# Interactive digital interventions for prevention of sexually transmitted HIV

## Characteristics of included studies

### Bauermeister 2015

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| **Methods** | Two arm RCT |
| **Participants** | Young men who have sex with men (MSM) aged 15 to 24  Michigan, USA. |
| **Interventions** | **IDI:** *Get Connected!* website, tailored based on age, race/ethnicity, sexual identity, relationship status, HIV/STI testing history and testing motivations, recent sexual behavior, sources of support, structural barriers, and self-reported values. Content (messaging) and images on the site were tailored to these characteristics. Tailored content included three web-pages: (1) STI facts, (2) encouraging participants to 'assess their motivations, values, and strengths regarding STI testing', (3) barriers to getting tested for STIs/HIV and how to overcome them. A fourth web-page was the service provider directory (identical to the comparator).  **Theory:** Self-determination theory, Integrated Behavioral Model  **Consumer involvement:** Community Advisory Board: 7 community organisation members who work with young MSM informed study and intervention content and development. Youth Advisory Board of 8 MSM aged 17-24 recruited online and from the community, contributing to design of recruitment materials, intervention design, content and language, and study participant recruitment.  **Methods for enhancing engagement:** None (aside from incentive and community/consumer involvement - mentioned elsewhere)  **Comparator:** Non-tailored test-locator webpage: Online service provider directory, where testing sites could be sorted by geographic area, opening hours, ability to test without an appointment, access to public transport, and insurance or personal identification requirements. Sorted testing sites were ranked based on the study team's evaluation of the testing sites (including LGBTQ inclusivity). Participants were provided with a list of questions they could ask the provider during a testing visit. Participants could choose to print their customized clinic list or have it emailed or texted to them.  **Incentives for research participation:** Up to US$30 as VISA e-gift cards (US$20 for completing the baseline and intervention; US$10 for completing the 30-day follow-up). |
| **Outcomes** | Baseline and 30 days  **Self-efficacy** to discuss HIV and STI testing with partners:  Perceived barriers to STI/HIV testing  **Sexual behaviour** in the last 30 days (total number of male sexual partners, oral sex, anal sex [receptive, insertive], condomless anal sex)  **HIV/STI testing behaviours** [authors' primary outcomes]: making an appointment with a testing provider, testing for STI/HIV, received treatment (if necessary)  **STI diagnoses** (self-reported) |
| **Aim and target population** | To encourage HIV/STI testing among young MSM |
| **Notes** | Feasibility trial. Data from authors. |

#### Risk of bias

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| **Bias** | **Authors' judgement** | **Support for judgement** |
| Random sequence generation (selection bias) | Low risk | Online consent, baseline assessment and randomisation on a 2:1 basis. 'We used a computer program to generate random numbers and allocate participants to the conditions' (information from authors) |
| Allocation concealment (selection bias) | Low risk | Participants 'did not know what group they were allocated to' [information from authors] |
| Large or differential losses to follow up | Low risk | 104/130 at 30 days (80%) |
| Selective reporting (reporting bias) | Unclear risk | Additional data from authors. |
| Blinding of participants | Low risk | Participants 'did not know what group they were allocated to' [information from authors]; IDI and control were both online |
| Blinding of research personnel | Low risk | Research personnel were blind to participant allocation [information from authors] |
| Blinding of outcome assessment (detection bias) | Unclear risk | Data were collected online |

### Billings 2015

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| **Methods** | Two-arm RCT |
| **Participants** | African American women  High HIV prevalence neighbourhood within Washington, DC, USA |
| **Interventions** | **IDI:** *Safe Sistah*, interactive HIV prevention website individually tailored to women's risk profile. Audio narration, video, interactive exercises and quizzes.  Assessment of risk dimensions (number and type of sexual partner/s; condom use; anal sex; quality of partner communication). 'The 411 on HIV' personalized risk reduction plan. Training based on user-specific risk: 'Condom isn't a 4 letter word; Talking to your man; Things to avoid (alcohol and drugs); Healthy relationships; No means no.  **Theory:** Positive ethnic identity and self-esteem: addressed through 'messages of gender empowerment and positive racial identity'. Pedagogical sequencing: goals and importance of each area are described; users receive training in a particular strategy/skill (to increase their self-efficacy); the skill is practiced (e.g. through an interactive exercise). Behavioural modeling through videos.  **Consumer involvement:** unknown.  **Methods for enhancing engagement:** Intervention group were given 'a list of free Internet sites around Washington, DC (e.g. community centers, public libraries, etc.)'  **Comparator:** Waiting list (access to *Safe Sistah* after study completion)  **Incentives for research participation:** US$25 for completing baseline, US$50 for completing 1-month follow-up, and US$50 for completing 4-month follow-up. |
| **Outcomes** | Baseline, 1 month and 4 months.  Baseline behavioural measures assessed behaviour over the previous 60 days; follow up measures, over the previous 30 days  **Knowledge:** HIV prevention knowledge  **Self efficacy** regarding **'Sex refusal':** 'how sure they were that they would be able to say no to having vaginal sex with a man across a variety of situations: known for a few days or less; unknown sex and drug history; dated for a long time; wanted to date again; previous sexual intercourse; wanted him to fall in love; pushing to have vaginal sex; after drinking alcohol; after smoking marijuana' (Likert scale 'from (1) not at all to (5) very sure').  **'Safer sex intentions'**  2-item scale: 'I will have only one sexual relationship at a time' and 'I would only have with a person who I have a long-term relationship with'  **Behaviour:**  **Consistent condom use** (primary outcome): (number of occasions of condom use divided by total number of sex acts; number of unprotected sex acts)  Condom use after alcohol consumption  'Sexual communication' - assessment of partners' HIV risk for the five most recent partners: total number of past vaginal sex partners; sex with a man; sex with a prostitute; frequency of condom use with past sexual partners; concurrent sexual partner; IV drug use; HIV status. |
| **Aim and target population** | Aim: 'to teach African American women HIV prevention skills adapted to the specific challenges they face in their daily lives'  **Inclusion criteria:** High risk African American women aged 18-50, defined as either (1) multiple male sexual partners in the past 2 months or (2) inconsistent condom use over that same timeframe with a man who was HIV positive, was an injection drug user, had concurrent sexual partners, or had not been tested for HIV since the onset of the sexual relationship. |
| **Notes** | Women were recruited in the community but attended clinic for assessment of eligibility, and returned to clinic after baseline data collection, for payment and group assignment. |

#### Risk of bias

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| **Bias** | **Authors' judgement** | **Support for judgement** |
| Random sequence generation (selection bias) | Low risk | Information from authors: 'The numbers were generated online using randomizer.org (I believe)'. A list of 1 and 0s was generated in a block randomisation scheme, then the list was printed. |
| Allocation concealment (selection bias) | Unclear risk | 'the RAs got informed consent, and then went to the list to see what the next assignment was...if an RA wanted to, she could have known about allocation before it happened' |
| Large or differential losses to follow up | Low risk | 'Of the 38 women assigned to the delayed HIV education control condition, 89% completed the 1- and 4-month follow-ups'. 'Of the 45 women assigned to the online HIV behavioral intervention, 76% completed the 1-month while 87% completed the 4-month follow-up'. |
| Selective reporting (reporting bias) | Low risk | All outcomes reported (in Table 2) |
| Blinding of participants | High risk | No, because control was delayed HIV education (waiting list) |
| Blinding of research personnel | Low risk | 'The research assistant was blind to condition for all phone interviews' |
| Blinding of outcome assessment (detection bias) | Low risk | Participants could choose to complete follow-up data collection online or by phone. 'The research assistant was blind to condition for all phone interviews' |

### Bowen 2007

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| **Methods** | Two-arm randomised controlled trial |
| **Participants** | Rural Men who have Sex with Men, 18 years old or above, recruited online or face-to-face  USA |
| **Interventions** | **IDI:** Two twenty minute online modules of the intervention, accessed not less than 24 hours apart, included HIV prevention information presented using principle of peer-delivery (conversation between an HIV+ gay man who represented the 'expert' & an 'inexperienced' HIV-ve man who had recently engaged in high-risk sex) about issues related to HIV testing, living with HIV and treatment, routes of infection. Conversation continues after the character has a negative HIV result focusing on safer sex options, condom types and correct condom application. Interactive graphics was provided to individualise the experience.  **Theory**: Social cognitive theory  **Consumer involvement:** Focus groups, and an Internet-based assessment  **Methods for enhancing engagement:**  **Comparator**: Waiting list  **Incentives for research participation:** financial incentives after each of the three assessments |
| **Outcomes** | Pre-test, post-test and one week following intervention.  **HIV/AIDS knowledge**  **Outcome expectancies** (condom use and insisting on safe sex)  **Self-efficacy** (safe sex assertiveness and safer sex communication) |
| **Aim and target population** | Internet delivered intervention via peer-delivery and individualisation would increase precursors of sexual HIV risk reduction (i.e., develop positive outcome expectancies for risk reduction and increase risk reduction self-efficacy)  Rural MSM |

#### Risk of bias

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| **Bias** | **Authors' judgement** | **Support for judgement** |
| Random sequence generation (selection bias) | Low risk | Computer randomised. Participants were randomly assigned by the computer to the intervention group or to the wait-list control group. |
| Allocation concealment (selection bias) | Low risk | Concealment until revealed by computer allocation. |
| Large or differential losses to follow up | Low risk | 20% of IDI group and 21% of waiting list group were lost to follow-up (no significant differences in demographics). Intention to treat analysis was conducted. Pre-test scores used as follow-up scores for drop-outs. |
| Selective reporting (reporting bias) | Low risk | Data presented for all outcomes. No comment on blinding of outcome assessors |
| Blinding of participants | Unclear risk | Not stated but participants may have been aware of the intervention allocation because they are randomised either to the intervention or a wait-list group. |
| Blinding of research personnel | Low risk | Not stated but unlikely to influence results because the intervention was administered online |
| Blinding of outcome assessment (detection bias) | Unclear risk | Not stated but participants self-completed the questionnaire |

### Bull 2009

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| **Methods** | Two-arm randomised controlled trials: clinic sample and online sample |
| **Participants** | 18-24 year youth recruited online and in a clinic  USA |
| **Interventions** | **IDI:** Online HIV risk assessment and five role model stories tailored by gender and ethnicity. Pictures and audio stories which addressed theoretical constructs about condom use and condoms including attitudes, norms, knowledge, self-efficacy for condom negotiation and for condom use. Repeat of same session (booster) at one month.  **Theory:** Theory of Planned behaviour and Social Cognitive theory  **Consumer involvement:** six focus group discussions  **Methods for enhancing engagement:** automated email at one month to login booster session. Those viewing booster session within 8 hours received another $5.  **Comparator:** Online HIV risk assessment and text based generic HIV prevention information between modules instead of role model stories  **Incentives for research participation:** $35 for participation in study, at baseline $10 amazon gift certificate and $5 gift certificate at one month. At follow-up participants were offered $10 incentive and $5 bonus for completion of the survey within 48 hours. |
| **Outcomes** | 2 months (online sample), 3 months (clinic sample)  **Self-efficacy** (for condom use andcondom negotiation)  Outcome expectations towards condom use, Condom use norms  **History of STD**  Change in the number of sex acts protected by a condom in sixty days between baseline and follow-up |
| **Aim and target population** | To evaluate the efficacy of IDI for HIV prevention delivered exclusively online or in a clinic setting at a computer kiosk.  Young people aged 18-24 years |
| **Notes** | This trial was conducted in two settings: online and in clinic setting. Data were analysed separately for each setting. |

#### Risk of bias

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| **Bias** | **Authors' judgement** | **Support for judgement** |
| Random sequence generation (selection bias) | Low risk | Participants were randomly assigned via computer |
| Allocation concealment (selection bias) | Low risk | Assignment was concealed until randomisation |
| Large or differential losses to follow up | High risk | 47% loss to follow-up in the Internet recruited sample and 39% in the clinic recruited sample.Only 37% and 39% of the follow up sample was included in the analysis because outcome data were missing. |
| Selective reporting (reporting bias) | Low risk | All specified outcomes were analysed |
| Blinding of participants | Unclear risk | Not stated |
| Blinding of research personnel | Low risk | Not stated but unlikely to influence results because the intervention was administered online |
| Blinding of outcome assessment (detection bias) | Unclear risk | Not stated but participants self-completed the questionnaire |

### Calderon 2013

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| **Methods** | Two-arm randomised controlled trial |
| **Participants** | Emergency department patients aged 15 to 21  USA |
| **Interventions** | All participants viewed an HIV pre-test educational video and were offered an HIV test.  **IDI:** HIV post-test counselling video vignettes, tailored by the participant's stage of change. Participants in the intervention group who accepted an HIV test also received standard in-person counselling when they received test results.  **Theory:** Stages of Change and Theory of Reasoned Action. Tailoring by stage of change.  **Consumer involvement:** Qualitative research with adolescents.  **Methods for enhancing engagement:** IDI in clinic whilst waiting for HIV test results  **Comparator:** In-person counselling from HIV counsellors trained to provide age-appropriate, culturally sensitive education and counselling. Information on how to interpret HIV test results, partner notification, and condom use.  **Incentives for research participation:** none |
| **Outcomes** | Baseline and immediately post-intervention  HIV knowledge (at baseline only)  **Condom self-efficacy**  Condom outcome expectancy  **Condom use intention: for vaginal sex**, oral sex, anal sex, carrying condoms |
| **Aim and target population** | To compare the effectiveness of a theory-based HIV educational tool with in-person counselling in promoting safer sex behaviours. |
| **Notes** | Clarification from authors regarding research procedures. |

#### Risk of bias

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| **Bias** | **Authors' judgement** | **Support for judgement** |
| Random sequence generation (selection bias) | Low risk | Computer-generated block randomisation scheme obtained from www.randomization.com. |
| Allocation concealment (selection bias) | Low risk | 'The randomization was kept in an opaque envelope that was not opened until patients signed informed consent' |
| Large or differential losses to follow up | Low risk | No drop-out (immediate post-intervention measurement). |
| Selective reporting (reporting bias) | Low risk | Data presented for all primary and secondary outcomes |
| Blinding of participants | High risk | Participants would have been aware of allocation group |
| Blinding of research personnel | High risk | Clinic personnel would have been aware of allocation to video or counselling |
| Blinding of outcome assessment (detection bias) | Unclear risk | Outcome data were entered by subjects in a computer kiosk. |

### Carpenter 2010

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| **Methods** | Two-arm randomised controlled trial |
| **Participants** | HIV negative/unknown status MSM aged 18-39 years who had engaged in unprotected sex (oral or anal) with a man in the last 3 months, recruited via banners on same-sex community websites  USA |
| **Interventions** | **IDI:** an online intervention consisting of a 90 minute tutorial about risk assessment and targeted individualised feedback, motivational exercises, skills training, and education to be completed within one week (7 brief motivational, informational and skills training modules).  **Theory:** Information Motivational Behaviour theory of HIV risk reduction and Motivational interviewing techniques  **Consumer involvement:** pilot testing with 21 MSM aged 18-28 years via a questionnaire survey and semi-structured interviews.  **Methods for enhancing engagement:**$35 for completing tutorials and satisfaction questionnaire.  **Comparator:** Control website focusing on stress reduction training  **Incentives for research participation:** financial incentive of$35 after completion of 1st questionnaire and $50 for follow-up assessment completion. |
| **Outcomes** | Baseline and 3 months  **Behavioural:** Number of acts of unprotected anal intercourse with any male partner and with positive/unknown serostatus , unprotected receptive anal intercourse, unprotected insertive anal intercourse, unprotected receptive oral intercourse, unprotected insertive oral intercourse. |
| **Aim and target population** | To evaluate the effectiveness of a single session Internet delivered multimedia safer sex intervention  Young MSM |
| **Notes** | The sexual act with greatest risk of HIV acquisition was chosen for inclusion in meta-analysis (URAI with HIV positive/unknown serostatus partners) |

#### Risk of bias

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| **Bias** | **Authors' judgement** | **Support for judgement** |
| Random sequence generation (selection bias) | Low risk | computerized randomisation algorithm used random number tables to randomise participants after completing the baseline questionnaire and was designed to produce a comparable racial and ethnic distribution between groups. |
| Allocation concealment (selection bias) | Low risk | computerized randomisation algorithm |
| Large or differential losses to follow up | High risk | 50% lost to follow-up. Those lost to follow-up were more likely to be African American and were more likely to report their status as HIV unknown. Besides those in experimental condition were more likely to be Asian American compared to participants in the control group and were more likely to report unprotected anal intercourse, particularly insertive. Intent-to-treat analysis was not possible because only participants who completed tutorial were provided a link to complete follow-up measures in the intervention group. |
| Selective reporting (reporting bias) | Low risk | All planned outcomes reported |
| Blinding of participants | Unclear risk | Not stated but unclear risk as sufficient information not provided about information used to advertise study on websites for participant recruitment |
| Blinding of research personnel | Low risk | Not stated but unlikely to influence results because the intervention was administered online |
| Blinding of outcome assessment (detection bias) | Low risk | Not stated but likely to be low because the questionnaire was self-completed by the participants online and data analysis is unlikely to be influenced by assessors bias |

### Christensen 2013

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| **Methods** | Two-arm randomised controlled trial |
| **Participants** | HIV-negative men who have sex with men (MSM), aged 18-24, engaged in UAI with a non-primary partner in preceding 3 months, USA |
| **Interventions** | **IDI:** SOLVE (Socially Optimised Learning in Virtual Environments) intervention - a virtual world simulating common obstacles to safer sex. Serious game. User can personalise avatar, then work through two levels of virtual situations, making a number of self-regulatory decisions. Tailored recap is given, evaluating virtual behaviour and linking it to real-life consequences.  **Theory:** Theory of planned behaviour, Social Cognitive Theory. 'Also capitalizing on recent advances in neuroscience that suggest emotions are critical during decision-making'.  **Consumer involvement:** None stated.  **Methods for enhancing engagement:** None stated - appears to be a one-off intervention.  **Comparator:** No intervention control.  **Incentives for research participation:** Opportunity to enter a lottery draw on participation (1:40 chance of winning 100USD). 25USD gift card offered at 3 month follow-up. |
| **Outcomes** | 3 and 6 months  Cognitive:  Shame  Behavioural:  Unprotected anal intercourse ('receptive and insertive anal sex without a condom') |
| **Aim and target population** | To test the relationship between shame and UAI, and whether shame mediates the effect intervention of SOLVE, in MSM. |

#### Risk of bias

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| **Bias** | **Authors' judgement** | **Support for judgement** |
| Random sequence generation (selection bias) | Low risk | 'Online data collection software (Qualtrics) automatically generated the random allocation sequence and assigned participants to condition' |
| Allocation concealment (selection bias) | Low risk | 'Online data collection software (Qualtrics) automatically generated the random allocation sequence and assigned participants to condition' |
| Large or differential losses to follow up | High risk | 69% retention at 3 month follow-up; however:  'Randomization was imbalanced (2:1) to compensate for differential loss of participants in the SOLVE treatment condition due to technical issues identified in the pre-trial piloting'  Participants were excluded post-randomisation if they didn't complete baseline measures (573 in intervention, 202 in control), and if they couldn't download the intervention (257 in intervention, none in control).  These participants were not included in analyses. Inappropriate imputation of missing values for 'shame' outcome (mean scores). Method of imputation for UAI: 'UAI change scores of those lost to follow-up were estimated in MPlus 7 using a full-information maximum likelihood procedure'. |
| Selective reporting (reporting bias) | Low risk | Primary and secondary outcomes are reported to be consistent with the trial registry. The registry entry identified (NCT00653991) reports the same primary outcome, but secondary outcome as 'Affect'. Trials register also reports 3 and 6 month follow-ups. No specific mention of 'shame' (however, shame was not included in our analyses as it did not fit within our model of 'sexual health') |
| Blinding of participants | Low risk | Information from author:  "given IRB requirements (and comments made to us in past NIH review processes by reviewers) we had to alert participants in both that at some point during the study they might be asked to participate in a game in which they might view explicit sexual scenarios and animations and make decisions on a virtual date.  All participants were told that the purpose of the research is to compare an HIV prevention educational game versus no game. One group (the experimental game group) was told that they would receive the game in session 1; the other group (control) was told that they would receive the game in session 3.  Group 1 was not told that another group (group 2) would receive the game in session 3 instead of 1; Group 3 was not told that Group 1 got the game in session 1 whereas they would get it in session 3).  Both groups may have assumed that their data would be compared to a group of men who received no game at all ever (but no such group existed)." |
| Blinding of research personnel | Low risk | 'Researchers and staff were blind to condition assignment at enrolment, but some were subsequently unblinded to prohibit participant re-enrolment'; however, the study was conducted online and so this is unlikely to have influenced outcome. |
| Blinding of outcome assessment (detection bias) | Low risk | 'Researchers and staff were blind to condition assignment at enrolment, but some were subsequently unblinded to prohibit participant re-enrolment'; however, the study was conducted online and so this is unlikely to have influenced outcome. |
| Other bias | Unclear risk | Participants were excluded post-randomisation if they didn't complete baseline measures (573/1284 in the intervention group, 202/736 in control), and if they couldn't download the intervention or play one level of the game (257/1284 of the intervention group). |

### Davidovich 2006

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| **Methods** | Three arm online randomised controlled trial |
| **Participants** | Dutch-speaking men who have sex with men, recruited online |
| **Interventions** | **IDI (tailored):** Delivered online.Information: Negotiated Safety and HIV testing Motivation: emphasising risk of HIV and burdens of combination therapy, correcting faulty beliefs. Skills: communication strategies for reaching agreements with partners. Tailored according to knowledge, motivation, and skills. One online session.  **Theory**: Information, motivation, behavioural skills model, tailored. Cognitive behavioural.  **Consumer involvement:** 20 gay men were involved in testing of the intervention  **Methods for enhancing engagement:**  **Comparator 1:** IDI (non-tailored), delivered online:(all of the intervention modules)  **Comparator 2:** No intervention  **Incentives for research participation:** 40 raffle prizes of 50 euros each. |
| **Outcomes** | Baseline, immediately post, and at 6 months. Immediate only for controls  **Response efficacy** (knowledge of and belief in benefits of negotiated safety) **Intention** to practice negotiated safety, intention to use condoms **Perceived behavioural control** (cf. self-efficacy): safer sex outside relationship, mutual HIV testing, monogamy agreement, warning partner  **Negotiated safety with new steady partners** (HIV testing, then monogamy or condoms outside the relationship) **Condom use with steady partner**  **Self-reported HIV status** |
| **Aim and target population** | Reduce HIV risk in MSM (increase negotiated safety between steady partners) |
| **Notes** | 35% had a steady partner by 6 months (130/668). Analysis based only on these. |

#### Risk of bias

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| **Bias** | **Authors' judgement** | **Support for judgement** |
| Random sequence generation (selection bias) | Low risk | Individually randomised by computer. 'A computer program allocated at random each person... to one of the study's arms' (info from author). |
| Allocation concealment (selection bias) | Low risk | Concealment until revealed by computer allocation. |
| Large or differential losses to follow up | High risk | Retention at 6 months: 42% control arm (n = 140), 31% non-tailored arm (n = 107), 38% tailored arm (n = 128). No significant differences by demographic variables. No differential drop-out by motivation. Drop-outs excluded |
| Selective reporting (reporting bias) | Low risk | Data presented for all outcomes. No comment on blinding of outcome assessors |
| Blinding of participants | Unclear risk | Not stated |
| Blinding of research personnel | Low risk | Not stated but unlikely to affect performance or detection bias |
| Blinding of outcome assessment (detection bias) | Unclear risk | Not stated |

### Di Noia 2004

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| **Methods** | Cluster randomised control trial. |
| **Participants** | Girls from social services agencies, USA |
| **Interventions** | **IDI**: Keeping it Safe' CD-ROM. Information about HIV, game with feedback re. facts and myths, video personal story of HIV, four-step model of assertive responding using scenarios and simulations. Single 30 minute session.  **Theory:** Four-step model of assertive responding  **Consumer involvement:** not stated  **Methods for enhancing engagement:** None  **Comparator:** Waiting list for intervention  **Incentives for research participation:** |
| **Outcomes** | 2 weeks after intervention **HIV-AIDS** **Knowledge** **Risk-reduction self-efficacy** |
| **Aim and target population** | To forestall initiation of HIV related risk behaviours among adolescent girls (to alter HIV/AIDS related knowledge, protective attitudes and self-efficacy for risk reduction) |
| **Notes** | Data adjusted for baseline differences in age and ethnicity. Randomised by site (not clear how many sites were involved) |

#### Risk of bias

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| **Bias** | **Authors' judgement** | **Support for judgement** |
| Random sequence generation (selection bias) | Unclear risk | Not stated. 'The efficacy of the program was evaluated in a randomized blocks design with site as the unit of randomization' |
| Allocation concealment (selection bias) | Unclear risk | Not stated. Sequence generation and allocation concealment rated 'B' |
| Large or differential losses to follow up | Unclear risk | Drop-out rate not stated. |
| Selective reporting (reporting bias) | Low risk | Data presented for all outcomes. No comment on blinding of outcome assessors |
| Blinding of participants | Unclear risk | Not stated |
| Blinding of research personnel | Unclear risk | Not stated |
| Blinding of outcome assessment (detection bias) | Unclear risk | Not stated |

### Evans 2000

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| **Methods** | Three arm randomised controlled trial. |
| **Participants** | Students on sexuality course (college)  USA |
| **Interventions** | **IDI**: 'AIDS Interactive'. Individual interaction with computer. Stories, role modelling, demonstrations. Video vignettes, rehearsal of communication skills (typing). 1 hour with computer  **Theory**: Social cognitive theory  **Consumer involvement:** reviewed by several experts in adolescent sexual health and pilot-tested with 31 college students.  **Methods for enhancing engagement:** none  **Comparator 1**: Lecture to group (on same content and theoretical principles). 1 hour  **Comparator 2**: 'No intervention'  **Incentives for research participation:** |
| **Outcomes** | Immediately post-intervention  **HIV knowledge**  **HIV preventative self-efficacy**  **Intended condom use with current and future partners**  **Physical outcomes motivation, social motivation, self-evaluative outcome motivation** |
| **Aim and target population** | To influence HIV prevention behaviours |

#### Risk of bias

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| **Bias** | **Authors' judgement** | **Support for judgement** |
| Random sequence generation (selection bias) | Unclear risk | Not stated. 'All students who volunteered and signed a consent form (n = 162) were randomly assigned to one of three groups'. |
| Allocation concealment (selection bias) | Unclear risk | Not stated. Sequence generation and allocation concealment rated 'B' |
| Large or differential losses to follow up | Low risk | Drop-out rates immediately post-intervention were 7% in IDI arm, 4% in lecture group arm, 2% in no-intervention arm. Drop-outs were excluded |
| Selective reporting (reporting bias) | Low risk | Data presented for all outcomes. |
| Blinding of participants | Unclear risk | Not stated |
| Blinding of research personnel | Unclear risk | Not stated |
| Blinding of outcome assessment (detection bias) | Unclear risk | Not stated |

### Festinger 2016

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| **Methods** | Two arm RCT |
| **Participants** | Adult participants in an adult, felony pre-adjudication drug court (community corrections program providing a judicially supervised regimen of drug abuse treatment for nonviolent drug-abusing offenders in lieu of criminal prosecution or incarceration).  Philadelphia, USA |
| **Interventions** | **IDI:** Criminal Justice Computer Assessment and Risk Reduction Education (CJ-CARE), a self-directed, computer-facilitated HIV intervention, delivered in three sessions of approx. 20 minutes, after their first three scheduled judicial status hearings. 'Each session [...] included a brief risk assessment, review of identified risks, structured skill building videos, and the development of a risk prevention action plan [...] tailored to address the current risks of the participant'. Also quizzes with feedback. For those with HIV, the program provided referral to treatment if they were not currently receiving medical care, and education on adherence to HIV treatment.  **Theory**: Client-centred motivational interviewing Information, Motivation, and Behavioural Skills (IMB). Transtheoretical Model. CARE 'incorporates elements from the counselling evidence base including Project RESPECT'.  **Consumer involvement:** Customisation of CARE to the criminal justice system was done with the help of a 'multidisciplinary advisory team of experts' but it is unclear whether this involved consumers or just professionals  **Methods for enhancing engagement:** Participants completed the intervention or control following their first three judicial status hearings  **Comparator:** Attention control: three educational videos focussing on 'life skills including (1) stress reduction, (2) anger management, and (3) positive listening', each lasting about the same duration as the intervention modules. These videos 'did not directly address HIV or substance abuse'.  **Incentives for research participation:** Baseline: US$30. US$25 gift cards upon completion of each of 3 computer sessions; US$40 for completion of follow-up (total: US$145). |
| **Outcomes** | Baseline and weeks 12, 18, and 36 weeks  **Behaviour**  **HIV testing rate** (obtained from HIV testing facility), on the same day of the 6-, 12- and 18-week interventions\*, and at 36 week follow-up [not clear whether this was assessed before or after the interventions received at 6, 12 and 18 weeks]  **Condom procurement:** condoms taken from a bowl containing 25 male and 5 female condoms, adjacent to the computer desk with a placard reading "Help yourself", at 6, 12 and 18 week intervention sessions  **High-risk** (for HIV) **drug and sexual behaviour**, measured using a 'Risk Assessment Battery' at baseline and 36 week follow-up |
| **Aim and target population** | To reduce HIV risk among adult felony drug court participants  **Inclusion:** at least 18 years of age, charged with a non-violent felony offense and in need of treatment for drug abuse or dependence |
| **Notes** | No response from authors |

#### Risk of bias

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| **Bias** | **Authors' judgement** | **Support for judgement** |
| Random sequence generation (selection bias) | Unclear risk | Randomisation method not mentioned |
| Allocation concealment (selection bias) | Unclear risk | Unclear. No details given |
| Large or differential losses to follow up | Low risk | IDI 89/99 = 90% Control 89/101= 88% |
| Selective reporting (reporting bias) | Unclear risk | Unclear |
| Blinding of participants | Unclear risk | Unclear: Intervention and control are 'about the same duration' |
| Blinding of research personnel | Unclear risk | Unclear |
| Blinding of outcome assessment (detection bias) | Unclear risk | Unclear |
| Other bias | Unclear risk |  |

### Fiellin 2017

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| --- | --- |
| **Methods** | Two arm RCT |
| **Participants** | Adolescents aged 11-14 years old, in 12 urban community-based settings (school-based after-school programs, independent after-school programs, and a summer camp) USA |
| **Interventions** | **IDI:** *PlayForward: Elm City Stories*, 'a two-dimensional, role-playing adventure video game' on an iPad, which allows the player to see how their individual decisions are influenced by their social surroundings, and impact on short-term and long-term goals. The player's goal is to acquire and practice skills to reduce HIV risk behaviors. The player creates an Aspirational Avatar in an interactive world who faces challenges and makes decisions. Players played their assigned game for two sessions per week, approximately an hour per session, for 6 weeks.  **Theory:** Social learning theory, self-efficacy, message framing, and delay discounting.  **Consumer involvement:** developed 'through an iterative process working with [...] adolescents, and community program staff'  **Methods for enhancing engagement:** participants took part whilst attending after-school programs or summer camp  **Comparator:** 'Attention/time control games': 12 video-games 'such as *Angry Birds*, *Dragon Box*, and *Subway Surfer*' which 'were devoid of content relevant to our study goals and mirrored the number of sessions and length of game-play in the experimental group'  **Incentives for research participation:** gift-cards totalling US$180 per participant, for completing baseline and subsequent assessments. 'Creative methods were used to re-engage with participants over time to encourage participation in follow-up assessments [including] [...] pizza and cupcake parties.' |
| **Outcomes** | Baseline, 6 weeks, and 3, 6, 12, and 24 months  **Knowledge**: sexual health knowledge (HIV knowledge score)  **Intentions** to delay intercourse  **Attitudes:** Sexual health attitudes  **Behaviour**  Delay of initiation of sexual intercourse (vaginal or anal) at 12 months (primary outcome) |
| **Aim and target population** | To 'improve sexual health outcomes in adolescents' |

#### Risk of bias

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| --- | --- | --- |
| **Bias** | **Authors' judgement** | **Support for judgement** |
| Random sequence generation (selection bias) | Low risk | 'Computerized single randomization scheme' used. Randomization was stratified by gender and age. Randomization was under the control of an investigator who was not involved with the eligibility assessment. |
| Allocation concealment (selection bias) | Unclear risk | 'Study personnel accessed the computerized randomization system, retrieved the assignment, and notified participants of their group assignment' |
| Large or differential losses to follow up | High risk | 129/166 (78%) in the intervention arm, and 129/167 (77%) in the control arm at 12 months |
| Selective reporting (reporting bias) | High risk | Additional assessment data were collected but not reported |
| Blinding of participants | High risk | Intervention and control groups sat at different tables or in different sections of the classroom. |
| Blinding of research personnel | High risk | 'Study personnel accessed the computerized randomization system, retrieved the assignment, and notified participants of their group assignment' |
| Blinding of outcome assessment (detection bias) | High risk | Research staff were aware of allocation. Data were collected in person (input into a web-based database by research staff, or for 'assessments including sensitive data, participants filled out responses after questions were read to them'). |
| Other bias | High risk | Conflict of interest reported in Fiellin 2016 (but not Fiellin 2017). Some authors are affiliated with the 'commercial venture' which distributes 'evidence-based video games for risk reduction and prevention'.  Individually randomized, but there are likely to have been cluster effects, since the intervention was offered over 6 weeks in group settings, and children may have shared what they learnt. |

### Gilbert 2008

|  |  |
| --- | --- |
| **Methods** | Two arm risk profile based block-randomised control trial |
| **Participants** | HIV positive for 3 or more months and aged 18 or above.  USA |
| **Interventions** | **IDI:** IDI tailored by participants risk profile (drug use, alcohol use, sexual behaviour), gender and readiness to change with an education tailored worksheet produced for the patient at the end of the module and a cueing sheet for the providers with information about the patients risk profile, readiness to change and suggested risk reduction counselling with a booster session at 3 months.  **Theory:** Motivational Interviewing  **Consumer involvement:** not stated  **Methods for enhancing engagement:** Financial incentive of $40 gift card. Frequent reminders via phone and emails were also sent.  **Comparator:** Completion of risk assessment online and usual care  **Incentives for research participation:** Financial incentive of $40 gift card for baseline session and additional $50 and $60 at 3 and 6 month follow-ups. |
| **Outcomes** | Assessed online at baseline, 3 and 6 months for participants reporting risky behaviour at baseline and by group assignment  **Behavioural:** number of drinks per week (for participants drinking over recommended limits), number of binge drinking episodes, total days of all drug use, absolute percent change in self-reported condom use with main and casual partners and number of casual sex partners. |
| **Aim and target population** | HIV positive patients. To test the efficacy of an interactive computer program to reduce illicit drug use, risky alcohol drinking and unprotected anal or vaginal sex |

#### Risk of bias

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| **Bias** | **Authors' judgement** | **Support for judgement** |
| Random sequence generation (selection bias) | Low risk | Computer generated randomisation to intervention or control arm |
| Allocation concealment (selection bias) | Low risk | Study personnel (until completion of baseline) and participants were unaware of the arm of randomisation but participants and providers received educational worksheets and cue sheets respectively and may have probably guessed the study group |
| Large or differential losses to follow up | Low risk | Loss to follow up was 18% in treatment arm and 17% in control arm. It was assumed that participants who did not return for follow up continued with their reported risky behaviour. Alternate outcomes analyses with complete cases only assuming participants lost to follow up were similar to those completing follow up was conducted. There was no substantive change in outcomes in a model using the latter assumption compared to the former assumption. |
| Selective reporting (reporting bias) | Low risk | Data on all outcomes presented. |
| Blinding of participants | Unclear risk | Participants were unaware of the treatment allocation but participants who received educational worksheets may have probably guessed their allocation and this may influence reporting of outcomes |
| Blinding of research personnel | Low risk | Self-completed questionnaires by the participants so unlikely to have a major impact |
| Blinding of outcome assessment (detection bias) | Unclear risk | Not stated |

### Hightow-Weidman 2012

|  |  |
| --- | --- |
| **Methods** | Two-arm randomised control trial |
| **Participants** | Young black/African American men who have sex with men  USA |
| **Interventions** | **IDI:** Tailored theory-based intervention for HIV/STI prevention among young black MSM  **Theory:** Integrated model of behaviour theory  **Consumer involvement:** Focus group discussions, semi-structured interviews and usability testing with young black men who have sex with men to inform development of the online intervention  **Methods for enhancing engagement:**  **Comparator:** List of five web sites that provide general HIV/STI information  **Incentives for research participation:** Participants received financial incentive of $30 per survey for completing three surveys, $30 for completing weekly online diaries, and an additional $30 if they completed the entire study. |
| **Outcomes** | Assessed using online questionnaire at baseline, one and three months  **Cognitive:** Intention to use condoms, engage in preparatory condom use behaviours (buying and carrying), discuss HIV status with partners, attitudes and extent of motivations for engaging in safer sex, condom use self-efficacy, HIV/AIDS knowledge  **Behavioural:** number of male and female partners in the preceding 30 days, number of times engaged in various sexual activities with their partners by sero-status and number of times engaged in each activity with and without a condom.  **Other:** overall reaction to the web site, overall satisfactions with the web site, depression symptoms |
| **Aim and target population** | To assess the feasibility and acceptability of delivering theory-based, tailored HIV/STI prevention intervention  Young black men who have sex with men |

#### Risk of bias

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| --- | --- | --- |
| **Bias** | **Authors' judgement** | **Support for judgement** |
| Random sequence generation (selection bias) | Low risk | Participants were randomised by computer generated code that directed them to one of two web sites upon enrolment. More HIV positive persons in the control group than the intervention group. |
| Allocation concealment (selection bias) | Low risk | Participants were randomised by computer generated code |
| Large or differential losses to follow up | High risk | Between baseline and 3 month follow-up 16% of intervention group and 28% of control group were lost to follow up. 13% HIV negative participants were lost to follow-up whereas 33% of HIV positive persons did not complete the 3 month assessment. No data on how missing data was dealt with was given but cases with missing data appear to have been excluded. |
| Selective reporting (reporting bias) | Low risk | Data presented on all pre-specified outcomes |
| Blinding of participants | High risk | Participants were not blinded as they were aware which site they were directed to |
| Blinding of research personnel | Low risk | Not stated but intervention was delivered online and outcomes self-reported by participants |
| Blinding of outcome assessment (detection bias) | Unclear risk | Not stated but participants self-completed the questionnaire |

### Ito 2008

|  |  |
| --- | --- |
| **Methods** | Two arm RCT |
| **Participants** | 15-19 year old adolescent new female patients attending a family planning clinic  USA |
| **Interventions** | **IDI:** Culturally-tailored interactive CD-ROM intervention plus standard care (didactic session led by educator). Video clips, cartoons, quiz, games. Tailoring by ethnicity and sexual experience of a virtual host.  **Theory:** Integrative model of behavioural prediction  **Consumer involvement:** Panel of adolescents were involved in development process and a randomised trial of 3 different versions of the CD-ROM among female undergraduate students was conducted.  **Methods for enhancing engagement:**  **Comparator:** 30 minute educator-led group didactic session  **Incentives for research participation:** Participants received a financial incentive of $10 for study completion |
| **Outcomes** | Assessed using written questionnaire at baseline and immediately after intervention  **Knowledge:** STI/HIV knowledge  **Intention**: to engage in sexual intercourse and to use condoms at next intercourse  **Self-efficacy**: to refuse sex, buying and using condoms, and condom communication  **Attitudes**: towards sexual intercourse and condom use  **Norms**: about sexual intercourse, and condom use  **CD-ROM acceptability and feasibility** |
| **Aim and target population** | To prevent HIV/STI |

#### Risk of bias

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| --- | --- | --- |
| **Bias** | **Authors' judgement** | **Support for judgement** |
| Random sequence generation (selection bias) | Low risk | Clinic sessions were randomly assigned to receive the intervention or standard of care using a computer generated random number contained in an opaque envelope |
| Allocation concealment (selection bias) | Low risk | opaque envelopes |
| Large or differential losses to follow up | Low risk | There was no loss to follow-up because the assessment was done immediately post-intervention |
| Selective reporting (reporting bias) | Low risk | Data on all outcomes reported |
| Blinding of participants | Unclear risk | Not stated |
| Blinding of research personnel | Unclear risk | Not stated |
| Blinding of outcome assessment (detection bias) | Unclear risk | Not stated |

### Jenkins 2000

|  |  |
| --- | --- |
| **Methods** | Four arm randomised controlled trial. |
| **Participants** | Army men with urethritis, clinic attenders  USA |
| **Interventions** | **IDI: interactive video disc:** computer tailored feedback based on responses to questions. videodisc done alone. One session  **Theory:** designed to fit with military behavioural norms  **Consumer involvement:** not stated  **Methods for enhancing engagement:** None  **Comparator 1: STD/HIV risk appraisal:** computerised risk profile and specific feedback messages with problem-focused counselling.  **Comparator 2: Targeted situational behaviour:** face-to-face counselling based on usual partner-seeking behaviour  **Comparator 3:** standard clinical care: STD counselling and medication advice  **Incentives for research participation:** |
| **Outcomes** | Two weeks and two months post intervention  **HIV knowledge**  **Readiness to change (condom use, partner choice, alcohol consumption)**  **Peer approval, perceived vulnerability to HIV**  **Sex with high risk partners, condom use with risky partners, sharing needles, sexual bingeing, use of alcohol, new partners in high risk venues, carrying condoms, having partners with genital warts or sores. Adherence to medication. Proportion of men with >1 partner at 2 weeks. Proportion going to meet new sex partner.** |
| **Aim and target population** | To reduce STD and HIV infection risk behaviours |
| **Notes** | Not included in meta-analysis as data for control arm not available (authors were contacted) |

#### Risk of bias

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| --- | --- | --- |
| **Bias** | **Authors' judgement** | **Support for judgement** |
| Random sequence generation (selection bias) | Low risk | Random number table. 'Patients were randomised to 1 of the 4 study conditions, with assignment based on a random number table'. |
| Allocation concealment (selection bias) | Unclear risk | Sequence generation and allocation concealment rated 'B'. |
| Large or differential losses to follow up | High risk | 27% were lost to follow up at at two weeks, and 51.5% were lost to followup at two months. No statistically significant differences between groups |
| Selective reporting (reporting bias) | High risk | Many variables measured, but few results presented, particularly the 2 month outcome data |
| Blinding of participants | Unclear risk | Not stated |
| Blinding of research personnel | Unclear risk | Not stated |
| Blinding of outcome assessment (detection bias) | Unclear risk | Not stated |

### Kiene 2006

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| --- | --- |
| **Methods** | Two arm randomised controlled trial |
| **Participants** | Psychology students (university)  USA |
| **Interventions** | **IDI:** Condom use information, motivation and behavioural skills. Goal setting. Tailoring by baseline Information, Motivation and Behavioural skills. Self-selected goals. 2 sessions: 1) 15-40 minutes 2) 2 weeks later follow up. Private room  **Theory:** Information, Motivation, Behavioural skills model; Motivational Interviewing and Stages of Change  **Consumer involvement:** not stated  **Methods for enhancing engagement:**  **Comparator:** Nutrition education tutorial (also computer delivered): no more details given  **Incentives for research participation:** |
| **Outcomes** | 4 weeks  **Condom knowledge**  **Condom use behavioural skills (efficacy and difficulty)**  **Condom use intentions, condom use stage of change**  **Condom-related attitudes and social norms (family and friends' beliefs)**  **Condom use in last 30 days, keeping condoms handy, persuading a partner to use condoms** |
| **Aim and target population** | To increase HIV/AIDS preventive behaviours |

#### Risk of bias

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| --- | --- | --- |
| **Bias** | **Authors' judgement** | **Support for judgement** |
| Random sequence generation (selection bias) | Low risk | 'A software random number function assigned participants to condition'. |
| Allocation concealment (selection bias) | Unclear risk | Sequence generation and allocation concealment rated. |
| Large or differential losses to follow up | Low risk | 5% lost to follow up and no significant differences in lost to follow up rates between study arms. All participants included in analysis of IMB constructs (including intention), but not for safer sex behaviours. Missing data was imputed by carrying last observation forward and intention to treat analysis was conducted. |
| Selective reporting (reporting bias) | Low risk | Data presented for all outcomes. No comment on blinding of outcome assessors |
| Blinding of participants | Unclear risk | Not stated |
| Blinding of research personnel | Low risk | Not stated but unlikely to influence performance and detection bias |
| Blinding of outcome assessment (detection bias) | Unclear risk | Not stated if participants were blinded to the type of intervention they were assigned to but awareness of assignment could influence self-reported outcomes |

### Klein 2013

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| --- | --- |
| **Methods** | Two arm randomised controlled trial |
| **Participants** | African-American HIV-positive women, aged 18-50, recruited through health departments and community-based AIDS service organisations. USA. |
| **Interventions** | **IDI:** WiLLOW (Women Involved in Life Learning from Other Women) - a multimedia adaptation of a face-to-face intervention to enhance HIV-protective sexual behaviours and psychosocial outcomes among HIV-positive African-American women. Two one-hour sessions, broken into 2-8 minute activity modules. Videos, quizzes, and interactive activities based on 4 sessions: pride, values, and goals; stress management; risk-reduction and condom management; building healthy relationships and practice becoming peer educators.  **Theory:** Social cognitive theory: modelling activities, self-management behaviours, and risk-reduction strategies  Theory of gender and power: 'recognition that societal expectation as women as caregivers constrain many HIV-positive women's ability to access social support networks'  **Consumer involvement:** None stated (intervention is adaptation of face-to face intervention)  **Methods for enhancing engagement:** None - one-off session  **Comparator:** HIV prevention brochures  **Incentives for research participants:** 75USD for completing baseline, 50USD for completing follow-up |
| **Outcomes** | 3 months  Behavioural:  Number of partners in last 90 days (HIV+, HIV-, unknown)  Percentage of condom protected vaginal or anal intercourse in last 30 days (by HIV status and relationship type - primary or non-primary)  100% condom use in last 30 days  Cognitive:  Knowledge  Condom use self-efficacy  Sexual communication  Communication self-efficacy |
| **Aim and target population** | To evaluate a multi-media adaptation of a face-to face intervention (WiLLOW) in enhancing HIV-protective sexual behaviours and psychosocial outcomes among HIV-positive African-American women |
| **Notes** | Other factors measured (mental health, social support, stress, coping, self-esteem) - appear to be covariates, so not classed as outcomes here. |

#### Risk of bias

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| --- | --- | --- |
| **Bias** | **Authors' judgement** | **Support for judgement** |
| Random sequence generation (selection bias) | Low risk | "Prior to enrolment, a randomization scheme was created using a computer-generated block-randomization...via sealed opaque envelopes using a 1:1 intervention-comparison randomization allocation" |
| Allocation concealment (selection bias) | Low risk | "Study recruiters and coordinators were blinded to which condition the participant had been assigned until they opened the envelope at the start of the participant's designated time slot"  Information from the author: "The research team created lists of randomized study ID numbers for each of the two study sites. These random lists included intervention and control participants. We then assembled individual participant study packets, each with a unique study ID number printed on the outside of sealed 9” X 12” envelopes. These packets contained the consent form, the study instruments, incentive receipts, and, in the case of control condition participants, several health education brochures. Research personnel did not know which arm participants were in until they opened the participant’s envelop." |
| Large or differential losses to follow up | Low risk | Retention 98.9% in control condition, 93.1% in intervention condition. |
| Selective reporting (reporting bias) | Unclear risk | Insufficient information, no published protocol available.  Findings reported for stated primary outcomes, but not for some secondary outcomes (knowledge, condom use self-efficacy) |
| Blinding of participants | Low risk | Information from author: "Participants were not ever informed whether they were in the intervention or control arm." |
| Blinding of research personnel | Low risk | No blinding; however, interventions were completed individually in a private room, so lack of blinding is unlikely to have influenced outcome. |
| Blinding of outcome assessment (detection bias) | Unclear risk | "Data collection occurred at baseline and three-month follow-up via pen and paper"  Unclear exactly how assessments were taken, who by, and whether they were blinded. |

### Kurth 2014

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| --- | --- |
| **Methods** | Two-arm randomised controlled trial |
| **Participants** | HIV-positive adults (18 and over) on anti-retroviral therapy (ART), USA |
| **Interventions** | **IDI:** Computer Assessment and Rx Education for HIV positive people (CARE+), a software application designed for touch-screen computers (tablets), including audio narrated assessment, tailored feedback, skill-building videos, and health plans, aimed at improving ART adherence and reducing sexual risk behaviours in people living with HIV. 4 sessions at 3 monthly intervals over 9 months.  **Theory:** Information-motivation- behavioural skills model - "'importance' and 'confidence' scales around ART use and transmission risk-reduction"  Transtheoretical model - "stages of change questions around condoms"  Social-cognitive role-modelling - "peers demonstrating healthy behaviours in videos"  Motivational interviewing - "messages acknowledging ambivalence around behaviour change and highlighting user's commitment"  **Consumer involvement:** "Content recommendations were obtained through 30 qualitative interviews conducted with people living with HIV"; "software usability was evaluated with 30 HIV-positive clients"  **Methods for enhancing engagement:** Sessions delivered on same day as clinic visit, where possible.  **Comparator:** Standard care control, assessment only using tablet computer.  **Incentives for research participants:** 20USD at the first 3 sessions, 40USD at final session. |
| **Outcomes** | 9 months  Biological: HIV-1 RNA Viral Load (measuring adherence, therefore not of interest to this review)  Behavioural: 'Sexual transmission risk' - composite variable of no condom use or condom use with errors/problems  Cognitive: Condom stages of change  (Note - additional outcomes are reported as measured, but findings are not reported) |
| **Aim and target population** | To evaluate a computerized intervention supporting ART adherence and HIV transmission prevention in HIV-positive adults. |

#### Risk of bias

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| --- | --- | --- |
| **Bias** | **Authors' judgement** | **Support for judgement** |
| Random sequence generation (selection bias) | Low risk | "assigned through an automated pseudo-random number generation algorithm" |
| Allocation concealment (selection bias) | Low risk | Allocated automated using a computer. |
| Large or differential losses to follow up | Low risk | 87% follow-up rate, no differential attrition between groups. |
| Selective reporting (reporting bias) | High risk | Sexual transmission primary outcome reported as 'composite variable of no condom use or condom use with errors/problems'; however, protocol on trials register (NCT00443378) reports primary sexual transmission outcome as 'Self-reported unprotected sex with a non-concordant partner'. |
| Blinding of participants | Unclear risk | Insufficient information. |
| Blinding of research personnel | Unclear risk | Insufficient information. |
| Blinding of outcome assessment (detection bias) | Low risk | Insufficient information; however, it appears that assessments were conducted online, and so are unlikely to have been influenced by lack of blinding. |

### Leiby 2016

|  |  |
| --- | --- |
| **Methods** | Three-arm RCT, comparing tailored IDI about voluntary medical male circumcision (VMMC) with non-tailored messaging about VMMC, and no messaging about VMMC. |
| **Participants** | Uncircumcised males aged 15-30, who had subscribed to '*Zambia U-Report*' national SMS platform, 'which provides free confidential and interactive counseling to adolescents and youths with trained 24-hour counselors on HIV/AIDS and other sexual and reproductive health topics'.  Zambia |
| **Interventions** | **IDI:** Package of 7 SMS (text messages) every 2 months, over a 6-month period (total 21 messages), which were tailored by addressing each attitude-social influence-self-efficacy barrier to VMMC and stage of change. 'Participants with lower intention mainly received simpler VMMC information; participants reporting greater intention mainly received information related to accessing VMMC services and undergoing the procedure.' All study participants were subscribers to the U-Report service which remained available throughout the study. [Information from authors] Intention to get circumcised was a criterion for tailoring messages in the tailored group, but not in the standard messaging group.  **Theory:** 'Stages of change framework' and 'Attitude-social influence-self-efficacy framework'  **Consumer involvement:** Not reported.  **Comparator 1:** Non-tailored intervention (same mix of messages for all participants, regardless of self-reported stage of change).  **Comparator 2:** No intervention  **Methods for enhancing engagement:** IDI and non-tailored intervention - packages of 7 SMS messages every 2 months for 6 months.  **Incentives for research participation:** 2 Zambian kwacha (approx. US$0.32) airtime incentive per survey completed, 'enough to cover about 6 SMS messages or about 3 minutes of airtime'. 4 surveys: baseline, 2, 4 and 6 months, total: 8 kwacha, US$1.28. 'Participants could decline to complete any of the SMS surveys and still received the airtime incentive.' |
| **Outcomes** | Baseline, 2, 4 and 6 months  Intention to get circumcised or reported behaviour: 1) No intention, 2) intention at some point, 3) intention w/i next 2 months, 4) reported circumcision [Intention was not therefore used as an outcome]  **Behavioural**  VMMC uptake (two primary outcomes):  - self-reported VMMC uptake  - verified VMMC uptake (at a public or private facility in the study area)  Engagement with U-report counselors (outside of study data collection) |
| **Aim and target population** | To increase uptake of voluntary medical male circumcision  Uncircumcised men, Lusaka province, Zambia. |
| **Notes** | Two comparisons used in meta-analyses: IDI *vs.* no intervention (Group 1) and IDI *vs.* non-tailored SMS intervention (Group 3) |

#### Risk of bias

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| --- | --- | --- |
| **Bias** | **Authors' judgement** | **Support for judgement** |
| Random sequence generation (selection bias) | Low risk | 'The study sample was stratified by district (Lusaka or Chongwe), age (<18 or ≥18), and self-reported VMMC intention (within 2 months or not). Participants were then randomly assigned to one of the 3 study arms.'  Information from authors: 'We stratified on 3 variables, and then individually randomized within each stratum using Stata'. |
| Allocation concealment (selection bias) | Low risk | Information from authors: 'Randomization allocations were done electronically with our participant list, so the randomization scheme and the allocation was simultaneous'. |
| Large or differential losses to follow up | High risk | Survey responses:  Control 550/648 = 85%  Non-tailored 569/662 = 86%  IDI 533/644 = 83%  Verified circumcision uptake: 'Only 12.6% of self-reported outcomes were verified using client data' |
| Selective reporting (reporting bias) | Low risk | All outcomes reported. |
| Blinding of participants | Unclear risk | Not feasible. |
| Blinding of research personnel | Unclear risk | Not reported |
| Blinding of outcome assessment (detection bias) | Unclear risk | Survey data collected via SMS. Information from authors: 'There were no outcome assessors, as the outcome was based on self-report. We did try to verify the self-report by asking service providers to confirm who had been circumcised. The service providers were blinded to the allocation, but the researchers requesting the verification were not.' |
| Other bias | High risk | Probable over-reporting of self-reported VMMC uptake, and under-reporting of verified circumcision, since it was only possible to verify uptake at a facility in the area. It is not possible to say how this differed between study arms: 'An unrealistic proportion of participants (11.5%) reported circumcision uptake without any contradiction across multiple surveys, and an additional 15.2% reported contradictory information'. Authors state that it is 'possible that participants who made up their mind to obtain the procedure (but had not yet done so) were more likely to report positively'. 'Treatment-arm participants received information on VMMC and could have reported their [circumcision] status more accurately.' 12.6% of self-reported outcomes were verified using clinic data. |

### Marsch 2011

|  |  |
| --- | --- |
| **Methods** | Two arm randomised control trial |
| **Participants** | Participants aged 12-18 years attending community-based adolescent treatment for substance abuse  USA |
| **Interventions** | **IDI:** Educator-delivered one group session of one hour on HIV/STI prevention as well as access to an interactive, web-based HIV, hepatitis, STI prevention program. Tailoring of content by alcohol and drug use, and HIV and hepatitis status; quizzes with adjustment of pace and level of content presented. Graphics and animations.  **Theory:** "Fluency-based" computer-assisted instruction  **Consumer involvement:** authors have previously conducted few studies exploring the potential of using computer technology among adolescents with substance abuse problems.  **Methods for enhancing engagement:** none  **Comparator:** Educator delivered one group session of one hour on HIV/STI prevention and participants watched a 15 minute video on HIV prevention  **Incentives for research participation:** |
| **Outcomes** | Assessed at 1 and 3 months post-intervention  **Knowledge:** HIV/STI prevention knowledge  **Self-efficacy:** condom use skills  **Intention:** to use condoms in the future  **Attitudes:** towards condoms |
| **Aim and target population** | To evaluate the effectiveness of an interactive, customisable, web-based program for prevention of HIV/STI  Adolescents in treatment for substance use |
| **Notes** | Not included in meta-analysis as data were not available (authors were contacted) |

#### Risk of bias

|  |  |  |
| --- | --- | --- |
| **Bias** | **Authors' judgement** | **Support for judgement** |
| Random sequence generation (selection bias) | Low risk | Participants were randomly assigned to the intervention or control arm using a computer generated randomisation procedure in SAS. |
| Allocation concealment (selection bias) | Unclear risk | Not stated |
| Large or differential losses to follow up | High risk | 43% were lost to follow up at 3 months. Although authors have stated that there was no difference in follow up completion rates by study condition, there are no further details provided. |
| Selective reporting (reporting bias) | Low risk | Data on all outcomes reported |
| Blinding of participants | Unclear risk | Not stated |
| Blinding of research personnel | Unclear risk | Not stated |
| Blinding of outcome assessment (detection bias) | Unclear risk | Not stated |

### Marsch 2015

|  |  |
| --- | --- |
| **Methods** | Two-arm RCT. Stratified by study site, gender, and whether the participant met/did not meet dependence criteria (vs. abuse criteria) on any substance (excluding nicotine). |
| **Participants** | New patients (12 to 18 years old) at outpatient adolescent substance abuse treatment centres  New York City, USA |
| **Interventions** | **IDI:** Therapeutic Education System (TES). Interactive, web-based HIV, hepatitis and STI prevention program. Total of 26 modules providing information about HIV, hepatitis, STI; alcohol and substance use and infection risk; risk reduction; decison-making and negotiation skills. Seven of the modules were for those with hepatitis or HIV. Tailoring through computerized risk behaviour assessment with tailored, ordered selection of TES modules to complete; individually paced presentation of content and testing to check for mastery of the material.  **Theory:** not stated.  **Consumer involvement:** not stated.  **Methods for enhancing engagement:** Participants were asked to complete their customized plan in multiple 60 minute sessions using a dedicated computer at their treatment program.  **Comparator:** Intervention delivered face-to-face, consisting of two sessions lasting approximately one hour each, individually or in small groups (2-4 participants). Educator was an HIV and infectious disease prevention specialist experienced with working with youth. Sessions covered: descriptions and basic transmission dynamics of HIV, hepatitis A, B, C and STIs; strategies for reducing drug-related and sexual risks of these infections; information on testing. Sessions included a condom-use demonstration, used visual aids, and included a 20-minute youth-centred HIV prevention video.  **Incentives for research participation:** $40 gift cards for completing scheduled assessments |
| **Outcomes** | Baseline, and within 2 weeks of completing interventions  **Knowledge:** HIV, hepatitis and STI knowledge  **Self-efficacy:** Condom use self-efficacy scale  **Intention:** Behavioural Intentions Scale  **Condom use skills**: enact 9 steps involved in using a condom (on a penis model)  **Behavioural:** Sexual activity scale of the Risk Behavior Survey (number of partners; frequency of oral, vaginal and anal sex and use of condoms [unprotected sex]) |
| **Aim and target population** | To compare the effectiveness of the TES web-based intervention to educator-delivered HIV prevention, for substance using youth. |

#### Risk of bias

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| **Bias** | **Authors' judgement** | **Support for judgement** |
| Random sequence generation (selection bias) | Unclear risk | Stratified randomisation |
| Allocation concealment (selection bias) | Unclear risk | "Randomization occurred immediately after an individual was determined to be eligible for the trial and appropriate consent/assent procedures and baseline assessments had been completed." Unclear if allocation concealment took place. |
| Large or differential losses to follow up | High risk | Large and differential losses to follow-up: intervention arm: 44/69 reached at follow-up (64%), control arm: 30/72 reached at follow-up (42%) |
| Selective reporting (reporting bias) | Low risk | All outcomes described in Methods are reported. |
| Blinding of participants | Unclear risk | Not reported; unclear whether participants were aware of the nature of the interventions being compared. |
| Blinding of research personnel | Unclear risk | Not reported. Unclear. |
| Blinding of outcome assessment (detection bias) | Unclear risk | Unclear. Mode of outcome data collection not reported. |
| Other bias | Unclear risk | Contamination is a potential limitation as participants in study arms had frequent access to one another. However authors judged it unlikely that they spoke to each other about intervention content, on the basis that young people are unlikely to discuss such topics with peers that they are not close to. |

### McKinstry 2017

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| **Methods** | Two-arm RCT |
| **Participants** | HIV-positive men and women receiving care  Washington, DC, and the Bronx, NY, USA |
| **Interventions** | **IDI:** *CARE+ PfP* (Computer Assessment and Rx Education for HIV Positive People - *Prevention for Positives*). *CARE+* is a computer-based prevention counselling intervention ([Kurth 2014](#STD-Kurth-2014)), which was modified: 'the ART adherence/viral supression component was removed'. Touch screen tablet with headphones, in clinic waiting rooms. Participants selected a *CARE+* avatar that audio-narrated text and questions. 'Based on the responses to the risk behaviour questionnaire, the tool summarized the things that participant had been doing to stay healthy, then listed the things [to] work on...in order to reduce their HIV risk'. Skills building videos and personalized risk reduction plan which could be printed out. Referrals for STI, suicide prevention, domestic violence, sexual assault services, as indicated.  **Theory:** Several theoretical frameworks including Information-Motivation-Behavioral skills (IMB) model, the Transtheoretical model, Social Cognitive Theory, and Motivational Interviewing.  **Consumer involvement:** the 'revised *CARE+* software was pilot tested with the intended study population'.  **Methods for enhancing engagement:** 'study visits scheduled on the same day as regularly scheduled clinic visits where possible' 'however some participants...only needed to visit their HIV care providers every six months, and an extra trip to the clinic might be required to complete the study visit'  **Comparator:** Usualcare (in HIV services)  **Incentives for research participation:** 'payment amounts differed by site but ranged from $10-$25 per visit, enough to cover transportation costs' (to visits 'at baseline and 3, 6, 9 and 12 months'). |
| **Outcomes** | Baseline and months 3, 6, 9 and 12.  **Behaviour:**  Unprotected vaginal or anal sex the last time participants had sex, with a primary (e.g. regular) or non-primary (e.g. casual) partner/s (primary outcome)  Unprotected vaginal or anal sex at last sex with HIV-negative or HIV-unknown-status partners (all partners; primary and non-primary partners')  Frequency of unprotected vaginal or anal sex in the previous three months with non-primary partners  Transmission risk composite measure comprised of two elements: 1) condom problems in the last 3 months with any partner and 2) sex without a condom at last sex within the last 3 months'  **Biological:**  Viral load from clinic chart review (detectable was defined as >50 copies per ml) |
| **Aim and target population** | Computer-based counseling (*CARE+ PfP*) for HIV-positive people receiving care, to reduce the number of episodes of unprotected sex' |
| **Notes** | Viral load data were available for 51% (274/536) of the intervention group and 53% (283/539) of the control group |

#### Risk of bias

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| **Bias** | **Authors' judgement** | **Support for judgement** |
| Random sequence generation (selection bias) | Low risk | 'Participants were randomized 1:1 using a blocked randomization scheme' which was programmed into the computer tablet which housed the *CARE+* software.  'Errors in study-arm allocation and intervention delivery occurred for 17 participants due to both user and software errors.'  'Following intention-to-treat principles, these 17 subjects ... were analysed in the arm to which they were originally assigned' |
| Allocation concealment (selection bias) | Low risk | 'Site staff members would assign eligible participants a unique participant identifier (PTID)' [and] 'then log into the *CARE+* software and enter the PTID for that participant...the computer program would look up the PTID in the randomization scheme and find the study arm assignment. Site staff would not know what the study arm assignment was' because the tablet routed participants in both arms to the Patient Survey. [information from authors] |
| Large or differential losses to follow up | Low risk | 'One site was terminated due to an inability to perform and 104 participants enrolled and randomized from that site were excluded from all analyses.'  Intervention arm: 441/536 were followed up = 82% (441/483 excluding participants in the site that became unable to perform and was excluded from analyses)  Control arm: 453/539 were followed up = 84% (453/488 excluding participants in the site that became unable to perform and was excluded from analyses) |
| Selective reporting (reporting bias) | Low risk |  |
| Blinding of participants | High risk | Not feasible; control was usual care |
| Blinding of research personnel | Low risk | Yes, research personnel were blinded [information form authors] |
| Blinding of outcome assessment (detection bias) | Low risk | Low risk for primary outcome and most secondary outcomes, which were 'collected via the tablet-based HIV risk behaviour questionnaire', self-completed by participants. Low/unclear risk for viral load, which researchers 'collected via chart review'. It is unclear whether patients' clinicians would have been aware of their allocation, however viral load was ascertained primarily for clinical reasons. |
| Other bias | Unclear risk | Study was conducted in health care sites - could have been cluster randomised |

### Merchant 2011

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| **Methods** | Two arm randomised control trial |
| **Participants** | Emergency department (ED) patients aged 18-64 years who were critically ill or injured or presenting for a psychiatric illness or physical or mental disability and were English speaking  USA |
| **Interventions** | **IDI:** Audio-computer delivered assessment about reported and self-perceived HIV risk and tailored feedback about risk of having or acquiring HIV according to reported risk.  **Theory:** Tailored feedback messages to responses about the reported HIV risk behaviours.  **Consumer involvement:** not stated  **Methods for enhancing engagement:** none  **Comparator:** Assessment of reported and self-perceived risk of HIV without feedback about their risk of having or acquiring HIV  **Incentives for research participation:** |
| **Outcomes** | Assessment immediate post-intervention  **Behavioural:** uptake of rapid HIV testing |
| **Aim and target population** | To determine the effectiveness of an audio computer assisted interview system delivered tailored feedback intervention about HIV risk behaviours on increasing uptake of opt-in universal rapid HIV screening  Adult ED patients |

#### Risk of bias

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| **Bias** | **Authors' judgement** | **Support for judgement** |
| Random sequence generation (selection bias) | Low risk | Participants were randomly assigned to the intervention or control arm and the dates and shifts during which patients were approached for the study were also randomly selected. |
| Allocation concealment (selection bias) | Unclear risk | Not stated |
| Large or differential losses to follow up | Low risk | no differential or large loss to follow up due to post-intervention assessment |
| Selective reporting (reporting bias) | Low risk | All outcomes reported |
| Blinding of participants | Low risk | Participants were informed that they may or may not receive feedback to the interview questions. However they were not informed about the intent of the intervention and that they would be offered an HIV test at the end of the study. |
| Blinding of research personnel | Unclear risk | Not stated |
| Blinding of outcome assessment (detection bias) | Unclear risk | Not stated |

### Milam 2016

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| **Methods** | Two-arm RCT |
| **Participants** | HIV-infected men who have sex with men, aged >18 years  'engaged in ongoing clinical care in primary care HIV services' in southern California, USA |
| **Interventions** | **IDI:** Internet intervention: monthly online sexual behaviour survey andrisk-reduction messages, tailored to the participants' risk of HIV transmission in the previous month (based on unprotected sex and needle sharing). 'Based on this [risk] stratification, there were different intensities of other static internet pages that had specific themes: (1) condom use; (2) disclosure to sex partners; (3) use of drugs and alcohol; (4) initiation of ART.' 'Messages used social influences and promoted positive movements in behavior based on the participant's current behavior/intent'. 'The intervention group was able to select behavioral goals for their next visit'. IDI messages were partly adapted from the Partnership for Health intervention  **Theory:** Social Cognitive Theory, and Transtheoretical Model of Change  **Consumer involvement:** 'Messages were partially adapted from the clinic-based Partnership for Health intervention and pre-tested through focus-groups with HIV-infected MSM who informed development and changes to the intervention content and approach.'  **Methods for enhancing engagement:** study clinic visits (every 3 months) could (but 'did not need to') coincide with treatment visits  **Comparator:** monthly online sexual behaviour survey (data collection only)  **Incentives for research participation:** Not reported |
| **Outcomes** | Baseline, 3 months, 6 months, 9 months, 12 months for STI screening  Monthly self-reported sexual behaviour (over 12 months)  **Behavioural:**  Any unprotected anal/vaginal sex with an HIV negative/unknown status partner during the past month  Disclosure of HIV status to HIV-negative/unknown status partners '(defined at each visit as disclosure to *all* partners)'  **Biological:**  HIV RNA and CD4 counts from clinical records  Any new STI at any anatomical site (Syphilis, Gonorrhoea, Chlamydia laboratory tests) (primary outcome) |
| **Aim and target population** | HIV-infected MSM at risk of transmitting HIV  to evaluate 'the efficacy of a brief internet-based intervention, provided monthly for a year, to reduce STIs and HIV transmission behaviours' |

#### Risk of bias

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| **Bias** | **Authors' judgement** | **Support for judgement** |
| Random sequence generation (selection bias) | Unclear risk | Randomization method not reported.  'Randomization was stratified based on site, having a computer at home, and use of anti-retroviral therapy' |
| Allocation concealment (selection bias) | Unclear risk | Unclear. Concealment of allocation not reported |
| Large or differential losses to follow up | High risk | IDI 72/90 = 80%  Control 67/89 = 75% |
| Selective reporting (reporting bias) | Unclear risk | 'Additional pre-specified analyses' were conducted on a subset of 'High Adherers' (participants with '75% internet visits completed') |
| Blinding of participants | High risk | Not feasible; control was an online survey only |
| Blinding of research personnel | Unclear risk | 'Data was collected by both confidential in-person interview and computer assisted survey self-report. 'Clinicians [...] were blind to group assignment' |
| Blinding of outcome assessment (detection bias) | Low risk | 'All STIs were verified by an independent and blinded adjudication committee'. 'Clinicians [...] were blind to group assignment'  Secondary outcomes were self-reported in an internet-based survey. |

### Perry 1991

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| **Methods** | Three arm randomised controlled trial. |
| **Participants** | Adults at risk of HIV, recruited for free HIV testing and counselling as part of a longitudinal study.  USA |
| **Interventions** | Tailored pre-HIV test counselling with psychiatric nurse, post-HIV test psychiatric nurse counselling (for all 3 groups).  **IDI**: Post-HIV test counselling plus interactive video on computer terminal. 3 x 45 min sessions in private on HIV testing, transmission, informing others, seeking medical care and social support. MCQs as tailored feedback. PI in white coat for re-framing and relaxation messages.  **Theory:** not stated  **Consumer involvement:** not stated  **Methods for enhancing engagement:**  **Comparator 1** (face-to-face intervention): post-HIV test counselling plus HIV education and stress prevention training. Individual, six 60 min sessions (CBT and stress inoculation)  **Comparator 2** standard care  **Incentives for research participation:** Mail and telephone reminders were sent to non-responders during follow up |
| **Outcomes** | Pre- and 3 months post-intervention  (Card 1993) **Knowledge** about HIV and AIDS (higher score=improvement), **HIV serology**  ([Perry 1991](#STD-Perry-1991)) **Beck Depression inventory, Trait Anxiety Inventory, State Anxiety Inventory, Brief Symptom Inventory, Hamilton Depression Rating Scale** |
| **Aim and target population** | To enhance HIV counselling to increase knowledge about HIV and AIDS and reduce emotional distress and HIV-related risk behaviours. |
| **Notes** | Same study as Card 1993, but reporting different outcomes  Not included in meta-analysis because data for analysis were not available (authors were contacted) |

#### Risk of bias

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| **Bias** | **Authors' judgement** | **Support for judgement** |
| Random sequence generation (selection bias) | Unclear risk | Not stated. 'We randomized subjects immediately after completion of post-test [HIV] counseling'. |
| Allocation concealment (selection bias) | Unclear risk | Not stated. |
| Large or differential losses to follow up | High risk | (Card 1993) 32% were lost to follow up at 3 months (328/481). Differential drop-out was reported (73% IDI and 83% the control groups). Subjects who returned tended to be the less knowledgeable at intake (but non-significant trend).  ([Perry 1991](#STD-Perry-1991)). 3/12 outcome data for 307/380. Drop-outs excluded. |
| Selective reporting (reporting bias) | Low risk | Data presented for all outcomes. No comment on blinding of outcome assessors |
| Blinding of participants | Unclear risk | Participants would be aware of the nature of intervention they were receiving |
| Blinding of research personnel | Low risk | The personnel who delivered the intervention to the Standard counselling and Stress prevention training arm were blinded to the baseline scores of depression of the participants |
| Blinding of outcome assessment (detection bias) | Low risk | The nurses who assessed the participants for the outcome measures were blinded. |

### Read 2006

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| **Methods** | Two arm randomised controlled trial |
| **Participants** | MSM recruited after negative HIV test results  USA |
| **Interventions** | **IDI:** Interactive virtual date. Physically, emotionally and socially realistic situation. Modelling and directed practice of the cognitive and behavioural skills needed to negotiate safer sex. 2 sessions, the second after 3 months.  **Theory:** importance of replicating realistic situations including emotional/sexual feelings.  **Consumer involvement:** focus groups, and consultation with staff from a gay and lesbian community centre.  **Methods for enhancing engagement:** $95 for completing the entire study  **Comparator:** usual post-HIV test counselling  **Incentives for research participation:** $95 for completing the entire study |
| **Outcomes** | Weekly for 8 weeks, 3 months and 5 months  **No significant effects on self-efficacy, attitudes, behavioural intention, but data not presented**  **Protected and unprotected sexual behaviour (anal, oral, rimming),** although different scales so can't be compared. Adjusted means (by ethnicity). |
| **Aim and target population** | To prevent HIV in MSM (reduce risky sex) |
| **Notes** | -Adjustment for baseline differences in ethnicity.  Two experimental groups n = 38; n = 36 and one control group (n = 36) …'we collapsed findings across conditions and report the comparisons between the combined experimental groups and the control condition'.  -Not included in meta-analysis because data for analysis were not available (authors were contacted) |

#### Risk of bias

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| **Bias** | **Authors' judgement** | **Support for judgement** |
| Random sequence generation (selection bias) | Unclear risk | 'Participants were randomly assigned to receive IAV....... or not'. |
| Allocation concealment (selection bias) | Unclear risk | Not stated. |
| Large or differential losses to follow up | Low risk | 19% participants lost to follow up at 8 weeks. No differences in attrition rates. Missing data not addressed (info from authors). |
| Selective reporting (reporting bias) | Unclear risk | Unclear exactly which outcome variables had been measured: giving and receiving anal sex with and without a condom were combined into measures of protected or unprotected anal sex respectively.  No comment on blinding of outcome assessors |
| Blinding of participants | Unclear risk | Not stated |
| Blinding of research personnel | Unclear risk | Not Stated |
| Blinding of outcome assessment (detection bias) | Unclear risk | Not stated |

### Rosser 2010

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| **Methods** | Two arm randomised control trial |
| **Participants** | Men who use Internet to seek sex with men, aged >17 years, engaged in unprotected anal intercourse with at least one other man, recruited via banners on two gay websites and emails sent to men who had participated in a previous survey.  USA |
| **Interventions** | **IDI:** Sexpulse, an Internet based intervention which used seminar based online sexual health curriculum in a modular form using interactive elements like videos, virtual peers etc. to address issues of safer sex, commitment to reduce risk and long term sexual health.  **Theory:** Sexual Health Model approach to HIV prevention, principles of e-learning, persuasive computing and human-computer interaction.  **Consumer involvement:** online survey with 2716 MSM to assess acceptability and nature of content of the intervention and HIV risk behaviour  **Methods for enhancing engagement:** Two automated email reminders following enrolment and if needed telephone call, and reminder emails at each subsequent follow-up were sent. Quarterly e-raffle with monetary first prize of $150 was employed to maintain study contact.  **Comparator:** No intervention  **Incentives for research participation:** Financial incentive of $80 for completing pre-test, intervention and post-test survey and additional $20-25 for subsequent follow up survey was given. |
| **Outcomes** | Baseline, immediate post-intervention, 3,6,9,12 months  **Behavioural**: Number of male unprotected anal sex during the prior 90 days |
| **Aim and target population** | To test whether an Internet based sexual health promotion intervention for men who use net to seek sex with men can reduce their unprotected anal intercourse  Adult men who use the Internet to seek sex with men |
| **Notes** |  |

#### Risk of bias

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| **Bias** | **Authors' judgement** | **Support for judgement** |
| Random sequence generation (selection bias) | Low risk | Computer algorithm used to randomly assign participants to one of the 2 experimental arms. |
| Allocation concealment (selection bias) | Unclear risk | Not stated |
| Large or differential losses to follow up | Low risk | 18% and 11% lost to follow-up at 12 m in treatment and control group respectively. No information on treatment of missing data or how analysis was conducted is provided. |
| Selective reporting (reporting bias) | Low risk | No data presented on changes in outcome at 6, and 9 months although data collected but data has been presented for 3 and 12 months. |
| Blinding of participants | Unclear risk | Not stated and likely to influence reporting of outcome |
| Blinding of research personnel | Low risk | Not stated but unlikely to be influenced by lack of blinding |
| Blinding of outcome assessment (detection bias) | Unclear risk | Not stated |
| Other bias | Unclear risk | “Study staff proctored the questionnaires under test-taking conditions, and scores were calculated by a computer.” The impact of this is unclear |

### Schonnesson 2016

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| **Methods** | Two-arm RCT |
| **Participants** | MSM *>*15 years, reporting sex with a man in the past 12 months, recruited via an LGBTQ community website, Sweden |
| **Interventions** | **IDI:** *SMART* intervention, delivered as 3 modules over 6 sessions, each of approximately 20 minutes. The information module covered: living with HIV; preventing HIV transmission and staying HIV negative (presenting a informative conversation between an 'expert' who is HIV positive and his friend who has recently engaged in high risk sexual behaviour, and interactive graphics and activities. Motivation and Behaviour modules presented conversations between small groups of men speaking with a facilitator, and 'screens are presented that allow the participant to choose answers or direct a conversation depending upon his choices'. The motivation module 'used a life goal clarification approach' to motivate safer sex choices with new partners or regular casual sex partners. Interactive exercises explored potential effects of choices and potential outcomes on life goals. Participants could evaluate their satisfaction and confidence with implementing safer sexual behaviors. The behaviour module focused on behaviour skills to reduce sexual risk when looking for sex partners in bars and online, helping participants to identify attitudes and behaviours that lead to high risk sexual encounters. Printable feedback tailored to a participant's responses was provided at the end of each session.  **Theory:** Information-Motivation-Behavioral (IMB) skills model  **Consumer involvement:** Adaptation of WRAPP to the Swedish context involved qualitative research with HIV-positive and HIV-negative Swedish MSM. Then, the WRAPP intervention was presented to the Swedish Federation for Lesbian, Gay, Bisexual and Transgender Rights (RFSL), the Stockholm County HIV/AIDS prevention programme, and at a HIV/STI clinic predominantly for MSM.  **Methods for enhancing engagement:** recruitment via an LGBTQ community website; advertised as an online sexual health game. Email reminders to complete sessions - dropped from the study if they did not complete a session in 24 hours from the email.  **Comparator:** Waiting list to receive the same intervention after study completion  **Incentives for research participation:** lottery tickets for completing the pre- and post-test questionnaires, total 200 Swedish krona (US$28). |
| **Outcomes** | Baseline and one month  **HIV knowledge**  **Self-efficacy**  Condom use self-efficacy (3 scales): situational self-efficacy (condom use in challenging situations); partner self-efficacy (use a condom when a partner did not want to or when the participant wanted to demonstrate commitment to the partner); condom-use communication self-efficacy  **Attitudes:** 'Motivation': Pros and cons of condom use  **Intention:** Willingness to reduce HIV sexual risk behaviours  **Behaviour:**  Frequency of anal sex in past 30 days with primary partner  Number of times condom was used  Number of casual sex partners  Number of casual sex partners with whom the participant had anal sex  Number of anal sex partners with whom they always used a condom  Converted to 'anal sex index, and 'condom-use index' for casual and primary partners |
| **Aim and target population** | 'To decrease HIV sexual risk behavior in Swedish MSM' |
| **Notes** | Developed from the Wyoming Rural AIDS Prevention Project (WRAPP, Bowen 2008). Bowen 2008 WRAPP intervention is an expansion of the intervention trialled in Bowen 2007. |

#### Risk of bias

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| **Bias** | **Authors' judgement** | **Support for judgement** |
| Random sequence generation (selection bias) | Low risk | Computer algorithm (information from authors) |
| Allocation concealment (selection bias) | Low risk | Participants were informed which group they had been allocated to, upon completing the first questionnaire. Allocation was electronic (email) with no human intervention. Allocation was available to researchers at the same time as participants, but was not looked at until analysis (information from authors) |
| Large or differential losses to follow up | High risk | High post-randomization drop-out (48%). Participants in the intervention arm were automatically dropped from the study if they did not complete each session within 48 hours (with 24 hours between sessions). This did not apply to the control arm. Differential drop-out:  Retention: IDI 25/58 = 43% Control 33/54 = 61% |
| Selective reporting (reporting bias) | High risk | 'Condom use was not analyzed due to the small sample size'  No data shown for many outcomes. Statistically signficant outcomes only reported in the abstract. |
| Blinding of participants | High risk | Not feasible given study design |
| Blinding of research personnel | Unclear risk | Not reported |
| Blinding of outcome assessment (detection bias) | Unclear risk | Data collection by questionnaire, but method of administering questionnaire not reported |

### Ybarra 2013

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| **Methods** | Two-arm randomised controlled trial |
| **Participants** | Secondary school children in Mbarara, Uganda, aged 12 and above |
| **Interventions** | **IDI:** 'CyberSenga' computerised intervention with five hour-long modules, each delivered a week apart. One-hour review session was also delivered as a 'booster' to half of intervention participants, at 4 months, between the follow-up assessments. Modules included 'information about HIV', 'decision making and communication', 'motivations to be health', 'how to use a condom to be healthy', and 'health relationships'. Tailored to biological sex and sexual experience.  **Theory:** Information-Motivation-Behavioural Skills model.  **Consumer involvement:** 'Formative research in the target population'; beta tested by a 'Youth Advisory Council'; 'Community Advisory Board' of local adult community members.  **Methods for enhancing engagement:** Intervention delivered in school setting, immediately after school.  **Comparator:** No intervention (usual care)  **Incentives for research participation:** No monetary incentive; certificate of programme completion provided. |
| **Outcomes** | Outcome assessments at 3 and 6 months (6 month selected as primary outcome point)  **Behavioural**: Unprotected sex in the last 3 months dichotomous, any unprotected sex); 'Abstinence' - dichotomous, vaginal or anal sex in the last 3 months at 6 month follow-up  **Knowledge** about condoms and HIV  **Attitudes** towards abstinence and condom use  **Behavioural intentions** towards abstinence and condom use  **Self-efficacy:** Behavioural skills for abstinence and condom use  Subjective norms for abstinence and condom use  Physical health  Self-esteem |
| **Aim and target population** | To increase HIV preventive behaviour and HIV preventive information, motivation, and behavioural skills in young people (grades 9-11 US) in areas with a high prevalence of HIV |
| **Notes** | RCT paper (Ybarra 2013) located during search, reporting findings for behaviour. Author provided more recent paper (Ybarra 2015) reporting findings for all other outcomes. |

#### Risk of bias

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| **Bias** | **Authors' judgement** | **Support for judgement** |
| Random sequence generation (selection bias) | Low risk | "Randomization to the intervention or control arm was executed using code embedded in the software program the minimized imbalance between the study arms with respect to biological sex and prior sexual activity at baseline, while maintaining a ratio of 1:1 in the two groups"  "Participants were randomized by the software program after they has completed the baseline survey" |
| Allocation concealment (selection bias) | Low risk | "Randomization to the intervention or control arm was executed using code embedded in the software program"; "participants were randomized at the end of the baseline survey. As such, all participants were blind to their arm assignment at enrolment" |
| Large or differential losses to follow up | Low risk | 3 month attrition: 4% in intervention, 7% in control. 6 month attrition: 8% in intervention, 7% in control. No difference between intervention and control groups. Missing data imputed using multiple imputation techniques. Intention to treat analysis performed.  6 month attrition: 8% in intervention, 7% in control. No difference between intervention and control groups.  Multiple imputation methods used for missing data, including best set regression; however, it is unclear how much missing data there was. |
| Selective reporting (reporting bias) | Low risk | Outcomes reported in protocol (clinicaltrials.gov: NCT00906178) match those reported in the paper. |
| Blinding of participants | Unclear risk | "Neither the research staff or participants were masked to study arm assignment". Impact of this is unclear. |
| Blinding of research personnel | Unclear risk | "Neither the research staff or participants were masked to study arm assignment". Impact of this is unclear. |
| Blinding of outcome assessment (detection bias) | Low risk | Information from author: "The data were collected at the schools in online surveys accessed through netbooks provided by the study. Data collection took place after school and in the absence of school personnel. Although study staff were not blind to the study allocation, we ensured that intervention youth and control youth completed the surveys in separate rooms, and ideally on separate days."  As outcome data collection was completed online, lack of blinding is unlikely to have had an impact. |