TECHNICAL REPORT

Effectiveness of behavioural and psychosocial HIV/STI prevention interventions for MSM in Europe

ECDC TECHNICAL REPORT

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Abbreviations

ARD	Adjusted absolute risk difference
CBA	Controlled before-and-after study
CCT	Controlled clinical trials
CI	Confidence interval
ECDC	European Centre for Disease Prevention and Control
HAART	Highly active antiretroviral therapy
HIV	Human immunodeficiency virus
HIV/STI	Human immunodeficiency virus/Sexually transmitted infections
MSM	Men who have sex with men
RCT	Randomised controlled trial
RR	Risk ratio
SM	Sadomasochistic sex
STI	Sexually transmitted infections
UAI	Unprotected anal intercourse
UNAIDS	Joint United Nations Programme on HIV/AIDS
WHO	World Health Organization

Executive summary

Background: In the absence of an effective and affordable vaccine and non-curative abilities of current antiretroviral therapies, behavioural and psychosocial prevention with the goal of limiting sexual risk behaviours remains central to the efforts to decrease sexual HIV/STI transmissions among men who have sex with men (MSM). Given programme planners' and policymakers' need for descriptions of specific interventions and quantitative estimates of intervention effects to make informed decisions concerning prevention funding and research, there is a need for a systematic review that updates the current knowledge base about HIV/STI preventive interventions targeted at MSM in Europe.

Objectives: The aims were to summarise and assess the effectiveness of HIV/STI prevention interventions for MSM living in Europe and to identify intervention characteristics associated with effectiveness, as well as potential gaps, in the evidence base.

Methods: A systematic search for relevant literature in eight international databases and in reference lists of relevant reviews and included studies was performed. Studies were selected according to pre-specified criteria and appraised for risk of bias. We summarised results using tables and calculated effect estimates for sexual behaviour outcomes.

Results: Results were drawn from data of six controlled studies, involving a total of 4 111 participants at entry from four different European countries. The results showed that there was 'high' or 'unclear' risk of bias in one or more of the assessed domains in all studies. The pooled effect estimate of the four interventions for which data were available suggested that MSM who participate in HIV/STI prevention initiatives may be somewhat less likely to report unprotected anal intercourse (UAI). The evidence base was insufficient to examine characteristics of interventions most closely associated with magnitude of effect. Very few study participants had a non-white background and only one study used biological measurement of STI as an index of change.

Discussion: Despite the maturity of the HIV epidemic, rigorous outcome evaluations of any form of behavioural HIV/STI intervention for MSM in Europe are far and few between. The results point to possible short-term effects of interventions in terms of reductions in the proportion of MSM who engage in UAI, but the paucity of controlled studies indicates the need for research in this area. The scientific community should deliberate the potential for intervention transferability and ideally conduct extensive formative research prior to launching a new programme.

Conclusion: There is an overall deficit in outcome evaluations of interventions aimed at reducing HIV/STI risk behaviour among MSM in Europe. Designing behavioural HIV/STI preventive strategies to avert new infections, and the evaluation of such prevention programmes for MSM is an important component of a comprehensive HIV/STI containment strategy across the continuum of prevention and care.

1 Introduction

Across Europe, the HIV/AIDS epidemic has caused tremendous human suffering and financial loss as the number of new diagnoses of HIV infections has continued to increase: from 2000 to 2007, the annual rate of HIV infection increased from 39 to 75 per million population [1]. In Europe, men who have sex with men (MSM) continue to be the population most affected by HIV, and the rate of infections is increasing faster among MSM than among other populations [2,3]. In fact, in high-income European countries, MSM remain the group at highest risk for HIV [1]. Notably, the HIV epidemic exhibits very different patterns across regions of Europe. While MSM accounted for a disproportionate amount of transmissions in all regions in recent years, especially in the United Kingdom and in the Netherlands, heterosexual contact was the most common route of transmission in the West and Centre of Europe, while injection drug use was the main mode of transmission in the East of Europe [1].

Although HIV can be transmitted through four routes, unprotected sex remains the most frequent mode of transmission. There has been an increase in the rate of MSM who report unprotected anal intercourse (UAI). For example, in London, between 1998 and 2002 there was a doubling in the percentage of MSM reporting UAI with a casual partner of unknown or discordant HIV status, increasing from 7% to 16% [4]. Recent outbreaks of syphilis and gonorrhoea in several major European cities suggest a trend for increased sexual risk taking among MSM [5,6,7,8,9]. In fact, UAI remains the greatest risk factor identified for HIV transmission. A recent Australian study found that the odds of becoming infected with HIV were 57 times more likely among men who reported receptive UAI to ejaculation with casual partners compared to men who did not report such behaviour [10]. While receptive UAI to ejaculation with casual partners carries the greatest risk of HIV transmission, insertive UAI and sex without ejaculation with main or casual partners may also transmit HIV. Among some MSM, harm reduction strategies, such as strategic positioning, withdrawal before ejaculation, negotiated safety, and serosorting are used as imperfect means to reduce HIV transmission risk [11]. Serostatus assortive behaviour – where partners communicate that they are of the same HIV status and assume transmission is not a problem – is especially used as a risk reduction strategy, despite limited evidence that such harm reduction strategies actually decrease the likelihood of seroconversion [12]. Furthermore, individuals most recently infected may be the most infectious and least likely to know their serostatus, thus, reliance on own and partners' serostatus is an unsound strategy [13].

In the absence of an effective and affordable vaccine and non-curative abilities of current antiretroviral therapies, behavioural and psychosocial prevention with the goal of limiting sexual risk behaviours remains central to the efforts to decrease sexual HIV/STI transmissions among MSM [14]. Furthermore, while antiretroviral therapy treatments have tremendous life-saving potential, they are expensive and carry debilitating side effects for some people [15].

Behavioural and psychosocial HIV/STI risk reduction interventions to reduce unprotected sex among MSM range from individual level interventions – such as one-on-one counselling, peer education, counselling and testing, relationship training – to group level programmes – such as sexuality education, risk-reduction skills training – and community-level interventions – such as empowerment activities, chat room involvement, mass media campaigns [16,14]. Behavioural and psychosocial interventions to reduce unprotected sex among MSM are widely used and will continue to be vital in the battle against HIV/STIs; therefore, it is important to find out whether they help, harm or are ineffective.

The effectiveness of HIV/STI preventive interventions targeted at MSM has been assessed in various publications. Most recently, Johnson and colleagues' [17] systematic Cochrane review evaluated the effects of behavioural interventions to reduce risk for sexual transmission of HIV among MSM. The review included 58 RCTs, of which almost three quarters were from the United States (US). The review concluded that behavioural interventions for MSM reduce self-reported UAI; interventions reduced UAI by 27% compared to minimal or no HIV preventive intervention. Another important review, a review of reviews, assessed the effectiveness of behavioural interventions to reduce the sexual risk of HIV transmission among priority populations in the United Kingdom [18]. It identified two core reviews that were relevant to MSM: Oakley and colleagues [19] and Kegeles and Hart [20]. Taken together, these two reviews reported on 12 different intervention evaluations, most of which were group-level interventions, but there were also a few community-level interventions and one individual-level intervention. The review of reviews concluded that group- and community-level interventions can work, but it remained unclear as to whether individual-level interventions are effective in changing sexual risk behaviours [18].

A few other reviews have been published about the effectiveness of HIV prevention interventions, but most of these are not specific for MSM. For example, Stephenson and colleagues [21] identified seven robust trials of sexual behaviour interventions in HIV/STI prevention, but only one that was targeted at gay men. Weinhardt and colleagues [22] and Wolitski and colleagues [23] assessed the effectiveness of HIV counselling and testing programmes, while Kalichman and colleagues [24], who published the first meta-analytic review of the behavioural

outcome literature, confirmed that the effects of HIV risk-reduction interventions were encouraging. Furthermore, among 68 separate reports of outcome evaluations of behavioural HIV/AIDS prevention interventions summarised in 1995, only 11 concerned MSM and only nine covered Europe [25]. Lastly, Choi and Coates [26] critically reviewed the scientific literature on AIDS prevention programmes. According to their assessment, seven clinical intervention studies targeting men engaged in same-gender sex indicated that small group and community interventions produced some short-term behaviour change.

The majority of reviews have neither utilised a comprehensive search strategy nor clear inclusion criteria, and they have not been specific to MSM. When the target population comprised MSM in Europe, this group has not been the focus. In addition, many of them are out of date, being published before or shortly after the year 2000. This is important, since they consequently have included studies conducted before the advent of highly active antiretroviral therapy (HAART). There are reasons to believe that the impact of HAART has altered MSM's sexual risk behaviours [16], as evidenced by the rise in behaviours like barebacking [27], and interventions likely changed, accordingly, in order to be culturally responsive and relevant. It is also reasonable to question whether post-HAART interventions are as effective as pre-HAART interventions.

Therefore, there is a need for a systematic review that incorporates explicit inclusion criteria and that updates the current knowledge base about HIV/STI preventive interventions targeted at MSM in Europe. This systematic review may be useful for researchers, practitioners, and especially programme planners and policymakers who need descriptions of specific interventions and quantitative estimates of intervention effects to make informed decisions concerning prevention funding and research. The objectives of the systematic review were to:

- identify and describe outcome studies evaluating the effectiveness of HIV/STI prevention interventions on UAI for MSM living in Europe;
- summarise the effectiveness of HIV/STI prevention interventions for MSM in reducing unprotected anal sex, and, if available and possible, HIV/STI infections;
- identify intervention characteristics associated with effectiveness; and
- identify gaps in:
  – subpopulations targeted,
  – intervention characteristics incorporated,
  – outcomes evaluated, and
  – methodological matters.

2 Methods

Completion of the systematic literature review was in accordance with the Cochrane Collaboration standards [28], including a thorough search for empirical studies, screening of studies, extraction of data and summarisation and analysis of data.

2.1 Search methods for identification of studies

The primary method of study identification was electronic searches. Under the guidance of the author, a research librarian designed and executed the electronic database search (5 September 2009), which included eight databases: British Nursing Index, CENTRAL, EMBASE, MEDLINE, Pre-MEDLINE, PsycINFO, Sociological Abstracts and SveMed+. Databases were searched using a strategy incorporating subject headings (e.g. MeSH terms in MEDLINE) and text words, in title and abstract, relating to MSM (the population), sexual behaviour (the behaviour), and HIV/STI (the outcome). This search strategy had the advantage of not restricting the types of HIV/STI risk reduction interventions included. Due to the interest in an updated review, year of publication was limited to 2000 and later. Searches were not restricted by country or language (see Appendix 1). In addition, references in obtained reviews and included primary studies were scanned to identify new leads. Lastly, included studies were looked up in ISI Web of Knowledge (21 September 2009) in order to identify further studies. All identified references were imported to a Reference Manager database, which was used to keep track of references to be screened and inclusion status during the screening process.

2.1.1 Criteria for considering studies

Given that the review was designed to examine the effectiveness of behavioural and psychosocial HIV/STI interventions for MSM, we applied a model called PICO [29] with respect to inclusion criteria. The model considers four facets: Population, Intervention, Comparison, and Outcomes.

With respect to population, the intervention had to be received by MSM, who resided in the European region (defined as the 53 countries in the WHO European region [30]). For the purposes of this review, we defined MSM as men who have sexual relationships with other men, regardless of their sexual orientation or identification. This is because sexual behaviour does not always correspond to sexual orientation and sexual identity. For example, men who have sex with other men do not necessarily identify themselves as 'gay' although some or all of their sexual behaviour is 'homosexual' [31]. Thus, gay, homosexual, bisexual or heterosexually identified men who report engaging in sex with other men were considered MSM. We introduced the regional specification to ensure the included studies were clearly relevant for European-based research and intervention activities. We enforced no limitations on age, race/ethnicity, HIV status, nationality, or other participant characteristics.

All forms of behavioural and psychosocial interventions designed to promote safer sexual risk behaviours among MSM were eligible for inclusion. There were no restrictions in level or mode of delivery. Regarding types of comparisons, we accepted no intervention, minimal intervention, placebo psychotherapy, standard treatment or other active HIV/STI preventive intervention condition. We viewed studies in scope if they included measurement of at least one sexual behavioural or biological outcome indicative of HIV/STI transmission risk. Specifically, studies eligible for inclusion had to report intervention effects on either sexual behaviours among MSM understood to potentially transmit HIV/STI or a biological measure of new HIV infection or STI. We defined UAI as insertive or receptive anal intercourse that is engaged in without the use of a condom for part or the whole sexual act.

Study design was another important inclusion criterion. Non-random assignment is a potential threat to internal validity and the randomised controlled trial (RCT) is the design best suited reliably to assess effect of interventions [28]. However, a recent review found that intervention effects were in fact stronger in RCTs compared to studies with non-random assignment, offering reassurance that the inclusion of non-randomised studies may not introduce a bias in favour of non-randomised studies [17]. Thus, for this systematic review, eligible studies were those that, as a minimum, included two groups, of which at least one received an intervention, and for which baseline and follow-up measures were available. Specifically, we accepted RCTs, controlled clinical trials (CCTs), and controlled before-and-after (CBA) studies. We excluded studies that:

- included baseline and follow-up measures with no separate comparison condition;
- had only follow-up measures without baseline measures; and
- included only qualitative data.

Lastly, only publications written in English, German or one of the Scandinavian languages (Danish, Norwegian, Swedish) were included. To ensure that all included research was relatively new, we included only publications that were published in or after year 2000.

2.2 Selection of literature

Screening of literature was carried out in a three-stage procedure whereby each level consisted of increasing scrutiny of the studies based on the inclusion and exclusion criteria of the review. For level one screening, one reviewer read the title, and when available, abstract. Publications that unmistakably failed to meet the inclusion criteria were excluded, such as editorials or studies about lesbians. At level two screening, the abstract was evaluated for inclusion, using multiple screening questions. Publications meeting the inclusion criteria were promoted to level three screening and were obtained in full text. In reading the full text of each reference promoted to level three screening, the reviewer used a pre-developed inclusion form, based on the previously described inclusion criteria. Studies meeting all inclusion criteria were included, while studies that failed to meet one or more criteria were excluded, and assembled in a list of excluded studies.

2.3 Data extraction and analysis

Data from each included study were extracted using a pre-designed data extraction form. Information that was extracted and summarised included characteristics of the study, participants (e.g. age, serostatus), intervention (e.g. level, type, dose, mode of delivery) and control condition, as well as details about the outcome measures (e.g. UAI type of partner, insertive vs. receptive UAI, measurement tool). All data were entered twice and the accuracy of all data extracted by the main reviewer was checked, including data in tables, before analyses were initiated.

With respect to quality of the evidence, we used the Cochrane Collaboration's tool for assessing risk of bias, as described in chapter eight of the Cochrane Handbook for Systematic Reviews of Interventions [28]. Two reviewers assessed and agreed on six domains at study level: sequence generation, allocation concealment, blinding, incomplete outcome data, selective reporting and other potential bias. Two reviewers discussed and agreed about the adequacy of each risk of bias domain by assigning a judgement of 'yes' indicating low risk of bias, 'no' indicating high risk of bias, and 'unclear' indicating unclear or unknown risk of bias. Criteria set by the Cochrane handbook and adapted to the health promotion field were used to make these judgements. Next, statistical analyses were performed. Effects of interventions were estimated in two ways for binary outcome measures. One, by the adjusted absolute risk difference (ARD) in which the pre-post change score (in percentage points) in the control group was subtracted from the pre-post change score in the intervention group, and two, by the risk ratio (RR) and 95% confidence interval (95%CI) based on the post intervention data. It was also decided, *a priori*, to perform meta-analyses to estimate intervention effect. We used Mantel–Haenszel random effects meta-analyses because it was assumed that the intervention effects would vary across studies. All analyses were conducted using RevMan5 (the latest version of the Cochrane Collaboration's meta-analysis software). Any continuous measures would have been calculated as weighted mean differences or, when different scales were used, standardised mean differences, but no continuous measures were included. Where there were several follow-up times, we analysed them separately.

3 Results

The literature search resulted in 2 199 potentially relevant records (Figure 1).

Figure 1: PRISMA flow diagram of the literature reviewing process

Identification	**3 424 records identified through database searching** British Nursing Index 6 CENTRAL 56 EMBASE 1 017 MEDLINE 1 533 Pre MEDLINE 30 PsycINFO 735 Sociological Abstracts 45 SweMed+ 2 ISI Web of Knowledge 0	**1 additional record identified through other sources** Manual search 1
Screening	2 199 records after duplicates removed	
Eligibility	2 199 records screened → 2 166 records excluded	
Included	33 full text articles assessed for eligibility → 27 full text articles excluded, due to: – population not European MSM (18) – not outcome data from 2 groups (8) – not an effectiveness evaluation (1) **6 studies included in quantitative synthesis**	

We excluded 2 166 records, leaving 33 potentially relevant records, which were read in full text. We excluded 27 full text publications (see reference list) and included six studies presented in eight publications:

- Amirkhanian et al, 2005 [32];
- Elford et al, 2001 [33];
- Elford et al, 2000 [34];
- Flowers et al, 2002 [35];
- Flowers et al, 2000 [36];
- Harding et al, 2004 [37];
- Imrie et al, 2001 [38];
- van Kesteren et al, 2007 [39].

One study is unpublished (van Kesteren et al [39])[1].

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[1] One study identified in the search referred to a process evaluation and when the reviewer contacted the authors to ask whether an outcome evaluation had been conducted, the authors sent the write-up of the unpublished outcome evaluation.

3.1 Description of studies

Four of the included studies employed a randomised controlled (RCT) design [32,37,38,39], including two cluster RCTs [32,39], and the remaining two included studies were controlled before-and-after studies [33,35] (see Table 1).

Table 1. Description of included studies (N=6)

Author, year (data collected) (follow up)	Population characteristics				Intervention	Comparison	Outcome
	n	Residency	Age	HIV status			
RCTs							
Amirkhanian, 2005 (2003–2004) (3 months, 12 months follow-up)	276	Russia (St. Petersburg), Bulgaria (Sofia)	Mean 22.5	Not reported	Standard individual HIV risk-reduction educational counselling (20 min) + HIV prevention advice, by trained network leaders. Participants reported mean of 6.1 conversations about AIDS and 8 about safer sex	Wait list control usual care	UAI; UAI with multiple partners
Harding, 2004 (~2000) (2 months, 5 months follow-up)	50	England	Mean 41.5	22% HIV+, 57% HIV-, 20% untested	Course about SM sex. Four group sessions of 7h (total 28h), by volunteers at community-based, volunteer-led organisation	Wait list control	UAI
Imrie, 2001 (1995–1997) (6 months, 12 months follow-up)	343	England (London)	Median 29	Not reported	Standard 20 min sexual risk behaviour counselling + one day cognitive behavioural (group) workshop, by trained counsellors from STI clinic	Standard treatment (20 min counselling)	UAI; new STI
van Kesteren, 2007 (2004–2005) (3 months follow-up)	162	Netherlands	Mean 43.2	100% HIV+	Self-help booklet + motivational interview (face-to-face) + motivational interview (telephone), by HIV specialist nurses	Wait list control usual care	UAI with casual partner; UAI with steady partner
CBAs							
Elford, 2001 (1997–1999) (6 months, 12 months, 18 months follow-up)	1 004	England (London)	Mean 33.0	~15.5% HIV+	Gym-based HIV risk reduction education, by trained popular opinion leaders. 46 peers engaged on average 10 conversations each	No intervention	Status unknown UAI
Flowers, 2002 (1996–1999) (7 months follow-up)	2 276	Scotland (Glasgow, Edinburgh)	Mean 31.7	Not reported	Gay specific GUM services + sexual health info hotline + bar-based sexual health promotion, by trained peers. 42 peer educators interacted with 1 484 men, ~10 min each	No intervention	UAI with casual partner

Across the six studies data were collected over a decade, from 1995 to 2005, and publication dates varied accordingly, from 2001 to 2007. The included studies involved a total of 4 111 participants at entry (range 50–2 276) from four different European countries: Russia and Bulgaria [32], the Netherlands [39], and the United Kingdom [33,35,37,38].

The studies targeted gay and bisexual men[2] who either visited sexual health-related clinics [38,39], the commercial gay scene [32,33,35], or wished to attend a course about sadomasochistic (SM) sex [37]. One study specifically targeted young MSM [32], and across the studies most men were relatively young, with a mean age from 22.5 to 43.2. Three studies did not report participants' HIV status [32,35,38], while one study aimed to promote sexual health in HIV-positive MSM [39]. In the four studies that reported information about ethnic background [33,37,38,39], the populations were overwhelmingly white (about 90%).

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[2] Amirkhanian et al [32] included 55 women. The reason for this decision is not provided.

HIV/STI interventions for MSM eligible for inclusion in the review could be delivered to individuals, practices/offices, organisations/institutions or communities. Van Kesteren and colleagues' [39] self-help and motivational enhancement intervention was individual-based and consisted of a self-help guide, a face-to-face motivational interview and a motivational interviewing telephone call. Two interventions consisted of group sessions; one covered various aspects about SM sex [37], while the other was a cognitive behavioural workshop [38].

The remaining three studies were community-based and modelled after the popular opinion leader interventions developed by Kelly and colleagues [40,41] and Kegeles and colleagues [42,43]. Amirkhanian et al [32] trained 52 network leaders to 'establish regular HIV prevention communication between the leaders and their network members' (p. 1900) and encouraged them to talk with as many network members as possible. In the gym-based peer education intervention [33], popular opinion leaders engaged HIV risk reduction conversations with their gym peers. The leaders were asked to have at least 20 conversations during the five months of intervention, but few conversations with gay gym members occurred (average 10).

Lastly, Flowers and colleagues' [35] intervention consisted of mainly 'peer-led sexual health promotion conducted on the gay scene' (p. 103). In sum, not two interventions were identical, but the three peer-led, social behavioural interventions [32,33,35] were similarly modelled and two interventions were cognitive behavioural in nature [38,39]. Five of the interventions were theory-based. The study by Imrie and colleagues [38] drew from the transtheoretical model, the model of relapse prevention, social learning theory, and motivational interviewing; the study by van Kesteren and colleagues [39], from self-regulation theory and the cognitive behavioural model; and the three peer-based interventions [32,33,35] were based on the diffusion of innovations model.

With respect to intensity and duration (dose) of the interventions, this was not clearly ascertained from the publications, but the programmes appeared to have 'intervened' from one peer conversation of about 10 minutes duration to about 28 hours of education. Mode of delivery was in person, generally one-on-one, except:

- the motivational enhancement intervention [39], which also included bibliotherapy (self-help booklet) and a motivational interviewing telephone call; and
- the bar-based intervention [35], which also included a free-phone hotline providing sexual health information.

While the peer-led interventions naturally were delivered by peers, the SM education sessions were delivered by 'volunteer facilitators' at a community-based volunteer-led organisation [37], and the two cognitive behavioural interventions [38,39] were delivered by clinic staff.

Only one category of comparison was used in the six included studies: minimal to no intervention. Imrie and colleagues [38] used standard treatment at an STI clinic as comparison, which consisted of a 20 minute one-on-one counselling session about sexual risk behaviour. Three studies [32,37,39] placed the comparison group on a wait list.

The outcomes of interest in this review were behavioural or biological outcomes indicative of sexual HIV transmission risk between men. All the included studies had collected self-report data about UAI with men, with recall varying from one to 12 months, but the most common recall was three months. In most studies, UAI was not specified according to partner type (primary vs. casual), partners' serostatus or position (insertive vs. receptive), but one study [33] reported on status unknown UAI, and another [35] on UAI with casual partner. One study [38] included a biological measure of new STI infection (*Chlamydia* and gonorrhoea). The shortest follow-up was two months post intervention [37] and the longest was a re-assessment at 18 months [33]. Several studies incorporated multiple follow-ups [32,33,37,38].

3.2 Risk of bias in included studies

The risk of bias assessment comprised six domains: sequence generation, allocation concealment, blinding, incomplete outcome data, selective reporting, and other bias. We judged that there was 'high' or 'unclear' risk of bias in one or more of the assessed domains in all studies (see Figure 2).

Figure 2: Result of risk of bias assessment
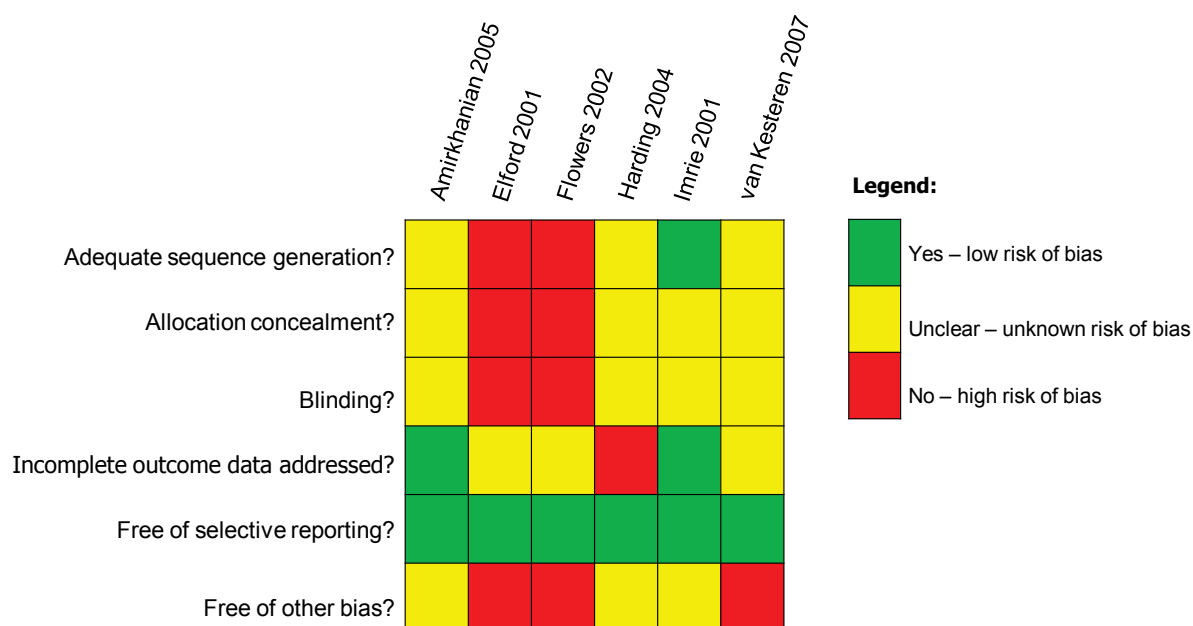
Note: Adapted from a figure produced in RevMan 5.

With respect to sequence generation, there was insufficient information in all studies, except Imrie et al [38], to judge whether it was adequate. Detailed results of the risk of bias assessment are presented in Appendix 2. Although blinding of participants and providers is usually not feasible for psychosocial types of interventions, blinding of assessor is, but none of the studies addressed this issue (except in Imrie et al [38], where screening of laboratory and clinic databases was done by blinded assessors). The issue of incomplete outcome data was adequately addressed in two studies [32,38] and unclear or insufficiently addressed in the remaining four studies because of high loss to follow-up that was neither balanced across conditions nor described, and absence of intent to treat analyses. Loss to follow-up at 2–6 months varied from 8% to 62%, and overall, loss to follow-up was higher in the intervention group. All studies were judged to be free of selective reporting. Lastly, we judged other risk of bias, including measurement and intervention exposure. All studies relied on self-reported measures of sexual risk, and one study [38] also included biological outcome measure of new STI. Whether the participants received the exposure of interest varied greatly. It was lowest in the gym-based study [33] – 3% of the participants reported having spoken to a peer educator during the intervention – and the bar-based intervention [35], where less than a third of the patrons said they had spoken to a peer educator. In conclusion, the proportion of information from studies at high risk of bias was sufficient to affect the interpretation of results.

3.3 Effects of HIV/STI prevention interventions for MSM

A priori we decided to focus our effectiveness analyses on UAI because it is the most epidemiologically pertinent behaviour for MSM in an HIV risk context [44], and likely to be included in most studies. UAI was reported as a dichotomous outcome (proportion of respondents reporting UAI during the recall period), thus, we calculated the adjusted absolute risk difference (ARD) and risk ratio (RR) with 95% confidence interval (95%CI) based on the post intervention data.

Two studies [37,39] did not provide data in sufficient detail for us to include them in analyses[3] and we reproduce the results of their significance tests. With respect to sexual risks, we could calculate effect estimates for six outcomes (multiple assessment points) across four studies (Table 2).

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[3] We contacted the authors with requests for data, but they were not received in time to allow for inclusion in this systematic review.

Table 2: Sexual risk behaviour outcomes at baseline and follow-up, and effect estimates for included studies

Author, year	Outcomes (follow-up)	Intervention		Control		Adjusted ARD	RR	95% CI for RR
		Pre (%)	Post (%)	Pre (%)	Post (%)			
RCTs								
Amirkhanian, 2005[a]	UAI (3 months)	57.3	35.5	54.5	57.7	25.0	0.62	0.47–0.81
	UAI with multiple partners (3 months)	22.6	9.7	17.4	16.2	11.7	0.60	0.31–1.17
	UAI (12 months)	57.3	39.5	54.5	50	13.3	0.79	0.59–1.05
	UAI with multiple partners (12 months)	22.6	7.6	17.4	16.1	13.7	0.47	0.22–0.99
Harding, 2004	UAI	Not stated		Not stated		–	No significant differences[b]	
Imrie, 2001	UAI (6 months)	37	24	30	32	15	0.74	0.50–1.10
	UAI (12 months)	37	27	30	32	12	0.86	0.58–1.29
	New STI (12 months)		31		21		1.66	1.00–2.74[c]
van Kesteren, 2007	UAI with casual partner	Not stated		Not stated		–	No significant differences[b]	
CBA studies								
Elford, 2001	Status unknown UAI (6 months)	13	11	15	14	1	0.79	0.57–1.10
	Status unknown UAI (12 months)	13	14	17	16	-2	0.88	0.63–1.23
	Status unknown UAI (18 months)	14	12	15	15	2	0.81	0.49–1.33
Flowers, 2002	UAI with casual partner (7 months)	38.9	35.4	36.3	37.4	4.6	0.95	0.78–1.11

Note: Pre- and post scores are reproduced from the study publication. We calculated change scores in percentage points, adjusted absolute risk difference (ARD) and relative risk (RR) with 95% confidence interval (CI).
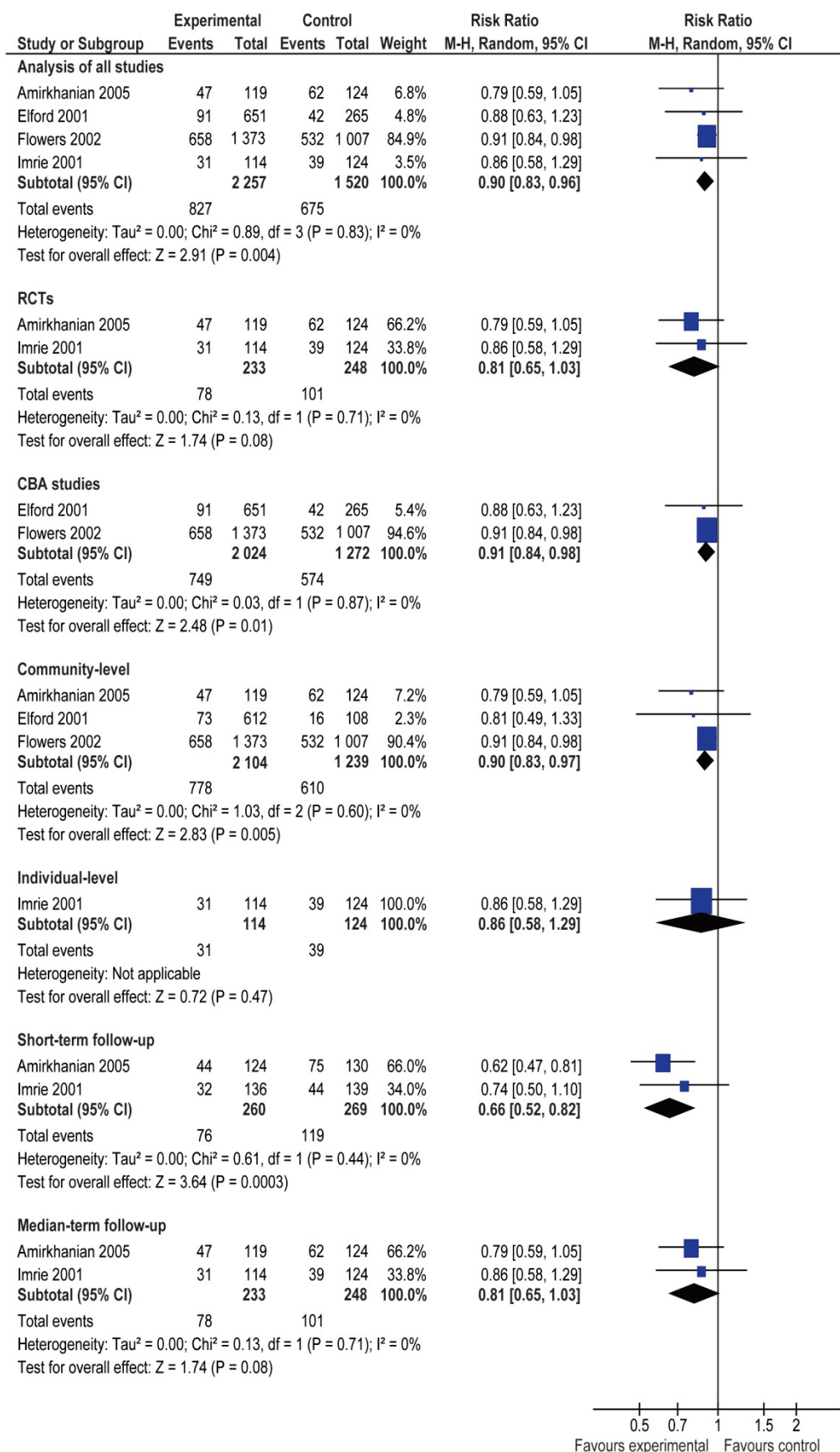*Legend:*
[a] n for various groups and outcomes were not given in Amirkhanian (2005) table1, therefore n is assumed as stated in text: at baseline, n=133 for intervention group and n=143 for comparison group; at three-month follow-up, n=124 for intervention group and n=130 for comparison group; at 12-month follow-up, n=119 in intervention group and n=124 for comparison group;
[b] stated in study publication;
[c] adjusted odds ratio reproduced from publication.

At study level, all ARD results indicated that the interventions had positive effect, i.e. from baseline to endline, the proportion of men who reported UAI declined more among men who participated in the interventions compared to men in the control groups. However, inspection of the effect estimates show that the majority (73%) of the outcomes failed to reach significance. One effect estimate was borderline significant. In the study by Imrie and colleagues [38], the proportion of men who were clinically diagnosed with a new STI at endline was higher in the intervention group than the control group (31% vs. 21%): the authors report that the adjusted odds ratio for new STI infection at 12-months follow-up was 1.66 (95%CI 1.00–2.74). Two effect estimates were significant. In the social network study [32], the proportion of men who engaged in UAI had declined significantly more in the intervention group (18.6 percentage points) than in the control group at three-months follow-up. Intervention participants were 38% less likely to report UAI than control participants (RR 0.62, 95%CI 0.47–0.81). Additionally, the proportion of men who reported UAI with multiple partners at 12-months follow-up was lower in the intervention group than the control group (RR 0.47, 95%CI 0.22–0.99).

We used Mantel-Haenszel random effects meta-analyses to estimate the intervention effect of the four interventions for which we obtained data. Collectively, the four interventions that were measured against minimal to no HIV prevention intervention appeared to reduce the probability of gay- or bisexually identified men engaging in UAI (Figure 3).

Figure 3: Forest plot of effect sizes, main effect and subgroup analyses for UAI

Study or Subgroup	Experimental Events	Experimental Total	Control Events	Control Total	Weight	Risk Ratio M-H, Random, 95% CI
Analysis of all studies						
Amirkhanian 2005	47	119	62	124	6.8%	0.79 [0.59, 1.05]
Elford 2001	91	651	42	265	4.8%	0.88 [0.63, 1.23]
Flowers 2002	658	1 373	532	1 007	84.9%	0.91 [0.84, 0.98]
Imrie 2001	31	114	39	124	3.5%	0.86 [0.58, 1.29]
Subtotal (95% CI)		**2 257**		**1 520**	**100.0%**	**0.90 [0.83, 0.96]**
Total events	827		675			
Heterogeneity: Tau² = 0.00; Chi² = 0.89, df = 3 (P = 0.83); I² = 0%						
Test for overall effect: Z = 2.91 (P = 0.004)						
RCTs						
Amirkhanian 2005	47	119	62	124	66.2%	0.79 [0.59, 1.05]
Imrie 2001	31	114	39	124	33.8%	0.86 [0.58, 1.29]
Subtotal (95% CI)		**233**		**248**	**100.0%**	**0.81 [0.65, 1.03]**
Total events	78		101			
Heterogeneity: Tau² = 0.00; Chi² = 0.13, df = 1 (P = 0.71); I² = 0%						
Test for overall effect: Z = 1.74 (P = 0.08)						
CBA studies						
Elford 2001	91	651	42	265	5.4%	0.88 [0.63, 1.23]
Flowers 2002	658	1 373	532	1 007	94.6%	0.91 [0.84, 0.98]
Subtotal (95% CI)		**2 024**		**1 272**	**100.0%**	**0.91 [0.84, 0.98]**
Total events	749		574			
Heterogeneity: Tau² = 0.00; Chi² = 0.03, df = 1 (P = 0.87); I² = 0%						
Test for overall effect: Z = 2.48 (P = 0.01)						
Community-level						
Amirkhanian 2005	47	119	62	124	7.2%	0.79 [0.59, 1.05]
Elford 2001	73	612	16	108	2.3%	0.81 [0.49, 1.33]
Flowers 2002	658	1 373	532	1 007	90.4%	0.91 [0.84, 0.98]
Subtotal (95% CI)		**2 104**		**1 239**	**100.0%**	**0.90 [0.83, 0.97]**
Total events	778		610			
Heterogeneity: Tau² = 0.00; Chi² = 1.03, df = 2 (P = 0.60); I² = 0%						
Test for overall effect: Z = 2.83 (P = 0.005)						
Individual-level						
Imrie 2001	31	114	39	124	100.0%	0.86 [0.58, 1.29]
Subtotal (95% CI)		**114**		**124**	**100.0%**	**0.86 [0.58, 1.29]**
Total events	31		39			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.72 (P = 0.47)						
Short-term follow-up						
Amirkhanian 2005	44	124	75	130	66.0%	0.62 [0.47, 0.81]
Imrie 2001	32	136	44	139	34.0%	0.74 [0.50, 1.10]
Subtotal (95% CI)		**260**		**269**	**100.0%**	**0.66 [0.52, 0.82]**
Total events	76		119			
Heterogeneity: Tau² = 0.00; Chi² = 0.61, df = 1 (P = 0.44); I² = 0%						
Test for overall effect: Z = 3.64 (P = 0.0003)						
Median-term follow-up						
Amirkhanian 2005	47	119	62	124	66.2%	0.79 [0.59, 1.05]
Imrie 2001	31	114	39	124	33.8%	0.86 [0.58, 1.29]
Subtotal (95% CI)		**233**		**248**	**100.0%**	**0.81 [0.65, 1.03]**
Total events	78		101			
Heterogeneity: Tau² = 0.00; Chi² = 0.13, df = 1 (P = 0.71); I² = 0%						
Test for overall effect: Z = 1.74 (P = 0.08)						

Risk Ratio M-H, Random, 95% CI
0.5 0.7 1 1.5 2
Favours experimental   Favours control

The pooled effect estimate of the four interventions suggested that MSM who participate in HIV/STI prevention initiatives were 10% less likely to report UAI (RR 0.90, 95%CI 0.83–0.96). The total MSM sample in these four interventions was 3 777. One study included 2 380 MSM, and consequently, the study contributed disproportional weight (84.9%) to the pooled effect estimate. In subgroup analyses, the pooled effect estimate showed that the result of the two interventions with design of highest internal validity (RCT) became non-significant (RR 0.81, 95%CI 0.65–1.03), while the result of the CBA studies was significant (RR 0.91, 95%CI 0.84–0.98), with one study (sample n=2 380) contributing disproportional weight (94.6%) to the pooled effect estimate. Similarly, the pooled effect estimate of the three community-level interventions reached significance (RR 0.90, 95%CI 0.83–0.97), with the study by Flowers and colleagues [35] contributing disproportionate weight (90.4%).

In subgroup analyses, the pooled effect estimate for the short-term effects (three to six months) of the two RCTs with least risk of bias suggested that MSM participating in HIV/STI interventions were 34% less likely to report engaging in UAI (RR 0.66, 95%CI 0.52–0.82). The effect was not significant at median-term follow-up (12 months) (RR 0.81, 95%CI 0.65–1.03).

3.3.1 Intervention characteristics associated with effectiveness

The characteristics of interventions most closely associated with magnitude of effect could not be examined due to the low number of studies included in this systematic review. At study level, the community-level, peer-based intervention in Russia/Bulgaria [32] reported positive significant effects, but the two community-level, peer-based interventions in the United Kingdom [33,35] did not. Similarly, the individual-level intervention in the Netherlands [39] found no support for positive effects, while the comparable study from England [38] concluded that 'analysis of the self-reported behavioural outcomes suggested a weak beneficial effect, but analysis of the clinical endpoints indicated that the intervention was more likely to be harmful' (p. 1455).

3.3.2 Gaps

The evidence base is insufficient to draw conclusions about unique gaps in the evaluation literature on HIV/STI interventions for MSM in Europe. Nonetheless, this systematic review found that among the six studies that were included, four targeted gay- and bisexually identified men in general, one study targeted HIV-positive MSM in particular, and one was aimed at young MSM. Very few participants had a non-white background (on average, no more than 10% in any study). Only one study used biological measurement of STI as an index of change. With respect to methodological matters, four of the studies used a randomised controlled design.

4 Discussion

This is the first systematic review to summarise and assess the effectiveness of HIV/STI prevention interventions for MSM living in Europe. It aimed to examine the extent to which psychosocial and behavioural interventions reduce UAI and HIV/STI infections, and to identify intervention characteristics associated with effectiveness as well as potential gaps in the evidence base.

The main finding of the review is the small proportion of HIV/STI prevention interventions for European MSM, which have been evaluated in such a way as to enable reliable conclusions about effectiveness. Among the six studies identified and included, the proportion of information from studies at high risk of bias was sufficient to affect the interpretation of results.

4.1 Effectiveness of HIV/STI prevention interventions for MSM

Six studies with a total sample of 4 111 MSM were identified and included in this systematic review. The meta-analysis results of four studies showed that one pooled effect size is most valid. The subgroup analysis for the short-term effects of the interventions by Amirkhanian and colleagues [32] and Imrie and colleagues [38] suggested that MSM participating in HIV/STI interventions were significantly less likely to report engaging in UAI than MSM in the control groups. An effect size associated with significant reduction in UAI was not found at 12-months follow-up. The findings mirror other high-quality reviews [14,17,24] showing that effects of non-U.S. interventions are limited and become attenuated over time. In stratified analyses of rate ratios for small group and individual-level interventions, a recent Cochrane review [17] found that while studies performed in the US yielded a net reduction of 22% in unprotected sex, studies performed elsewhere in the world showed a much smaller net reduction that was not statistically significant. Nonetheless, the findings in the current systematic review give cause for guarded optimism. The controlled studies included in this systematic review demonstrate that it is possible to successfully conduct rigorous HIV/STI prevention trials for MSM in Europe, and there may be some effect of interventions aimed at reducing HIV/STI risk behaviour among this population. However, the risk of bias in the body of evidence included affects the interpretation of these findings.

4.1.1 Characteristics associated with effectiveness

At study level, only the study by Amirkhanian and colleagues [32] and Imrie and colleagues [38] evidenced significant sexual risk reduction effects and weak beneficial effects, respectively. These effects were reflected in our meta-analyses of short-term effects but not long-term effects. Both studies were based on theory. This supports previous findings that interventions reporting a theoretical basis are associated with significantly greater reductions in UAI than interventions not based on theory [14,24].

Several of the other included studies also incorporated theory, which is encouraging. It is possible that the study by Amirkhanian and colleagues [32] may have worked better than the comparable diffusion of innovations-based studies from the United Kingdom because it relied on natural, intact social networks [45]. Furthermore, process evaluations run in tandem with the outcome evaluations of the British studies suggest barriers to implementation, enrolment and retention, which likely affected the outcome results. According to Elford and colleagues' process evaluation [4], the project was administratively complex and required a lot of time and input from the team (16.4 hours per week). Attrition of educators was a problem: only one in five of the enrolled peer educators remained with the project until the end, because of lack of time, interest or confidence in talking about sex. This limited the potential for programme diffusion. Only 3% of participants said they had talked to a peer educator. Thus, the researchers explain that it is quite likely that the critical mass required for diffusion was never established. In effect, the intervention did not actually take place.

Similarly, Flowers and colleagues' study [35] struggled with the fact that peer educators found it difficult to talk about safer sex behaviour. In this study, about a third of respondents said they had talked to a peer educator [46]. The small number of studies limits our ability to draw conclusions. If there were a dozen or twenty completed programmes to assess, we would be closer to understanding what makes an HIV/STI intervention for MSM in Europe successful.

4.1.2 Gaps

This review highlights an overall deficit in outcome evaluations of interventions aimed at reducing HIV/STI risk behaviour among MSM in Europe. While it is beyond the scope of this review to speculate about the reasons for the dearth of such outcome research, Wright [47] has suggested that research in Europe has traditionally been

concerned with macro-level changes in the form of legislative and structural policies, more so than with the results of specific interventions. This development, Wright reasons, is a reflection of the welfare state principles that have shaped social policy in Europe. In addition, the lack of sexual behaviour interventions that have been evaluated rigorously for European MSM likely reflects the challenges involved in trialling complex interventions for sexual behaviours [21], where causal pathways of unsafe sexual behaviour are neither linear nor static, and where difficulties regarding implementation, recruitment, and retention must be overcome. Although solid trials require considerable investment and skill, the resources involved are small in comparison with the amount spent on unevaluated interventions and treatment [21].

It is not presently possible to know which unique gaps in the evaluation literature on HIV/STI interventions for MSM in Europe exist. Nonetheless, it should be noted that all but one of the six included studies are from Western Europe; four of them were set in the United Kingdom. One study specifically targeted young MSM and one was aimed at HIV-positive MSM. Furthermore, the samples were overwhelmingly white MSM. Non-white MSM appear to be underserved. Only one study included a biological outcome measure.

4.2 Implications for future behavioural HIV/STI interventions for MSM

Almost 30 years into the HIV epidemic, it is disheartening to find so few behavioural HIV/STI prevention interventions that have been rigorously evaluated for MSM in Europe. The paucity of controlled studies indicates the need for research in this area: more and better outcome evaluations of HIV/STI prevention interventions for MSM living in Europe are needed. The development, careful evaluation and rapid dissemination of intervention strategies must be the cornerstone of preventative health promotion in this area, because changing sexual risk behaviours will remain important until – and likely after – a widely available and affordable prophylactic vaccine is developed.

That the scientific community needs to expand the evidence base about HIV/STI prevention interventions for MSM living in Europe with controlled trials is not to say that researchers should rely exclusively on RCTs as a means of evaluating interventions. While there is no reliable substitute for evaluating the effect of interventions than controlled trials [48,28,20,25,21], other designs such as interrupted time-series designs can be used. Researchers who are concerned about the ethics of allocation to experimental groups can use waiting list controls whereby the control group receives the potential beneficial intervention post-data collection. The drawback is the difficulty of establishing long-term effectiveness of the intervention [25]. Not only a variety of research designs is needed to illuminate the effectiveness of HIV/STI prevention strategies, but it also remains important to apply qualitative methodologies and integrate process assessment into the evaluation design in order to learn about feasibility, acceptability, practical constraints and related issues. To establish solid evidence-based health promotion for MSM at risk of HIV infection, we need to know what went wrong, as well as what went right, in interventions. Researchers and journal editors should strive to disseminate also null findings and related issues in intervention research [20]. Four of the six included studies reported null effect. It is important to note that designing behavioural HIV-preventive strategies to avert new infections, and the evaluation of such prevention programmes for MSM, is only one component of a comprehensive HIV/STI containment strategy across the continuum of prevention and care.

Three of the included studies in this review were modelled after a diffusion of innovation-based interventions with persuasive evidence of effectiveness in the US [42,43,40,41]. While the study in Russia/Bulgaria produced sexual risk behaviour change, the two in the United Kingdom did not. This highlights challenges with respect to transferability and the value of formative research. As explained by Elford and Hart [16], we cannot expect that an intervention successful in one setting at one moment in time will necessarily be repeated successfully in another. It seems prudent for future programme planners to carefully deliberate the potential for intervention transferability and ideally to conduct extensive formative research prior to launching a new programme.

Stephenson and colleagues [21] argue the importance of formative research, stating that 'some degree of formative research is required in each new setting to … determine the appropriateness of the intervention and make modifications if necessary' (p. S122). Making sure that preventive strategies are reflective of national and regional traditions and politics, as well as cultural attitudes, seems part of the key to successful interventions. Among countries in Europe there are many similarities with respect to cultural attitudes about sexual behaviours, but there are also many differences. For example, as standardised data from the International Social Survey programme [49] show, 'sexual conservative' countries (with stronger than average level of disapproval for all forms of non-marital sex) included Northern Ireland, Poland and the Republic of Ireland. In contrast, a cluster of countries with higher than average level of acceptance for homosexuality and premarital sex, termed 'homosexual permissives', included the Czech Republic, the Netherlands, Norway and Spain. Not only should formative research ensure that interventions are appropriate to the current political and social climate, it should also make sure that

interventions have appeal and a culturally relevant programme content to address the HIV prevention needs of MSM subgroups.

It is not presently possible to conclude which type of intervention is most effective for MSM living in Europe. However, given the landscapes of homosexual behaviour in different areas embody different sexual cultures, and the rapidly changing sexual contexts in which MSM engage in unsafe sex, it seems that the prevention community needs to continually adapt to these evolving dynamics of MSM's sexual lives. As an example, the changing patterns of sexual behaviour in many MSM communities include a trend towards barebacking, serosorting and use of recreational drugs, like Viagra and crystal meth, to enhance the sexual experience [50,51]. A recent meta-analysis showed that high-risk sexual behaviour was more likely among MSM who sought partners online than those who did not [52]. Second-generation internet-based interventions have been evaluated in the US, and there is some documentation showing that such strategies are being developed in Europe [53], but most internet-based interventions have not been developed beyond the proof-of-concept stage [54]. In the end, to be effective, preventive strategies should be diverse, reflective of local politics, traditions, cultural attitudes and the evolving sexual marketplace of the different micro-communities of MSM, and each country and area needs to find its own way to reach at-risk MSM [55].

The current evidence base about the effectiveness of behavioural HIV/STI interventions for MSM living in Europe is too limited to tell what is the smallest 'dose' of an intervention that will produce sustained behavioural effects. The 'dosage' of the six interventions included in this systematic review was relatively small, and may not have offered sufficient input to induce change. One-off workshops or conversations often lack the necessary in-depth support to change sexual behaviour patterns [24]. Lasting change requires reinforcement over a period of time. Previous reviews have found that sustained interventions over several sessions are more likely to result in greater risk reduction [26]. As Kalichman and colleagues [24] explain, longer interventions provide greater exposure time, an opportunity to space intervention components, the possibility to use homework assignments, and more social support opportunities and social reinforcement. On the other hand, single-sessions are more feasible and may be more accepted by the target population. The cognitive behavioural intervention by Imrie and colleagues [38] was intended as a multi-day workshop but 'in a pilot study using an intervention spread across three occasions, too few men had attended all sessions' (p. 1452) and a one-day workshop was therefore used. Often, intervention dosage becomes a resource issue, as longer lasting interventions are more demanding [26].

As far as possible, prevention professionals should strive to design culturally relevant interventions with an intended target group through a combination of formative research and pilot evaluations. Interventions shown to be promising should then be evaluated in larger trials that emphasise clinical HIV/STI outcomes, and not just rely on self-reported changes in cognitions and behaviours [21].

With respect to outcomes, cognitive processes are not necessarily prerequisites for behaviours and, as self-reported behavioural outcomes, tend to overestimate intervention benefits [21,56]. Measurement of unprotected sex appeared to be acceptable in the six studies included in this review, but because risk assessment for HIV transmission by self-report is inherently idiosyncratic – unsafe sex with a casual partner of unknown antibody status is different from UAI within a monogamous relationship – it would be important to specify UAI according to partner type (i.e. primary vs. casual) and partners' serostatus, as done by two of the included studies [33,35].

One alternative suggested by Newman and colleagues [57] is to use new technology, such as computer-assisted self-assessment, to improve the veridicality of self-reported sexual behaviours. As far as possible, it is advisable that future intervention studies complement self-reported behavioural measures with more objective biological outcomes in assessments of intervention effectiveness. This would assess potential harms as well as benefits. Of the six included studies in this systematic review, only one included clinical outcomes and it found that incidence of STI significantly increased in the intervention group compared to the control group. Imrie and colleagues [38] state that screening of asymptomatic infection was not part of the original study protocol because they believed it would affect recruitment, but the return of specimens by post worked well. Researchers explain that while it is entirely possible to include HIV antibody status as an index of change, the low base rate of HIV (and STI) infection requires extremely large sample sizes to obtain adequate statistical power for detecting differences, and such testing therefore becomes too resource- and time intensive [24].

A few observations regarding length of follow-up, delivery, and implementation and adherence conclude the discussion about completeness of evidence. First, multiple follow-up assessments allow for an evaluation of the longevity of effectiveness and should be attempted. Several of the included studies in this systematic review did, but the longest follow-up was 18 months. Ideally, since incidence of HIV/STI infections is the most important and reliable outcome and changes cannot be reliably measured in a short time period, long-term follow-up of several years is desirable. In the cognitive behavioural intervention included in this review [38], the intervention was delivered by counsellors rather than psychologists with skills in cognitive behavioural interventions. The 'message bearer' used in this study may have affected the results. Researchers should consider who delivers the intervention. Lastly, implementation and adherence are typically difficult to measure in multi-component

intervention programmes [58], but provide critical information about the programme. For example, Elford and colleagues' [59] process evaluation helped explain the likely reasons for lack of programme effectiveness. Future evaluations of HIV prevention interventions should strive to include measurements of programme exposure and fidelity, including procedures used to promote fidelity, aspects of intervention verified, and methods for assessing fidelity.

In sum, what seems clear is that the expertise of Europe as a whole is needed in order to develop effective HIV/STI interventions for MSM, and research needs to be driven by planning imperatives. Overall recommendations for future work include the importance of developing and evaluating behavioural HIV/STI prevention interventions for MSM using controlled designs and relevant programme content, as well as dissemination of evaluations showing negative and positive results.

5 Strengths and limitations of this review

This systematic literature review was conducted according to the Cochrane Collaboration [28] standards, which includes several strengths:

- a clearly stated set of objectives;
- an explicit, reproducible methodology;
- a systematic search that attempted to identify all studies that would meet the eligibility criteria;
- an assessment of the validity of the findings of the included studies by assessment of risk of bias; and
- a systematic presentation, and synthesis, of the characteristics and findings of the included studies.

A further strength is that controlled studies were evaluated, i.e., studies that can reliably say something about effects of interventions. Additionally, meta-analyses were conducted to synthesise independent and diverse studies to derive an overall estimate of effectiveness of interventions, allowing also for an exploration of differences across studies.

Findings must be viewed within the context of the limitations of the available evidence and this systematic review. Only six studies that met the inclusion criteria were identified and retrieved. Meta-analysis statistics reflect all the weaknesses of the original literature it reviews, and the included studies all had 'high' or 'unclear' risk of bias in one or more of the assessed domains.

The GRADE (Grades of Recommendation, Assessment, Development and Evaluation) system was not used for grading the quality of the evidence for outcomes in included primary studies [28]. Application of this tool would have provided a statement about the extent to which one could be confident that an estimate of effect or association was close to the quantity of specific interest. Likely, due to the included studies' within-study risk of bias, directness, and precision of effect estimates, the result would have been 'low' quality of the evidence for all outcomes. The reviewer was not at any screening level blinded to the authors or other information about the publication when assessing the studies. It is unlikely that this had any impact on the results of the systematic review because the reviewer had no pre-conceptions about the study authors and have not personally conducted any HIV/STI prevention studies with MSM living in Europe.

Lastly, only recent publications (since 2000) in five languages were included in the literature search because of resource limitations. While it is possible that the resulting search may have excluded relevant studies, this does not seem likely because the reviewer inspected 14 related literature reviews, which had no publication year or language restrictions [26,18,14,55,60,17,20,24,19,25,21,61,22,23], and no other behavioural HIV/STI outcome evaluations for MSM in Europe were identified. Other behavioural HIV/STI interventions for MSM in Europe exist. The author assembled a list of such interventions, but they were not considered in scope for this systematic review because they did not report outcome data for an intervention and comparison group, hence reliable estimates of effectiveness were not available.

6 Conclusion

This systematic review of the effectiveness of interventions designed to reduce sexual risk behaviour among MSM living in Europe identified six studies that met the inclusion criteria. There was 'high' or 'unclear' risk of bias for one or more of the assessed domains in all studies, and the proportion of information from studies at high risk of bias was sufficient to cause doubt about the validity of the findings. Nevertheless, the results point to possible short-term effects of interventions in terms of reductions in the proportion of MSM who engage in UAI.

The main finding is that despite the maturity of the HIV epidemic, rigorous outcome evaluations of any form of behavioural HIV/STI intervention for MSM in Europe are far and few between. Evaluating the effectiveness of interventions poses significant challenges to the scientific community, but if we are to have evidence-based policies and practices to prevent HIV/STI among MSM in the decades to come, additional behavioural interventions with accompanying outcome evaluations should be implemented.

Interventions should have individuals, groups and communities as targets, be preceded by formative research so as to ensure their relevance to the evolving dynamics of MSM's sexual lives, strive for biological outcomes alongside behavioural measures, and include multiple follow-up assessments. Evidence from this systematic review demonstrates that it is possible to successfully conduct rigorous HIV/STI prevention studies for MSM in Europe that meet these criteria – they indicate sexual risk behaviour change – and such studies should to a greater extent become part of a comprehensive continuum of behavioural and biomedical HIV/STI prevention and care.

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Carrico AW, Chesney MA, Johnson MO, Morin SF, Neilands TB, Remien RH, et al. AIDSBehav 2009,13(3):555-563.

Dilley JW, Woods WJ, Loeb L, Nelson K, Sheon N, Mullan J, et al. Brief cognitive counseling with HIV testing to reduce sexual risk among men who have sex with men: results from a randomized controlled trial using paraprofessional counselors. J Acqui Immune Defic Syndr 2007;44(5):569-577.

Hoff CC, Pals SL, Purcell DW, Parsons JT, Halkitis PN, Remien RH, et al. Examining the role of partner status in an HIV prevention trial targeting HIV-positive gay and bisexual men: The Seropositive Urban Men's Intervention Trial (SUMIT). AIDS Behav 2006;10(6):637-648.

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Velasquez MM, von Sternberg K, Johnson DH, Green C, Carbonari JP, Parsons JT. Reducing sexual risk behaviors and alcohol use among HIV-positive men who have sex with men: A randomized clinical trial. J Consult Clin Psychol 2009;77(4):657-667.

Woods WJ, Sabatino J, Bauer PL, Adler B, Dilley JW, Binson D. HIV testing in gay sex clubs. Int J STD & AIDS 2000;11(3):173-175.

Excluded because there were not outcome data from two groups:

Amirkhanian YA, Kelly JA, Kabakchieva E, McAuliffe TL, Vassileva S. Evaluation of a social network HIV prevention intervention program for young men who have sex with men in Russia and Bulgaria. AIDS Educ Prev 2003;15(3):205-220.

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French R, Power R, Mitchell S. An evaluation of peer-led STD/HIV prevention work in a public sex environment. AIDS Care 2000;12(2):225-234.

Harding R, Dockrell MJ, Dockrell J, Corrigan N. Motivational interviewing for HIV risk reduction among gay men in commercial and public sex settings. AIDS Care 2001;13(4):493-501.

Huebner DM, Binson D, Woods WJ, Dilworth SE, Neilands TB, Grinstead O. Bathhouse-based voluntary counseling and testing is feasible and shows preliminary evidence of effectiveness. J Acqui Immune Defic Syndr 2006;43(2):239-246.

Schwappach DLB, Bruggmann P. An integrated model of care to counter high incidence of HIV and sexually transmitted diseases in men who have sex with men – initial analysis of service utilizers in Zurich. BMC Public Health 2008;8:180.

Williamson LM, Hart GJ, Flowers P, Frankis JS, Der GJ. The Gay Men's Task Force: the impact of peer education on the sexual health behaviour of homosexual men in Glasgow. Sex Transm Infect 2001;77(6):427-432.

Ziersch A, Gaffney J, Tomlinson DR. STI prevention and the male sex industry in London: evaluating a pilot peer education programme. Sex Transm Infect 2000;76(6):447-453.

Excluded because it was not an outcome evaluation:

Bailey AC, Roberts J, Weatherburn P, Hickson FCI, Reid DS, Fisher M, et al. Community HIV testing for men who have sex with men: Results of a pilot project and comparison of service users with those testing in genitourinary medicine clinics. Sex Transm Infect 2009;85(2):145-147.

Appendix 1: Literature search in MEDLINE

Database: MEDLINE
Date: 03.09.2009
Retrieved: 1533

Strategy:

1. Homosexuality, Male/
2. Bisexuality/
3. homosexual$.tw.
4. bisexual$.tw.
5. gay$.tw.
6. men who have sex with men.tw.
7. msm.tw.
8. bareback$.tw.
9. or/1-8
10. Unsafe Sex/
11. ((unsafe or high-risk or unprotected) adj2 sex$).tw.
12. or/10-11
13. HIV Infections/
14. hiv.tw.
15. or/13-14
16. Sexually Transmitted Diseases/
17. (sexual$ adj3 transmi$).tw.
18. (sti or stis or std or stds).tw.
19. or/16-18
20. 15 or 19
21. 9 and 12 and 20
22. Sexually Transmitted Diseases/pc [Prevention & Control]
23. HIV Infections/pc [Prevention & Control]
24. 22 or 23
25. 9 and 24
26. 21 or 25
27. 21 or 25
28. limit 27 to yr="2000 - 2009"

The MEDLINE search strategy served as the model for the other database searches using appropriate controlled vocabulary as applicable. The search strategies are available by contacting the corresponding author (rigmor.berg@nokc.no).

Appendix 2: Risk of bias assessment

The Cochrane Collaboration's tool for assessing risk of bias was used in this systematic review (Table 3).

Table 3: **Cochrane Collaboration's tool for assessing risk of bias**

Domain	Description	Review authors' judgement
Sequence generation	Describe the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.	Was the allocation sequence adequately generated?
Allocation concealment	Describe the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment.	Was allocation adequately concealed?
Blinding of participants, personnel and outcome assessors	Describe all measures used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.	Was knowledge of the allocated intervention adequately prevented during the study?
Incomplete outcome data	Describe the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. State whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomised participants), reasons for attrition/exclusions where reported, and any re-inclusions in analyses performed by the review authors.	Were incomplete outcome data adequately addressed?
Selective outcome reporting	State how the possibility of selective outcome reporting was examined by the review authors, and what was found.	Are reports of the study free of suggestion of selective outcome reporting?
Other sources of bias	State any important concerns about bias not addressed in the other domains in the tool. If particular questions/entries were pre-specified in the review's protocol, responses should be provided for each question/entry.	Was the study apparently free of other problems that could put it at a high risk of bias?

Source: Higgins and Green, 2008 [28].

Table 4: **Results of risk of bias assessment for each included study (N=6)**

Domain	Judgement	Description
Study: Amirkhanian, 2005		
Adequate sequence generation?	Unclear	'Eligible networks were then randomised, in equal numbers and within each city, to experimental and control conditions.'
Allocation concealment?	Unclear	'Eligible networks were then randomised, in equal numbers and within each city, to experimental and control conditions.'
Blinding?	Unclear	Blinding of participants and providers usually not feasible for this type of intervention. Insufficient information about assessors to permit judgement.
Incomplete outcome data addressed?	Yes	Loss to follow-up 8% (I 6.8%, C 9.1%) (3 months), 12% (I 10.5%, C 13.3%) (12 months), relatively balanced between groups, reasons for loss not addressed. Not ITT.
Free of selective reporting?	Yes	The published article included all expected outcomes based on the stated objective.
Free of other bias?	Unclear	Only self-report measures. 'No baseline differences across conditions were found.' Different unit of allocation (network) and unit of analysis (individual). Received exposure of interest: participants reported mean of 6.1 conversations with friends about AIDS and 8 about safer sex in past 3 months.

Domain	Judgement	Description
Study: Elford, 2001		
Adequate sequence generation?	No	Controlled before-and-after study. 'For administrative reasons the randomisation of gyms was not feasible.'
Allocation concealment?	No	As above.
Blinding?	No	Controlled before-and-after study. It is not stated whether assessor was blinded.
Incomplete outcome data addressed?	Unclear	Response rate 51% (baseline), 47% (6 months), 49% (12 months), 39% (18 months), not balanced between groups, reasons for refusal suggested. ITT not applicable.
Free of selective reporting?	Yes	The published article included all expected outcomes based on the stated study purpose.
Free of other bias?	No	Only self-report measures. Not stated whether there were baseline differences across conditions. Received exposure of interest: 46 peer educators (27 remained with the project) engaged on average 10 conversations, 3% of participants said they had spoken to a peer educator during the intervention.
Study: Flowers, 2002		
Adequate sequence generation?	No	Controlled before-and-after study. 'The evaluation of the GMTF [Gay Men's Task Force] involved a quasi-experimental, two-by-two, repeat cross-sectional design.'
Blinding?	No	Controlled before-and-after study. It is not stated whether assessor was blinded.
Allocation concealment?	No	As above.
Incomplete outcome data addressed?	Unclear	Response rate in intervention city 77% (baseline), 75% (35 months), in control city 80% (baseline), 80% (35 months), not balanced between groups, reasons for refusal not addressed. ITT not applicable.
Free of selective reporting?	Yes	The published article included all expected outcomes based on the stated study purpose.
Free of other bias?	No	Only self-report measures. There were baseline differences across conditions. Received exposure of interest: 42 peer educators engaged in 1 484 conversations (average 10 min each), 29.4% (n=424) reported having spoken to a peer educator, 25% of calls to hotline were genuine, gay-specific genito-urinary medicine services observed increase in new clients.
Study: Harding, 2004		
Adequate sequence generation?	Unclear	'Participants were randomised to either intervention or waiting list control.'
Allocation concealment?	Unclear	'Participants were randomised to either intervention or waiting list control.'
Blinding?	Unclear	Blinding of participants and providers usually not feasible for this type of intervention. Insufficient information about assessors to permit judgement.
Incomplete outcome data addressed?	No	Loss to follow-up 36% (I 28%, C 44%) (2 months), 62% (I 68%, C 56%) (5 months), not balanced between groups, reasons for loss not addressed. Not ITT.
Free of selective reporting?	Yes	The published article included all expected outcomes based on the stated study aim.
Free of other bias?	Unclear	Only self-report measures. 'No significant group differences on any variable were found at baseline.' Received exposure of interest: 3 men (12%) did not attend all 4 sessions.

Domain	Judgement	Description
Study: Imrie, 2001		
Adequate sequence generation?	Yes	'Participants were randomly allocated using sealed opaque envelopes.'
Allocation concealment?	Unclear	'Participants were randomly allocated using sealed opaque envelopes.'
Blinding?	Unclear	Blinding of participants and providers usually not feasible for this type of intervention. Assessors partially blind to participants' allocation.
Incomplete outcome data addressed?	Yes	Loss to follow-up 19.5% (I 21.7%, C 17.3%) (6 months), 28.9% (I 33.7%, C 23.8%) (12 months), not balanced between groups, reasons for loss addressed. ITT.
Free of selective reporting?	Yes	The published article included all expected outcomes based on the stated study objective.
Free of other bias?	Unclear	Self-report measures and biological measure. Whether there were baseline differences across condition was not addressed. Received exposure of interest: 'Of the 175 men allocated to the intervention, 124 (71%) attended.'
Study: van Kesteren, 2007		
Adequate sequence generation?	Unclear	'Eight HIV treatment centers were randomly assigned to the intervention group and eight to the waiting list control group.'
Allocation concealment?	Unclear	'Eight HIV treatment centers were randomly assigned to the intervention group and eight to the waiting list control group.'
Blinding?	Unclear	Blinding of participants and providers usually not feasible for this type of intervention. Insufficient information about assessors to permit judgement.
Incomplete outcome data addressed?	Unclear	Loss to follow-up 16.7% (I 20.6%, C 14.1%) (3 months), not balanced between groups, reasons for loss not addressed. Not ITT.
Free of selective reporting?	Yes	The write-up (unpublished document) included all expected outcomes based on the stated study objective and hypotheses.
Free of other bias?	No	Only self-report measures. There were baseline differences across conditions. Different unit of allocation (clinic) and unit of analysis (individual). Received exposure of interest: 60% reported reading most of self-help guide, 85% participated in motivational interview, 40% received follow-up motivational interview phone call.

ITT = Intention to treat analysis; Not ITT = ITT analysis not used.