4. Branson BM, Peterman TA, Cannon RO, Ransom R, Zaidi AA. Group counseling to prevent sexually transmitted disease and HIV: a randomized controlled trial. *Sex Transm Dis* 1998;**25**:553-60.

5. Fisher WA. A theory-based framework for intervention and evaluation in STD/HIV prevention. *The Canadian Journal of Human Sexuality* 1997;**6**:105-11.

6. Imrie JM, Stephenson JM, Cowan FM, Wanigaratne S, Billington AJP, Copas AJ *et al*. A cognitive behavioural intervention to reduce sexually transmitted infections among gay men: randomised trial. *BMJ* 2001;**322**:1451-6.

7. Kalichman SC, Cherry C, Browne-Sperling F. Effectiveness of a video-based motivational skills-building HIV risk-reduction intervention for inner-city African American men. *J Consult Clin Psychol* 1999;**67**:959-66.

8. Kamb ML, Fishbein M, Douglas JMJ, Rhodes F, Rogers J, Bolan G *et al.* Efficacy of risk-reduction counseling to prevent human immunodeficiency virus and sexually transmitted diseases. A randomized controlled trial. *JAMA* 1998;**280**:1161-7.

9. Maher JE, Peterman TA, Osewe PL, Odusanya S, Scerba JR. Evalution of a community-based organization's intervention to reduce the incidence of sexually transmitted diseases: a randomized controlled trial. *Sex Transm Dis* 2003;**96**:248-53.

10. Metzler CW, Biglan A, Noell J, Ary DV, Ochs L. A randomized controlled trial of a behavioral intervention to reduce high-risk sexual behavior among adolescents in STD clinics. *Behavior Therapy* 2000;**31**:27-54.

11. The National Institute of Mental Health (NIMH) Multisite HIV Prevention Trial Group. The NIMH Multisite HIV Prevention Trial: Reducing HIV sexual risk behavior. *Science* 1998;**280**:1889-94.

12. O'Leary A, Ambrose TK, Raffaelli M, Maibach E, Jemmot LS, Jemmott JBI *et al.* Effects of an HIV risk reduction project in sexual risk behavior of low-income STD patients. *AIDS Educ Prev* 1998;**10**:483-92.

13. Orr DP, Langefeld CD, Katz BP, Caine VA. Behavioral intervention to increase condom use among high-risk female adolescents. *J Pediatr* 1996;**128**:288-95.

14. Shain RN, Piper JM, Newton ER, Perdue ST, Ramos R, Champion JD *et al.* A randomized, controlled trial of a behavioral intervention to prevent sexually transmitted disease among minority women. *N Engl J Med* 1999;**340**:93-100.

15. Shrier LA, Ancheta R, Goodman E, Chiou VM, Lyden MR, Emans SJ. Randomized controlled trial of a safer sex intervention for high-risk adolescent girls. *Arch Pediatr Adolesc Med* 2001;**155**:73-9.

16. Solomon MZ,.DeJong W. Preventing AIDS and other STDs through condom promotion: a patient education intervention. *Am J Public Health* 1989;**79**:453-8.