EDITORIAL REVIEW

Do prevention interventions reduce HIV risk behaviours among people living with HIV? A meta-analytic review of controlled trials

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Objective: To conduct a meta-analytic review of HIV interventions for people living with HIV (PLWH) to determine their overall efficacy in reducing HIV risk behaviours and identify intervention characteristics associated with efficacy.

Methods: Comprehensive searches included electronic databases from 1988 to 2004, hand searches of journals, reference lists of articles, and contacts with researchers. Twelve trials met the stringent selection criteria: randomization or assignment with minimal bias, use of statistical analysis, and assessment of HIV-related behavioural or biologic outcomes at least 3 months after the intervention. Random-effects models were used to aggregate data.

Results: Interventions significantly reduced unprotected sex [odds ratio (OR), 0.57; 95% confidence interval (CI) 0.40–0.82] and decreased acquisition of sexually transmitted diseases (OR, 0.20; 95% CI, 0.05–0.73). Non-significant intervention effects were observed for needle sharing (OR, 0.47, 95% CI, 0.13–1.71). As a whole, interventions with the following characteristics significantly reduced sexual risk behaviours: (1) based on behavioural theory; (2) designed to change specifically HIV transmission risk behaviours; (3) delivered by health-care providers or counsellors; (4) delivered to individuals; (5) delivered in an intensive manner; (6) delivered in settings where PLWH receive routine services or medical care; (7) provided skills building, or (8) addressed a myriad of issues related to mental health, medication adherence, and HIV risk behaviour.

Conclusion: Interventions targeting PWLH are efficacious in reducing unprotected sex and acquisition of sexually transmitted diseases. Efficacious strategies identified in this review should be incorporated into community HIV prevention efforts and further evaluated for effectiveness.

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Keywords: HIV/AIDS prevention, behavioural intervention, HIV transmission risk behaviour, risky sex, needle sharing, people living with HIV

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Introduction

Historically, prevention efforts have primarily focused on HIV-seronegative or untested people. Working effectively with people living with HIV (PLWH) has become increasingly important in the era of expanded treatment access [1–7]. Without prevention to help PLWH to adopt and maintain healthier and safer behaviours, the growing number of people living longer with HIV forms a potential source of infection [1,2] and may facilitate the evolution and spread of drug resistance [8,9]. While many PLWH eliminate or reduce behaviours that may expose others to HIV [10–14], a considerable percentage (ranging from 10 to 60% depending on type of behaviours, recall period, and partner's serostatus) do not consistently practice safer behaviours [15–23], thus placing others at risk for HIV infection and themselves at risk for sexually transmitted infections (STI) and possible superinfection with other strains of HIV [24]. Although interventions designed primarily for uninfected persons have been shown to reduce self-reported HIV risk behaviours [25–28], it is not known whether interventions for PLWH are similarly efficacious.

This systematic review synthesizes the available literature on prevention interventions for reducing risky sex and needle-sharing behaviours in PLWH. The goal was to locate and describe controlled trials that rigorously evaluated the effects of interventions for PLWH. The present study expands the scope of earlier qualitative reviews [5,29,30] by conducting meta-analyses to assess quantitatively the overall efficacy of interventions in reducing HIV risk behaviours of PLWH and to identify intervention characteristics associated with efficacy.

Methods

Database and search strategy

As part of the HIV/AIDS Prevention Research Synthesis project at the US Centers for Disease Control and Prevention (CDC), five search strategies were implemented to identify published or unpublished interventions reported in English or non-English languages. First, a comprehensive search of electronic bibliographic databases was conducted including AIDSLINE (1988 to discontinuation in December 2000), EMBASE, Medline, PsycINFO, CINHAL and SocioFile from 1988 through 2004. Standardized search terms were cross-referenced (keywords and medical subject heading terms) reflecting four constructs: (a) HIV, AIDS, STI, (b) prevention intervention evaluation, (c) target population (i.e., PLWH) and (d) behavioural or biological outcome. Second, a hand search was conducted of 30 key journals from June 2002 to December 2004, using the same constructs as in the electronic database searches. Third, searches were made in on-line trial registry databases (i.e., Cochrane Controlled Trials Register, EPPI-Centre Education Database, Current Controlled Trials Register, and the US National Institutes of Health CRISP database) and the websites of international organizations that fund HIV/AIDS prevention programs worldwide (i.e., World Health Organization, UNAIDS, USAID, Family Health International, Kaiser Family Foundation). Fourth, HIV researchers were contacted to obtain unpublished manuscripts and upcoming publications. Finally, the references of all pertinent reports were reviewed for additional citations.

Trial selection

Interventions were included if they met all of the following criteria: (a) HIV/AIDS or STI behavioural interventions specifically designed for PLWH; (b) data collected on at least one HIV-related behavioural outcome (i.e., unprotected insertive or receptive anal intercourse, unprotected vaginal intercourse, condom use, needle or works sharing) or biological outcome (i.e., acquisition of STI or hepatitis B or C); (c) at least one follow-up assessment at 3 months (or longer) after the completion of the intervention, a practice recommended for demonstrating sustainable effects of an intervention [31]; (d) randomized controlled trials (RCT) [32] or controlled trials with designs that minimized systematic bias associated with non-randomization [33–35] (trials were excluded if they explicitly allowed participants to self-select into the intervention or if they provided intervention to only one group and assessed effect on the basis of behavioural change of the participants from before to after the intervention); and (e) data were necessary and sufficient for calculation of effect sizes.

Authors were contacted to obtain additional information before trials were excluded [36,37].

Data abstraction

Information from eligible reports was independently abstracted by pairs of trained reviewers. Linkages among reports were identified to ensure that multiple reports describing an intervention were included in the coding. Using standardized coding forms, each intervention was coded for trial information (e.g., intervention dates, city/country), participant characteristics (e.g., sexual orientation, injection drug use, disease stage, age, gender, race/ethnicity), intervention features (e.g., theory, content, delivery method, duration, setting), and outcomes (e.g., type of behaviour, behaviour recall period, follow-up time). The methodological quality was assessed by coding: assignment method, type of control group, participation rate, overall and differential retention, and intent-to-treat [31]. There was 91% agreement between reviewers across all variables. Discrepancies were reconciled through discussion.

Effect size calculation

Effect sizes were estimated with odds ratios (OR) because the majority of the trials compared two groups on a

dichotomous outcome. For trials reporting means and SD values on continuous outcomes, standardized mean differences were calculated to be converted into OR values [38]. An OR < 1 indicates a greater reduction in odds of a risky behaviour in the intervention group relative to the comparison group.

Standard meta-analytical methods [38–40] were used. The natural logarithm was used to obtain log OR and its corresponding weight (i.e., inverse variance) was calculated for each trial. To estimate the overall effect size, each log OR value was multiplied by its weight; the weighted log OR values were summed across trials and then divided by the sum of the weights. The magnitude of heterogeneity of the effect sizes was tested using the Q statistic. The final aggregation was based on a random-effects model, which provides a more conservative estimate of variance and generates more accurate inferences about a population of trials beyond the set of trials included in this review [41]. The aggregated log OR was then converted back to OR by exponential function and a 95% confidence interval (CI) was derived.

Analytic approach

The following rules were used to guide effect size abstraction for estimating the overall intervention effect.

Multiple intervention arms. To meet the independence of the effect size assumption, the contrast between the condition expected to have the greatest (e.g., enhanced intervention) and the least (e.g., standard of care) influence in producing intervention effects was selected, usually hypothesized by the author. If no hypothesis was indicated, the first group discussed in detail in the report was used as the intervention condition for analysis.

Multiple HIV risk behaviours. Separate analyses were conducted for sexual behaviours, needle sharing and biological outcomes. If multiple sex behaviours were reported, the behaviour representing the greatest risk of HIV transmission was selected (e.g., unprotected insertive anal intercourse). If a trial reported sexual behaviour data for two or more types of partner, the analysis focused on sex with at-risk partners (e.g., HIV-seronegative or serostatus-unknown partners) rather than HIV-seropositive or all partners.

Multiple follow-ups. In order to evaluate the long-term intervention effects on behavioural change, data collected at the longest follow-up were selected for calculating the overall effect size estimate.

Although the need for adjustment is much less in RCTs than non-RCTs, an adjusted analysis is more conservative, especially when one or more prognostic variables (e.g., baseline risk behaviours) may impact outcomes of interest [39,42]. Data were used from adjusted models reported by the authors for effect size calculation because baseline differences of potential confounding variables are typically controlled in these models. Otherwise, effect sizes were calculated for the follow-up outcome data by adjusting for baseline differences.

Sensitivity analyses were conducted to determine the robustness of intervention effects by assessing whether the overall results were sensitive to the aforementioned decision rules to guide effect size calculation. The overall effect size was recalculated using all available contrasts between study arms, different sexual behaviour outcomes (type of sex, type of partner) and data without adjustment for baseline behaviour. In addition, the combined effect size estimate among all trials was compared with the estimate obtained after excluding a trial (or set of trials) that might influence the overall estimate.

Stratified analyses, via random-effects models, determined whether methodological quality or particular characteristics of the interventions were associated with efficacy. Publication bias that may favour trials with significant findings was ascertained by inspection of a funnel plot of standard error estimates versus effect size estimates from individual samples [40] and also by a linear regression test [43]. The results of both tests suggested no evidence of publication bias (not shown).

Results

Twelve controlled trials that met the inclusion criteria (Fig. 1) are summarized in Table 1. All 12 trials were conducted in the United States and most trials were carried out after 1996 when HAART became available. One trial specifically targeted HIV-seropositive women only [44], while the remaining 11 trials consisted of 100% or majority male participants. Four trials [45–48] included samples that were more than two-thirds men who have sex with men and three trials [49–51] specifically targeted injection drug users or substance abusers. The median age across all study samples was 35 years (range, 20.7–41). Among the trials reporting participants' health and medical status, the median length of time diagnosed with HIV ranged from 2 to 6 years [44–47,52,53]; the percentage of AIDS cases ranged from 9 to 50% [46,48–50,53], and the percentage on HIV treatment ranged from 50 to 100% [47–50,54].

Ten trials [44–51,54,55] were RCTs while two trials [52,53] were non-RCTs with minimal assignment bias. The median participation rate was 83.5% of eligible persons (range, 38–100) and the median retention rate was 72% (range, 50–90) at the longest follow-up assessment (median, 6.5 months; range, 3–12). All trials used intent-to-treat for data analysis.

Regarding intervention characteristics, most trials were guided by behavioural theories including social cognitive

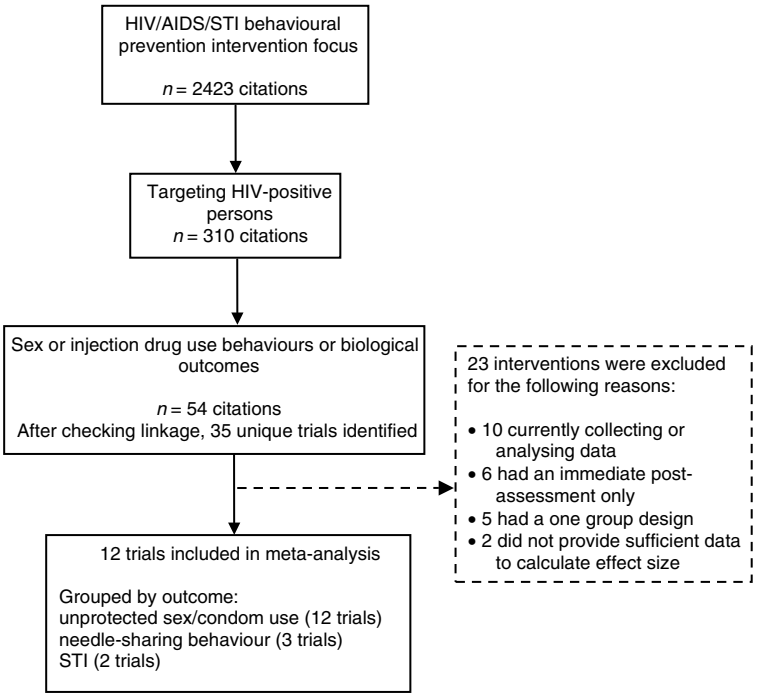

Fig. 1. Study selection process. STI, sexually transmitted infection.

theory/social learning theory [56], cognitive–behavioural coping [57], information–motivation–behavioural skills model [58] and theory of planned behaviour [59]. All interventions provided information to increase HIV knowledge and motivated participants to eliminate or reduce risky drug use and/or sexual practices. Nine interventions [44–46,48–50,53–55] provided skill building through multiple activities, including live demonstrations, role plays or practice. The skills included technical (e.g., correct use of condoms or needle cleaning), personal (e.g., coping, problem solving) or interpersonal skills (e.g., communication about safer sex, harm reduction negotiation, disclosing one's seropositive status).

The interventions were commonly delivered by health-care providers/counsellors (75%) or peers (41%), delivered to small groups (67%) with 5–10 persons, and in settings where HIV-seropositive individuals receive services (e.g., outpatient clinics, community service centres, 58%). Two trials [47,51] provided on-going intervention activities to the participants (e.g., every time participants visited the clinic). For the remaining 10 trials, the number of intervention sessions ranged from 3 to 48 sessions; the amount of time to deliver the intervention ranged from 4.5 to 48 h; and, the total time span of the intervention ranged from 2 weeks to 1 year.

Overall efficacy of interventions

The overall weighted effect size estimate based on the 12 interventions indicated a significant reduction in odds of unprotected sexual behaviour assessed at the longest follow-up in the intervention group relative to the comparison group (OR, 0.57; 95% CI, 0.40–0.82; $n = 2719$). Although Fig. 2 shows the heterogeneity of trials ($Q_{11} = 35.25$; $P < 0.001$), sensitivity tests did not reveal any single trial that exerted influence on the overall effect size. The overall effect size estimate was robust as it remained significant when using data from multiple intervention contrasts, different sex outcomes, or without adjustment for baseline behaviour.

For the STI outcome (acquisition of chlamydia or gonorrhoea) [44,48], the effect size estimate was significant (OR, 0.20, 95% CI, 0.05–0.73; $n = 1,177$). For the needle-sharing outcome [49,51,52], the reduction was relatively large but the effect size estimate was not statistically significant (OR, 0.47; 95% CI, 0.13–1.71; $n = 403$). Stratified analyses were not conducted for these two outcomes because of the small number of trials.

Stratified analysis of trials reporting unprotected sex behaviours

Stratified analyses were implemented to assess efficacy based on trial and intervention characteristics (Table 2). With regarding to methodological quality, a significant effect was observed for trials that were RCT, had > 80% participation rate or had a comparison group that did not receive HIV behavioural intervention. Intervention effects were not affected by the retention rate. The significant intervention effect was also seen in the eight trials with the most rigorous methodological quality

Table 1. Description of eligible trials.

Reference study; location (intervention date)	Sample Characteristics	Study design and evaluation characteristics (participation rate[a], overall retention)	Description of intervention and comparison group	Sex, drug and biological outcomes[b]
Cleary *et al*. [55]; New York, NY (1986–1989)	HIV-positive blood donors ($n = 271$); mean age, 32.2 years; 78% male; 55% MSM; 45% White, 31% AA, 23% Hispanic, 1% other; percentage with AIDS diagnosis not reported; percentage on HIV treatment not reported; mean time since HIV diagnosis, not reported	RCT with 2 arms: structured intervention (IG) versus community referral (CG); participation rate: 38%; overall retention: 74% at 12 months after intervention	*Intervention goal* To encourage risk reduction behaviour; provide support and facilitate coping responses *Intervention theory* Not reported *Content* IG: provide support through group experience, help participants to accept serostatus, facilitate positive behaviour changes. CG: telephone referrals for HIV information, support or advice available in community *Delivery* IG: in groups (7–9 participants) by a social worker and a psychiatric nurse clinician. CG: to individuals by study nurse *Duration* IG: 6 session, 90 min each, over 6 weeks. CG: on-going referral as needed *Setting* IG: New York Blood Center (other setting). CG: over telephone	*Sex outcome* No significant difference in unsafe sexual behaviour (percent engaged in unprotected vaginal or anal intercourse and oral or oral-anal sex) in past week at 12-month follow-up (OR, 1.38; 95% CI, 0.77–2.49)
Grinstead *et al*. [52]; City not reported; CA (1996–1998)	HIV-positive male prison inmates ($n = 123$); mean age, 37.7 years; 100% male; 20% MSM; 3% bisexual; 55% AA, 31% White, 8% Hispanic, 5% mixed ethnicity, 1% API; percentage with AIDS diagnosis not reported; percentage on HIV treatment not reported; mean time since HIV diagnosis, 5 years	Minimally biased 2 non-equivalent groups: pre-release intervention (IG) versus non-intervention comparison (CG); participation rate: 57.6%; overall retention: 66% at average 8 months' post-release	*Intervention goal To* decrease HIV transmission behaviours and increase utilization of community services *Intervention theory* Not reported *Content* IG: educating about HIV transmission and teaching risk-reduction skills (through group discussion, written materials and presentation); providing referrals and appointments; and encouraging the use of existing drug treatment, needle-exchange, and other services in community after release through case management *Delivery* In groups by facilitator and case manager/community service provider *Duration* 8 sessions; 2–2.5 h each; over 2 weeks *Setting* Medium security state prison (other setting)	*Sex outcome* No significant difference in percentage condom use at first sex since release (OR, 0.57; 95% CI, 0.18–1.80) *Drug outcome* Among injectors, significant difference in percent needle sharing at post-release (OR, 0.11; 95% CI, 0.03–0.41)
Kalichman *et al*. [54]; Atlanta, GA (not reported)	HIV-positive persons (n = 328); 70% male; mean age, 40.1 years (SD, 7.0); 52% gay, 39% heterosexual, 9% bisexual; 74% AA, 22% White, 4% non-White; 9% with AIDS diagnosis; 94.5% on HIV treatment; mean time since HIV diagnosis not reported	RCT with 2 arms: healthy relationship (IG) intervention versus health maintenance/social support group (CG); participation rate: not reported; overall retention: 78% at 6 months after intervention	*Intervention goal* To reduce HIV transmission sex-risk behaviours by addressing issues related to disclosure *Intervention theory* Social cognitive theory *Content* IG: developing skills to cope effectively with HIV-related stressors and sexual risk-producing situations; self-disclosing HIV serostatus to sex partners; facilitating development and maintenance of safer sex practices through personal feedback reports, exercises, group discussion, role-play and video. CG: providing information on health service, support, and treatment resources and personal feedback reports on stress management and medication adherence and management through group discussion and video *Delivery* IG and CG: in groups (6–10 same-sex participants) by one male and one female community-based group facilitator, one of whom was a HIV-positive peer	*Sex outcome* Significant difference in unprotected vaginal or anal intercourse with HIV-negative or unknown partners in past 3 months at 6-month follow-up [OR, 0.6; 95% CI, 0.38–0.94; mean 6-month follow-up: IG, 0.2 (SD, 1.1) and CG, 1 (SD, 6.9); mean mean at baseline: IG, 0.9 (SD, 4.9) and CG, 0.4 (SD, 4.3)]

Table 1 (*continued*)

Reference study; location (intervention date)	Sample Characteristics	Study design and evaluation characteristics (participation rate[a], overall retention)	Description of intervention and comparison group	Sex, drug and biological outcomes[b]
			Delivery IG and CG: in groups (6–10 same-sex participants) by one male and one female community-based group facilitator, one of whom was a HIV-positive peer *Duration* IG and CG: 5 sessions, 2 h each; 2 sessions/week over 2.5 weeks *Setting* IG and CG: community AIDS service organization (service setting)	
Kelly *et al*. [45]; Milwaukee, WI (1991)	Depressed HIV-positive men ($n = 115$); mean age, 34 years (SD, 7.2); 100% male; 94% MSM; 62% White, 29% AA, 9% other; 18% with AIDS diagnosis; percentage on HIV treatment not reported; mean time since HIV diagnosis, 2.6 years	RCT with 3 arms: cognitive–behavioural group intervention (IG) versus social support group intervention (SSGI) versus non-intervention comparison (CG); participation rate: not reported; overall retention: 59% at 3 months after intervention	*Intervention goal* Facilitate coping responses and improve emotional distress *Intervention theory* Cognitive–behaviour coping theory *Content* IG: skills training to manage and reduce stress, alter cognitions that exacerbate depression, and develop adaptive behavioural coping strategies through teaching, group discussion, behavioural rehearsal, and practice of skills learned. *Delivery* In groups (8–10 participants) delivered by 2 psychologists, counsellors or psychiatry residents *Duration* 8 sessions 90 min each, over 8 weeks *Setting* Research facility (stand alone setting)	*Sex outcome* No significant difference in mean number of unprotected insertive anal intercourse instances in past 3 months at 3-month follow-up [OR, 0.92; 95% CI, 0.35–2.45; mean 3-month follow-up: IG, 2.9 (SD, 10.2) and CG, 0.1 (SD, 0.4); mean at baseline: IG, 1.6 (SD, 4.2) and CG, 0.3 (0.7)]
Margolin *et al*.[49]; New Haven, CT (1997–2000)	HIV-positive methadone-maintained IDU ($n = 90$); mean age, 41 (SD, 6.5); 70% male; sexual orientation not reported; 48.9% AA, 35.6% White, 15.6% Hispanic; 28% with AIDS diagnosis; 100% on HIV treatment; mean time since HIV diagnosis not reported	RCT with 2 arms: HIV harm reduction program (IG) versus enhanced methadone maintenance program (CG); participation rate: 79%; overall retention: 70% at 3 months after intervention	*Intervention goal* To reduce unsafe drug and sex-related behaviour *Intervention theory* Information–motivation-behavioural skills theory *Content* IG and CG: received weekly individual-level substance abuse counseling, case management and methadone; individualized feedback to increase motivation; video demonstration and practice of needle cleaning and correct condom use; harm reduction negotiation role plays, and sharing information with social network. IG: received additional group therapy that addressed medical, emotional and spiritual needs of HIV-positive including harm-reduction skills, relapse prevention, increasing medication adherence, participation in medical care and healthy lifestyle choices. *Delivery* IG: to individuals by substance abuse counsellor and to groups by group leaders. CG: to individuals by substance abuse counsellor *Duration* IG and CG: received daily methadone, individual substance abuse counselling and case management, and a 6 session HIV risk reduction intervention over 6 months. IG: additional 48 sessions of 1 h each, over 24 weeks *Setting* IG and CG: inner-city methadone maintenance programme (service setting)	*Sex outcome*[c] No significant difference in percentage engaged in unprotected sex in past 3 months at 3-month follow-up (OR, 0.33; 95%CI, 0.08–1.40) *Drug outcome*[c] No significant difference in percentage engaged in needle sharing in past 3 months at 3- month follow-up (OR, 1.59; 95% CI, 0.32–7.77)

Patterson *et al.*[46]; San Diego, CA (1996–2001)	HIV positive who engaged in unprotected sex 4 months before study enrolment with partners who were HIV negative or unknown serostatus ($n = 387$); mean age, 37.4 years (range, 22–62); 91% male; 85% bisexual/homosexual; 65% White, 15% AA, 12% Hispanic, 8% other; 45% with AIDS diagnosis; percentage on HIV treatment not reported; mean time since HIV diagnosis, 5 years	RCT with 4 arms: single-session targeted counseling intervention versus single-session comprehensive intervention versus single-session comprehensive intervention plus 2 monthly booster sessions (IG) versus 3-session diet and exercise attention control (CG); participation rate: not reported; overall retention: 69% at 12 months after intervention	*Intervention goal* To increase safer sex practices *Intervention theory* Social cognitive theory *Content* IG, the group had counselling, role-playing and skill-building exercises to learn how to negotiate safer sex practices and disclose serostatus to sex partners; problem solving real-life situations, positive reinforcement, exercises, support, demonstrations and rehearsal to enhance knowledge, self-efficacy and positive outcome expectancies. CG: attention control that addressed diet and exercise as related to HIV *Delivery* IG: delivered to individuals by counsellor. CG: not reported *Duration* IG and CG: received 3 sessions, 90 min each, over 3 months *Setting* IG and CG: research facilities (stand alone setting)	*Sex outcome* No significant difference in mean number of unprotected sex in past 4 months at 12-month follow-up [OR, 0.66; 95% CI, 0.33–1.33; mean at 12-month follow-up: IG, 17.9 (SD, 32.7) and CG, 21.8 (SD, 47.5); mean at baseline: IG, 29.2 (SD, 44.2), CG, 24.1 (SD, 32.3)]
Richardson *et al.* [47]; San Francisco, San Diego, Los Angeles, CA (1998–2001)	Sexually active HIV-positive clinic patients ($n = 886$); mean age, 38 years; 86% male; 74% MSM; 1% transgender; 1% female homosexuals; 41% White, 37% Hispanic, 16% AA, 6% other; percentage with AIDS diagnosis not reported; 82% on HIV treatment; mean time since HIV diagnosis, 6 years	RCT with 3 intervention groups: gain-framed versus loss-framed (IG) versus attention control (CG); participation rate: 69%; overall retention: 66% at 7 months after intervention	*Intervention goal* To reduce unprotected anal or vaginal intercourse *Intervention theory* Message framing theory *Contents* IG: emphasized importance of patient-provider team approach; loss framed prevention messages; brochures; posters. CG: emphasized adherence to antiretroviral therapy *Delivery* IG and CG: each individual was taught by nurses, nurse practitioners, physicians and physician assistants *Duration* IG and CG: received an ongoing intervention; each received a minimum of 1 session; 3–5 min each, over 10-11 months *Setting* IG and CG: 6 HIV clinics (service setting)	*Sex outcome* Significant difference in unprotected anal or vaginal intercourse with 2 or more baseline sex partners in past 3 months at 7-month follow up (OR, 0.34; 95% CI, 0.24–0.49)
Rotheram-Borus *et al.* [53]; Los Angeles, CA; New York, San Francisco, CA; Miami, FL (1994–1996)	HIV-positive youth ($n = 310$); mean age, 20.7 years (SD, 2.1); 72% male; 62.9% MSM; 37% Hispanic, 27% AA, 19% White, 17% non-White; 9% with AIDS diagnosis; percentage on HIV treatment not reported; mean time since HIV diagnosis, 2.1years	Non RCT/sequential cohort allocation: teens linked to care (IG) intervention versus non-intervention control (CG); participation rate: 79%; overall retention: 89% at 3 months after module 2	*Intervention goal* To change the health behaviour and transmission acts of youth with HIV *Intervention theory* Social action model; cognitive–behavioural theory; social learning theory *Content* IG: module 1, stay healthy (coping with HIV; implementing new daily routines to stay healthy; issues of disclosure; participating in health-care decisions); module 2 act safe (reduce substance use and unprotected sex; identify risk-behaviour triggers; modify patterns of substance use; increase self-efficacy of condom use and negotiation skills); module 3, being together (identify values that define personal identity as a person living with HIV; reduce negative emotional reactions to serostatus; increasing perception of personal self-control; reduce self-destructive motivations; living in the moment *Delivery* In groups (15 participants), delivered by 1 male and 1 female counsellors	*Sex outcome*[d] Significant difference in unprotected sex acts in past 3 months at 3-month follow-up (after module 2) (OR, 0.13; 95% CI, 0.02–0.70)

Table 1 (*continued*)

Reference study; location (intervention date)	Sample Characteristics	Study design and evaluation characteristics (participation rate[a], overall retention)	Description of intervention and comparison group	Sex, drug and biological outcomes[b]
			Duration Module 1, 12 sessions, 2 h each, over 12 weeks; module 2, 11 sessions, 2 h each, over 11 weeks; module 3, 8 sessions, 2 h each; over 8 weeks *Setting* Adolescent clinical care sites (service setting)	
Rotheram-Borus *et al*. [50]; Los Angeles and San Francisco, CA; New York, NY (1999–2003)	HIV positive substance-abusing adolescents and young adults ($n = 175$); median age, 23 years (range, 16–29); 78% male; 76% homosexual, bisexual or questioning; 42% Latino, 26% AA, 23% White, 8% Other; 23% with AIDS diagnosis; 50% on HIV treatment; mean time since HIV diagnosis not reported	RCT with 3 arms: (CLEAR) one-on-one intervention delivered in person (IG) versus one-on-one intervention delivered by phone versus non-intervention control (CG); participation rate: 95%; overall retention: 82% at 10.5 months after intervention	*Intervention goal* To change the health behaviour and transmission acts of youth with HIV *Intervention theory*: Social action model; cognitive–behavioural theory; social learning theory *Contents* As in Rotheram-Borus *et al*. [53] above *Delivery* One-to-one sessions delivered over the telephone or in-person by licensed therapists or clinical social workers *Duration* Module 1, 6 sessions, 1.5 h each, over 6 weeks; module 2, 6 sessions, 1.5 h each, over 6 weeks; module 3, 6 sessions, 1.5 h each, over 6 weeks *Setting* Community agencies (service setting)	*Sex outcome* Significant difference in percentage of protected acts with HIV-negative partners in past 3 months at 3-month follow-up (OR, 0.26; 95% CI, 0.12–0.59)
Sorensen *et al*.[51]; San Francisco, CA (1994–1998)	HIV-positive out of treatment substance abusers ($n = 190$); mean age, 38.5 years; 73% male; 52% heterosexual; 43% AA, 42% White, 8% other, 7% Hispanic; percentage with AIDS diagnosis not reported; percentage on HIV treatment not reported; mean time since HIV diagnosis not reported	RCT with 2 arms: case management (IG) versus brief contact (CG); participation rate: 68%; overall retention: 79% at 6 months after intervention	*Intervention goal* To increase service utilization and change HIV risk behaviour *Intervention theory*: Not reported, but mentioned NIDA model *Contents* IG: in addition to brief contact, actively linking participants with services, educating about the link between unsafe drug and sexual practices and HIV, helping to obtain condoms and other prevention equipment, referring to needle-exchange programs, and counselling about notifying non-infected partners. CG: education about reducing the risk of HIV transmission; information about HIV service and referrals to substance abuse treatment, social services, and HIV services in the community *Delivery* IG: to individuals by certified chemical dependency counsellors who are former consumers of HIV and substance abuse services. CG: to individuals by social workers or former consumers of HIV and substance abuse services *Duration* IG: ongoing; over 1 year *Setting* IG: hospital, community site of service, participant's residence (service setting). CG: hospital (service setting)	*Sex outcome* No significant difference in sex risk behaviours in past month at 6-month follow-up [OR, 0.97; 95% CI, 0.54–1.74; mean at 6-month follow-up: IG, 0.9 (SD, 1.44) and CG, 1.1 (SD, 1.54); mean at baseline: IG, 1.3 (SD, 1.66) and CG, 1.5 (SD, 1.71)] *Drug outcome* No significant difference in needle-sharing behaviour in past month at 6-month follow-up (OR, 0.63; 95% CI, 0.35–1.13); mean at 6-month follow-up: IG, 0.3 (SD, 0.65) and CG, 0.5 (SD, 0.89); mean at baseline: IG, 1.2 (SD, 0.99) and CG, 1.2 (SD, 1.06)]

Wingood *et al*. [44]; city not reported, AL and GA (1997–2002)	Sexually active HIV-positive female clinic patients ($n = 366$); mean age, 34.7 years (SD, 7.6); 100% female; 100% heterosexual; 84.2% AA, 15.8% unspecified race; percentage with AIDS diagnosis not reported; percentage on HIV treatment not reported; mean time since HIV diagnosis, 5 years	RCT with 2 study arms: WiLLOW (Women involved in Life Learning from Other Women) intervention (IG) versus health promotion comparison (CG); participation rate: 88.2%; overall retention: 88% at 12 months after intervention	*Intervention goal* To reduce HIV sexual transmission risk behaviours, STIs and to enhance psychosocial mediators and structural factors associated with preventative behaviours over 1 year *Intervention theory* Social cognitive theory; theory of gender and power *Contents* IG: session 1, discussed gender pride emphasis, joys, challenges, female achievements, impact of abusive partners; helped females to identify socially supportive people and their qualities; session 2, how to maintain and seek supportive people, and how to disengage from non-supportive people; session 3, HIV transmission risk-behaviour education, debunk myths, taught safer sex communication and negotiation skills, benefits of condom use, educators modelled condom use skills; session 4, how to distinguish between healthy/unhealthy relationships; information about local shelters. CG: information about nutrition, medication adherence, provider interaction skills *Delivery* IG and CG: delivered in small groups (8–10 participants) that were cofacilitated by HIV-positive female peer educator and female health educator *Duration*: IG and CG: received 4 sessions, 4 h each, over 4 weeks *Setting*: IG and CG: community service organization (service setting)	*Sex outcome* Significant difference in proportion of participants that never used condoms in past month at 12- month follow up (OR, 0.02; 95% CI, 0.05–0.8) *STI outcome* Significant difference in incident STI (chlamydia or gonorrhoea) in past month at 12- month follow up (OR, 0.1; 95% CI, 0.01–0.84)
Wolitski *et al*. [48]; New York and San Francisco, CA (1996–2002)	HIV-positive gay and bisexual men ($n = 811$); 100% male; 87.5% gay; 11.4% bisexual; 0.4% straight; 50.6% White, 23.1% AA, 17.4% Hispanic, 6.7% mixed ethnicity/other, 1.1% Native American; 1.1% API; 50.1% with AIDS diagnosis; 78.7 percentage on HIV treatment; mean time since HIV diagnosis not reported	RCT with 2 study arms: enhanced intervention (IG) versus standard intervention (CG); participation rate: 100%; overall retention: 90% at 6 months after intervention	*Intervention goal* To reduce unprotected sex, increase condom use, and increase serostatus disclosure to sex partners *Intervention theory* Social cognitive theory, information-motivation-behavioural theory, theory of planned behaviour *Contents* IG: in addition to the standard intervention, received information about HIV/STI, drug/alcohol use, partner HIV status, disclosure, mental health and condoms; referrals were given. CG: raise awareness of prevention issues; gave information on STI, HIV transmission and safer sex practice *Delivery* IG: delivered in small groups by 2 HIV-positive MSM peer facilitators. CG: delivered in small groups by HIV-positive facilitator and local experts *Duration* IG: 6 sessions, 3 h each, once a week, over 6 weeks. CG: 1 session 1.5–2 h in 1 day *Setting*: IG and CG: research facilities (stand alone setting)	*Sex outcome* No significant difference in unprotected insertive anal sex with HIV-negative/unknown status partner in past 3 months at 6-month follow up (OR, 0.92; 95% CI, 0.61–1.40) *STI outcome* No significant difference in incident STI (chlamydia or gonorrhoea) in past month at 12-month follow up (OR, 0.41; 95% CI, 0.04–3.68)

AA, African-Americans; API, Asian and Pacific Islanders; IDU, injection drug use; MSM, men who have sex with men; RCT, randomized controlled trial; IG, intervention group; CG, comparison group; STI, sexually transmitted infection.
[a]Participation rate is defined as percentage of eligible participants who enrolled in the study.
[b]Odds ratios (OR) and 95% confidence intervals (CI) adjusted for baseline outcome differences and based on the longest follow-up assessment.
[c]Findings different from authors' conclusion because sex and drug outcomes were combined in original report.
[d]Intervention non-attendees were excluded from the analysis.

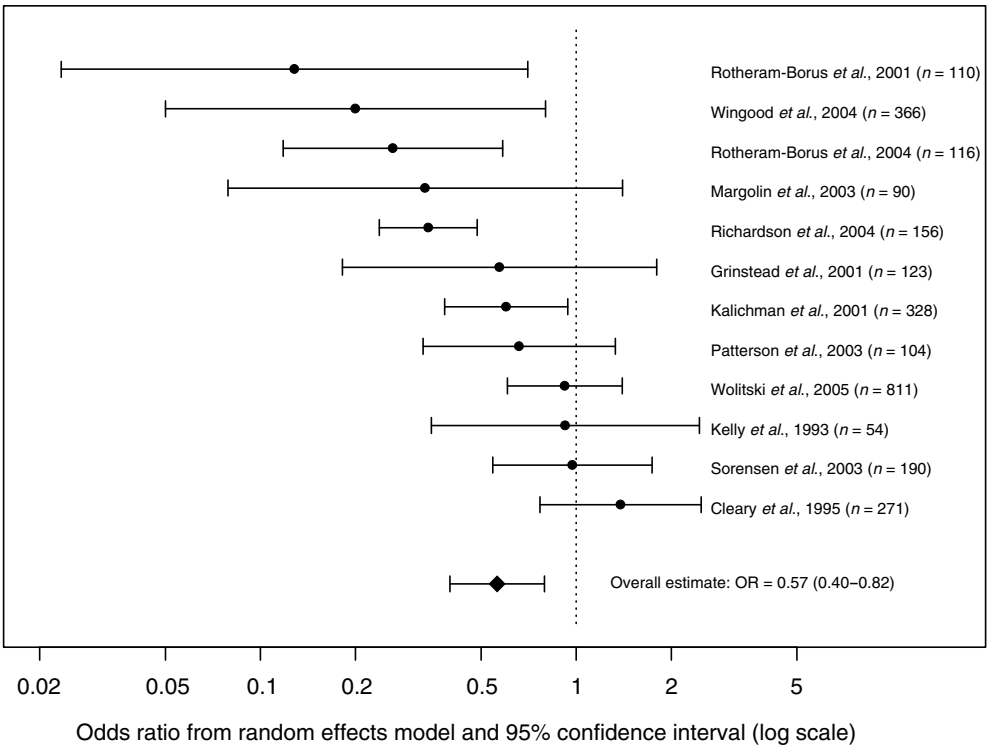

Fig. 2. Study specific and overall effect size(ES) estimates (12 trials) for unprotected sex.

(i.e., RCTs with $\geq$ 70% retention and intent-to-treat: OR, 0.66; 95% CI, 0.45–0.97).

Interventions with the following characteristics were found to reduce unprotected sex significantly:

- guided by behavioural theory
- specifically focused on HIV transmission behaviours (more than two-thirds of sessions)
- provided skills building, such as demonstrating correct condom use, practicing coping or problem-solving skills, or role-playing safer sex communication with partners
- delivered to individuals on a one-to-one basis
- delivered by health-care providers or professional counsellors
- delivered in settings where people living with HIV receive services
- delivered in an intensive manner ($>$ 10 intervention sessions, $>$ 20 h)
- delivered over a longer duration ($\geq$ 3 months)
- addressed a myriad of issues related to coping with one's serostatus, medication adherence, and HIV risk behaviours.

Three interventions [49,50,53] that included all the aforementioned intervention features, except individual-level delivery, showed a highly significant reduction in the OR unprotected sexual behaviour (OR, 0.25; 95% CI, 0.13–0.47). In addition, interventions delivered to groups or delivered by peers were marginally significant.

The length and number of follow-ups varied across trials, allowing analysis of whether the reduction in the OR of unprotected sex was consistent at different follow-up time points. Intervention effects were estimated at two follow-up intervals: 3–4 months and 6–12 months. Significant intervention effects were found at both times [3–4 months: OR, 0.55; 95% CI, 0.32–0.95 (seven interventions); 6–12 months: OR, 0.61; 95% CI, 0.43–0.87 (eight interventions)].

Discussion

Our meta-analysis of 12 controlled trials showed that interventions, as a whole, successfully reduce self-reported unprotected sex among PLWH. This significant intervention effect is robust as it was not affected by the rules used to guide our meta-analyses. The reduced rates of unprotected sex were observed not only at 3–4 months but also at 6–12 months post-intervention. Most importantly, the overall intervention effect observed here for PLWH (OR, 0.57) was comparable to, or slightly stronger in magnitude, than the intervention effects observed in the literature for primarily uninfected or serostatus unknown men who have sex with men (OR,

Table 2. Stratified analysis of intervention effects on unsafe sexual behaviours.

Stratified variable	No. trials	OR (95% CI)
Assignment		
Randomization	10	0.61 (0.42–0.89)*
Non-randomization with minimal bias	2	0.31 (0.07–1.31)
Participation rate		
< 80%	5	0.65 (0.33–1.29)
≥ 80%	5	0.42 (0.21–0.84)*
Comparison group received any intervention on HIV risk behaviour		
No	9	0.51 (0.33–0.78)*
Yes	3	0.89 (0.64–1.23)
Retention at longest follow-up		
≥ 70%	8	0.66 (0.45–0.97)*
< 70%	4	0.43 (0.23–0.80)*
Primary population		
Men who have sex with men	4	0.63 (0.35–1.14)
Injection drug users/substance abusers	3	0.47 (0.18–1.25)
Other	5	0.53 (0.27–1.07)
Proportion of intervention sessions addressing HIV risk behaviour		
More than two thirds	9	0.49 (0.30–0.79)*
Less than two thirds	3	0.74 (0.53–1.03)
Intervention based on behavioural theories		
Theory reported	10	0.52 (0.36–0.75)*
Theory not reported	2	1.02 (0.45–2.32)
Intervention setting		
Service	7	0.41 (0.26–0.65)*
Stand alone (for study purpose)	3	0.85 (0.61–1.19)
Others	2	1.02 (0.45–2.32)
Unit of delivery		
Group	8	0.66 (0.43–1.00)
Individual	4	0.49 (0.27–0.89)*
Intervention deliverer[a]		
Health-care provider/counsellor	8	0.52 (0.33–0.82)*
Peer	5	0.72 (0.50–1.03)
Skills building		
Any	9	0.59 (0.39–0.89)*
None	3	0.56 (0.26–1.22)
Intervention content (HIV risk behaviour, coping, adherence)		
All three topics	3	0.25 (0.13–0.47)*
One or two topics	9	0.68 (0.47–0.99)*
Number of intervention sessions/duration		
≤ 10 sessions/≤ 20 h	7	0.77 (0.55–1.07)
> 10 sessions/> 20 h	3	0.25 (0.13–0.47)*
On-going activities	2	0.56 (0.2–1.57)
Total time to deliver intervention		
1–2 months	6	0.78 (0.53–1.15)
3 months or longer	6	0.43 (0.26–0.72)*

OR, odds ratios; CI, confidence intervals.
[a]Not mutually exclusive groups.
*$P < 0.05$.

0.77) [25], drug users (OR, 0.86) [28], sexually active youth (OR, 0.66) [26] or heterosexual adults (OR, 0.81) [27]. When extrapolated to a population with 30% (range, 10–60) prevalence of sexual risk behaviour [15,16,18], we estimated a 43% (range, 21–63) relative risk reduction in unprotected sex. Risk reduction of this magnitude is well within the range considered to be cost-effective when translated into final health outcomes [60,61]. It is also encouraging to see evidence of efficacy in reducing chlamydia or gonorrhoea acquisition. A relatively large but non-significant intervention effect was observed for needle sharing. The findings on STI and needle sharing were based on a small set of trials and, therefore, the robustness of these findings needs to be reassessed when additional controlled trials are completed.

Aside from overall efficacy, intervention characteristics associated with efficacy were identified and summarized (see list on page 152). Interestingly, while interventions with a greater number of sessions over a longer duration and time span were associated with significant risk reduction, two interventions [47,51] with on-going activities failed to demonstrate efficacy. It is possible that the combination of the characteristics listed influenced intervention success as the three most intensive interventions, which were overall efficacious, were also delivered by professional counsellors in service settings, provided skills building and addressed a myriad of issues related to PLWH. Although the independent contributions of these characteristics cannot be disentangled within these data, the findings, taken as a whole, suggest that integrating prevention into settings where PLWH receive medical care or other services and addressing the health, behaviour and well-being of PLWH may be important for achieving success [15,48,62].

The findings of our meta-analytic review must be viewed within the context of the limitations of the available evidence and point to future research needs. Although not statistically significant, the magnitude of the intervention effect estimates for the subgroups of PLWH (i.e., men who have sex with men, injection drug users/substance abusers, other population) are comparable to the magnitude of the overall estimate in this review and in previous reviews [25–28]. The lack of statistical significance may be because of the small number of trials conducted within each subgroup. While subgroups of PLWH may share common experience in living with HIV, each subgroup may face unique challenges. For example, HIV-seropositive heterosexual women may wish to become pregnant and may struggle with the care of young children, while substance-using men who have sex with men must deal with homophobia and drug addiction. Consequently, it is important to examine further whether and to what extent the findings are applicable across different subgroups of PLWH when data from other controlled trials become available.

Several trials did not report important variables (e.g., medical status of participants, serostatus of partner, number of partners with whom unprotected intercourse occurred, cost data), which could have provided additional insights into the intervention effects, applicability of interventions, connection between unprotected sex and STI transmission and cost-based recommendations. Clear and transparent reporting of these key elements in intervention trials would greatly improve the quality of future meta-analytic work [63–65].

The majority of the trials were unblinded and relied on self-reported sexual behaviour, which may be open to socially desirable responding [66]. Acknowledging this possible bias, many trials attempted to ensure the confidentiality of data, including asking participants to

answer questionnaires without the presence of an interviewer. In addition, all the trials had a comparison group and the assignment method was either randomization or an unbiased method, which reduced the likelihood that individual characteristics (e.g., impression management) influenced the intervention effect. Given that blinded trials are not feasible in HIV behavioural prevention research, future intervention trials should consider complementing self-reported behavioural measures with biological endpoints to assess intervention efficacy [67]. It should be noted, however, that an STI may be acquired from seroconcordant or serodiscordant partners and are not a specific measure of reduced HIV transmission risk to uninfected partners [48]. New technologies (e.g., computer-assisted assessments) that are likely to improve the internal consistency of self-reported sexual behaviour and increase the reporting of stigmatized behaviours [68–70] are currently available and should also be widely utilized.

Few interventions in this review incorporated contextual, societal or structural factors. While addressing psychological processes, behavioural skills and communication within a relationship is important, socioecological models that identify multiple determinants of behaviours, including dyad/family, social/community (e.g., networks), structural and societal/cultural factors (e.g., stigma, social norms, social and economic status) can also be essential because individual behavioural change does not occur in a vacuum [15,29]. Future research should consider comprehensive efforts that intervene on HIV risk behaviours at the individual, group, structural and societal levels. In addition, it is also important to incorporate newly identified predictors of risky behaviours, including HIV treatment optimism [71], use of the Internet to meet sex partners [72,73] and serosorting [74] into the next generation of prevention interventions for PLWH.

Our findings showed that significant intervention effects were observed at 3–4 months and 6–12 months post-intervention. However, it is not known whether the intervention effect sustains beyond 12 months after the intervention. The on-going NIMH Healthy Living Project [75], which follows participants for 25 months, may provide some insights into longer-term intervention effects. Adopting and maintaining healthier and safer behaviours over a lifetime can be challenging for some PLWH and may require on-going behavioural reinforcement to prevent relapse. In addition, given that not all PLWH require on-going prevention programmes [15,76], it may be more cost-effective to identify specific groups of individuals who require on-going behavioural reinforcement and determine the types of intervention that work best for them. It is likely that those who are struggling with multiple health and social problems, such as substance abuse, severe and persistent mental illness, relationship abuse or poverty, may benefit most from intensive prevention interventions [77]. Further research is recommended to examine the efficacy of interventions designed for PLWH who are struggling with multiple problems that increase their risk of transmitting HIV to others.

The generalizability of our meta-analytic findings warrants comment. All 12 controlled trials evaluated in this review were conducted in the United States. Although we identified two published reports [37,78] and a few on-going prevention programmes with seropositive persons outside the United States, none of these trials met our stringent inclusion criteria, which had been designed to derive valid conclusions about intervention efficacy. This research gap is not surprising as many countries allocate the limited resources that are available to providing medical treatment for those who are in need of care, preventing mother-to-child transmission and identifying individuals with undiagnosed HIV to reduce the HIV infection rate, rather than for conducting controlled trials to evaluate behavioural interventions specifically designed for PLWH [3,79]. However, the US funding agencies have increased support for developing and evaluating interventions to help PLWH to reduce HIV transmission risk behaviours because the importance of primary prevention with PLWH has been recognized and given priority as a key component of the CDC's national HIV prevention agenda [1,2,5]. Although it is unclear the extent to which our meta-analytic findings (based on the experience in the United States) can be generalized to resource-poor settings and other populations, the lessons learned may provide insights into which strategies have the best chance of success in the global prevention efforts. As antiretroviral therapy programmes are expanded worldwide [3,8,79], effective prevention strategies should be integrated within routine medical care and services provided for PLWH.

Moving evidence-based research for people living with HIV into practice is an important step in making a greater impact on the HIV epidemic. As the effective strategies are woven into prevention efforts, both in the United States and internationally, the focus must also include assessing the effectiveness and the deployment of these strategies in real-world settings. Continually evaluating and maximizing the effectiveness of these activities in the field is critical for a sustainable impact on the HIV epidemic.

In conclusion, the behavioural interventions included in this review, as a whole, are efficacious in reducing HIV sexual risk taking across a wide range of PLWH. When selecting interventions for PLWH, prevention providers should consider those with the following characteristics: integrating theory-based prevention within routine medical care and services; addressing aspects of mental health and medical adherence in addition to HIV risk behaviour; and providing PLWH with the necessary skills for successful risk reduction. Given that the potential of

an intervention delivered to a single HIV-seropositive person may prevent multiple HIV infections, prevention with PLWH offers an unprecedented opportunity for significantly reducing HIV transmission.

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