National Institute for Health and Care Excellence

Draft for Consultation

Reducing sexually transmitted infections (STIs)

[A] Evidence review for interventions to reduce the acquisition and transmission of STIs in high risk groups

NICE guideline <number>

Evidence reviews underpinning recommendations 1.1.1 to 1.1.14 and research recommendations in the NICE guideline

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Draft for Consultation

These evidence reviews were developed by Public Health Internal Guideline team

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Contents

1 Reducing the acquisition and transmission of STIs in high risk groups

1.1 Review question

What interventions designed to reduce the acquisition and transmission of STIs, including HIV, are effective and cost effective at preventing STIs in:

- Gay, bisexual and other men who have sex with men (MSM)[a]
- Young people age 16 to 24 years
- People from a Black African or Caribbean family background
- Trans people
- Migrant communities
- People who are homeless
- Asylum seekers

This review is supported by a qualitative review question and a mixed methods synthesis of the quantitative and qualitative evidence, which are presented in evidence review B.

1.1.1 Introduction

STI incidence increased by 5% from 2018 to 2019. Preventive interventions designed to prevent STI acquisition in uninfected people or prevent transmission from infected to uninfected people may be effective in reducing the spread of STIs in the specified risk groups.

1.1.2 Summary of the protocol

Table 1: PICO inclusion criteria

Eligibility criteria	Content
Population	Gay, bisexual and other men who have sex with men, young people aged 16 to 24 years, people from a Black African or Caribbean family background, trans people, migrant communities, asylum seekers, homeless people. Specific consideration will also be given to subgroup analysis within these populations and people from the groups identified in the equality impact assessment (EIA) (older adults and people with low socioeconomic status).
Interventions	Interventions with the primary aim of reducing or preventing STI acquisition or transmission in each of the risk groups identified. Interventions will largely seek to promote the uptake of specific preventative behaviours or to reduce risk behaviours but may also include efforts to improve knowledge or change attitudes and beliefs. Main intervention approaches may include: • Behaviour change approaches (such as goal setting, comparison of outcomes, self-belief, skills building with feedback). • Informational, educational or knowledge-based approaches (raising awareness, providing information and facts about STIs, routes and rates of transmission, risk and protective factors). May also include skills-based information provision (e.g. training in how to use a condom) and testing-focused approaches that are primarily designed to promote,

[a] Throughout this review, the term men who have sex with men (MSM) is used to refer to gay, bisexual and other men who have sex with men

Eligibility criteria	Content
	encourage and normalise testing through information provision. May also include normalising condom use. • Relationship focused approaches (such as promoting healthy sexual relationships, negotiating condom use, increasing assertiveness, understanding power and control within relationships, pleasure-based approaches) • Peer-to-peer approaches. These interventions involve the teaching or sharing of information, values, and behaviours by members of similar age or status group. They are often delivered in community settings and can involve peer supporters who are influential in their networks delivering sexual health advice, information or education to their peer group. • One-to-one approaches including risk reduction counselling. Single or multi-component interventions that include at least one of the listed approaches will be considered. All listed interventions may differ with respect to: Delivery format: (for example, passive or active approaches, remote or in-person approaches, workshops, demonstrations, interactive sessions, traditional media (e.g. posters, leaflets), broadcasting media (e.g. radio and TV), eHealth interventions Delivery location: (e.g. sexual health clinics; GP waiting rooms; gay bars and clubs; sex on premise venues such as saunas; universities and further education colleges, public settings such as posters on public transport)
Comparator	No intervention Usual care Comparator as defined by the paper
Outcomes	Primary outcomes • Condom use (including correct use, use at last sexual encounter, proportion of sex acts protected by condoms, frequency and/or consistency of use) • Incidence of STIs • Changes in sexual health knowledge or attitudes, measured as: - STI knowledge such as the prevalence, transmission route, health implications, treatment options for that condition - STI testing knowledge such as where to get tested, what testing involves Secondary outcomes • Safety or adverse effects • Engagement with the intervention • Unintended consequences • Sexual wellbeing such as, but not limited to, sustainability of healthy relationships, self-efficacy, consent, empowerment, control in relationships

1.1.3 Methods and process

This evidence review was developed using the methods and process described in Developing NICE guidelines: the manual. Methods specific to this review question are described in the review protocol in Appendix A and the methods document.

Selecting evidence for included populations

When identifying evidence for young people aged 16-24 years, studies that reported an age range overlapping 16-24 years were included if a) the range did not extend below 12 years or above 29 years and b) the mean age for that study sample fell within 16-24 years. The same rules relating to sample age applied when identifying evidence for the combined subgroups (i.e. young MSM; young people from a Black African or Caribbean family background; young men from a Black African or Caribbean family background who have sex with men). When identifying evidence for people from a Black African or Caribbean family background, studies that reported a sample comprising less than 80% Black African or Caribbean participants were excluded.

Declarations of interest

Declarations of interest were recorded according to NICE's conflicts of interest policy.

1.1.4 Identification of public health evidence

Evidence reviews A and B were carried out using two separate literature searches (Appendix B): one search identified quantitative and qualitative effectiveness evidence for people who are homeless, asylum seekers and migrants, and one search identified quantitative and qualitative effectiveness evidence for young people, trans people, people from a Black African or Caribbean family background, and MSM. The population groups were separated into two searches to make searching, sifting and screening more manageable due to the high number of search results.

For the first search, 1364 references were identified. Titles and abstracts were checked for relevance against the protocols and 84 papers were ordered for full-text screening. Of these, 4 RCTs met the inclusion criteria for the effectiveness review and no qualitative evidence was identified. 80 studies were excluded.

For the second search, 20,098 references were identified. Titles and abstracts were checked for relevance against the protocols and 387 papers were ordered for full-text screening. Of these, 44 RCTs published in 45 papers met the inclusion criteria for the effectiveness review and 13 studies met the inclusion criteria for the qualitative review. 329 studies were excluded.

Combining the two searches resulted in a total of 48 included RCTs for the effectiveness review and 13 included qualitative studies for the qualitative review. This review chapter contains the results for the quantitative evidence only; the committee discussion of the quantitative evidence is provided in evidence review B, which also contains the qualitative evidence review, a mixed methods synthesis, and committee discussion of the quantitative and qualitative evidence.

Included effectiveness studies

Of the 48 RCTs included in the effectiveness review, 3 studies were of people from migrant communities, 1 study was of people who are homeless, 5 were studies of young people aged 16-24 years, 2 were studies of trans people, 13 were studies of gay, bisexual and other men who have sex with men (MSM), and 3 studies were of people from a Black African or Caribbean family background. There were also 7 studies of young people from a Black African or Caribbean family background, 2 studies of young MSM, 9 studies of MSM from a

Black African or Caribbean family background, 2 studies of young MSM from a Black African or Caribbean family background, and one study of MSM and transwomen of mixed immigrant status. There were no studies of asylum seekers. See Table 3 for a summary of studies. See Table 4 for a summary of intervention characteristics.

Excluded studies

The full list of excluded studies and reasons for exclusion are in Appendix J. These are presented separately for the two searches.

1.1.5 Summary of studies included in the effectiveness evidence

Table 3: Summary of effectiveness studies included in the evidence review

Study	Setting	Population and number of participants	Intervention	Comparator	Outcome(s)	Follow-up
Migrants (n = 3)						
Peragallo 2012 RCT	Areas in Miami, USA with a high proportion of Hispanic immigrants Community settings	Hispanic women aged 18-50 years Participants were born in Columbia, Cuba, Peru, and the Dominican Republic. Only 8% were born in the US 548 participants	SEPA (Salud/Health, Educacion/Education, Prevencion/Prevention, Autocuidado/Self-care): a culturally-specific community-based group HIV risk reduction intervention for Hispanic women	Waitlist control	Any condom use in prior 3 months Intention to use a condom Chlamydia incidence HIV knowledge	3 months 6 months 12 months
Peragallo-Montano 2019 RCT	Miami, USA Participants were recruited from the Miami Refugee Centre, the Florida Department of Health, and public locations in Miami. Assessment and intervention sessions were conducted in a	Hispanic migrant women aged 18-50 years Participants were born in Cuba, Nicaragua, Columbia and other countries in Central and South America. Only 4.4% were born in the US. 320 participants	HIV testing and counselling plus SEPA (Salud/Health, Educacion/Education, Prevencion/Prevention, Autocuidado/Self-care): a culturally-specific community-based group HIV risk reduction intervention for Hispanic women	HIV testing and counselling only	Proportion of condom-protected sex events Any condom use in prior 30 days Number of condomless sex events Self-efficacy for condom use HIV knowledge	6 months 12 months

Study	Setting	Population and number of participants	Intervention	Comparator	Outcome(s)	Follow-up
	private room at the University of Miami Hospital.					
Sanchez 2013 RCT	Florida, USA Offices of the Farmworker Association of Florida, an organisation that works with low-income immigrant communities	Latino migrant workers 18 years of age or older 290 participants	Culturally Adapted Stage-Enhanced Motivational Interviewing (A-SEMI) condition. Enhances existing cognitive behavioural risk reduction approaches by integrating key contextual components from effective HIV prevention interventions (i.e., peer counselling) linked to maintenance of risk reduction effects.	Health Promotion condition (HPC) targeted specific health issues of special relevance to Latino migrant workers (LMWs), including general health strategies such as hygiene and living in crowded conditions, first aid, and skin problems	Self-reported consistent condom use. HIV prevention knowledge Perceived barriers to condom use. Condom use self-efficacy	3 months 9 months
People who are homeless (n = 1)						
Tucker 2017 Crossover RCT	Los Angeles, USA Drop-in centres for homeless youth	Homeless young adults aged 18-25 years 73% male 200 participants	AWARE, a brief group-based motivational interviewing intervention addressing sexual risk behaviour and drug and alcohol use, as well as addressing the connection between the two. All intervention participants also had access to usual care at the drop-in centre.	Usual care at the drop-in centre which includes access to all basic services (food, hygiene), case management, and any other support programs available.	Proportion of unprotected sexual events Condom use self-efficacy	3 months

Study	Setting	Population and number of participants	Intervention	Comparator	Outcome(s)	Follow-up
Young people 16-24 years (n = 5)						
Calderon 2013 RCT	New York, USA Emergency Department	Young people aged 15-21 years 203 participants	Educational video on HIV prevention intervention delivered in ED after HIV testing whilst waiting for test results	In-person HIV counselling with HCP (standard care)	Condom use self-efficacy	Immediate post-intervention
Champion 2012 RCT	USA Community based clinic	Adolescent women aged 14-18 years with a history of STIs and physical or sexual abuse Sample was African-American (16.4%) or Mexican-American (83.6%)[a] 409 participants	ProjectIMAGE, culturally informed, cognitive behavioural intervention for sexual risk reduction comprising workshops, group support sessions and individual counselling.	Waitlist control[b]	STI incidence	6 months 12 months
Giminez-Garcia 2018 RCT	Valencia, Spain University meeting rooms	Young people aged 18-25 years 225 participants	Peer facilitator delivered HIV prevention intervention based on Information Motivation Behavioural Skills (IMB) model	Expert facilitator delivered HIV prevention intervention based on Information Motivation Behavioural Skills (IMB) model	HIV knowledge Condom use for vaginal sex Condom use for anal sex	1 month 4 months
Miller 2021 RCT	Midwestern US Paediatric emergency department of a	Sexually active adolescents aged 14-19 years 91 participants	A brief motivational interviewing intervention delivered by health educators in paediatric EDs. Included condom use	Printed materials which included a brochure on safer sex practices and a list of local resources for	Condom use at last sex Condom use intention	6 months

Study	Setting	Population and number of participants	Intervention	Comparator	Outcome(s)	Follow-up
	children's hospital		skills training and tailored risk reduction counselling	sexual and mental health care	Confidence in condom use	
Morrison-Beedy 2013 RCT	New York, US Youth development centres, adolescent health services and school-based centres	Females aged 15-19 years from low-income, urban settings 639 participants	Group-based sexual risk reduction intervention based on the Information Motivation Behavioural Skills (IMB) model, plus booster sessions – included fames, interactive group activities and skits	Time and attention matched control group sessions; health promotion topics	Unprotected vaginal sex (any episodes) Unprotected vaginal sex (number of episodes)	3 months 6 months 12 months
Trans people (n = 2)						
Garofalo 2018 RCT	Boston and Chicago, USA Community-based locations	Young trans women aged 16 to 19 years 21% reported HIV-positive serostatus at baseline 190 participants	Project LifeSkills, an empowerment-based group-delivered behavioural HIV prevention intervention addressing challenges to sexual safety among young trans women.	Standard of care	Number of condomless sex acts	4 months 8 months 12 months
Sevelius 2019 RCT	California, USA Community-based venues	Trans women 49% were Black/African American 45.5% reported HIV-positive serostatus at baseline	'Sheroes', a peer-led group HIV risk reduction intervention for transgender women emphasising empowerment and gender affirmation	Time- and attention-matched control (group movie nights with discussion)	Number of condomless sex partners	6 months

Study	Setting	Population and number of participants	Intervention	Comparator	Outcome(s)	Follow-up
		77 participants				
People from a Black African or Caribbean family background (n = 3)						
Diallo 2010 Cluster RCT	Atlanta, USA Intervention delivered in settings of participants' choosing including college campuses, churches, participants' homes, and community centres.	Self-identified Black women Age 18-69 years (M=31.3; SD=11.6) Pre-existing groups of women e.g. sororities, church groups, friendship circles. *k* = 30 groups *n* = 313 participants	Healthy Love Workshops (HLW); interactive, single session HIV prevention intervention for established groups of Black women. On completion of the workshops, participants received male and female condoms, dental dams, HIV risk reduction brochures and information on where to obtain HIV counselling and testing services.	Comparison workshop on STIs and HIV facts; similar information but delivered in lecture style format rather than interactive approach On completion of the workshops, participants received male and female condoms, dental dams, HIV risk reduction brochures and information on where to obtain HIV counselling and testing services.	Unprotected vaginal sex with any male partner Condom use with any male partner Condom use at last vaginal, oral or anal sex HIV knowledge	3 months 6 months
Wilson 2019 Cluster RCT	Brooklyn, New York, USA Barbershops located in neighbourhoods with high	Self-identified Black men Age 18-76 years (M=33; SD=11)	Barbershop Talk with Brothers (BTWB); single small-group peer-led session focused on HIV risk reduction with a strengths-based lens	Attention control group focused on prostate cancer screening Condoms were distributed at all	Condomless sex[c]	6 months

Study	Setting	Population and number of participants	Intervention	Comparator	Outcome(s)	Follow-up
	prevalence of HIV infection	52% had a history of incarceration *k* = 53 barbershops *n* = 860 participants	on men and masculinity Condoms were distributed at all participating barbershops	participating barbershops		
Wingood 2011 RCT	Atlanta, USA Planned Parenthood clinics	African-American women Age 21-29 years (M=24)[d] 135 participants	SAHARA - computer based HIV prevention intervention emphasising ethnic and gender pride and building HIV risk reduction knowledge. Additional small group session.	Usual care comprising a group session on general health and HIV prevention	Proportion of condom-protected sex acts Consistent condom use for vaginal sex Consistent condom use for oral sex Condom-use self-efficacy HIV/STI knowledge	3 months
Young people age 16-24 years from a Black African or Caribbean family background (n = 7)						
Brawner 2021 RCT	Philadelphia, USA University and clinical settings	Heterosexually active Black youth aged 14-17 years Age M=15.78; SD=0.97	Project GOLD: a culturally and contextually relevant psychoeducational STI/HIV prevention intervention that addresses the role of mental illness and	General health comparison condition (diet and exercise based content)	Proportion of condom use for vaginal sex Condom use self-efficacy	3 months 6 months 12 months

Study	Setting	Population and number of participants	Intervention	Comparator	Outcome(s)	Follow-up
		62% male, 38% female 109 participants	emotion regulation in sexual risk.		Condom use knowledge HIV/STI knowledge	
Brothers 2016 RCT (Pilot study)	Maryland, Illinois and Florida, USA Clinical settings	Young African American women Age 16-24 years (Median = 21; IQR = 17-22) 43 participants All participants were HIV positive	EVOLUTION: Young Women Taking Charge and Growing Stronger. Group-based behavioural intervention designed to decrease sexual risk by enhancing young women's knowledge and skills pertaining to HIV risk reduction while also addressing gender, power and inequality.	Attention-matched healthy life-skills control	Unprotected vaginal or anal sex Condom use self-efficacy	Immediately post-intervention 3 months
Chandler 2019 RCT (Pilot study)	Florida, USA 2 southern universities: 1 Traditionally White Institution (TWI) and 1 Historically Black College/University (HBCU)	Young Black Women Age 18-24 years (M=20.5; SD=1.6) 57 participants	The Health Improvement for Ladies (HIP Ladies) intervention; an IMB-based small-group progressive HIV risk-reduction program designed for Black adolescent females. Provides information about HIV transmission and prevention.	Time and attention matched control group sessions addressing breast health, nutrition, stress management and sleep hygiene.	HIV knowledge Condom use self-efficacy	3 months

Study	Setting	Population and number of participants	Intervention	Comparator	Outcome(s)	Follow-up
			Addresses behavioural skills including assertiveness, condom use and other risk reduction practices. Interactive, peer facilitator approach to program delivery.			
Crosby 2014 RCT	New Orleans, Baton Rouge and Charlotte, USA STI clinics	Young Black males Age 15-23 years (M=19.6; SD=1.9) 42% had a history of incarceration 702 participants	Adaptation of Focus on the Future (FoF): a sex-positive intervention focusing on correct and consistent condom use. Includes discussion of barriers to condom use, skills-based exercises for correct condom use, discussion of planning and negotiating condom use. All participants received free access to condoms and lubricants.	Attention-matched control including slides on basic STI knowledge and prevention. All participants received free access to condoms and lubricants	Correct and consistent condom use STI incidence	2 months 6 months
DiClemente 2010	Atlanta, USA	Pregnant African American adolescents	The intervention was implemented by a peer educator and focused	Enhanced standard care: routine STI prevention education	Condom use at last sex Consistent condom use	6 months

Study	Setting	Population and number of participants	Intervention	Comparator	Outcome(s)	Follow-up
RCT	A large prenatal clinic	14-20 years (M=17.8; SD=1.6) Average of 10 weeks pregnant at enrolment 170 participants	on enhancing adolescents' self-worth and self-concept, as well as heightening awareness of HIV/STI risk reduction knowledge and adverse consequences of STIs. Reinforced the importance of condom use when having sex during pregnancy. Taught condom use skills, negotiation skills and skills for refusing risky sex.	plus 'Good nutrition during pregnancy' session		
DiClemente 2014 Randomised supplemental treatment trial[e]	Atlanta, USA Sexual health clinics plus telephone contacts	Young African American females Age 14-20 years (M=17.6; SD=1.66) 701 participants	HORIZONS group-based STI prevention intervention plus a prevention maintenance intervention (PMI) consisting of brief telephone contacts every 8 weeks for 36 months. PMI calls involved tailored strategies to address individual risk factors	HORIZONS group based STI prevention intervention plus dose-matched control telephone calls focused on general health	STI incidence Proportion of condom use prior 90 days Proportion of condom use prior 6 months	36 months

Study	Setting	Population and number of participants	Intervention	Comparator	Outcome(s)	Follow-up
			guided by risk appraisal procedure.			
Wingood 2013 RCT	Atlanta, USA Kaiser Permanente Health centres	Young African American females Age 18-29 years (M=22; SD=3.6) 848 participants	Group-based HIV intervention sessions focusing on partner concurrency and gender and power. Designed to enhance self-sufficiency and attitudes and skills associated with condom use. Also encouraged STI testing, treatment of male sex partners, reducing vaginal douching and partner concurrency.	Comparison condition focusing on health promotion and nutrition	STI incidence Condom use for oral sex HIV/STI knowledge Condom use self-efficacy	6 months 12 months
Men who have sex with men (MSM) (n = 13)						
Brown 2019 RCT	Northeastern city in USA Outpatient HIV clinics	HIV positive MSM attending outpatient HIV medical visits. Age 22-62 years (M=40.6; SD=8.0) 80 participants	Two-session group based secondary prevention intervention focusing on sexual health and stress management skills for HIV-positive MSM. Addressed key motivational and skills-based barriers to sexual risk reduction	Waitlist control	Frequency of unprotected anal sex in the past 3 months Frequency of unprotected anal or oral sex in the past 3 months	3 months

Study	Setting	Population and number of participants	Intervention	Comparator	Outcome(s)	Follow-up
			whilst also focusing on coping with sexual minority status, HIV related stressors and psychosocial aspects of HIV.		HIV transmission knowledge	
Cruess 2018 RCT	Atlanta, USA Online study	HIV positive men self-identifying as gay or bisexual. Age M=44.7; SD=10.8 years 167 participants	HIV Internet Sex (HINTS); a brief, exclusively online, group-based sexual risk reduction intervention for sexual minority men living with HIV. Based on IMB model, it addressed issues relating to online partner seeking and HIV transmission risk reduction, including condom negotiation and HIV serostatus disclosure.	Healthy Living comparison; followed the same format as HINTS but sessions addressed nonsexual health-related topics such as nutrition, exercise and stress reduction.	Condomless anal sex – all partners Condomless anal sex – HIV-/unknown serostatus partners Condomless anal sex – HIV+ partners	6 months
Hart 2021 RCT	Toronto and Vancouver, Canada Community settings	HIV+ GBMSM Age M = 40.77; SD=11.37 183 participants	Gay Poz Sex (GPS), a group-based, sex positive, peer delivered sexual health promotion intervention based on MI and behavioural strategies	Waitlist control	Serodiscordant condomless anal sex with a male partner Serodiscordant condomless anal sex with a casual male partner	3 months 6 months

Study	Setting	Population and number of participants	Intervention	Comparator	Outcome(s)	Follow-up
					Condom use self-efficacy	
Mansergh 2010 RCT	Chicago, Los Angeles, New York City and San Francisco, USA Unclear; assumed clinic based	Substance-using MSM. 50% of participants were HIV positive. Age: over 18 years 1206 participants	Group-based CBT intervention using techniques such as skills building, behavioural rehearsal, feedback and positive reinforcement to reduce risk behaviour of substance-using MSM. Participants encouraged to identify situational triggers for risky behaviour, develop behavioural alternatives, learn negotiation strategies, and plan for change.	Attention control group focused on MSM-related issues unrelated to substance use, sexual risk behaviour or HIV.	Unprotected anal sex HIV-discordant unprotected anal sex Drug use soon before or during unprotected anal sex Drug use soon before or during unprotected anal sex with any non-primary partners of different or unknown HIV serostatus	3 months 6 months 12 months
McKirnan 2010 RCT	Chicago, USA Three primary care clinics	HIV positive MSM Mean age = 42 years. 313 participants	Treatment Advocacy Program (TAP): an individual peer-based counselling intervention for sexual safety and general coping among HIV+ MSM. Sessions combine motivational interviewing and cognitive behavioural techniques, and use	Standard HIV care	Unprotected anal intercourse with HIV- or unknown status partners Number of transmission risk partners	6 months 12 months

Study	Setting	Population and number of participants	Intervention	Comparator	Outcome(s)	Follow-up
			HIV+ MSM peer advocates to provide coping models and decrease isolation.			
Mimiaga 2019 Pilot RCT	Boston, USA The Fenway Institute, a large health centre caring for sexual and gender minority populations	MSM who met DSM-IV criteria for crystal methamphetamine dependence. Age 25-65 years (M=39.8; SD=11.6) 41 participants	Behavioural Activation and Sexual Risk Reduction Counselling (BA-SRR). Uses BA and CBT methods to develop mood management skills and address substance misuse; and IMB-informed SRR counselling to address sexual risk. All sessions employ a therapeutic stance informed by Motivational Interviewing.	2 sessions of Sexual Risk Reduction counselling	Number of condomless anal sex acts with partner who was HIV serodiscordant or status unknown. Number of condomless anal sex acts with partner who was HIV serodiscordant or status unknown, while using meth	3 months 6 months
Nostlinger 2016 RCT	Multi-centre trial in 8 European countries: Belgium, Italy, France, Germany, the Netherlands,	HIV positive MSM. For intervention participants, median age was 40 years (IQR=32-47) and for control participants, median age was 42 years (IQR=33-45).	Computer-assisted intervention for safer sex (CISS): 3 semi-structured counselling sessions delivered by trained service providers using interactive videos and computer-assisted	Sexual health advice delivered as part of their regular HIV care	Condom use at last intercourse HIV transmission risk score	3 months 6 months

Study	Setting	Population and number of participants	Intervention	Comparator	Outcome(s)	Follow-up
	Poland, Spain and England. HIV care centres serving MSM populations in each of the included countries	112 participants	tools. Sessions incorporated Motivational Interviewing and cognitive behavioural goal setting strategies.			
O'Donnell 2014 RCT	New York City, USA Community health centre study sites	Latino MSM Age 18-49 years (M=36.6; SD=9.6) 370 participants	No Excuses / Sin buscar excusas: a brief, single session group intervention for Latino MSM focusing on sexual safety, condom use and partner negotiation. Participants could choose whether it was delivered in Spanish or English. All intervention participants were offered an HIV test after completing the intervention session.	Non-attention control condition. Participants were offered an HIV test.	Number of unprotected anal intercourse acts Condom use at last sex	3 months
Rhodes 2017	North Carolina, USA	Hispanic/Latino MSM	HOLA en Grupos; a Spanish-language	Attention-equivalent general health	Consistent condom use (reported separately for	6 months

Study	Setting	Population and number of participants	Intervention	Comparator	Outcome(s)	Follow-up
RCT	Community-based settings	Age 18-55 years (M=30; SD=8.9) 304 participants	small group behavioural HIV prevention intervention designed to increase condom use and HIV testing among Hispanic/Latino gay, bisexual and other men who have sex with men.	education comparison	MSM who report sex with men or women, and MSM who report sex with men only) Condom use skills Condom use self-efficacy HIV knowledge STI knowledge Sexual communication	
Safren 2013 RCT	Boston, USA HIV primary care clinics caring for sexual and gender minority populations	HIV positive MSM. Mean age = 40.7 years; SD=7.8 201 participants	Case management provided by a medical social worker plus tailored counselling and motivational interviewing to address psychosocial concerns and HIV risk reduction for MSM with HIV.	Standard care – counselling and case management as per routine clinic care	HIV transmission risk behaviour	3 months 6 months 9 months 12 months
Schwarcz 2013 RCT	San Francisco, USA	HIV positive MSM Age range: 18-30 years: n=20	Personalised Cognitive Counselling (PCC): individual counselling sessions that focus on self-justifications and	Standard HIV risk reduction counselling	Unprotected anal intercourse with a non-primary partner of	6 months 12 months

Study	Setting	Population and number of participants	Intervention	Comparator	Outcome(s)	Follow-up
	Unclear but paper states the intervention tested in this study is designed to be administered in care settings.	31-40 years: n=11 41-50 years: n=173 >50 years: n=64 374 participants	rationalisations for sexual risk behaviour. Includes working with the therapist to reframe these cognitions and develop plans to reduce future risk behaviour.		different or unknown HIV status Gonorrhoea incidence Chlamydia incidence	
Sikkema 2011 Pilot RCT	New York City, USA HIV primary medical care settings specialising in the care for LGBT communities	MSM diagnosed with HIV in the past 3 months. 67,6% reported drug use in the past 3 months Mean age = 32.4 years; SD=7.8. 65 participants	Comprehensive standard of care plus Positive Choices (PC): a brief HIV primary care-based risk reduction intervention for newly HIV diagnosed MSM. Based on the IMB model and focused on developing a personalised risk reduction plan.	Comprehensive standard of care (including regular meetings with nurses, cases managers, and physicians; referrals for mental health or substance abuse services, and optional participation in a newly diagnosed support group)	Unprotected anal intercourse Self-reported STI diagnosis or symptoms	3 months 6 months
Sikkema 2014 RCT	New York City, USA A Federally Qualified Health Centre (FQHC) specialising in	MSM diagnosed with HIV in the past 3 months Mean age = 32.2 years; SD=8.8. 102 participants	Comprehensive standard of care plus Positive Choices (PC): a brief HIV primary care-based risk reduction intervention for newly HIV diagnosed MSM. Based on the IMB	Comprehensive standard of care (including regular meetings with nurses, cases managers, and physicians; referrals for mental health or substance abuse services, and optional	Unprotected insertive or receptive anal intercourse with any partner Unprotected insertive or receptive anal intercourse with HIV	3 months 6 months 9 months

Study	Setting	Population and number of participants	Intervention	Comparator	Outcome(s)	Follow-up
	care for LGBT communities.		model and focused on developing a personalised risk reduction plan. Same as above intervention for Sikkema 2011.	participation in a newly diagnosed support group)	negative or unknown status partners	
Young (age 16-24) men who have sex with men (YMSM) (n = 2)						
Hidalgo 2015 Pilot RCT	Large Midwestern city in the USA A LGBT community health centre	YMSM Age 16-20 years M=18.8; SD=1.2 101 participants	MyPEEPS (Male Youth Pursuing Empowerment, Education and Prevention around Sexuality): an interactive group-level intervention to reduce sexual risk behaviours among young MSM. Sessions cover topics such as HIV/STI epidemiology and transmission, minority stress, emotion regulation, substance use, and overcoming barriers to safer sex.	Time-matched group level intervention focusing on HIV risk reduction but relying on lecture format and didactic delivery (not interactive, content not tailored to male-male sex).	Unprotected anal sex Unprotected sex under the influence of alcohol or drugs Number of unprotected anal sex acts Condom errors Self-efficacy for safer sex Health protective communication	6 weeks 12 weeks
Parsons 2014	New York City, USA	Non-treatment-seeking young gay and bisexual men (YGBM) reporting	Four sessions of Motivational Interviewing focusing on club drugs and the	Four sessions of content-matched education about club drug use and HIV	Unprotected anal intercourse	3 months 6 months 9 months

Study	Setting	Population and number of participants	Intervention	Comparator	Outcome(s)	Follow-up
RCT	Research centre	recent recreational drug use and UAI with a high-risk male partner. Age 18-29 years[f] 143 participants	risks of UAI with casual male partners. It used a participant-centred therapeutic approach to enhance motivation for change.	sexual risk reduction; all session content focused on objective, factual information.		12 months
Men from a Black African or Caribbean family background who have sex with men (n = 9)						
Arnold 2019 RCT	San Francisco Bay Area, USA Private mobile clinics or the project office	African American men who have sex with men and women (MSMW) who do not identify as gay/homosexual or bisexual. 16.7% were HIV positive. 51.4% reported being homeless in the past 12 months; 15.2% reported being in prison/jail in the past 3 months and 77.2% reported being in prison/jail	Culturally tailored HIV testing and counselling plus The Bruthas Intervention: four IMB-based individual tailored counselling sessions with a trained peer educator focusing on HIV and STI transmission risk, HIV testing, condom use, and sexual risk behaviours with female partners and male partners. Motivational counselling, interactive role plays, homework assignments, feedback and reinforcement were all used	Culturally tailored HIV testing and counselling only; based on standardised HIV testing and counselling but tailored to African American MSMW and includes non-judgemental and open discussion of sexual activities with both men and women.	Condomless intercourse events with any partner (men, women and transwomen) Condomless intercourse events with any main partner (men, women and transwomen) Condomless intercourse events with any causal partners (men, women and transwomen)	6 months 9 months

Study	Setting	Population and number of participants	Intervention	Comparator	Outcome(s)	Follow-up
		more than 3 months ago. Mean age = 45.90 years; SD = 9.64 396 participants				
Eaton 2018 RCT	Atlanta, USA Community based research site	Black MSM (44% identified as gay; 41% identified as bisexual; and 15% identified as heterosexual) 50.1% of the sample reported depressive symptoms above the clinical threshold. Mean age = 35.36 years; SD=11.95 (intervention group) and mean age = 33.77 years; SD=12.06 (control group).	A single-session Conflict Theory of Decision Making intervention focusing on sexual risk decision making, partner selection and the limitations of serosorting.	A single-session CDC-based sexual risk reduction intervention (standard care)	Proportion of condom protected sex acts Number of condomless sex acts Number of condomless anal insertive sex acts Number of condomless anal receptive sex acts Self-reported STI diagnosis Lab diagnosed gonorrhoea or chlamydia	3 months 6 months 12 months

Study	Setting	Population and number of participants	Intervention	Comparator	Outcome(s)	Follow-up
		597 participants				
Fernandez 2016 RCT	Chicago, USA Online	Self-identified Black men who have sex with men and women (MSMW). 62.9% were HIV positive and 17.7% reported having an STI in the previous 12 months. 64.9% reported incarceration history; 55% reported drug use in past 3 months; 32% reported being homeless in past 12 months. Mean age = 44.7 years; SD=8.8 211 participants	POWER: IMB based online HIV risk reduction intervention delivered via live chat by trained facilitators. 3 sessions focused on providing culturally relevant information on HIV risk and protection, increasing motivation and behavioural skills to promote adoption of safe practices. All study participants had access to condoms and lubricants for the duration of the study	HEALTH information comparison; also delivered online via live chat but content covered health issues disproportionately affecting Black men. Included strategies to improve their physical and sexual health including preventing STIs and condom use. All study participants had access to condoms and lubricants for the duration of the study	Any condomless vaginal or anal intercourse (CVAI) Condomless anal intercourse with males Condomless vaginal or anal intercourse with females Any serodiscordant anal or vaginal intercourse (SDAI or SDVI) Any SDAI with males Any SDAI or SDVI with females	3 months
Harawa 2013	Los Angeles, USA	Black MSMW. 49% of participants were HIV positive.	Men of African American Legacy Empowering Self (MAALES): a multi-	HIV education and risk reduction session based on a standard	Unprotected anal intercourse with males	6 months

Study	Setting	Population and number of participants	Intervention	Comparator	Outcome(s)	Follow-up
RCT	Community-based agencies providing services to at-risk and HIV-infected clients	High unemployment (45%) and housing instability (35%). 75% had a lifetime history of incarceration. Mean age = 42.8 years; SD=10.2 381 participants	session, small group, culturally congruent HIV risk reduction intervention designed to build skills, address sociocultural issues and reduce risk behaviours in Black MSMW. All participants had access to condoms at each assessment visit.	HIV test counselling approach. All participants had access to condoms at each assessment visit. Control participants were also waitlisted and invited to attend MAALES after their 6 month assessment.	Unprotected vaginal or anal intercourse with females Unprotected intercourse with males or females Any risky drug use with sex	
Jemmott 2015 RCT	Philadelphia, USA University research centre	African American MSM 29.5% were HIV positive. Unemployment was high (71.5%); 48.9% reported a history of childhood sexual abuse; 37.1% reported a history of intimate partner violence; 44.5% were alcohol dependent; 16.7% were drug	Being Responsible for Ourselves (BRO): a one-to-one HIV/STI risk reduction intervention designed to increase consistent condom use. Session content focused on self-efficacy for condom use, technical skills to use condoms correctly, impulse control, condom use negotiation, and the influence of alcohol or drugs.	Attention-matched health promotion intervention	Consistent condom use Proportion of condom-protected intercourse Any unprotected intercourse HIV risk reduction knowledge Condom-use knowledge	6 months 12 months

Study	Setting	Population and number of participants	Intervention	Comparator	Outcome(s)	Follow-up
		dependent; and 51.8% reported a history of incarceration. Age 18-69 years M=41.6; SD=10.7 593 participants				
Koblin 2012 RCT	New York City, USA No information on study setting	Black MSM 62.5% were HIV positive Age 18-68 years M=39.3 years 283 participants	Standard HIV testing and counselling plus DiSH intervention sessions which focused on creating a group environment with sexual risk reduction information and exercises woven into joint meal preparation and sharing activities.	Standard HIV testing and counselling	Unprotected insertive anal intercourse Unprotected receptive anal intercourse Unknown / serodiscordant unprotected insertive anal intercourse Unknown / serodiscordant receptive anal intercourse Unprotected anal sex with drug or alcohol use	3 months

Study	Setting	Population and number of participants	Intervention	Comparator	Outcome(s)	Follow-up
					Sexual self-efficacy	
Lauby 2018 RCT	Philadelphia, USA Community healthcare settings providing services to LGBT people of colour	Black MSMW 17.7% were HIV positive 51.7% had been homeless in the last 12 months; 63.4% had history of incarceration; 60.8% had history of drug use in last 3 months Age 21-61 years M=44.94; SD=8.92 143 participants	Project RISE: a 6-session individual-level intervention developed for Black MSMW using an ecosystems approach. Sessions focused on the relationship between the person and their social environment and were designed to address issues of stress and coping; experiences of stigma, discrimination and other life concerns; alongside sexual risk behaviours. All participants were offered HIV and STI testing.	Single session individual-level HIV risk reduction intervention. All participants were offered HIV and STI testing.	Change in number of episodes of condomless sex with male partners Change in number of episodes of condomless sex with female partners	3 months
Tobin 2013 RCT	Baltimore, USA Research clinic	Black MSM 50% were HIV positive	Unity in Diversity (UND): a group-based culturally tailored HIV prevention intervention for African American MSM. Informed by IMB	Single small group-based HIV prevention and care session.	Consistent condom use with all partners Consistent condom use with male partners	3 months

Study	Setting	Population and number of participants	Intervention	Comparator	Outcome(s)	Follow-up
		71% reported a history of incarceration; 12% had been homeless in the last 3 months; high rates of drug use reported. Mean age = 38.9 years; SD=10.2 147 participants	model, it was designed to increase knowledge about HIV risk and testing, and to increase motivation and skills to engage in preventive behaviours.		Consistent condom use with HIV positive partners Consistent condom use with HIV negative / unknown status partners Drug use during last sex	
Williams 2013 RCT	Los Angeles, USA Not reported	African American MSMW with a history of childhood sexual abuse (CSA). All participants were HIV positive. Inclusion criteria was that they did not self-identify as gay. 83.95 were unemployed or	Enhanced Sexual Health Intervention for Men (ES-HIM): a stress-focused sexual risk reduction intervention for African American MSMW with a history of childhood sexual abuse (CSA). Small group sessions guided by CBT approaches and addressing the individual, interpersonal, social and cultural factors that may influence sexual	Attention matched health promotion intervention	Unprotected insertive anal sex Unprotected receptive anal sex Unprotected vaginal sex	3 months 6 months

Study	Setting	Population and number of participants	Intervention	Comparator	Outcome(s)	Follow-up
		unable to work; 68.6% had a history of incarceration Mean age = 46.6 years; SD=8.3 88 participants	behaviour and psychological health. Addresses issues relating to minority group status, stigma and social isolation; and impact of CSA on sexual behaviour.			
Young men from a Black African or Caribbean family background who have sex with men (n = 2)						
Crosby 2018a RCT Crosby 2018b (secondary publication)	Jackson, Mississippi, USA Sexual health clinics	Young Black MSM 28.2% were HIV positive Mean age = 22.6 years; SD = 3.2 600 participants	Focus on the Future (FoF): a single session sex positive 1:1 intervention focusing on correct and consistent condom use. Includes discussion of barriers to condom use, skills-based exercises for correct use, and how to plan and negotiate condom use. All participants received free access to high quality condoms and lubricants.	Standard of care: STI and HIV testing, and discussion with a clinician about their sexual risk and protective behaviours. All participants received free access to high quality condoms and lubricants.	Chlamydia/gonorrhoea incidence Consistent condom use	12 months

Study	Setting	Population and number of participants	Intervention	Comparator	Outcome(s)	Follow-up
Crosby 2019 RCT (secondary publication of Crosby 2018a with HIV negative subgroup)	Jackson, Mississippi, USA Sexual health clinics	Young Black MSM HIV negative subsample of above trial. Mean age = 21.1 years, SD = 3.1 277 participants	Focus on the Future (FoF): a single session sex positive 1:1 intervention focusing on correct and consistent condom use. Includes discussion of barriers to condom use, skills-based exercises for correct use, and how to plan and negotiate condom use. All participants received free access to high quality condoms and lubricants.	Standard of care: STI and HIV testing, and discussion with a clinician about their sexual risk and protective behaviours. All participants received free access to high quality condoms and lubricants.	Condomless insertive anal sex Condomless receptive anal sex Any condomless anal sex Any condomless oral sex	3 months
MSM and transwomen of mixed immigrant status (n = 1)						
Rhodes 2020 RCT	North Carolina, USA Community and social settings	Latinx gay and bisexual MSM and transwomen of mixed immigrant status. Less than 10% were born in the US; most born in Mexico and other Central or	HOLA; a community-level, Spanish language, peer navigation intervention. Lay community leaders were recruited and trained to work within their existing social networks to increase awareness, provide information, and	Waitlist control	Percent condom use during past 3 months Condom use knowledge and skills Condom use self-efficacy HIV knowledge	12 months

Study	Setting	Population and number of participants	Intervention	Comparator	Outcome(s)	Follow-up
		South American countries. 166 participants	promote behaviour change, particularly focusing on HIV/STI testing and condom use.		STI knowledge	

Notes

[a] Although this was a study of ethnic minority adolescent women, the proportion of participants from a Black African or Caribbean family background was too low for it to be grouped with the studies of this population group, where a threshold of 80% or more of the sample being from a Black African or Caribbean family background was used.

[b] This paper describes the control group as enhanced counselling. All study participants were encouraged to attend the clinic throughout the course of the study for contraception, pregnancy testing and examination and treatment of suspected STI and received enhanced counselling during these visits. As both groups were offered this (and overall rates of attendance or by group were not reported), this was not considered a control procedure. The paper states that control participants were told they would receive the intervention after study completion, therefore the comparator for this study has been classed as waitlist control.

[c] The paper reports the outcome as 'no condomless sex' but for the purposes of data analysis this outcome has been reverse scored to provide a measure of condomless sex.

[d] This paper has been included as a study of people from a Black African or Caribbean family background and not young people from a Black African or Caribbean family background because although the mean age is 24 years (falling within the 16-24 years range of young people), the higher range of ages up to 29 years indicated this intervention is not specifically designed for young people under 21 years.

[e] A randomised supplemental treatment trial is one in which all participants receive a primary treatment and subsequently receive a different supplemental treatment to enhance the effects of the primary treatment.

[f] Although the age range extends beyond 16-24 years, the sample has been classed as young gay and bisexual men (YGBM) and the intervention designed for that population, so this paper has been included as a study of young MSM. The paper does not report mean age.

1 See Appendix D for full evidence tables.

2 **Table 4: Summary of intervention characteristics included in the evidence review.**

Intervention name and studies	Primary or secondary prevention	Theoretical model	Key components	Includes access to condoms	Delivery format	Delivery setting	Delivered by	Group based / 1-to-1	Duration and intensity
Interventions for migrants									
SEPA (Salud / Health, Educacion / Education, Prevencion /	Primary HIV risk reduction	Social Cognitive Theory	- Information and education on HIV/AIDs and STIs, specific to the Hispanic community	No	Group discussion, role plays, practicing negotiation	Private rooms at the University of Miami Hospital	Bilingual Hispanic bicultural facilitators	Small group sessions (6-8 participants)	Three 2.5 hour sessions per week

Intervention name and studies	Primary or secondary prevention	Theoretical model	Key components	Includes access to condoms	Delivery format	Delivery setting	Delivered by	Group based / 1-to-1	Duration and intensity
Prevention, Autocuidado / Self-care) Peragallo 2012; Peragallo-Montano 2019		Informed by Hispanic cultural values	- Addresses wider issues including IPV and substance abuse. - Condom use demonstration - Role plays to practice negotiating condom use		skills, skills building activities. Participants could choose whether sessions were delivered in English or Spanish				
Culturally Adapted Stage-Enhanced Motivational Interviewing (A-SEMI) Sanchez 2013	Primary STI risk reduction	Community-based participatory research (CBPR) approach Social cognitive theory Motivational-enhancing therapy	- Information and education about HIV - Discussion about condom use, including attitudes towards using condoms and pros and cons of condom use - Support to develop personalised risk reduction plan; emphasis on participants developing their own strategies rather than prescribing specific strategies - Motivational enhancement and goal setting; increasing commitment to and empowerment for safe sex - Identifying high risk situations and developing negotiation skills through problem solving, assertiveness and communication - Peer counselling component and provision of normative feedback	No	Interactive group sessions	Offices of Farmworkers Association of Florida, an organisation serving the needs of migrant farmworkers	Trained peer facilitators – community members were trained to deliver the intervention	Small group sessions (6 participants)	Four 2.5 hour sessions that took place on 2 consecutive weekends

Intervention name and studies	Primary or secondary prevention	Theoretical model	Key components	Includes access to condoms	Delivery format	Delivery setting	Delivered by	Group based / 1-to-1	Duration and intensity
Interventions for homeless people									
AWARE Tucker 2017	Primary STI risk reduction	Social Learning Theory Decision Making Theory Self-efficacy Theory Motivational Interviewing	- Information on HIV/STI transmissions and the effects of alcohol and drug use on the brain - Condom use skills training - Discussion of risky situations and coping strategies or techniques to avoid risk - Behaviour change techniques including active learning, reinforcing skills, providing personalised feedback, and capitalising on social processes such as norm change and vicarious learning.	No	Interactive group sessions	Drop-in centres for homeless youth	Trained facilitators	Small group sessions	Four 45 minute sessions that rotated on a weekly basis throughout a 16 week study period
Interventions for young people age 16-24 years									
Intervention name not reported Calderon 2013	Primary HIV prevention	Theory of Reasoned Action Stages of Change Theory	- Attitudes and skills around condom use including negotiation and communication - Condom use demonstration	No	Videos	Private room in Emergency Departments; after HIV testing and while waiting for HIV test results	Videos	1-to-1	Very brief; under 1 hour
ProjectIMAGE Champion 2012	AIDS risk reduction	The AIDS Risk Reduction Model	- Information on STIs, symptoms, transmission and prevention - Increase awareness of personal risk - Interpersonal relationships, sexual decision making, communication - Attitudes and skills around condom use	No	Workshops, discussion groups, and individual risk reduction counselling sessions	Community-based research clinic	Nurse practitioners; individual sessions provided by licensed therapist.	Mainly small group sessions (4-8 participants) but also included some	2 workshop sessions lasting 3-4 hours, 3-5 small group sessions, and 2+ individual

Intervention name and studies	Primary or secondary prevention	Theoretical model	Key components	Includes access to condoms	Delivery format	Delivery setting	Delivered by	Group based / 1-to-1	Duration and intensity
			- Condom use demonstration and opportunity to practice					individual sessions	counselling sessions
Intervention name not reported Giminez-Garcia 2018	Primary HIV prevention	Information-Motivation-Behavioural Skills (IMB) model	- Information on HIV prevalence, risk and transmission - Attitudes and skills around condom use including negotiation skills - Condom use demonstration and opportunity to practice	No	Structured content and participatory learning activities including videos, role plays and group discussions	University meeting rooms	Peer facilitator	Small group sessions (7 participants)	1 session lasting 1 hour
The Sex-Health Intervention Miller 2021	Primary STI risk reduction	Theory of Planned Behaviour Social Ecological Model Motivational Interviewing principles guided the counselling	- Patient-centred tailored risk reduction counselling - Discussion of current sexual behaviours then exploration of options to facilitate improved motivation for safer behaviours - Condom skills training video - Printed brochure describing safer sex behaviours, and printed list of local resources for sexual and mental health care.	No	The intervention included tablet-based components including short, publicly available educational video clips and a computerised sexual health screening that fed directly into a clinical decision support system to generate	Emergency department of a children's hospital	Trained female health educators	1-to-1	Brief single session; mean duration 24.6 minutes

Intervention name and studies	Primary or secondary prevention	Theoretical model	Key components	Includes access to condoms	Delivery format	Delivery setting	Delivered by	Group based / 1-to-1	Duration and intensity
					tailored service recommendations and a condom skills training video				
Intervention name not reported Morrison-Beedy 2013	Primary STI risk reduction	Information-Motivation-Behavioural Skills (IMB) model Motivational Interviewing	- Information on HIV prevalence and how to reduce risk - Attitudes and skills around condom use including negotiation and communication skills - Condom use demonstration and opportunity to practice	No	Sessions included games, interactive group activities, discussions and skills practice.	Healthcare settings	Trained facilitators	Small group sessions	Four 120 minute sessions, once per week for 4 weeks, plus 2 90 minute booster sessions at 3 and 6 months
Interventions for trans people									
Project LifeSkills Garofalo 2018	Primary HIV prevention	Empowerment-based approach	- Addresses specific challenges to sexual safety for young trans women, including structural, developmental, and interpersonal factors, using an empowerment framework. - Specific content included environmental factors impacting young trans women such as securing safe housing, accessing medical care, and obtaining employment. It also addressed the lure of commercial sex work. - Information and education on basic HIV-related information such	No	Group sessions; no further detail	Not reported	Peer facilitators	Small group sessions	6 x 2 hour sessions conducted twice a week for 3 weeks

Intervention name and studies	Primary or secondary prevention	Theoretical model	Key components	Includes access to condoms	Delivery format	Delivery setting	Delivered by	Group based / 1-to-1	Duration and intensity
			as transmission modes and related risks. - Develop motivation to protect oneself - Promote behavioural skills such as condom use and sexual partner negotiation and communication.						
Sheroes Sevelius 2019	Primary HIV prevention	Model of Gender Affirmation	- Focus on gender affirmation and the impact of stigma and internalised oppression on HIV-related risk behaviours. - Discussion on trans identities, gender pride, and gender affirmation - Information on HIV/STI rates and risk factors specific to trans women - Discussion of self-care and self-worth in the context of sexual health; transition related healthcare (e.g. hormone therapy, surgery); and taking care of physical health - Discussion of importance of testing and getting treatment for HIV and STIs; and referral to transgender-friendly services - Assertiveness skills, negotiating safer behaviours, and communicating with HCPs - Increasing social support and fostering alliances between trans women	No	Role models, group discussion, gender-affirming interactive exercises and activities.	Community-based venues	Peer facilitators (transgender women of colour)	Group based (6-8 participants)	5 weekly sessions
Interventions for people from a Black African or Caribbean family background									

Intervention name and studies	Primary or secondary prevention	Theoretical model	Key components	Includes access to condoms	Delivery format	Delivery setting	Delivered by	Group based / 1-to-1	Duration and intensity
Healthy Love Workshop Diallo 2010	Primary HIV prevention	Social Cognitive Theory The Health Belief Model The Transtheoretical Model	- Information on the transmission and prevention of STIs - Increase awareness of personal risk - Attitudes and skills around condom use including negotiation - Condom use demonstration and opportunity to practice - Sex-positive approach, eroticises safe sex and encourages participants to connect with their sexuality - Considers Black women's sexual oppression and empowerment	Yes	Highly interactive group sessions including discussions, activities and skills practice	Group delivery in settings of their choosing e.g. college campuses, participant's homes, community centres	Peer facilitators	Group based (4-15 participants); delivered to pre-existing groups of women (e.g. sororities, church groups)	One 3-4 hour session
Barbershop Talk with Brothers Wilson 2019	Primary HIV prevention	Social Cognitive Theory Community- and Individual-level Empowerment Theory Assets- and Strengths-based Approach	- Attitudes and skills around condom use including self-efficacy, perceived norms, negotiation, and communication - Setting behaviour change goals - Empowering men with skills and motivation to co-educate men and women in their social networks about sexual risk reduction	Yes	Educational messages, role-play activities and self-evaluation activities	Private University settings	Peer facilitators	Small group sessions	Duration not reported. Single session.
SISTA's Accessing HIV/AIDS Resources at A Click (SAHARA) Wingood 2011	Primary HIV prevention	Social Cognitive Theory Theory of Gender and Power	- Focused on enhancing ethnic and gender pride for African American women - Addressed assertive communication skills and choice in sexual decision making - Attitudes and skills around condom use including the	No	Computer-based sessions including vignettes and interactive tasks, followed by	Planned Parenthood clinic	Computer-based sessions delivered via laptop; small group sessions delivered by peer-	Both	Two 60-minute computer-based sessions administered on consecutive Saturdays

Intervention name and studies	Primary or secondary prevention	Theoretical model	Key components	Includes access to condoms	Delivery format	Delivery setting	Delivered by	Group based / 1-to-1	Duration and intensity
			importance of consistent condom use - Condom use demonstration and opportunity to practice skills and receive feedback		brief small group session		matched health educator		followed by one 15-minute small group session
Interventions for young people from a Black African or Caribbean family background									
Project GOLD Brawner 2021	Primary HIV/STI prevention	The intervention drew from psychology, developmental and behaviour change theories, and a social determinants of health framework.	- Psychoeducational intervention focused on links between mental health, emotional distress and risk-related sexual behaviours - Content on emotion regulation (e.g. meditation) and the way emotions can affect decisions about sex. - Activities to highlight social determinants of sexual behaviours such as financial instability, residential instability, parental conflict, and daily stressors such as racism.	No	Unclear but appears mainly discussion based	University settings	Trained facilitators	Unclear; assumed 1-to-1 as no information on groups	Two 3 hour sessions.
EVOLUTION: Young Women Taking Charge and Growing Stronger Brothers 2016	Secondary HIV prevention	Theory of Gender and Power	- Designed for young women living with HIV - Information and education about HIV risk reduction - Behavioural and cognitive skills building activities designed to empower women to reduce their risk of transmitting HIV to others - Addressed broader issues relating to relationships, cultural norms, gender, power and inequality	No	Education and skills building activities	Research clinics	Trained facilitators	Group sessions (6-8 participants)	Nine 2-3 hour sessions (7 group and 2 individual) delivered every week for 9 weeks.

Intervention name and studies	Primary or secondary prevention	Theoretical model	Key components	Includes access to condoms	Delivery format	Delivery setting	Delivered by	Group based / 1-to-1	Duration and intensity
The Health Improvement for Ladies (HIP Ladies) intervention Chandler 2019	Primary HIV prevention	Information-Motivation-Behavioural Skills (IMB) model	- Designed for Black adolescent females; addressed culturally specific issues - Information and education about HIV/STIs, testing, and risk reduction - Development of behavioural skills including assertiveness, self-efficacy, and countering negative perceptions about condoms - Condom use demonstration - Goal setting and motivation/self-affirmation	No	Sessions used PowerPoint to deliver information with audio and videos embedded, as well as interactive activities, group discussion, role plays, and games	A Traditionally White Institution (TWI) and a Historically Black College / University (HBCU)	Peer facilitators	Small group sessions	Four 90-minute weekly sessions
Focus on the Future (FoF) Crosby 2014 Crosby 2018a Crosby 2018b Crosby 2019	Primary STI prevention	Information-Motivation-Behavioural Skills (IMB) model	- Sex positive intervention focusing on correct and consistent condom use - Attitudes and skills around condom use including barriers, planning, and negotiating condom use - Condom use demonstration and skills based exercises for correct condom use	Yes	Education-based session using discussion, role plays, illustrations, information sheets and condom application activities	Clinic setting	Trained health educators	1-to-1	Single 1 hour session
Intervention name not reported DiClemente 2010	Primary STI prevention	Social Cognitive Theory Theory of Gender and Power	- Designed specifically for pregnant African American adolescents - Focused on enhancing self-worth and self-concept - Information and education about HIV/STI risk reduction and preventive skills	No	Education, discussion, role plays and skills development activities	Prenatal clinics	Peer educators	Group sessions (5-7 participants)	Two 4-hour group sessions conducted on consecutive Saturdays

Intervention name and studies	Primary or secondary prevention	Theoretical model	Key components	Includes access to condoms	Delivery format	Delivery setting	Delivered by	Group based / 1-to-1	Duration and intensity
			- Attitudes and skills around condom use including negotiation and skills for refusing risky sex						
HORIZONS intervention plus telephone Prevention Maintenance Intervention (PMI) DiClemente 2014	Primary STI/HIV prevention	Not reported	- HORIZONS intervention session focused on sexual negotiation and refusal skills, safer sex norms, and preventive behaviours - Supplemental phone-based PMI involved risk appraisal then tailored behaviour change strategies to address individual risk factors	No	Telephone based risk appraisal and discussion	Telephone calls	Health educators	1-to-1	Single group session of HORIZONS plus 10 minute phone counselling PMI every 8 weeks for 36 months
Intervention name not reported Wingood 2013	Primary HIV prevention	Social Cognitive Theory Theory of Gender and Power	- Information and education about STI risk and HIV prevention strategies - Attitudes and skills around condom use including consistent condom use - Additional content on avoiding partner concurrency, refraining from vaginal douching and encouraging partners to seek STI testing. - Addresses issues relating to power imbalances and relationships that threaten safety.	No	Group session; no further detail	Health centres	Peer facilitators	Group sessions (average 10 participants)	Two 4-hour sessions administered on consecutive Saturdays
Interventions for gay, bisexual and other men who have sex with men (MSM)									
Intervention name not reported	Secondary HIV prevention	Coping Effectiveness Training	- Combined focus on coping with sexual minority status, HIV related stressors, and sexual health	No	Group discussion, Q&A sessions,	Outpatient HIV clinics	Peer facilitators	Group sessions (average 10 participants)	Two 4-hour sessions plus optional 2-hour group

Intervention name and studies	Primary or secondary prevention	Theoretical model	Key components	Includes access to condoms	Delivery format	Delivery setting	Delivered by	Group based / 1-to-1	Duration and intensity
Brown 2019		Information-Motivational-Behavioural Skills (IMB) model	- Information and education about HIV epidemiology, transmission, and treatment, tailored to HIV-infected MSM - Stress management and coping skills training, including stress of living with HIV. - Attitudes and skills around condom use, including assertiveness and negotiation skills - Condom use demonstration and opportunity to practice		exercises, skills practice				support sessions
The HIV Internet Sex Study (HINTS) Cruess 2018	Secondary HIV prevention	Information-Motivation-Behavioural Skills (IMB) model	- Focus on online partner seeking and sexual safety with partners met online - Content relating to HIV serostatus disclosure including motivation and behavioural strategies for managing productive dialogue about HIV serostatus - Attitudes and skills around condom use, including communication and negotiation, and how to make condom use enjoyable	No	Online group sessions using both voice chat and typed chat, including group discussion, interactive polls, video clips, brief assignments to be completed between sessions	Online	Trained facilitators	Online group sessions	Four 45-minute sessions conducted twice weekly for 2 consecutive weeks
Gay Poz Sex (GPS) Hart 2021	Secondary HIV prevention	Motivational Interviewing Sex Positive orientation	- Information and education about HIV transmission, STIs, and strategies to promote sexual health	No	Face to face group sessions, mixture of informational	Community settings	Peer facilitators who were HIV+ gay men and	Small group sessions (5-8 participants)	Eight 2-hour group sessions delivered weekly

Intervention name and studies	Primary or secondary prevention	Theoretical model	Key components	Includes access to condoms	Delivery format	Delivery setting	Delivered by	Group based / 1-to-1	Duration and intensity
			- Discussion of current sexual health behaviours and sexual health goals - Skills based training to help achieve those goals e.g. managing triggers, addressing substance use, avoiding loneliness - Emphasises choice, takes a sex positive approach, focus on sexual health and well-being rather than reducing sexual behaviour		and discussion based		non-credentialed lay workers trained in GPS protocol		
Intervention name not reported Mansergh 2010	Primary HIV risk reduction	Cognitive Behavioural Therapy (CBT) techniques	- Group CBT addressing risk behaviour in substance using MSM - Content consisted of CBT techniques, skills building, modelling, behavioural rehearsal, feedback and positive reinforcement	No	Information not reported	Not reported	Trained facilitators	Group sessions (5-10 participants)	Six 2-hour group sessions delivered weekly
Treatment Advocacy Program (TAP) McKirnan (2010)	Secondary HIV prevention	Basic coping and self-regulation frameworks Intervention content combined Motivational Interviewing and Cognitive Behavioural techniques	- Information on sexual safety, risks of unprotected sex, medication adherence, drug and alcohol reduction, and coping with HIV - Use of CBT strategies to identify and challenge barriers to adherence - Motivational interviewing-based session on intimacy and sexuality - Optional sessions on HIV transmission information, basic safety skills, HIV communication, drug and alcohol use, and moods and feelings.	No	Face to face sessions with peer advocate; use of PowerPoint slides to guide sessions; behavioural planning exercises	HIV primary care clinics	Trained peer advocates; HIV+ MSM	1-to-1	Four 60-90 minute sessions; 3-month “check-in” phone calls; and 6- and 12-month coping follow-up sessions.

Intervention name and studies	Primary or secondary prevention	Theoretical model	Key components	Includes access to condoms	Delivery format	Delivery setting	Delivered by	Group based / 1-to-1	Duration and intensity
			- Development of tailored goals and written behavioural plans; with personal feedback.						
Behavioural Activation and Sexual Risk Reduction Counselling (BA-SRR) Mimiaga 2019	Primary sexual risk reduction	Behavioural Activation component based on CBT principles. SRR component based on IMB model and MI techniques.	- Information gathering session to understand participants' mental health, substance use patterns and sexual risk behaviours - Information and education provision to promote knowledge of HIV acquisition risk behaviour and substance use - Use of MI-based strategies to enhance motivation to change sexual behaviour and substance use - Development of behavioural skills plan and strategies to change behaviour - CBT to address substance use - Behavioural Activation techniques, including problem solving training, mood and activity monitoring, and planning for relapse.	No	Information not reported	Health centre caring for sexual and gender minority populations	Trained counsellors	1-to-1	13 sessions; duration not reported
Computer Assisted Intervention for Safer Sex (CISS) Nostlinger 2016	Secondary HIV prevention	Information-Motivation-Behavioural Skills (IMB) model Social Cognitive Theory	- Semi-structured counselling sessions using videos depicting personal stories about safer sex using sexualised images rather than traditional methods of cognitive education - Content addresses emotional responses to safer sex, barriers to safer sex, personal problem solving, and relationship issues.	No	Sessions used computer-assisted tools including a series of video materials and interactive	HIV treatment centres	Trained facilitators	1-to-1	Three 50-minute sessions delivered 3 weeks apart

Intervention name and studies	Primary or secondary prevention	Theoretical model	Key components	Includes access to condoms	Delivery format	Delivery setting	Delivered by	Group based / 1-to-1	Duration and intensity
		Dual Process Theory	- Development of a personalised risk reduction plan and cognitive behavioural goal setting strategies		slide shows. Problem solving activities and self-assessment tools were also used.				
No excuses / Sin buscar excusas O'Donnell 2014	Primary HIV prevention	Social Cognitive Theory	- Short video modelling common risks, relationships and prevention messages in culturally relevant contexts - Group discussion on sexual safety - Condom education session addressing common problems (e.g. breakage, insufficient lubrication, and slipping) and barriers to use, including modelling 'comebacks' to excuses for not using condoms. - Access to a selection of condoms to take away	Yes	Soap-opera style videos; group discussion.	Community health centres	No information	Group sessions	Brief; single session lasting approx.. 45 minutes.
HOLA en Grupos Rhodes 2017	Primary HIV prevention	Social Cognitive Theory Empowerment Education Traditional Hispanic/Latino cultural values also inform the intervention	- Information and education about HIV and STI facts, transmission, prevention, testing and health care access - Attitudes and skills around condoms including negotiation and correct use. - Participants given various brands of condom to try and determine their personal preferences - Consideration of Hispanic/Latino cultural values and impact on sexual health	Yes	Interactive group sessions; skills development and practice	Community settings	Peer facilitators	Group sessions	Four 4-hour sessions on consecutive Sunday evenings

Intervention name and studies	Primary or secondary prevention	Theoretical model	Key components	Includes access to condoms	Delivery format	Delivery setting	Delivered by	Group based / 1-to-1	Duration and intensity
			- Information provision on locally available HIV- and STI-related services and how to overcome challenges in accessing services						
Intervention name not reported Safren 2013	Secondary HIV prevention	Information-Motivation-Behavioural Skills (IMB) model Motivational Interviewing techniques	- Regular sessions with medical social worker comprising 5 main sessions and 4 booster sessions - Information and education about HIV transmission, viral load, medications and HIV superinfection / reinfection - Identification of participants' individual risk behaviours and risk limits. - Participants can select 3 of 6 modules covering topics they deemed most relevant to their needs - Topics covered use of drugs during sex; managing stress; triggers to sexual risk behaviour, culture and the impact of racial or ethnic identity; HIV status disclosure; and sexual and romantic relationships - Session format followed IMB model: information on the topic; MI to discuss barriers to change; and behaviour change via new skills.	No	Open ended discussions, needs assessment, role play, skills building exercises, mindfulness, relaxation training, worksheets and action plans.	Community-based HIV clinics	Trained medical social workers	1-to-1	Five 50-90 minute sessions spread over 3 months, plus 4 booster sessions every 3 months
Personalised Cognitive Counselling (PCC)	Secondary HIV prevention	Not reported	- Individual counselling sessions focusing on self-justifications and rationalisations for sexual risk behaviour.	No	Completion of self-justification questionnair	Unclear	Licensed mental health professionals	1-to-1	One main 1 hour session and one booster

Intervention name and studies	Primary or secondary prevention	Theoretical model	Key components	Includes access to condoms	Delivery format	Delivery setting	Delivered by	Group based / 1-to-1	Duration and intensity
Schwarcz 2013			- Therapist supports the participant to reflect on self-justifications for recent high risk sex episode involving UAI and identify potential flaws in rationalisations. - Development of personalised plans to reduce future risk behaviour		e; in depth discussion of recent high risk UAI		trained in PCC		session (duration not reported) after 6 months
Positive Choices (PC) Skikema 2011 Sikkema 2014	Secondary HIV prevention	Information-Motivation-Behavioural Skills (IMB) model	- Brief early intervention for newly HIV diagnosed MSM - Information and education about sexual health in newly diagnosed MSM (e.g. increased transmission risk, high viral load) - Discussion of strategies to maintain healthy sexual relationships and the importance of disclosure - Increasing motivation for transmission risk reduction - Behavioural skills development such as disclosure decision making and communication skills - Development of personalised risk reduction plan	No	No detail provided	Sexual health clinics	HIV counsellors or social workers trained in the PC intervention	1-to-1	Three 60-minute sessions; 2 initial sessions plus one booster session 1 month later
Interventions for young gay, bisexual and other men who have sex with men (MSM)									
MyPeeps (Male Youth Pursuing Empowerment, Education, and Prevention	Primary HIV risk reduction	Social Cognitive Theory Theories of sexual minority stress, racial	- Information and education about HIV/STI epidemiology in YMSM; distinctions between viral, bacterial and parasitic STIs	No	Brief lectures, demonstrations, group exercises, small and	LGBT community health centre	Peer facilitators	Group sessions (5-10 participants)	Six 2-hour sessions delivered twice weekly for 3 weeks

Intervention name and studies	Primary or secondary prevention	Theoretical model	Key components	Includes access to condoms	Delivery format	Delivery setting	Delivered by	Group based / 1-to-1	Duration and intensity
around Sexuality) Hidalgo 2015		identity development and stigma management also informed intervention development	- Discussion of effective condom use and condom use self-efficacy - Discussion of minority stress and its influence on safe sex; address issues of homophobia and racism - Discussion of interpersonal factors including partner communication and assertiveness - Increase awareness of influence of substance use on sexual risk - Development of personalised risk reduction plan and situation-specific strategies to overcome barriers to success		large group discussions, role plays, cartoon vignettes.				
Motivational Interviewing Parsons 2014	Primary HIV risk reduction	Motivational Interviewing	- Collaborative, patient centred approach most suitable for non-treatment seeking YGBM who are ambivalent about changing risk behaviour - MI techniques used to increase commitment to change the two risk behaviours (UAI and substance use) - Development of a personalised plan for change including goals and potential barriers, and discussion of relapse prevention - Review of community resources and support services available	No	Exercises such as staging rule and decisional balance exercise	Research centre	Trained facilitators	1-to-1	Four 1-hour sessions; participants have 12 week window to complete all sessions
Interventions for men from a Black African or Caribbean family background who have sex with men									
The Bruthas Project	Primary HIV prevention	Information-Motivation-Behavioural	- Intervention content tailored to MSMW and emphasised a non-judgemental approach to complex	No	Some sessions included	Private mobile clinics or the project office	Trained African American	1-to-1	Four sessions delivered

Intervention name and studies	Primary or secondary prevention	Theoretical model	Key components	Includes access to condoms	Delivery format	Delivery setting	Delivered by	Group based / 1-to-1	Duration and intensity
Arnold 2019		Skills (IMB) model	sexual partnerships and interactions. - Information and education on sexual risk behaviours and routes of HIV transmission with male and female partners - Personal risk assessment and identifying situational contexts and motivational triggers for condomless sex - Condom use demonstration - Information and discussion on the importance of regular testing - Discussion of relationships and sexual communication - Development of an individualised risk reduction plan, including gender and type of partner (main or casual) - Use of Motivational counselling		interactive role play scenarios; skills practice with feedback and reinforcement; homework assignments to practice behavioural risk reduction skills.		male counsellors		once every 2 weeks. Session duration not reported.
Intervention name not reported Eaton 2018	Primary STI prevention	Conflict Theory of Decision Making	- Focuses on sexual risk decision making and the limitations of serosorting. - Uses a fictitious story to stimulate discussion of the limitations of serosorting as an HIV prevention strategy. - Participants create a sexual network diagram and use them to reflect on their own sexual risk - Development of a personalised risk reduction plan	No	Discussion of fictitious case where serosorting fails; creation of sexual network diagram; exercises involving weighing costs and benefits of decision making.	Community-based research setting	Trained counsellors	1-to-1	Single 45-minute session

Intervention name and studies	Primary or secondary prevention	Theoretical model	Key components	Includes access to condoms	Delivery format	Delivery setting	Delivered by	Group based / 1-to-1	Duration and intensity
POWER Fernandez 2016	Primary HIV prevention	Information-Motivation-Behavioural Skills (IMB) model	- Provision of culturally-relevant information on HIV risk and protection, including facts and myths about HIV - Development of communication and sexual negotiation skills - Development of a personal risk reduction plan and commitment to sexual health - Behaviour change techniques including skills building with coaching, feedback and reinforcement, and goal setting	Yes	Live chat, publicly available media clips, skills building exercises, quizzes, role plays	Online sessions delivered in real time via live chat	Trained facilitators	1-to-1	Three 60-90 minute sessions delivered over 3 weeks
Men of African American Legacy Empowering Self (MAALES) Harawa 2013	Primary HIV risk reduction	Theory of Reasoned Action and Planned Behaviour Empowerment Theory Critical Thinking and Cultural Affirmation model	- Addressed social influences and cultural norms; emphasis on gender and ethnicity - Discussion of communication and empowerment skills - Support to develop risk reduction goals and how to overcome challenges; strategies for committing to change	Yes	No information	Community-based settings for at-risk or HIV positive clients	Trained facilitators	Small group sessions	Six 2-hour sessions over 3 weeks plus 2 booster sessions at 6 and 18 weeks
Being Responsible for Ourselves (BRO) Jemmott 2015	Primary STI risk reduction	Social Cognitive Theory Theory of Reasoned Action	- Information and education on HIV/STI symptoms, transmission, prevention and risk reduction - Discussion of personal sexual risk behaviour and completion of risk assessment to raise awareness of own personal risk	No	Discussion, activities, role plays, mini-lecture, homework assignments and	University research centre	Trained facilitators	1-to-1	Three 90-minute sessions delivered over 3 consecutive weeks

Intervention name and studies	Primary or secondary prevention	Theoretical model	Key components	Includes access to condoms	Delivery format	Delivery setting	Delivered by	Group based / 1-to-1	Duration and intensity
			- Development of personal HIV sexual risk reduction plan, including consideration of barriers and strategies to overcome them - Attitudes and skills around condom use, including ways to make it pleasurable, how drug or alcohol use may affect condom use, and ways to neutralise excuses for not using condoms - Condom use demonstration and opportunity to practice - Development and practice of sexual negotiation and communication skills		interactive videos				
DiSH Koblin 2012	Primary HIV risk reduction	Social Cognitive Theory	- Participants jointly prepared healthy meals, ate them together, and discussed a range of nutrition and HIV related health topics - Session themes addressed parallels between healthy diet and healthy sex, including cultural factors and the role of shame, remorse and self-worth. - Some behaviour change techniques including commitment to change, goal setting, evaluation of progress toward goals, and strategy refinement.	No	Group discussion while cooking and eating meals	Unclear	Trained facilitators	Group sessions	Five 2-hour sessions delivered over 2 weeks
Project RISE Lauby 2018	Primary HIV risk reduction	Social Cognitive Theory	- Designed to address issues of stress and coping, experiences of stigma and discrimination, and other	No	Discussion, life coaching principles,	Community partner agency offices (catering for	Trained counsellors	1-to-1	Six 90-120 minute sessions delivered

Intervention name and studies	Primary or secondary prevention	Theoretical model	Key components	Includes access to condoms	Delivery format	Delivery setting	Delivered by	Group based / 1-to-1	Duration and intensity
		Stress and Coping Theory Ecosystems perspective Life Coaching techniques	life concerns alongside sexual risk behaviours - Focused on the promotion of a positive self-identity, the development of coping strategies, and generating action plans to work through problems and implement risk reduction behaviour. - Included a session on the importance of HIV testing; all participants were offered HIV/STI testing - Numerous topics covered and participants could select most relevant		eco-mapping exercise	LGBT people of colour)			over 6 weeks
Unity in Diversity (UND) Tobin 2013	Primary HIV prevention	Information-Motivation-Behavioural Skills (IMB) model Social Network Theory Social Cognitive Theory	- Capitalises on social influence processes to promote and maintain behaviour change - Information and education about HIV risk, HIV testing and preventative behaviours - Attitudes and skills around condom use, including communication and the impact of drugs or alcohol on condom use - Condom use demonstration and opportunity to practice - Focus on importance of knowing HIV status, HIV testing, asking partners their status, and talking to partners about testing - Personal risk assessment to increase awareness of personal risk and set goals for risk reduction	No	Group discussion, videos, problem-solving discussions, role play, skills practice, worksheets	Research clinics	Ethnically matched facilitators	Small groups (4-8 participants)	Six 2-hour group sessions and 1 individual session, delivered twice per week

Intervention name and studies	Primary or secondary prevention	Theoretical model	Key components	Includes access to condoms	Delivery format	Delivery setting	Delivered by	Group based / 1-to-1	Duration and intensity
			- Addresses HIV and MSM related stigma						
Enhanced Sexual Health Intervention for Men (ES-HIM) Williams 2013	Secondary HIV prevention	Guided by Cognitive Behavioural approaches	- Combined sexual risk and stress reduction intervention for HIV positive MSMW with history of childhood sexual abuse - Addresses the individual, interpersonal, social and cultural factors that may influence sexual behaviour and psychological health - Discussion of triple minority status (HIV positive and member of sexual and ethnic minority group); issues of stigma and social isolation; influence of gender, ethnicity and trauma history - Recognition of how learned coping strategies, affect regulation and cognitive distortions can impact sexual behaviours - Teaches participants to identify stress triggers and how they could lead to high risk behaviours - Emphasis on communication skills, negotiation and assertiveness training, and establishing safe-sex boundaries.	No	Discussion based	Unclear	Trained, ethnically matched male facilitators	Small groups	Six 2-hour sessions over 3 weeks
Interventions for MSM and trans women of mixed immigrant status									
HOLA Rhodes 2020	Primary HIV prevention	Community-based participatory research partnership	- Spanish language, culturally congruent intervention - Lay community leaders recruited as 'Navegantes' and trained to work within their existing social networks	Yes	Navegantes met with members of their social network and	Community and social venues	Peer Navegantes were trained by two Latinx gay men;	1-to-1	Study period lasted 12 months and Navegantes met with

Intervention name and studies	Primary or secondary prevention	Theoretical model	Key components	Includes access to condoms	Delivery format	Delivery setting	Delivered by	Group based / 1-to-1	Duration and intensity
		Social Cognitive Theory Empowerment Education	to provide information, increase awareness and promote behaviour change - Topics included impact of HIV and STIs on Latinx populations and sexual and gender minorities; HIV and STI prevention strategies; accessing health services and HIV/STI testing; condom use; impact of culture, values and reciprocal determinism; and effective communication and support strategies.		carried out formal and informal helping, including discussion, demonstrations, role play activities and distribution of materials		they then delivered the intervention to members of their social network		members of their social network regularly throughout this period, but unclear how often or the duration of these interactions.

1.1.6 Economic evidence

A search for relevant economic studies was undertaken, using the strategy in appendix B and applying a cost-effectiveness filter. 2,099 references were identified from this literature search; of which 2,090 were excluded during title and abstract screening. On full paper inspection all 9 of these studies did not to meet the inclusion criteria, and therefore no economic studies were included to inform this review question

Excluded studies

A list of excluded studies along with reasons for exclusion can be found in Appendix K.

1.1.7 Economic model

No economic modelling was undertaken for this review question. The model structure developed for the review question on increasing update of STI testing could in principle, but the committee agreed that none of the evidence from the clinical review enabled modelling that would provide additional useful evidence for making recommendations.

1.1.8 Summary of the effectiveness evidence

1.1.8.1 Summary of Findings for Migrants

1.1.8.1.1 Culturally adapted Motivational Interviewing group intervention

Condom use outcomes for Culturally adapted Motivational Interviewing group intervention vs. Health promotion control

Outcomes	Illustrative comparative risks* (95% CI) Assumed risk Control	Corresponding risk Culturally adapted MI	Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
Consistent condom use: past 90 days Follow-up: 3 months	**174 per 1000**	**450 per 1000** (299 to 677)	**RR 2.59** (1.72 to 3.89)	278 (1 study)	⨁⨁◯◯ **low**[1,2]	Sanchez 2013
Consistent condom use: past 90 days Follow-up: 9 months	**152 per 1000**	**385 per 1000** (247 to 603)	**RR 2.53** (1.62 to 3.96)	278 (1 study)	⨁⨁◯◯ **low**[1,2]	Sanchez 2013
Consistent condom use: past 30 days Follow-up: 3 months	**239 per 1000**	**514 per 1000** (366 to 722)	**RR 2.15** (1.53 to 3.02)	278 (1 study)	⨁⨁◯◯ **low**[1,2]	Sanchez 2013
Consistent condom use: past 30 days Follow-up: 9 months	**246 per 1000**	**443 per 1000** (313 to 626)	**RR 1.8** (1.27 to 2.54)	278 (1 study)	⨁⨁◯◯ **low**[1,2]	Sanchez 2013
Condom use at last sex Follow-up: 3 months	**319 per 1000**	**593 per 1000** (450 to 784)	**RR 1.86** (1.41 to 2.46)	278 (1 study)	⨁⨁◯◯ **low**[1,2]	Sanchez 2013
Condom use at last sex Follow-up: 9 months	**348 per 1000**	**501 per 1000** (376 to 664)	**RR 1.44** (1.08 to 1.91)	278 (1 study)	⨁◯◯◯ **very low**[1,2,3]	Sanchez 2013

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

[1] Downgraded once for some concerns of bias due to insufficient information on randomisation and lack of allocation concealment
[2] Latino migrant workers in the USA
[3] Downgraded once as 95%CI crosses one MID

1.1.8.1.2 Culturally specific community-based risk reduction intervention for Hispanic women

Condom use outcomes for Culturally specific community-based group risk reduction intervention for Hispanic women vs. Control

Outcomes	Illustrative comparative risks* (95% CI) Assumed risk Control	Corresponding risk Community-based prevention intervention	Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments

Percent of sex events where condoms were used Follow up: 6 months		The mean percent of sex events where condoms were used, at 6 months, (MID = 22.4) in the intervention groups was **8.42 lower** (18.94 lower to 2.1 higher)		259 (1 study)	⨁⊖⊖⊖ **very low**[1,2,3]	Peragallo Montano 2019
Percent of sex events where condoms were used Follow up: 12 months		The mean percent of sex events where condoms were used, at 12 months, (MID = 22.2) in the intervention groups was **4.38 lower** (15.22 lower to 6.46 higher)		259 (1 study)	⨁⊖⊖⊖ **very low**[1,2,3]	Peragallo Montano 2019
Number of condomless sex events Follow up: 6 months		The mean number of condomless sex events, at 6 months, (MID = 4.2) in the intervention groups was **1.42 higher** (0.54 lower to 3.38 higher)		259 (1 study)	⨁⊖⊖⊖ **very low**[1,2,3]	Peragallo Montano 2019
Number of condomless sex events Follow up: 12 months		The mean number of condomless sex events, at 12 months, (MID = 4.5) in the intervention groups was **0.37 lower** (2.28 lower to 1.54 higher)		259 (1 study)	⨁⊖⊖⊖ **very low**[1,2,3]	Peragallo Montano 2019
Self-efficacy for condom use Follow up: 6 months	**443 per 1000**	**580 per 1000** (452 to 735)	**RR 1.31** (1.02 to 1.66)	259 (1 study)	⨁⊖⊖⊖ **very low**[1,2,4]	Peragallo Montano 2019
Self-efficacy for condom use Follow up: 12 months	**489 per 1000**	**616 per 1000** (493 to 772)	**RR 1.26** (1.01 to 1.58)	259 (1 study)	⨁⊖⊖⊖ **very low**[1,2,4]	Peragallo Montano 2019
Behavioural intention to use a condom Follow up: 3 months	**639 per 1000**	**715 per 1000** (613 to 824)	**RR 1.12** (0.96 to 1.29)	345 (1 study)	⨁⊖⊖⊖ **very low**[2,5,6]	Peragallo 2012
Behavioural intention to use a condom Follow up: 6 months	**761 per 1000**	**784 per 1000** (700 to 875)	**RR 1.03** (0.92 to 1.15)	372 (1 study)	⨁⊖⊖⊖ **very low**[2,3,5]	Peragallo 2012
Behavioural intention to use a condom Follow up: 12 months	**818 per 1000**	**785 per 1000** (712 to 867)	**RR 0.96** (0.87 to 1.06)	381 (1 study)	⨁⊖⊖⊖ **very low**[2,3,5]	Peragallo 2012
Any condom use Follow up: 3 months	**322 per 1000**	**386 per 1000** (290 to 512)	**RR 1.2** (0.9 to 1.59)	345 (1 study)	⨁⊖⊖⊖ **very low**[2,5,6]	Peragallo 2012
Any condom use Follow up: 6 months	**422 per 1000**	**401 per 1000** (333 to 481)	**RR 0.95** (0.79 to 1.14)	631 (2 studies)	⨁⊖⊖⊖ **very low**[2,5,6]	Peragallo Montano 2019 Peragallo 2012

Any condom use Follow up: 12 months	**426 per 1000**	**472 per 1000** (298 to 745)	**RR 1.11** (0.7 to 1.75)	640 (2 studies)	⊕⊖⊖⊖ **very low**[2,5,7,8]	Peragallo Montano 2019 Peragallo 2012

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

[1] Downgraded once for some concerns of bias due to no information on allocation concealment or blinding. Adherence issues: not all participants completed all sessions (only 71% completed all 3 and 16% did not complete any) and impact of adherence not analysed. Trial not registered.
[2] US study of Hispanic migrants
[3] Downgraded once as 95%CI crosses line of no effect
[4] Downgraded once as 95%CI crosses 1 MID
[5] Downgraded twice for high concerns of bias due to adherence to the intervention was poor (only 43% attended all sessions and 41% did not attend any session) and the impact of adherence was not assessed. Relatively high attrition (48% at 3-months and 33% at 12 months for intervention group) and no comparison of completers vs those lost to follow-up. Outcome assessors were not blind to condition. All outcomes were dichotomised due to skewed response patterns which did not allow for as rich of an analysis as if they had been retained as continuous variables, and may attenuate intervention effects. Trial not registered
[6] Downgraded once as 95%CI crosses line of no effect and 1 MID
[7] Downgraded twice as I2 = 86%
[8] Downgraded twice as 95%CI crosses line of no effect and 2 MIDs

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2

STI incidence outcomes for Culturally specific community-based group risk reduction intervention for Hispanic women vs. Control

Outcomes	**Illustrative comparative risks* (95% CI)** Assumed risk **Control**	 Corresponding risk **Community-based prevention intervention**	**Relative effect (95% CI)**	**No of Participants (studies)**	**Quality of the evidence (GRADE)**	**Comments**
Chlamydia incidence Follow up: 6 months	**0 per 1000**	**0 per 1000** (0 to 0)	**RR 3.52** (0.14 to 85.93)	372 (1 study)	⊕⊖⊖⊖ **very low**[1,2,3]	Peragallo 2012
Chlamydia incidence Follow up: 12 months	**15 per 1000**	**5 per 1000** (1 to 52)	**RR 0.36** (0.04 to 3.44)	381 (1 study)	⊕⊖⊖⊖ **very low**[1,2,3]	Peragallo 2012

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

[1] Downgraded twice for high risk of bias due to adherence to the intervention was poor (only 43% attended all sessions and 41% did not attend any session) and the impact of adherence was not assessed. Relatively high attrition (48% at 3-months and 33% at 12 months for intervention group) and no comparison of completers vs those lost to follow-up. Outcome assessors were not blind to condition. All outcomes were dichotomised due to skewed response patterns which did not allow for as rich of an analysis as if they had been retained as continuous variables, and may attenuate intervention effects. Trial not registered
[2] US study of Hispanic migrants
[3] Downgraded twice as 95%CI crosses line of no effect and 2 MIDs

1

STI/HIV knowledge outcomes for Culturally specific community-based group risk reduction intervention for Hispanic women vs. Control

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk Control	Corresponding risk Community based prevention intervention				
HIV knowledge Follow up: 3 months	**485 per 1000**	**616 per 1000** (509 to 747)	**RR 1.27** (1.05 to 1.54)	345 (1 study)	⨁⊖⊖⊖ **very low**[1,2,3]	Peragallo 2012
HIV knowledge Follow up: 6 months	**461 per 1000**	**664 per 1000** (562 to 779)	**RR 1.44** (1.22 to 1.69)	631 (2 studies)	⨁⊖⊖⊖ **very low**[2,3,4]	Peragallo Montano 2019 Peragallo 2012
HIV knowledge Follow up: 12 months	**620 per 1000**	**682 per 1000** (614 to 756)	**RR 1.1** (0.99 to 1.22)	640 (2 studies)	⨁⊖⊖⊖ **very low**[2,4,5]	Peragallo Montano 2019 Peragallo 2012

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

[1] Downgraded twice for high risk of bias due to adherence to the intervention was poor (only 43% attended all sessions and 41% did not attend any session) and the impact of adherence was not assessed. Relatively high attrition (48% at 3-months and 33% at 12 months for intervention group) and no comparison of completers vs those lost to follow-up. Outcome assessors were not blind to condition. All outcomes were dichotomised due to skewed response patterns which did not allow for as rich of an analysis as if they had been retained as continuous variables, and may attenuate intervention effects. Trial not registered
[2] US study of Hispanic migrants
[3] Downgraded once as 95%CI crosses 1 MID
[4] Downgraded once for some concerns of bias for Peragallo Montano 2019 due to no information on allocation concealment or blinding; adherence issues: not all participants completed all sessions (only 71% completed all 3 and 16% did not complete any) and impact of adherence not analysed; trial not registered) and further downgraded for high risk of bias for Peragallo 2012 due to adherence to the intervention was poor (only 43% attended all sessions and 41% did not attend any session) and the impact of adherence was not assessed; relatively high attrition (48% at 3-months and 33% at 12 months for intervention group) and no comparison of completers vs those lost to follow-up; outcome assessors were not blind to condition; all outcomes were dichotomised due to skewed response patterns which did not allow for as rich of an analysis as if they had been retained as continuous variables, and may attenuate intervention effects; and trial not registered)
[5] Downgraded once as 95%CI crosses line of no effect

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3 ## 1.1.8.2 Summary of Findings for People who are homeless

Condom use outcomes for Brief group-based motivational interviewing intervention for homeless youth vs. Standard care

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk Control	Corresponding risk Group Motivational Interviewing Intervention				
Proportion of unprotected sexual events, at 3 months		The mean proportion of unprotected sexual events, at 3 months, (MID = 0.24) in the intervention groups was		181 (1 study)	⨁⊖⊖⊖ **very low**[1,2,3]	Tucker 2017

		0.01 higher (0.12 lower to 0.14 higher)			
Condom use self-efficacy, at 3 months		The mean condom use self-efficacy, at 3 months, (MID = 0.32) in the intervention groups was **0.13 higher** (0.04 lower to 0.3 higher)	181 (1 study)	⊕⊖⊖⊖ **very low**[1,2,3]	Tucker 2017

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval;

[1] Downgraded twice for high risk of bias due to randomised cross-over trial with no information on blinding.; intervention adherence was low and impact of intervention attendance on outcomes was not assessed; overall follow-up rates were high (91%) but follow-up was significantly higher in the intervention group (95%) than the control group (86%); trial not registered.
[2] US study
[3] Downgraded once as 95%CI crosses line of no effect

1.1.8.3 Summary of Findings for Young People

Condom use outcomes for Peer facilitator intervention vs. Expert facilitator intervention

Outcomes	**Illustrative comparative risks* (95% CI)**		**Relative effect (95% CI)**	**No of Participants (studies)**	**Quality of the evidence (GRADE)**	**Comments**
	Assumed risk **Expert facilitator**	Corresponding risk **Peer facilitator**				
Condom use consistency, for vaginal sex Follow-up: 1 month	**849 per 1000**	**790 per 1000** (697 to 909)	**RR 0.93** (0.82 to 1.07)	190 (1 study)	⊕⊖⊖⊖ **very low**[1,2]	Giminez-Garcia 2018
Condom use consistency, for vaginal sex Follow-up: 4 months	**857 per 1000**	**874 per 1000** (780 to 986)	**RR 1.02** (0.91 to 1.15)	166 (1 study)	⊕⊖⊖⊖ **very low**[1,2]	Giminez-Garcia 2018
Condom use consistency, for anal sex Follow-up: 1 month	**957 per 1000**	**919 per 1000** (852 to 986)	**RR 0.96** (0.89 to 1.03)	190 (1 study)	⊕⊖⊖⊖ **very low**[1,2]	Giminez-Garcia 2018
Condom use consistency, for anal sex Follow-up: 4 months	**976 per 1000**	**918 per 1000** (849 to 986)	**RR 0.94** (0.87 to 1.01)	166 (1 study)	⊕⊖⊖⊖ **very low**[1,2]	Giminez-Garcia 2018

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

[1] Downgraded twice for high risk of bias due to no information on participant blinding, adherence to intervention regimen, or baseline differences between groups; trial was not registered
[2] Downgraded once as 95%CI crosses line of no effect

Condom use outcomes for STI risk reduction intervention with booster sessions vs. attention matched control

Outcomes	**Illustrative comparative risks* (95% CI)**					**Comments**

	Assumed risk **Control**	Corresponding risk **Risk reduction intervention**	**Relative effect (95% CI)**	**No of Participants (studies)**	**Quality of the evidence (GRADE)**	
Unprotected sex – any episodes Follow-up: 3 months	**625 per 1000**	**582 per 1000** (507 to 669)	**RR 0.93** (0.81 to 1.07)	573 (1 study)	⨁⊖⊖⊖ **very low**[1,2,3]	Morrison-Beedy 2013
Unprotected sex – any episodes Follow-up: 6 months	**672 per 1000**	**544 per 1000** (470 to 625)	**RR 0.81** (0.7 to 0.93)	546 (1 study)	⨁⊖⊖⊖ **very low**[1,2,4]	Morrison-Beedy 2013
Unprotected sex – any episodes Follow-up: 12 months	**728 per 1000**	**684 per 1000** (611 to 764)	**RR 0.94** (0.84 to 1.05)	484 (1 study)	⨁⊖⊖⊖ **very low**[1,2,3]	Morrison-Beedy 2013
Unprotected sex – number of episodes Follow-up: 3 months		The mean unprotected sex – number of episodes; at 3 months (MID = 3.73) in the intervention group was **0.7 lower** (1.93 lower to 0.53 higher)		537 (1 study)	⨁⨁⊖⊖ **low**[1,2]	Morrison-Beedy 2013
Unprotected sex – number of episodes Follow-up: 6 months		The mean unprotected sex – number of episodes; at 6 months (MID = 4.42) in the intervention group was **0.97 lower** (2.41 lower to 0.47 higher)		546 (1 study)	⨁⨁⊖⊖ **low**[1,2]	Morrison-Beedy 2013
Unprotected sex – number of episodes Follow-up: 12 months		The mean unprotected sex – number of episodes; at 12 months (MID = 5.52) in the intervention group was **1.06 lower** (3.04 lower to 0.92 higher)		484 (1 study)	⨁⨁⊖⊖ **low**[1,2]	Morrison-Beedy 2013

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

[1] Downgraded once for some concerns of bias due to no information on participant blinding or intervention adherence. 24% lost to follow-up and no attrition analyses.
[2] US study
[3] Downgraded once as 95%CI crosses line of no effect
[4] Downgraded once as 95%CI crosses one MID

1

Condom use outcomes for Brief MI intervention delivered in paediatric EDs vs. standard care

Outcomes	**Illustrative comparative risks* (95% CI)** Assumed risk **Control**	 Corresponding risk **Brief MI intervention**	**Relative effect (95% CI)**	**No of Participants (studies)**	**Quality of the evidence (GRADE)**	**Comments**
Condom use at last sex Follow-up: 6 months	**571 per 1000**	**400 per 1000** (166 to 966)	**RR 0.7** (0.29 to 1.69)	24 (1 study)	⨁⊖⊖⊖ **very low**[1,2,3]	Miller 2021
Condom use intention Follow-up: 6 months		The mean condom use intention; at 6 months (MID = 0.48), in the intervention group was **0.54 lower** (1.27 lower to 0.19 higher)		37 (1 study)	⨁⊖⊖⊖ **very low**[1,2,4]	Miller 2021

Condom use confidence Follow-up: 6 months		The mean condom use confidence; at 6 months (MID = 0.62), in the intervention groups was **0.05 higher** (0.82 lower to 0.92 higher)		37 (1 study)	⊕⊖⊖⊖ **very low**[1,2,3]	Miller 2021

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

[1] Downgraded once for some concerns of bias due to high attrition (only 40.6% completion at 6 months) but no differential attrition by group. Small final sample (n=37)
[2] US study delivered in paediatric ED setting
[3] Downgraded twice as 95%CI crosses line of no effect and 2 MIDs
[4] Downgraded once as 95%CI crosses line of no effect and 1 MID

1

STI incidence outcomes for Group-based risk reduction workshops vs. waitlist control

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk **Control**	Corresponding risk **Group-based risk reduction workshops**				
STI incidence Follow-up: 6 months	**67 per 1000**	**3 per 1000** (0 to 52)	**RR 0.05** (0 to 0.77)	318 (1 study)	⊕⊕⊖⊖ **low**[1,2]	Champion 2012
STI incidence Follow-up: 12 months	**78 per 1000**	**36 per 1000** (14 to 93)	**RR 0.46** (0.18 to 1.19)	333 (1 study)	⊕⊕⊖⊖ **low**[1,3]	Champion 2012

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

[1] US study of adolescent women with a history of sexual or physical abuse
[2] Downgraded once as 95%CI crosses line of no effect
[3] Downgraded once as 95%CI crosses line of no effect and 1 MID

2

STI knowledge outcomes for Peer facilitator intervention vs. Expert facilitator intervention

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk **Expert facilitator**	Corresponding risk **Peer facilitator**				
STI knowledge Follow-up: 1 month		The mean STI knowledge, at 1 month (MID = 0.73), in the intervention group was **0.1 higher** (0.32 lower to 0.52 higher)		190 (1 study)	⊕⊖⊖⊖ **very low**[1,2]	Giminez-Garcia 2018
STI knowledge Follow-up: 4 months		The mean STI knowledge, at 4 months (MID = 0.59), in the intervention group was **0.07 higher** (0.32 lower to 0.46 higher)		166 (1 study)	⊕⊖⊖⊖ **very low**[1,2]	Giminez-Garcia 2018

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

[1] Downgraded twice for high risk of bias due to limited information on randomisation and allocation concealment, no information on intervention adherence, missing data not reported, no attrition analyses by group; and trial not registered
[2] Downgraded once as 95%CI crosses line of no effect

1.1.8.4 Summary of Findings for Trans People

Group-based HIV risk reduction and prevention interventions vs. standard care or attention-matched control

Outcomes	Illustrative comparative risks* (95% CI) Assumed risk Control	Corresponding risk Group-based HIV risk reduction intervention	Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
Number of condomless sex acts Follow-up: 4 months		The mean number of condomless sex acts at 4 months (MID = 1.91) in the intervention group was **0.88 lower** (1.9 lower to 0.14 higher)		167 (1 study)	⊕⊖⊖⊖ **very low**[1,2,3]	Garofalo 2018
Number of condomless sex acts Follow-up: 8 months		The mean number of condomless sex acts at 8 months (MID = 1.03) in the intervention group was **0.43 lower** (0.97 lower to 0.11 higher)		167 (1 study)	⊕⊖⊖⊖ **very low**[1,2,3]	Garofalo 2018
Number of condomless sex acts Follow-up: 12 months		The mean number of condomless sex acts at 12 months (MID = 1.27) in the intervention group was **0.69 lower** (1.37 lower to 0.01 lower)		164 (1 study)	⊕⊖⊖⊖ **very low**[1,2,4]	Garofalo 2018
Number of condomless sex partners Follow-up: 3 months		The mean number of condomless sex partners at 3 months (MID = 0.38) in the intervention group was **0.29 higher** (0.2 lower to 0.78 higher)		42 (1 study)	⊕⊖⊖⊖ **very low**[2,4,5]	Sevelius 2019
Number of condomless sex partners Follow-up: 6 months		The mean number of condomless sex partners at 6 months (MID = 0.41) in the intervention group was **0.42 lower** (0.84 lower to 0 higher)		42 (1 study)	⊕⊖⊖⊖ **very low**[2,4,5]	Sevelius 2019

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

[1] Downgraded for some concerns of bias due to an original third arm of the trial being dropped before study completion, and the trial was not registered
[2] US study
[3] Downgraded once as 95%CI crosses line of no effect
[4] Downgraded once as 95%CI crosses one MID

[5] Downgraded for some concerns of bias due to lack of participant blinding and relatively high attrition

1.1.8.5 Summary of Findings for people from a Black African or Caribbean family background

Interactive HIV prevention workshops vs. information only comparison workshops

Outcomes	Illustrative comparative risks* (95% CI) Assumed risk Control	Corresponding risk Interactive HIV prevention workshops	Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
Condom use at last sex Follow-up: 3 months	**491 per 1000**	**711 per 1000** (520 to 981)	**RR 1.45** (1.06 to 2)	112 (1 study)	⨁⨁◯◯ **low**[1,2]	Diallo 2010
Condom use at last sex Follow-up: 6 months	**493 per 1000**	**685 per 1000** (512 to 916)	**RR 1.39** (1.04 to 1.86)	137 (1 study)	⨁⨁◯◯ **low**[1,2]	Diallo 2010
Any unprotected sex in prior 3 months Follow-up: 3 months	**362 per 1000**	**376 per 1000** (260 to 546)	**RR 1.04** (0.72 to 1.51)	187 (1 study)	⨁◯◯◯ **very low**[1,3]	Diallo 2010
Any unprotected sex in prior 3 months Follow-up: 6 months	**316 per 1000**	**310 per 1000** (212 to 449)	**RR 0.98** (0.67 to 1.42)	237 (1 study)	⨁◯◯◯ **very low**[1,3]	Diallo 2010

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

[1] Downgraded once for indirectness as the intervention is delivered to pre-existing groups of women (e.g. church groups, sororities) in locations of their choice (e.g. college campuses, their home). This is not directly applicable to the UK sexual health services context.
[2] Downgraded once as 95%CI crosses 1 MID
[3] Downgraded twice as 95%CI crosses line of no effect and 2 MIDs

Brief small-group peer led HIV risk reduction intervention delivered in Barbershops vs. attention matched control

Outcomes	Illustrative comparative risks* (95% CI) Assumed risk Control	Corresponding risk Brief peer led HIV risk reduction intervention	Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
Any condomless sex Follow-up: 6 months	**462 per 1000**	**351 per 1000**	**RR 0.76**	657 (1 study)	⨁◯◯◯ **very low**[1,2,3]	Wilson 2019

	(291 to 425)		(0.63 to 0.92)

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

[1] Downgraded twice for high risk of bias due to baseline differences between groups on key variables; differential attrition by group, and no participant blinding.
[2] US study conducted in barbershops
[3] Downgraded once as 95%CI crosses 1 MID

1

Computer-based HIV prevention intervention with small group sessions vs. attention matched control

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	**Computer-based HIV prevention intervention**				
Proportion of condom-protected sex acts Follow-up: 3 months		The mean proportion of condom-protected sex acts, at 3 months (MID = 0.05), in the intervention group was **0.32 higher** (0.28 to 0.36 higher)		116 (1 study)	⊕⊕⊖⊖ **low**[1,2]	Wingood 2011
Condom use self-efficacy Follow-up: 3 months		The mean condom use self-efficacy at 3 months (MID = 0.26) in the intervention group was **1.85 higher** (1.66 to 2.04 higher)		116 (1 study)	⊕⊕⊖⊖ **low**[1,2]	Wingood 2011
HIV/STI prevention knowledge Follow-up: 3 months		The mean HIV/STI prevention knowledge at 3 months (MID = 0.05) in the intervention group was **0.46 higher** (0.43 to 0.49 higher)		116 (1 study)	⊕⊕⊖⊖ **low**[1,2]	Wingood 2011

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

[1] Downgraded once for some concerns of bias due to impact of intervention adherence not assessed; 10.4% did not attend both intervention sessions; and the trial was not registered.
[2] US study

2

3 ## 1.1.8.6 Summary of Findings for young people from a Black African or Caribbean family background

4

Psychoeducational STI/HIV prevention intervention vs. attention matched control

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	**Psychoeducational STI/HIV prevention intervention**				

Proportion of condom-protected vaginal sex Follow-up: 3 months		The mean proportion of condom-protected vaginal sex at 3 months (MID = 0.19) in the intervention group was **0.13 higher** (0.1 lower to 0.36 higher)	41 (1 study)	⊕⊖⊖⊖ **very low**[1,2,3]	Brawner 2021
Proportion of condom-protected vaginal sex Follow-up: 6 months		The mean proportion of condom-protected vaginal sex at 6 months (MID = 0.18) in the intervention group was **0.14 lower** (0.48 lower to 0.2 higher)	21 (1 study)	⊕⊖⊖⊖ **very low**[1,2,4]	Brawner 2021
Proportion of condom-protected vaginal sex Follow-up: 12 months		The mean proportion of condom-protected vaginal sex at 12 months (MID = 0.1) in the intervention group was **0.18 lower** (0.59 lower to 0.23 higher)	14 (1 study)	⊕⊖⊖⊖ **very low**[1,2,4]	Brawner 2021
Condom use self-efficacy Follow-up: 3 months		The mean condom use self-efficacy at 3 months (MID = 0.29) in the intervention group was **0.31 higher** (0.04 to 0.58 higher)	68 (1 study)	⊕⊖⊖⊖ **very low**[1,2,5]	Brawner 2021
Condom use self-efficacy Follow-up: 6 months		The mean condom use self-efficacy at 6 months (MID = 0.32) in the intervention group was **0.21 higher** (0.17 lower to 0.59 higher)	35 (1 study)	⊕⊖⊖⊖ **very low**[1,2,3]	Brawner 2021
Condom use self-efficacy Follow-up: 12 months		The mean condom use self-efficacy at 12 months (MID = 0.31) in the intervention group was **0.25 higher** (0.25 lower to 0.75 higher)	21(1 study)	⊕⊖⊖⊖ **very low**[1,2,3]	Brawner 2021
Condom use knowledge Follow-up: 6 months		The mean condom use knowledge at 6 months (MID = 0.12) in the intervention group was **0.05 higher** (0.09 lower to 0.19 higher)	35 (1 study)	⊕⊖⊖⊖ **very low**[1,2,3]	Brawner 2021
Condom use knowledge Follow-up: 12 months		The mean condom use knowledge at 12 months (MID = 0.16) in the intervention group was **0.09 higher** (0.14 lower to 0.32 higher)	23 (1 study)	⊕⊖⊖⊖ **very low**[1,2,3]	Brawner 2021
HIV/STI knowledge Follow-up: 3 months		The mean HIV/STI knowledge at 3 months (MID = 0.14) in the intervention group was **0.16 higher** (0.04 lower to 0.28 higher)	66 (1 study)	⊕⊖⊖⊖ **very low**[1,2,5]	Brawner 2021
HIV/STI knowledge Follow-up: 6 months		The mean HIV/STI knowledge at 6 months (MID = 0.09) in the intervention group was **0.04 higher** (0.09 lower to 0.17 higher)	35 (1 study)	⊕⊖⊖⊖ **very low**[1,2,3]	Brawner 2021
HIV/STI knowledge Follow-up: 12 months		The mean HIV/STI knowledge at 12 months (MID = 0.12) in the intervention group was **0.07 higher** (0.11 lower to 0.25 higher)	23 (1 study)	⊕⊖⊖⊖ **very low**[1,2,3]	Brawner 2021

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

[1] Downgraded once for some concerns of bias due to baseline differences between groups, high attrition, and the trial was not registered
[2] US study
[3] Downgraded once as 95%CI crosses line of no effect and 1 MID
[4] Downgraded twice as 95%CI crosses line of no effect and 2 MIDs
[5] Downgraded once as 95%CI crosses 1 MID

1

Group intervention addressing issues of gender, power and inequality vs. attention matched control

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	**Group-based intervention**				
Any unprotected vaginal or anal sex in prior 3 months Follow-up: immediately post-test	**333 per 1000**	**200 per 1000** (57 to 690)	**RR 0.6** (0.17 to 2.07)	30 (1 study)	⊕⊖⊖⊖ **very low**[1,2,3]	Brothers 2016
Any unprotected vaginal or anal sex in prior 3 months Follow-up: 3 months	**462 per 1000**	**498 per 1000** (222 to 1000)	**RR 1.08** (0.48 to 2.45)	25 (1 study)	⊕⊖⊖⊖ **very low**[1,2,3]	Brothers 2016
Condom use self-efficacy Follow-up: immediate post-test		The mean condom use self-efficacy immediately post-test (MID = 0.3) in the intervention group was **0.11 higher** (0.26 lower to 0.48 higher)		37 (1 study)	⊕⊖⊖⊖ **very low**[1,2,4]	Brothers 2016
Condom use self-efficacy Follow-up: 3 months		The mean condom use self-efficacy at 3 months (MID = 0.26) in the intervention group was **0.43 higher** (0.11 lower to 0.75 higher)		36 (1 study)	⊕⊖⊖⊖ **very low**[1,2,5]	Brothers 2016

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

[1] Downgraded twice for high risk of bias due to limited information on randomisation; baseline differences between groups; intervention adherence not assessed; and the trial was not registered
[2] US study
[3] Downgraded twice as 95%CI crosses line of no effect and 2 MIDs
[4] Downgraded once as 95%CI crosses line of no effect and 1 MID
[5] Downgraded once as 95%CI crosses 1 MID

2
3

Small group IMB-based HIV prevention intervention vs. attention matched control

Outcomes	Illustrative comparative risks* (95% CI)					Comments

	Assumed risk **Control**	Corresponding risk **Group-based IMB HIV prevention intervention**	**Relative effect (95% CI)**	**No of Participants (studies)**	**Quality of the evidence (GRADE)**	
Condom use self-efficacy Follow-up: 3 months		The mean condom use self-efficacy at 3 months (MID = 2.89) in the intervention group was **1.32 higher** (2.06 lower to 4.7 higher)		45 (1 study)	⨁⊖⊖⊖ **very low**[1,2,3]	Chandler 2019
HIV knowledge Follow-up: 3 months		The mean HIV knowledge at 3 months (MID = 1.01) in the intervention group was **3.07 higher** (1.85 lower to 4.29 higher)		46 (1 study)	⨁⨁⊖⊖ **low**[1,2]	Chandler 2019

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

[1] Downgraded once for some concerns of bias due to intervention adherence not assessed; and the trial was not registered
[2] US study
[3] Downgraded once as 95%CI crosses line of no effect and 1 MID

1

Sex positive condom focused intervention vs. attention matched control

Outcomes	**Illustrative comparative risks* (95% CI)** Assumed risk **Control**	 Corresponding risk **Sex positive condom focused intervention**	**Relative effect (95% CI)**	**No of Participants (studies)**	**Quality of the evidence (GRADE)**	**Comments**
Correct and consistent condom use Follow-up: 2 months	**496 per 1000**	**535 per 1000** (466 to 620)	**RR 1.08** (0.94 to 1.25)	702 (1 study)	⨁⊖⊖⊖ **very low**[1,2,3]	Crosby 2014
Correct and consistent condom use Follow-up: 6 months	**470 per 1000**	**517 per 1000** (442 to 597)	**RR 1.1** (0.94 to 1.27)	702 (1 study)	⨁⊖⊖⊖ **very low**[1,2,4]	Crosby 2014
STI incidence (CT or GC) Follow-up: 6 months	**74 per 1000**	**94 per 1000** (57 to 155)	**RR 1.28** (0.78 to 2.1)	702 (1 study)	⨁⊖⊖⊖ **very low**[1,2,5]	Crosby 2014

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

[1] Downgraded once for some concerns of bias due to baseline differences between groups on key variables (condom use and history of STIs); trial not registered.
[2] Downgraded twice for indirectness due to high rate of self-reported history of incarceration (42%) and because for participants younger than 18 years, only those who provided details of a parent or guardian who could provide in-person parental consent were eligible to participate. This group may not be representative of all sexually active males aged 15-18 years. US study
[3] Downgraded once as 95%CI crosses line of no effect
[4] Downgraded once as 95%CI crosses line of no effect and 1 MID
[5] Downgraded twice as 95%CI crosses line of no effect and 2 MIDs

2

Group intervention with brief telephone contacts to support risk reduction vs. group intervention only

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk Control	Corresponding risk Group intervention with telephone contact				
Proportion of condom-protected sex acts in prior 3 months Follow-up: 36 months	-	The mean proportion of condom-protected sex acts in the prior 3 months, at 36 months (MID = 0.15), in the intervention group was **0.09 higher** (0.04 to 0.14 higher)		429 (1 study)	⊕⊕⊖⊖ **low**[1,2]	DiClemente 2014
Proportion of condom-protected sex acts in prior 6 months Follow-up: 36 months	-	The mean proportion of condom-protected sex acts in the prior 6 months, at 36 months (MID = 0.15), in the intervention group was **0.09 higher** (0.04 to 0.14 higher)		429 (1 study)	⊕⊕⊖⊖ **low**[1,2]	DiClemente 2014
Chlamydia infection Follow-up: 36 months	**327 per 1000**	**304 per 1000** (242 to 383)	**RR 0.93** (0.74 to 1.17)	627 (1 study)	⊕⊖⊖⊖ **very low**[1,2,3]	DiClemente 2014
Gonococcal infection Follow-up: 36 months	**170 per 1000**	**155 per 1000** (109 to 222)	**RR 0.91** (0.64 to 1.31)	627 (1 study)	⊕⊖⊖⊖ **very low**[1,2,4]	DiClemente 2014

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

[1] Downgraded once for some concerns of bias due to no information on blinding; intervention group received more phone sessions than control; high attrition
[2] Downgraded for indirectness due to high rate of self-reported abuse history (56% emotional abuse, 39% physical abuse); US study
[3] Downgraded once as 95%CI crosses line of no effect and 1 MID
[4] Downgraded twice as 95%CI crosses line of no effect and 2 MIDs

1
2

Group intervention focusing on partner concurrency vs. attention matched control

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk Control	Corresponding risk Group intervention focusing on partner concurrency				
Condom use self-efficacy Follow-up: 6 months		The mean condom use self-efficacy at 6 months (MID = 2.67) in the intervention group was **1.72 higher** (0.86 to 2.58 higher)		635 (1 study)	⊕⊕⊖⊖ **low**[1,2]	Wingood 2013
Condom use self-efficacy Follow-up: 12 months		The mean condom use self-efficacy at 12 months (MID = 1.85) in the intervention group was		635 (1 study)	⊕⊖⊖⊖ **very low**[1,2,3]	Wingood 2013

		0.45 lower (1.08 lower to 0.18 higher)				
Non-viral STI incidence (CT, GC, TV) Follow-up: 6 months	**98 per 1000**	**62 per 1000** (35 to 108)	**RR 0.63** (0.36 to 1.1)	635 (1 study)	⊕⊖⊖⊖ **very low**[1,2,4]	Wingood 2013
Non-viral STI incidence (CT, GC, TV) Follow-up: 12 months	**120 per 1000**	**93 per 1000** (58 to 151)	**RR 0.77** (0.48 to 1.26)	635 (1 study)	⊕⊖⊖⊖ **very low**[1,2,5]	Wingood 2013
HPV incidence Follow-up: 12 months	**393 per 1000**	**236 per 1000** (153 to 358)	**RR 0.6** (0.39 to 0.91)	214 (1 study)	⊕⊖⊖⊖ **very low**[1,2,6]	Wingood 2013

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

[1] Downgraded once for some concerns of bias due to trial not registered
[2] US study and participants were limited to those with HMO health insurance
[3] Downgraded once as 95%CI crosses line of no effect
[4] Downgraded once as 95%CI crosses line of no effect and 1 MID
[5] Downgraded twice as 95%CI crosses line of no effect and 2 MIDs
[6] Downgraded once as 95%CI crosses 1 MID

1.1.8.7 Summary of Findings for MSM

1.1.8.7.1 IMB / Motivational Interviewing based approaches

Condom use outcomes for IMB / Motivational Interviewing based approaches vs. control

Outcomes	**Illustrative comparative risks* (95% CI)**		**Relative effect (95% CI)**	**No of Participants (studies)**	**Quality of the evidence (GRADE)**	**Comments**
	Assumed risk **Control**	Corresponding risk **IMB / Motivational Interviewing based approaches**				
Frequency of UAI in prior 3 months Follow up: 3 months		The mean frequency of UAI in prior 3 months, at 3 months (MID = 1.85) in the intervention groups was **0.01 higher** (1.32 lower to 1.35 higher)		201 (3 studies)	⊕⊖⊖⊖ **very low**[1,2,3]	Brown 2019 Sikkema 2011 Sikkema 2014
Frequency of UAI in prior 3 months Follow up: 6 months		The mean frequency of UAI in prior 3 months, at 6 months (MID = 8.32) in the intervention groups was **0.62 higher** (1.38 lower to 2.63 higher)		259 (3 studies)	⊕⊖⊖⊖ **very low**[2,3,4]	Cruess 2018 Sikkema 2011 Sikkema 2014

Frequency of unprotected anal or oral sex in prior 3 months Follow up: 3 months		The mean frequency of unprotected anal or oral sex in prior 3 months, at 3 months (MID = 0.04) in the intervention groups was **0.25 lower** (0.43 to 0.07 lower)		72 (1 study)	⊕⊕⊖⊖ **low**[5,6]	Brown 2019
Frequency of UAI in prior 3 months Follow up: 9 months		The mean frequency of UAI in prior 3 months, at 9 months (MID = 10.75) in the intervention groups was **5.07 higher** (9.89 lower to 20.03 higher)		59 (1 study)	⊕⊖⊖⊖ **very low**[6,7,8]	Sikkema 2014
Frequency of UAI with HIV- or unknown status partners in prior 3 months Follow up: 3 months		The mean frequency of UAI with HIV- or unknown status partners in prior 3 months, at 3 months (MID = 4.05) in the intervention groups was **0.09 lower** (2.01 lower to 1.83 higher)		228 (2 studies)	⊕⊖⊖⊖ **very low**[2,3,7]	Safren 2013 Sikkema 2014
Frequency of UAI with HIV- or unknown status partners in prior 3 months Follow up: 6 months		The mean frequency of UAI with HIV- or unknown status partners in prior 3 months, at 6 months (MID = 3.56) in the intervention groups was **0.06 higher** (1.21 lower to 1.34 higher)		373 (3 studies)	⊕⊖⊖⊖ **very low**[2,3,7]	Cruess 2018 Safren 2013 Sikkema 2014
Frequency of UAI with HIV- or unknown status partners in prior 3 months Follow up: 9 months		The mean frequency of UAI with HIV- or unknown status partners in prior 3 months, at 9 months (MID = 5.28) in the intervention groups was **0.7 higher** (5.48 lower to 6.87 higher)		222 (2 studies)	⊕⊖⊖⊖ **very low**[2,7,9,10]	Safren 2013 Sikkema 2014
Frequency of UAI with HIV- or unknown status partners in prior 3 months Follow up: 12 months		The mean frequency of UAI with HIV- or unknown status partners in prior 3 months, at 12 months (MID = 2.14) in the intervention groups was **0.5 higher** (1.4 lower to 2.4 higher)		172 (1 study)	⊕⊕⊖⊖ **low**[6,8]	Safren 2013
Frequency of UAI with HIV+ partners in prior 6 months Follow up: 6 months		The mean frequency of UAI with HIV+ partners in prior 6 months, at 6 months (MID = 6) in the intervention groups was **0.46 lower** (4.67 lower to 3.75 higher)		140 (1 study)	⊕⊕⊖⊖ **low**[3,6]	Cruess 2018
Condom use at last sex Follow up: 3 months	**447 per 1000**	**676 per 1000** (443 to 1000)	**RR 1.51** (0.99 to 2.29)	75 (1 study)	⊕⊖⊖⊖ **very low**[6,8,11]	Nostlinger 2016
Condom use at last sex Follow up: 6 months	**486 per 1000**	**661 per 1000** (437 to 986)	**RR 1.36** (0.9 to 2.03)	76 (1 study)	⊕⊖⊖⊖ **very low**[6,8,11]	Nostlinger 2016
Serodiscordant CAI with a male partner in prior 3 months Follow up: 3 months	**489 per 1000**	**504 per 1000** (377 to 675)	**RR 1.03** (0.77 to 1.38)	183 (1 study)	⊕⊖⊖⊖ **very low**[12,13,8]	Hart 2021

Serodiscordant CAI with a male partner in prior 3 months Follow up: 6 months	**479 per 1000**	**393 per 1000** (282 to 551)	**RR 0.82** (0.59 to 1.15)	183 (1 study)	⊕⊖⊖⊖ **very low**[12,13,8]	Hart 2021
Serodiscordant CAI with casual partner in prior 3 months Follow up: 3 months	**415 per 1000**	**461 per 1000** (332 to 639)	**RR 1.11** (0.8 to 1.54)	183 (1 study)	⊕⊖⊖⊖ **very low**[12,13,8]	Hart 2021
Serodiscordant CAI with casual partner in prior 3 months Follow up: 6 months	**426 per 1000**	**357 per 1000** (251 to 519)	**RR 0.84** (0.59 to 1.22)	183 (1 study)	⊕⊖⊖⊖ **very low**[12,13,8]	Hart 2021
Condom use self-efficacy Follow up: 3 months		The mean condom use self-efficacy, at 3 months (MID = 1.68) in the intervention groups was **0.07 higher** (0.86 lower to 1 higher)		183 (1 study)	⊕⊖⊖⊖ **very low**[12,13,3]	Hart 2021
Condom use self-efficacy Follow up: 6 months		The mean condom use self-efficacy, at 6 months (MID = 1.50) in the intervention groups was **0.03 higher** (0.84 lower to 0.9 higher)		183 (1 study)	⊕⊖⊖⊖ **very low**[12,13,3]	Hart 2021

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

[1] Downgraded twice for Brown 2019: No information on randomisation or allocation concealment; low intervention attendance (57%) and impact of adherence not included in analyses; trial not registered; Sikkema 2011: Limited information on randomisation and significant baseline differences on key study variables; no information on blinding; 77% retention and no comparison of completers and non-completers; unreliable assessment of STI incidence; and trial not registered; and Sikkema 2014: Limited information on randomisation and blinding of participants or outcome assessors; impact of intervention adherence not assessed; high attrition; trial not registered

[2] US studies

[3] Downgraded once as 95%CI crosses line of no effect

[4] Downgraded twice for Sikkema 2011: Limited information on randomisation and significant baseline differences on key study variables; no information on blinding; 77% retention and no comparison of completers and non-completers; unreliable assessment of STI incidence; and trial not registered; and Sikkema 2014: Limited information on randomisation and blinding of participants or outcome assessors; impact of intervention adherence not assessed; high attrition; trial not registered

[5] Downgraded once for some concerns of bias due to no information on randomisation or allocation concealment; low intervention attendance (57%) and impact of adherence not included in analyses; trial not registered

[6] US study

[7] Downgraded once for some concerns of bias due to limited information on randomisation and blinding of participants or outcome assessors; impact of intervention adherence not assessed; high attrition; trial not registered

[8] Downgraded once as 95%CI crosses line of no effect and 1MID

[9] Downgraded twice as 95%CI crosses line of no effect and 2 MIDs

[10] Downgraded once for high I^2

[11] Downgraded once for some concerns of bias due to 32% loss to follow-up; attrition by group not reported only overall attrition; intervention adherence not assessed; and trial not registered

[12] Downgraded once for some concerns of bias due to limited information on randomisation method, no information on allocation concealment or participant blinding, and trial not registered

[13] Canadian study

1

STI incidence outcomes for IMB / Motivational Interviewing based approaches vs. control

Outcomes	Illustrative comparative risks* (95% CI) Assumed risk Control	Corresponding risk IMB / Motivational interviewing based approaches	Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
Self-reported STI diagnosis or symptoms Follow up: 3 months	**238 per 1000**	**310 per 1000** (121 to 793)	**RR 1.3** (0.51 to 3.33)	50 (1 study)	⊕⊖⊖⊖ **very low**[1,2,3]	Sikkema 2011
Self-reported STI diagnosis or symptoms Follow up: 6 months	**286 per 1000**	**240 per 1000** (94 to 614)	**RR 0.84** (0.33 to 2.15)	50 (1 study)	⊕⊖⊖⊖ **very low**[1,2,3]	Sikkema 2011

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

[1] Downgraded twice for high risk of bias due to limited information on randomisation and significant baseline differences on key study variables; no information on blinding; 77% retention and no comparison of completers and non-completers; unreliable assessment of STI incidence; and trial not registered
[2] US study
[3] Downgraded twice as 95%CI crosses 2 MIDs

STI/HIV knowledge based outcomes for IMB / Motivational Interviewing based approaches vs. control

Outcomes	Illustrative comparative risks* (95% CI) Assumed risk Control	Corresponding risk IMB / Motivational interviewing based approaches	Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
HIV transmission knowledge Follow up: 3 months		The mean HIV transmission knowledge, at 3 months (MID = 0.89) in the intervention groups was **2.1 higher** (1.17 to 3.03 higher)		72 (1 study)	⊕⊕⊖⊖ **low**[1,2]	Brown 2019

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

[1] Downgraded once for some concerns of bias due to no information on randomisation or allocation concealment; low intervention attendance (57%) and impact of adherence not included in analyses; trial not registered
[2] US study

1

1.1.8.7.2 Cognitive and CBT based approaches

Condom use outcomes for Cognitive and CBT based interventions vs. control

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	Cognitive and CBT based interventions				
UAI during last sex with non-primary partner Follow up: 3 months	**439 per 1000**	**431 per 1000** (374 to 492)	**RR 0.98** (0.85 to 1.12)	1061 (1 study)	⊕⊕⊖⊖ **low**[1,2]	Mansergh 2010
UAI during last sex with non-primary partner Follow up: 6 months	**420 per 1000**	**433 per 1000** (374 to 496)	**RR 1.03** (0.89 to 1.18)	1058 (1 study)	⊕⊕⊖⊖ **low**[1,2]	Mansergh 2010
UAI during last sex with a non-primary partner Follow up: 12 months	**380 per 1000**	**399 per 1000** (346 to 464)	**RR 1.05** (0.91 to 1.22)	1079 (1 study)	⊕⊕⊖⊖ **low**[1,2]	Mansergh 2010
UAI during last sex with non-primary partner whose HIV status was unknown or serodiscordant Follow up: 3 months	**210 per 1000**	**191 per 1000** (149 to 242)	**RR 0.91** (0.71 to 1.15)	1061 (1 study)	⊕⊕⊖⊖ **low**[1,3]	Mansergh 2010
UAI during last sex with non-primary partner whose HIV status was unknown or serodiscordant Follow up: 6 months	**180 per 1000**	**169 per 1000** (130 to 220)	**RR 0.94** (0.72 to 1.22)	1058 (1 study)	⊕⊕⊖⊖ **low**[1,3]	Mansergh 2010
UAI during last sex with non-primary partner whose HIV status was unknown or serodiscordant Follow up: 12 months	**199 per 1000**	**181 per 1000** (141 to 231)	**RR 0.91** (0.71 to 1.16)	1079 (1 study)	⊕⊕⊖⊖ **low**[1,3]	Mansergh 2010
Number of episodes of UAI with a HIV serodiscordant or status unknown partner in the past 3 months Follow up: 3 months		The mean number of episodes of UAI with a HIV serodiscordant or status unknown partner in the past 3 months, at 3 months (MID = 1.03) in the intervention groups was **1.3 lower** (2.55 to 0.05 lower)		36 (1 study)	⊕⊕⊖⊖ **low**[1,4]	Mansergh 2010
Number of episodes of UAI with a HIV serodiscordant or status unknown partner in the past 3 months Follow up: 6 months		The mean number of episodes of UAI with a HIV serodiscordant or status unknown partner in the past 3 months, at 6 months (MID = 0.87) in the intervention groups was **1.7 lower** (2.58 to 0.82 lower)		40 (1 study)	⊕⊕⊖⊖ **low**[1,4]	Mansergh 2010

Number of men reporting any episodes of UAI with a non-concordant partner Follow up: 6 months	**285 per 1000**	**305 per 1000** (216 to 427)	**RR 1.07** (0.76 to 1.5)	316 (1 study)	⊕⊖⊖⊖ **very low**[1,3,5]	Schwarcz 2013
Number of men reporting any episodes of UAI with a non-concordant partner Follow up: 12 months	**224 per 1000**	**278 per 1000** (191 to 408)	**RR 1.24** (0.85 to 1.82)	316 (1 study)	⊕⊖⊖⊖ **very low**[1,3,5]	Schwarcz 2013

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio; **OR:** Odds ratio;

[1] US study
[2] Downgraded once as 95%CI crosses line of no effect
[3] Downgraded once as 95%CI crosses line of no effect and one MID
[4] Downgraded once as 95%CI crosses one MID
[5] Downgraded once for some concerns of bias due to intervention adherence not assessed and trial not registered

1
2
3

STI incidence outcomes for Cognitive and CBT based interventions vs. control

Outcomes	Illustrative comparative risks* (95% CI) Assumed risk **Control**	 Corresponding risk **Cognitive and CBT-based intervention**	Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
Incidence of gonorrhoea Follow up: 6 months	**6 per 1000**	**2 per 1000** (0 to 55)	**OR 0.38** (0.02 to 9.47)	304 (1 study)	⊕⊖⊖⊖ **very low**[1,2,3]	Schwarcz 2013
Incidence of gonorrhoea Follow up: 12 months	**32 per 1000**	**20 per 1000** (5 to 82)	**OR 0.63** (0.15 to 2.7)	302 (1 study)	⊕⊖⊖⊖ **very low**[1,2,3]	Schwarcz 2013
Incidence of chlamydia Follow up: 6 months	**43 per 1000**	**50 per 1000** (18 to 138)	**RR 1.16** (0.42 to 3.22)	304 (1 study)	⊕⊖⊖⊖ **very low**[1,2,3]	Schwarcz 2013
Incidence of chlamydia Follow up: 12 months	**58 per 1000**	**21 per 1000** (6 to 74)	**RR 0.36** (0.1 to 1.29)	302 (1 study)	⊕⊖⊖⊖ **very low**[1,2,3]	Schwarcz 2013

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

[1] Downgraded once for some concerns of bias due to intervention adherence not assessed and trial not registered
[2] US study
[3] Downgraded once as 95%CI crosses line of no effect and one MID

Secondary outcomes (so-called chemsex) for Cognitive and CBT based interventions vs. control

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	Cognitive and CBT based interventions				
Drug use soon before or during UAI with a non-primary partner Follow up: 3 months	**240 per 1000**	**259 per 1000** (211 to 319)	**RR 1.08** (0.88 to 1.33)	1061 (1 study)	⊕⊕⊖⊖ **low**[1,2]	Mansergh 2010
Drug use soon before or during UAI with a non-primary partner Follow up: 6 months	**230 per 1000**	**270 per 1000** (219 to 332)	**RR 1.17** (0.95 to 1.44)	1058 (1 study)	⊕⊕⊖⊖ **low**[1,2]	Mansergh 2010
Drug use soon before or during UAI with a non-primary partner Follow up: 12 months	**190 per 1000**	**220 per 1000** (173 to 277)	**RR 1.16** (0.91 to 1.46)	1079 (1 study)	⊕⊕⊖⊖ **low**[1,2]	Mansergh 2010
Drug use soon before or during UAI with a non-primary partner whose HIV status was unknown or serodiscordant Follow up: 3 months	**119 per 1000**	**120 per 1000** (87 to 167)	**RR 1.01** (0.73 to 1.4)	1061 (1 study)	⊕⊖⊖⊖ **very low**[1,3]	Mansergh 2010
Drug use soon before or during UAI with a non-primary partner whose HIV status was unknown or serodiscordant Follow up: 6 months	**89 per 1000**	**100 per 1000** (69 to 145)	**RR 1.12** (0.77 to 1.63)	1058 (1 study)	⊕⊖⊖⊖ **very low**[1,3]	Mansergh 2010
Drug use soon before or during UAI with a non-primary partner whose HIV status was unknown or serodiscordant Follow up: 12 months	**111 per 1000**	**101 per 1000** (71 to 143)	**RR 0.91** (0.64 to 1.29)	1079 (1 study)	⊕⊖⊖⊖ **very low**[1,3]	Mansergh 2010

Number of episodes of UAI with a HIV serodiscordant or status unknown partner, while using meth, in the past 3 months Follow up: 3 months		The mean number of episodes of UAI with a HIV serodiscordant or status unknown partner, while using meth, in the past 3 months, at 3 months (MID = 1.03) in the intervention groups was **0.9 lower** (2.15 lower to 0.35 higher)	36 (1 study)	⊕⊕⊖⊖ **low**[1,2]	Mansergh 2010
Number of episodes of UAI with a HIV serodiscordant or status unknown partner, while using meth, in the past 3 months Follow up: 6 months		The mean number of episodes of UAI with a HIV serodiscordant or status unknown partner, while using meth, in the past 3 months, at 6 months (MID = 0.87) in the intervention groups was **1.5 lower** (2.38 to 0.62 lower)	40 (1 study)	⊕⊕⊖⊖ **low**[1,4]	Mansergh 2010

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio; **OR:** Odds ratio;

[1] US study
[2] Downgraded once as 95%CI crosses line of no effect and one MID
[3] Downgraded twice as 95%CI crosses 2 MIDs
[4] Downgraded once as 95%CI crosses one MID

1.1.8.7.3 Culturally relevant Spanish-language group interventions

Condom use outcomes for Culturally relevant group intervention vs. control

Outcomes	Illustrative comparative risks* (95% CI) Assumed risk Control	Corresponding risk Culturally relevant group intervention	Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
Consistent condom use during past 3 months for MSM who report sex with men or women Follow up: 6 months	**343 per 1000**	**634 per 1000** (469 to 853)	**RR 1.85** (1.37 to 2.49)	217 (1 study)	⊕⊕⊕⊖ **moderate**[1]	Rhodes 2017
Consistent condom use during past 3 months among MSM who report sex with men only Follow up: 6 months	**362 per 1000**	**644 per 1000** (474 to 872)	**RR 1.78** (1.31 to 2.41)	189 (1 study)	⊕⊕⊕⊖ **moderate**[1]	Rhodes 2017

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

[1] US study

1.1.8.8 Summary of Findings for Young MSM

1.1.8.8.1 Group based HIV prevention intervention

Condom use outcomes for Group-based HIV prevention intervention vs. control

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk **Control**	Corresponding risk **Group-based HIV prevention intervention**				
Any UAI in prior 6 weeks Follow up: 6 weeks	**212 per 1000**	**214 per 1000** (89 to 515)	**RR 1.01** (0.42 to 2.43)	75 (1 study)	⨁⊖⊖⊖ **very low**[1,2,3,4]	Hidalgo 2015
Any UAI in prior 6 weeks Follow up: 12 weeks	**258 per 1000**	**255 per 1000** (116 to 560)	**RR 0.99** (0.45 to 2.17)	74 (1 study)	⨁⊖⊖⊖ **very low**[1,2,3,4]	Hidalgo 2015
Number of unprotected anal sex acts with male partners in prior 6 weeks (analyses restricted to those reporting any anal sex at baseline) Follow up: 6 weeks		The mean number of unprotected anal sex acts with male partners in prior 6 weeks, at 6 weeks (analyses restricted to those reporting any anal sex at baseline) (MID = 1.45) in the intervention groups was **0.39 lower** (1.5 lower to 0.72 higher)		67 (1 study)	⨁⊖⊖⊖ **very low**[1,2,3,5]	Hidalgo 2015
Number of unprotected anal sex acts with male partners in prior 6 weeks (analyses restricted to those reporting any anal sex at baseline) Follow up: 12 weeks		The mean number of unprotected anal sex acts with male partners in prior 6 weeks, at 12 weeks (analyses restricted to those reporting any anal sex at baseline) (MID = 1.15) in the intervention groups was **0.08 lower** (1.33 lower to 1.17 higher)		67 (1 study)	⨁⊖⊖⊖ **very low**[1,2,3,4]	Hidalgo 2015
Condom use errors Follow up: 6 weeks		The mean condom use errors, at 6 weeks (MID = 1.15) in the intervention groups was **0.03 lower** (0.24 lower to 0.18 higher)		75 (1 study)	⨁⊖⊖⊖ **very low**[1,2,3,4]	Hidalgo 2015
Condom use errors Follow up: 12 weeks		The mean condom use errors, at 12 weeks (MID = 0.24) in the intervention groups was **0.18 lower** (0.41 lower to 0.05 higher)		74 (1 study)	⨁⊖⊖⊖ **very low**[1,2,3,5]	Hidalgo 2015

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

[1] Downgraded once for some concerns of bias due to no information on participant blinding; ITT analyses not used; low intervention adherence; relatively high attrition
[2] Single study
[3] US study

[4] Downgraded twice as 95%CIs cross 2 MIDs
[5] Downgraded once as 95%CI crosses line of no effect and 1 MID

Secondary outcomes for Group-based HIV prevention intervention vs. control

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk **Control**	Corresponding risk **Group-based HIV prevention intervention**				
Any UAI under the influence of alcohol or drugs in prior 6 weeks Follow up: 6 weeks	**121 per 1000**	**47 per 1000** (10 to 245)	**RR 0.39** (0.08 to 2.02)	75 (1 study)	⨁⊖⊖⊖ **very low**[1,2,3,4]	Hidalgo 2015
Any UAI under the influence of alcohol or drugs in prior 6 weeks Follow up: 12 weeks	**194 per 1000**	**46 per 1000** (10 to 215)	**RR 0.24** (0.05 to 1.11)	74 (1 study)	⨁⊖⊖⊖ **very low**[1,2,3,5]	Hidalgo 2015
Self-efficacy for safer sex Follow up: 6 weeks		The mean self-efficacy for safer sex, at 6 weeks (MID = 2.35) in the intervention groups was **1.1 higher** (0.82 lower to 3.02 higher)		75 (1 study)	⨁⊖⊖⊖ **very low**[1,2,3,5]	Hidalgo 2015
Health protective communication Follow up: 12 weeks		The mean health protective communication, at 6 weeks (MID = 2.15) in the intervention groups was **2.1 higher** (0.01 lower to 4.21 higher)		75 (1 study)	⨁⊖⊖⊖ **very low**[1,2,3,5]	Hidalgo 2015
Health protective communication Follow up: 12 weeks		The mean health protective communication, at 12 weeks (MID = 2.35) in the intervention groups was **1.5 lower** (3.92 lower to 0.92 higher)		74 (1 study)	⨁⊖⊖⊖ **very low**[1,2,3,5]	Hidalgo 2015

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

[1] Downgraded once for some concerns of bias due to no information on participant blinding; ITT analyses not used; low intervention adherence; relatively high attrition
[2] Single study
[3] US study
[4] Downgraded twice as 95%CIs cross 2 MIDs
[5] Downgraded once as 95%CI crosses line of no effect and 1 MID

1.1.8.8.2 Motivational Interviewing intervention

Condom use outcomes for Motivational Interviewing intervention vs. control

Outcomes	Illustrative comparative risks* (95% CI) Assumed risk Control	Corresponding risk Motivational Interviewing intervention	Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
Any UAI with a casual partner during prior 30 days Follow up: 3 months	**565 per 1000**	**542 per 1000** (395 to 745)	**RR 0.96** (0.7 to 1.32)	123 (1 study)	⊕⊖⊖⊖ **very low**[1,2,3,4]	Parsons 2014
Any UAI with a casual partner during prior 30 days Follow up: 6 months	**527 per 1000**	**464 per 1000** (316 to 680)	**RR 0.88** (0.6 to 1.29)	109 (1 study)	⊕⊖⊖⊖ **very low**[1,2,3,4]	Parsons 2014
Any UAI with a casual partner during prior 30 days Follow up: 9 months	**614 per 1000**	**454 per 1000** (319 to 651)	**RR 0.74** (0.52 to 1.06)	112 (1 study)	⊕⊖⊖⊖ **very low**[1,2,3,5]	Parsons 2014
Any UAI with a casual partner during prior 30 days Follow up: 12 months	**407 per 1000**	**306 per 1000** (183 to 505)	**RR 0.75** (0.45 to 1.24)	113 (1 study)	⊕⊖⊖⊖ **very low**[1,2,3,5]	Parsons 2014

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

[1] Downgraded once for some concerns of bias due to no information on participant blinding and ITT not used, but deviations from intended intervention unlikely and intervention adherence good. Trial not registered
[2] Single study
[3] US study; high recreational drug use
[4] Downgraded twice as 95%CI crosses 2 MIDs
[5] Downgraded once as 95%CI crosses line of no effect and 1 MID

Secondary outcomes for Motivational Interviewing intervention vs. control

Outcomes	Illustrative comparative risks* (95% CI) Assumed risk Control	Corresponding risk Motivational Interviewing intervention	Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
Any UAI with a casual partner while under the influence of drugs or alcohol during prior 30 days Follow up: 3 months	**677 per 1000**	**576 per 1000** (434 to 759)	**RR 0.85** (0.64 to 1.12)	123 (1 study)	⊕⊖⊖⊖ **very low**[1,2,3,4]	Parsons 2014
Any UAI with a casual partner while under the influence of drugs or alcohol during prior 30 days Follow up: 6 months	**655 per 1000**	**576 per 1000** (425 to 772)	**RR 0.88** (0.65 to 1.18)	109 (1 study)	⊕⊖⊖⊖ **very low**[1,2,3,4]	Parsons 2014

Any UAI with a casual partner while under the influence of drugs or alcohol during prior 30 days Follow up: 9 months	**754 per 1000**	**604 per 1000** (460 to 777)	**RR 0.8** (0.61 to 1.03)	112 (1 study)	⊕⊖⊖⊖ **very low**[1,2,3,4]	Parsons 2014
Any UAI with a casual partner while under the influence of drugs or alcohol during prior 30 days Follow up: 12 months	**593 per 1000**	**474 per 1000** (338 to 670)	**RR 0.8** (0.57 to 1.13)	113 (1 study)	⊕⊖⊖⊖ **very low**[1,2,3,4]	Parsons 2014

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

[1] Downgraded once for some concerns of bias due to no information on participant blinding and ITT not used, but deviations from intended intervention unlikely and intervention adherence good. Trial not registered
[2] Single study
[3] US study; high recreational drug use
[4] Downgraded once as 95%CI crosses line of no effect and 1 MID

1.1.8.9 Summary of Findings for men from a Black African or Caribbean family background who have sex with men

1.1.8.9.1 IMB / Motivational Interviewing based interventions

Condom use outcomes for IMB / Motivational interviewing-based interventions vs. control

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	IMB / Motivational interviewing based interventions				
Any unprotected anal or vaginal intercourse in past 3 months, at 3 months	**769 per 1000**	**646 per 1000** (553 to 761)	**RR 0.84** (0.72 to 0.99)	263 (2 studies)	⊕⊖⊖⊖ **very low**[1,2,3,4]	Fernandez 2016 Tobin 2013
Any UAI with males in past 3 months, at 3 months	**679 per 1000**	**543 per 1000** (448 to 666)	**RR 0.8** (0.66 to 0.98)	262 (2 studies)	⊕⊖⊖⊖ **very low**[1,2,3,4]	Fernandez 2016 Tobin 2013
Any unprotected anal or vaginal intercourse with females in past 3 months, at 3 months	**402 per 1000**	**358 per 1000** (241 to 527)	**RR 0.89** (0.6 to 1.31)	166 (1 study)	⊕⊖⊖⊖ **very low**[2,3,5,6]	Fernandez 2016
Any serodiscordant anal or vaginal intercourse in past 3 months, at 3 months	**488 per 1000**	**405 per 1000** (288 to 571)	**RR 0.83** (0.59 to 1.17)	166 (1 study)	⊕⊖⊖⊖ **very low**[2,3,5,7]	Fernandez 2016
Any serodiscordant anal intercourse with males in past 3 months, at 3 months	**341 per 1000**	**201 per 1000** (120 to 341)	**RR 0.59** (0.35 to 1)	166 (1 study)	⊕⊖⊖⊖ **very low**[2,3,4,5]	Fernandez 2016
Any serodiscordant anal or vaginal intercourse with females in past 3 months, at 3 months	**329 per 1000**	**250 per 1000** (155 to 405)	**RR 0.76** (0.47 to 1.23)	166 (1 study)	⊕⊖⊖⊖ **very low**[2,3,5,7]	Fernandez 2016

Consistent condom use with HIV+ partners in past 3 months, at 3 months	**698 per 1000**	**831 per 1000** (670 to 1000)	**RR 1.19** (0.96 to 1.48)	101 (1 study)	⨁⊖⊖⊖ **very low**[2,3,7,8]	Tobin 2013
Consistent condom use with HIV- or unknown status partners in past 3 months, at 3 months	**426 per 1000**	**524 per 1000** (345 to 796)	**RR 1.23** (0.81 to 1.87)	98 (1 study)	⨁⊖⊖⊖ **very low**[2,3,7,8]	Tobin 2013

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

[1] Downgraded once for some concerns of bias for Fernandez 2016 due to no information on participant blinding; approx 25% of participants did not attend any intervention or control sessions; impact of adherence not assessed; approx 80% retention; comparisons of completers vs non-completers not reported; trial not registered; and some concerns of bias for Tobin 2013 dues to no information on participant blinding and baseline differences between groups on HIV status and health insurance; and trial not registered
[2] US study
[3] High history of homelessness, incarceration, and recent drug use
[4] Downgraded once as 95%CI crosses 1MID
[5] Downgraded once for some concerns of bias due to no information on participant blinding; approx 25% of participants did not attend any intervention or control sessions; impact of adherence not assessed; approx 80% retention; comparisons of completers vs non-completers not reported; trial not registered
[6] Downgraded twice as 95%CI crosses 2 MIDs
[7] Downgraded once as 95%CI crosses line of no effect and 1 MID
[8] Downgraded once for some concerns of bias due to no information on participant blinding and baseline differences between groups on HIV status and health insurance; and trial not registered

Secondary outcomes for IMB / Motivational Interviewing based interventions vs. control

Outcomes	**Illustrative comparative risks* (95% CI)**		**Relative effect (95% CI)**	**No of Participants (studies)**	**Quality of the evidence (GRADE)**	**Comments**
	Assumed risk **Control**	Corresponding risk **IMB / Motivational interviewing intervention**				
Drug use during last sex, at 3 months	**324 per 1000**	**165 per 1000** (87 to 305)	**RR 0.51** (0.27 to 0.94)	144 (1 study)	⨁⊖⊖⊖ **very low**[1,2,3]	Tobin 2013

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

[1] Downgraded once for some concerns of bias due to no information on participant blinding; approx 25% of participants did not attend any intervention or control sessions; impact of adherence not assessed; approx 80% retention; comparisons of completers vs non-completers not reported; trial not registered
[2] US study; high history of homelessness, incarceration, and recent drug use
[3] Downgraded once as 95%CI crosses 1 MID

1.1.8.9.2 Sexual risk decision making intervention

Condom use outcomes for Sexual risk decision making intervention vs. control

Outcomes	**Illustrative comparative risks* (95% CI)**					**Comments**

	Assumed risk **Control**	Corresponding risk **Sexual risk decision making intervention**	**Relative effect (95% CI)**	**No of Participants (studies)**	**Quality of the evidence (GRADE)**	
Proportion of condom-protected anal sex acts in prior 3 months Follow up: 3 months		The mean proportion of condom-protected anal sex acts in prior 3 months, at 3 months (MID = 1.01) in the intervention groups was **3.92 higher** (3.53 to 4.31 higher)		519 (1 study)	⊕⊕⊕⊖ **moderate**[1]	Eaton 2018
Proportion of condom-protected anal sex acts in prior 3 months Follow up: 6 months		The mean proportion of condom-protected anal sex acts in prior 3 months, at 6 months (MID = 1.23) in the intervention groups was **6.94 higher** (6.55 to 7.33 higher)		513 (1 study)	⊕⊕⊕⊖ **moderate**[1]	Eaton 2018
Proportion of condom-protected anal sex acts in prior 3 months Follow up: 12 months		The mean proportion of condom-protected anal sex acts in prior 3 months, at 12 months (MID = 1.22) in the intervention groups was **4.25 higher** (3.83 to 4.67 higher)		498 (1 study)	⊕⊕⊕⊖ **moderate**[1]	Eaton 2018
Number of UAI acts in prior 3 months Follow up: 3 months		The mean number of UAI acts in prior 3 months, at 3 months (MID = 0.33) in the intervention groups was **0.07 higher** (0.04 lower to 0.18 higher)		519 (1 study)	⊕⊕⊖⊖ **low**[1,2]	Eaton 2018
Number of UAI acts in prior 3 months Follow up: 6 months		The mean number of UAI acts in prior 3 months, at 6 months (MID = 0.41) in the intervention groups was **0.95 lower** (1.07 to 0.83 lower)		513 (1 study)	⊕⊕⊕⊖ **moderate**[1]	Eaton 2018
Number of UAI acts in prior 3 months Follow up: 12 months		The mean number of UAI acts in prior 3 months, at 12 months (MID = 0.45) in the intervention groups was **1.21 lower** (1.34 to 1.08 lower)		498 (1 study)	⊕⊕⊕⊖ **moderate**[1]	Eaton 2018
Number of insertive UAI acts in prior 3 months Follow up: 3 months		The mean number of insertive UAI acts in prior 3 months, at 3 months (MID = 0.2) in the intervention groups was **0.13 higher** (0.06 to 0.2 higher)		519 (1 study)	⊕⊕⊖⊖ **low**[1,3]	Eaton 2018
Number of insertive UAI acts in prior 3 months Follow up: 6 months		The mean number of insertive UAI acts in prior 3 months, at 6 months (MID = 0.33) in the intervention groups was **0.96 lower** (1.05 to 0.87 lower)		513 (1 study)	⊕⊕⊕⊖ **moderate**[1]	Eaton 2018
Number of insertive UAI acts in prior 3 months Follow up: 12 months		The mean number of insertive UAI acts in prior 3 months, at 12 months (MID = 0.33) in the intervention groups was		498 (1 study)	⊕⊕⊕⊖ **moderate**[1]	Eaton 2018

		1.2 lower (1.29 to 1.11 lower)			
Number of receptive UAI acts in prior 3 months Follow up: 3 months		The mean number of receptive UAI acts in prior 3 months, at 3 months (MID = 0.16) in the intervention groups was **0.2 higher** (0.14 to 0.26 higher)	519 (1 study)	⨁⨁⨀⨀ **low**[1,3]	Eaton 2018
Number of receptive UAI acts in prior 3 months Follow up: 6 months		The mean number of receptive UAI acts in prior 3 months, at 6 months (MID = 0.17) in the intervention groups was **0.08 higher** (0.02 to 0.14 higher)	513 (1 study)	⨁⨁⨁⨀ **moderate**[1]	Eaton 2018
Number of receptive UAI acts in prior 3 months Follow up: 12 months		The mean number of receptive UAI acts in prior 3 months, at 12 months (MID = 0.16) in the intervention groups was **0.01 lower** (0.07 lower to 0.05 higher)	498 (1 study)	⨁⨁⨀⨀ **low**[1,2]	Eaton 2018

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

[1] Downgraded once for indirectness as 50.1% of the sample reported depressive symptoms above the clinical threshold; US study
[2] Downgraded once as 95%CI crosses line of no effect
[3] Downgraded once as 95%CI crosses 1 MID

STI incidence outcomes for Sexual decision making intervention vs. control

Outcomes	Illustrative comparative risks* (95% CI) Assumed risk **Control**	 Corresponding risk **Sexual risk decision making intervention**	Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
Self-reported STI diagnosis in prior 3 months Follow up: 3 months	**218 per 1000**	**157 per 1000** (109 to 227)	**RR 0.72** (0.5 to 1.04)	519 (1 study)	⨁⨁⨀⨀ **low**[1,2]	Eaton 2018
Self-reported STI diagnosis in prior 3 months Follow up: 6 months	**194 per 1000**	**176 per 1000** (122 to 254)	**RR 0.91** (0.63 to 1.31)	513 (1 study)	⨁⨀⨀⨀ **very low**[1,3]	Eaton 2018
Self-reported STI diagnosis in prior 3 months Follow up: 12 months	**171 per 1000**	**130 per 1000** (85 to 198)	**RR 0.76** (0.5 to 1.16)	498 (1 study)	⨁⨁⨀⨀ **low**[1,2]	Eaton 2018

Lab diagnosed gonorrhoea or chlamydia; urine sample Follow up: 3 months	**48 per 1000**	**15 per 1000** (5 to 46)	**RR 0.31** (0.1 to 0.96)	519 (1 study)	⊕⊕⊖⊖ **low**[1,4]	Eaton 2018
Lab diagnosed gonorrhoea or chlamydia; urine sample Follow up: 6 months	**23 per 1000**	**20 per 1000** (6 to 63)	**RR 0.84** (0.26 to 2.73)	513 (1 study)	⊕⊖⊖⊖ **very low**[1,3]	Eaton 2018
Lab diagnosed gonorrhoea or chlamydia; urine sample Follow up: 12 months	**36 per 1000**	**24 per 1000** (9 to 67)	**RR 0.68** (0.25 to 1.89)	498 (1 study)	⊕⊖⊖⊖ **very low**[1,3]	Eaton 2018
Lab diagnosed gonorrhoea or chlamydia; rectal swab Follow up: 3 months	**60 per 1000**	**98 per 1000** (53 to 180)	**RR 1.64** (0.89 to 3.02)	519 (1 study)	⊕⊕⊖⊖ **low**[1,2]	Eaton 2018
Lab diagnosed gonorrhoea or chlamydia; rectal swab Follow up: 6 months	**47 per 1000**	**63 per 1000** (30 to 130)	**RR 1.35** (0.65 to 2.79)	513 (1 study)	⊕⊖⊖⊖ **very low**[1,3]	Eaton 2018
Lab diagnosed gonorrhoea or chlamydia; rectal swab Follow up: 12 months	**67 per 1000**	**77 per 1000** (41 to 145)	**RR 1.14** (0.61 to 2.15)	498 (1 study)	⊕⊖⊖⊖ **very low**[1,3]	Eaton 2018

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

[1] Downgraded once for indirectness as 50.1% of the sample reported depressive symptoms above the clinical threshold; US study
[2] Downgraded once as 95%CI crosses line of no effect and 1 MID
[3] Downgraded twice as 95%CI crosses 2 MIDs
[4] Downgraded once as 95%CI crosses 1 MID

1.1.8.9.3 Condom-focused intervention

Condom use outcomes for Condom-focused intervention vs. control

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				

	Control	Condom-focused intervention				
Consistent condom use for every episode of vaginal or anal sex in prior 3 months Follow up: 6 months	**653 per 1000**	**633 per 1000** (542 to 731)	**RR 0.97** (0.83 to 1.12)	393 (1 study)	⊕⊖⊖⊖ **very low**[1,2,3]	Jemmott 2015
Consistent condom use for every episode of vaginal or anal sex in prior 3 months Follow up: 12 months	**589 per 1000**	**637 per 1000** (542 to 749)	**RR 1.08** (0.92 to 1.27)	384 (1 study)	⊕⊖⊖⊖ **very low**[1,2,4]	Jemmott 2015
Any unprotected vaginal or anal intercourse in prior 3 months Follow up: 6 months	**353 per 1000**	**367 per 1000** (282 to 476)	**RR 1.04** (0.8 to 1.35)	389 (1 study)	⊕⊖⊖⊖ **very low**[1,2,4]	Jemmott 2015
Any unprotected vaginal or anal intercourse in prior 3 months Follow up: 12 months	**404 per 1000**	**356 per 1000** (275 to 461)	**RR 0.88** (0.68 to 1.14)	381 (1 study)	⊕⊖⊖⊖ **very low**[1,2,4]	Jemmott 2015
Proportion of condom-protected sex acts in prior 90 days Follow up: 6 months		The mean proportion of condom-protected sex acts in prior 90 days, at 6 months (MID = 0.19) in the intervention groups was **0 higher** (0.07 lower to 0.07 higher)		393 (1 study)	⊕⊖⊖⊖ **very low**[1,2,3]	Jemmott 2015
Proportion of condom-protected sex acts in prior 90 days Follow up: 12 months		The mean proportion of condom-protected sex acts in prior 90 days, at 12 months (0.2) in the intervention groups was **0.05 higher** (0.03 lower to 0.13 higher)		384 (1 study)	⊕⊖⊖⊖ **very low**[1,2,3]	Jemmott 2015

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

[1] Downgraded once for some concerns of bias due to trial not registered
[2] US study, and high unemployment, history of incarceration, high alcohol and/or drug dependence, high history of intimate partner violence, and high history of childhood sexual abuse
[3] Downgraded once as 95%CI crosses line of no effect
[4] Downgraded once as 95%CI crosses line of no effect and 1MID

1

STI/HIV knowledge-based outcomes for Condom-focused intervention vs. control

Outcomes	Illustrative comparative risks* (95% CI) Assumed risk Corresponding risk Control Condom-focused intervention	Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments

HIV risk reduction knowledge Follow up: 6 months		The mean HIV risk reduction knowledge, at 6 months (MID = 1.35) in the intervention groups was **0.39 higher** (0.07 lower to 0.85 higher)	505 (1 study)	⊕⊖⊖⊖ **very low**[1,2,3]	Jemmott 2015
HIV risk reduction knowledge Follow up: 12 months		The mean HIV risk reduction knowledge, at 12 months (MID = 1.48) in the intervention groups was **0.43 higher** (0.08 lower to 0.94 higher)	495 (1 study)	⊕⊖⊖⊖ **very low**[1,2,3]	Jemmott 2015
Condom use knowledge Follow up: 6 months		The mean condom use knowledge, at 6 months (MID = 0.48) in the intervention groups was **0.08 higher** (0.07 lower to 0.23 higher)	505 (1 study)	⊕⊖⊖⊖ **very low**[1,2,3]	Jemmott 2015
Condom use knowledge Follow up: 12 months		The mean condom use knowledge, at 12 months (MID = 0.55) in the intervention groups was **0.09 higher** (0.09 lower to 0.27 higher)	495 (1 study)	⊕⊖⊖⊖ **very low**[1,2,3]	Jemmott 2015

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

[1] Downgraded once for some concerns of bias due to trial not registered
[2] US study, and high unemployment, history of incarceration, high alcohol and/or drug dependence, high history of intimate partner violence, and high history of childhood sexual abuse
[3] Downgraded once as 95%CI crosses line of no effect

1.1.8.9.4 Coping-focused interventions addressing sociocultural issues

Condom use outcomes for Coping-focused interventions addressing sociocultural issues vs. control

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk **Control**	Corresponding risk **Coping-focused interventions addressing sociocultural issues**				
Number of UAI acts with males in prior 3 months Follow up: 6 months		The mean number of UAI acts with males in prior 3 months, at 6 months (MID = 4.64) in the intervention groups was **0.26 lower** (2.22 lower to 1.7 higher)		291 (1 study)	⊕⊖⊖⊖ **very low**[1,2,3]	Harawa 2013
Number of unprotected vaginal or anal intercourse acts with females in prior 3 months Follow up: 6 months		The mean number of unprotected vaginal or anal intercourse acts with females in prior 3 months, at 6 months (MID = 8.23) in the intervention groups was **1.71 lower** (4.51 lower to 1.09 higher)		291 (1 study)	⊕⊖⊖⊖ **very low**[1,2,3]	Harawa 2013

Number of unprotected intercourse acts with males or females in prior 3 months Follow up: 6 months		The mean number of unprotected intercourse acts with males or females in prior 3 months, at 6 months (MID = 12.4) in the intervention groups was **3.01 lower** (7.32 lower to 1.3 higher)		291 (1 study)	⊕⊖⊖⊖ **very low**[1,2,3]	Harawa 2013
Number of participants reporting no change / increase in number of episodes of UAI with male partners in prior 3 months Follow up: 3 months	**531 per 1000**	**308 per 1000** (202 to 467)	**RR 0.58** (0.38 to 0.88)	143 (1 study)	⊕⊖⊖⊖ **very low**[4,5,6]	Lauby 2018
Number of participants reporting a small to moderate decrease in number of episodes of UAI with male partners in prior 3 months Follow up: 3 months	**358 per 1000**	**483 per 1000** (329 to 712)	**RR 1.35** (0.92 to 1.99)	143 (1 study)	⊕⊖⊖⊖ **very low**[4,5,7]	Lauby 2018
Number of participants reporting a large decrease in number of episodes of UAI with male partners in prior 3 months Follow up: 3 months	**111 per 1000**	**210 per 1000** (96 to 459)	**RR 1.89** (0.86 to 4.13)	143 (1 study)	⊕⊖⊖⊖ **very low**[4,5,7]	Lauby 2018
Number of participants reporting no change / increase in number of episodes of UAI with female partners in prior 3 months Follow up: 3 months	**444 per 1000**	**418 per 1000** (284 to 613)	**RR 0.94** (0.64 to 1.38)	143 (1 study)	⊕⊖⊖⊖ **very low**[4,5,8]	Lauby 2018
Number of participants reporting a small to moderate decrease in number of episodes of UAI with female partners in prior 3 months Follow up: 3 months	**309 per 1000**	**370 per 1000** (235 to 586)	**RR 1.2** (0.76 to 1.9)	143 (1 study)	⊕⊖⊖⊖ **very low**[4,5,8]	Lauby 2018
Number of participants reporting a large decrease in number of episodes of UAI with female partners in prior 3 months Follow up: 3 months	**247 per 1000**	**210 per 1000** (114 to 388)	**RR 0.85** (0.46 to 1.57)	143 (1 study)	⊕⊖⊖⊖ **very low**[4,5,8]	Lauby 2018
Unprotected insertive anal sex in prior 3 months Follow up: 3 months		The mean unprotected insertive anal sex in prior 3 months, at 3 months (MID = 3.6) in the intervention groups was **0.26 higher** (3.5 lower to 4.02 higher)		88 (1 study)	⊕⊖⊖⊖ **very low**[7,9,10]	Williams 2013
Unprotected insertive anal sex in prior 3 months Follow up: 6 months		The mean unprotected insertive anal sex in prior 3 months, at 6 months (MID = 9.82) in the intervention groups was **0.44 lower** (7.45 lower to 6.57 higher)		88 (1 study)	⊕⊖⊖⊖ **very low**[3,9,10]	Williams 2013

Unprotected receptive anal sex in prior 3 months Follow up: 3 months		The mean unprotected receptive anal sex in prior 3 months, at 3 months (MID = 3.45) in the intervention groups was **0.14 lower** (2.83 lower to 2.55 higher)	88 (1 study)	⊕⊖⊖⊖ **very low**[3,9,10]	Williams 2013
Any unprotected receptive anal sex in prior 3 months Follow up: 6 months		The mean any unprotected receptive anal sex in prior 3 months, at 6 months (MID = 6.3) in the intervention groups was **0.2 lower** (4.34 lower to 3.94 higher)	88 (1 study)	⊕⊖⊖⊖ **very low**[3,9]	Williams 2013
Any unprotected vaginal sex in prior 3 months Follow up: 3 months		The mean any unprotected vaginal sex in prior 3 months, at 3 months (MID = 1.49) in the intervention groups was **0.09 higher** (1.57 lower to 1.75 higher)	88 (1 study)	⊕⊖⊖⊖ **very low**[8,9,10]	Williams 2013
Any unprotected vaginal sex in prior 3 months Follow up: 6 months		The mean any unprotected vaginal sex in prior 3 months, at 6 months (MID = 0.53) in the intervention groups was **0.03 higher** (0.66 lower to 0.72 higher)	88 (1 study)	⊕⊖⊖⊖ **very low**[8,9,10]	Williams 2013

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

[1] Downgraded once for some concerns of bias due to baseline differences between groups on key variables; impact of adherence not assessed; high attrition and no comparison of completers vs non completers
[2] US study and high history of incarceration, plus a relatively high number were currently in substance abuse treatment
[3] Downgraded once as 95%CI crosses line of no effect
[4] Downgraded once for some concerns of bias due to baseline differences between groups on HIV status; session adherence was moderate and impact of adherence not assessed; some concerns over conversion of condom use outcome into categorial variable; trial not registered
[5] US study, and high history of incarceration, homelessness and recent drug use
[6] Downgraded once as 95%CI crosses 1 MID
[7] Downgraded once as 95%CI crosses line of no effect and 1MID
[8] Downgraded twice as 95%CI crosses 2MIDs
[9] Downgraded once for some concerns of bias due to no information on randomisation procedures or blinding; intervention adherence not assessed; moderate attrition but no differential attrition; trial not registered
[10] US study; high unemployment; and high history of incarceration

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Secondary outcomes for Coping-focused interventions addressing sociocultural issues vs. control

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk **Control**	Corresponding risk **Coping focused interventions intervention**				
Any risky drug use with sex in prior 3 months Follow up: 6 months	**113 per 1000**	**148 per 1000** (81 to 269)	**RR 1.31** (0.72 to 2.39)	291 (1 study)	⊕⊖⊖⊖ **very low**[1,2,8]	Harawa 2013

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

[1] Downgraded once for some concerns of bias due to no information on participant blinding; approx 25% of participants did not attend any intervention or control sessions; impact of adherence not assessed; approx 80% retention; comparisons of completers vs non-completers not reported; trial not registered
[2] US study; high history of homelessness, incarceration, and recent drug use
[3] Downgraded once as 95%CI crosses 1 MID

1.1.8.10 Summary of Findings for Young men from a Black African or Caribbean family background who have sex with men

Condom focused intervention (Focus on the Future) vs. control

Outcomes	Illustrative comparative risks* (95% CI) Assumed risk Standard care	Corresponding risk Intervention (Focus on the Future)	Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
Consistent condom use for anal sex with all partners in prior 3 months Follow up: 12 months	**474 per 1000**	**517 per 1000** (422 to 631)	**RR 1.09** (0.89 to 1.33)	394 (1 study)	⊕⊖⊖⊖ **very low**[1,2,3]	Crosby 2018a
Consistent condom use for anal sex with 'side' (non-primary) partners in prior 3 months Follow up: 12 months	**356 per 1000**	**469 per 1000** (288 to 768)	**RR 1.32** (0.81 to 2.16)	96 (1 study)	⊕⊖⊖⊖ **very low**[1,2,3]	Crosby 2018a
Any condomless insertive anal sex in prior 3 months (analyses restricted to HIV- participants) Follow up: 3 months	**206 per 1000**	**111 per 1000** (62 to 200)	**RR 0.54** (0.3 to 0.97)	265 (1 study)	⊕⊖⊖⊖ **very low**[1,2,4]	Crosby 2019
Any condomless receptive anal sex in prior 3 months (analyses restricted to HIV- participants) Follow up: 3 months	**216 per 1000**	**119 per 1000** (69 to 208)	**RR 0.55** (0.32 to 0.96)	276 (1 study)	⊕⊖⊖⊖ **very low**[1,2,4]	Crosby 2019
Any condomless anal sex in prior 3 months (analyses restricted to HIV- participants) Follow up: 3 months	**311 per 1000**	**184 per 1000** (118 to 280)	**RR 0.59** (0.38 to 0.9)	277 (1 study)	⊕⊖⊖⊖ **very low**[1,2,4]	Crosby 2019

Any condomless oral sex in prior 3 months (analyses restricted to HIV-participants) Follow up: 3 months	**632 per 1000**	**461 per 1000** (341 to 619)	**RR 0.73** (0.54 to 0.98)	148 (1 study)	⨁⊖⊖⊖ **very low**[1,2,4]	Crosby 2019

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

[1] Some concerns of bias due to baseline differences between groups; no information on participant blinding; high attrition (68% retention) but no differences between those retained and those not retained; unplanned analyses using stratification of groups by HIV status and multiple publications of the same trial.
[2] US study
[3] Downgraded once as 95%CI crosses line of no effect and 1 MID
[4] Downgraded once as 95%CI crosses 1 MID

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1.1.9 Narrative findings

Four papers for MSM and 1 paper for young men from a Black African or Caribbean family background who have sex with men reported results that could not be pooled in meta-analyses or evaluated using GRADE because they did not report data in a useable format. Findings from these studies are reported narratively along with evidence statements reported in Table 5.

1.1.9.1 MSM

1.1.9.1.1 IMB / Motivational interviewing approaches

McKirnan 2010

Condom use outcomes at 6 and 12 months

"For transmission risk behaviour (UAI with HIV- or unknown status partners) there was a significant interaction of intervention group by study wave across the 12 months of follow-up, χ^2 (2, N = 249) = 6.59, p = .037. The rate of transmission risk among intervention participants went from 33.6% at baseline to about 20% at both 6 and 12 months, whereas transmission risk remained almost constant at approximately 23% among comparison participants. Intervention effects on transmission risk were reflected in simple contrasts. The intervention group showed a significantly greater decline in risk than did controls from baseline to 6 months and from baseline to the mean of 6 and 12 months, χ^2 (1, N = 249) = 6.57, p = .01, and χ^2 (1, N = 249) = 5.47, p = .019, respectively, although the shift from baseline to 12 months was not statistically significant, χ^2 (1, N = 249) = 2.55, p = .11. In sum, the intervention group showed a significantly greater linear decrease in transmission risk over waves, with the effect remaining significant over 6 and 12 months."

Secondary outcomes – sexual self-efficacy at 6 and 12 months

"Sexual self-efficacy increased over wave, Wald χ^2 (2, N = 249) = 24.4, p < .001, and showed a greater increase in the intervention than in the comparison group from baseline to 12 months and from baseline to the mean of 6 and 12 months, Wald χ^2 s(2, N = 249) > 4.5, ps < .05."

1.1.9.1.2 Cognitive and CBT based approaches

Schwarcz 2013

Condom use outcomes at 6 and 12 months

"Declines in the mean number of UAI episodes occurred in both groups at 6 months but increased in the control group at 12 months to 3.36 while the mean number of UAI episodes declined further in the PCC group to 1.60. The incidence risk ratios were 0.76 (95% CI 0.25-2.19) at 6 months and 0.48 (95% CI 0.12-1.84) at 12 months."

1.1.9.1.3 Culturally relevant Spanish language small group interventions

O'Donnell 2014

Condom use outcomes at 3 months

"From baseline to follow-up, there is a sharper drop in mean number of UAI acts in the intervention group, with a decrease of 59% over the two time points (from an average of 8.4 unprotected acts to 3.8), compared with a 39 % change among controls (6.2–3.8). Repeated measures ANOVA for number of UAI acts was significant: F (1, 320) = 4.10, p < .05."

"For condom use at last sex, men exposed to the intervention were more likely to report this protective behaviour: (AOR = 1.69; 95 % CI 1.02–2.81, p<.05)."

Rhodes 2017

Condom use outcomes at 6 months

"At 6-month follow-up, HOLA en Grupos participants reported significant increases in condom use skills: Intervention adjusted mean (95%CI) = 17.1 (16.7, 17.5); Control adjusted mean (95%CI) = 14.6 (14.3, 15.0); Difference of adjusted mean (SE) = 2.5 (0.22); p < .001."

"At 6-month follow-up, HOLA en Grupos participants reported significant increases in condom use self-efficacy: Intervention adjusted mean (95%CI) = 86.3 (84.1, 88.6); Control adjusted mean (95%CI) = 76.9 (74.7, 79.2); Difference of adjusted mean (SE) = 9.4 (1.33); p < .001."

Knowledge-based outcomes at 6 months

"At 6-month follow-up, HOLA en Grupos participants reported significant increases in HIV knowledge: Intervention adjusted mean (95%CI) = 16.3 (16.0, 16.6); Control adjusted mean (95%CI) = 13.8 (13.5, 14.1); Difference of adjusted mean (SE) = 2.5 (0.20); p < .001."

"At 6-month follow-up, HOLA en Grupos participants reported significant increases in STI knowledge: Intervention adjusted mean (95%CI) = 12.1 (11.7, 12.5); Control adjusted mean (95%CI) = 9.5 (9.1, 9.9); Difference of adjusted mean (SE) = 2.6 (0.24); p < .001."

"At 6-month follow-up, HOLA en Grupos participants reported significant increases in sexual communication skills: Intervention adjusted mean (95%CI) = 4.7 (4.0, 5.3); Control adjusted mean (95%CI) = 3.6 (2.9, 4.2); Difference of adjusted mean (SE) = 1.1 (0.41); p < .001."

Table 5: Effectiveness evidence statements for MSM

Outcome	Summary
UAI with HIV- or unknown status partners	Evidence from 1 study (n=313) showed a significantly greater decline in UAI with HIV negative or unknown status partners in participants receiving a peer-delivered motivational interviewing and CBT intervention than participants receiving standard care, from baseline to 6 months (χ^2 (1, N = 249) = 6.57, p = .01), and from baseline to the mean of 6 and 12 months (χ^2 (1, N = 249) = 5.47, p = .019), but not from baseline to 12 months (χ^2 (1, N = 249) = 2.55, p = .11).
Sexual self-efficacy	Evidence from 1 study (n=313) showed a significantly greater increase in sexual self-efficacy in participants receiving a peer-delivered motivational interviewing and CBT intervention than participants receiving standard care, from baseline to 6 months and from baseline to the mean of 6 and 12 months (Wald χ^2 s(2, N = 249) > 4.5, ps < .05).
Number of UAI episodes	Evidence from 1 study (n=374) showed no significant difference in the mean number of UAI episodes for participants receiving personalised cognitive counselling or standard sexual risk reduction counselling at 6 months: RR 0.76 (95%CI 0.25 to 2.19); or at 12 months: RR 0.48 (95%CI 0.12 to 1.84). Evidence from 1 study (n=370) showed a significantly greater decline in the mean number of UAI episodes in participants receiving a culturally relevant Spanish language small group intervention than participants in a non-attention control group, at 3 months: ANOVA F (1, 320) = 4.10, *p* < .05.
Condom use at last sex	Evidence from 1 study (n=370) showed a significantly higher rate of condom use at last sex for participants receiving a culturally relevant Spanish language small group intervention than

Outcome	Summary
	participants in a non-attention control group, at 3 months: AOR = 1.69 (95%CI 1.02 to 2.81).
Condom use skills	Evidence from 1 study (n=304) showed significantly greater increases in condom use skills in participants receiving a culturally relevant Spanish language small group intervention than participants receiving an attention matched control intervention, at 6 months: Difference of adjusted mean (SE) = 2.5 (0.22); $p < .001$.
Condom use self-efficacy	Evidence from 1 study (n=304) showed significantly greater increases in condom use self-efficacy in participants receiving a culturally relevant Spanish language small group intervention than participants receiving an attention matched control intervention, at 6 months: Difference of adjusted mean (SE) = 9.4 (1.33); $p < .001$.
HIV and STI knowledge	Evidence from 1 study (n=304) showed significantly greater increases in HIV knowledge and STI knowledge in participants receiving a culturally relevant Spanish language small group intervention than participants receiving an attention matched control intervention, at 6 months: Difference of adjusted mean (SE) = 2.5 (0.20); $p < .001$ for HIV knowledge and 2.6 (0.24); $p < .001$ for STI knowledge.
Sexual communication skills	Evidence from 1 study (n=304) showed significantly greater increases in sexual communication skills in participants receiving a culturally relevant Spanish language small group intervention than participants receiving an attention matched control intervention, at 6 months: Difference of adjusted mean (SE) = 1.1 (0.41); $p < .001$.

1.1.9.2 Young men from a Black African or Caribbean family background who have sex with men

1.1.9.2.1 Condom-focused intervention (Focus on the Future)

Crosby 2019

STI incidence outcomes at 12 months

"After adjusting for demographic characteristics and recent sexual behaviors, we examined differences between intervention and control groups and no group differences were detected on the likelihood of receiving a positive CT/NG result throughout the study period (EOR (95%CI) = 1.19 (0.95–1.48) P = 0.12). We also examined the likelihood of only rectal or urethral CT/NG infection (excluding oral test results), again with no difference observed between groups (EOR (95%CI) = 1.17 (0.90–1.53) P = 0.24)."

Table 6: Effectiveness evidence statements for Young men from a Black African or Caribbean family background who have sex with men

Outcome	Summary
STI incidence	Evidence from 1 study (n=277) showed no significant differences in STI incidence between those receiving a condom-focused intervention and those receiving standard care, at 12 months: EOR 1.19 (95%CI 0.95-1.48); $p = 0.12$. There was also no significant difference between groups when STI incidence was restricted to rectal or urethral infection only (excluding oral test results): EOR 1.17 (95%CI 0.90 to 1.53); $p = 0.24$.

1.1.10 Evidence from expert testimony

Due to the limited quantitative evidence identified for migrants, people who are homeless and asylum seekers, and the uncertainty in the quantitative evidence relating to the sexual health needs of people from Black African or Caribbean family backgrounds, expert testimony was sought. Details of the expert testimony obtained are in appendix D of review B.

Inclusion health groups

The committee heard evidence from an expert on Inclusion Health Groups, which includes people who are homeless, migrants, asylum seekers, refugees, sex workers, and people from Gypsy, Roma and Traveller communities. The expert highlighted that people in these inclusion health groups are socially excluded, experience stigma and discrimination, and experience multiple overlapping risk factors for poor health such as poverty, insecure or overcrowded housing, violence and trauma. The committee heard how these factors frequently lead to barriers in accessing and engaging with healthcare and other services, which can include difficulty registering with a GP (particularly for mobile populations or those without identity documents), challenges in understanding and navigating the system, misunderstanding of entitlements or rights to services, and overt discrimination.

The expert explained that most work in inclusion health has historically focussed on mental health, substance use and infectious diseases due to overcrowding, so sexual health is not something that is particularly well addressed in this area. There is also a lack of data on the sexual health needs of inclusion health groups, particularly asylum seekers and migrant groups. This made it difficult for the expert to recommend specific sexual health services or interventions for these groups. However, they talked to the committee about general approaches to improving access to health services, particularly primary care as this is often the first step in improving access to other services including specialist sexual health care. They described the 'All Our Health' framework which is considered an effective tool for frontline healthcare workers to have an impact on public health issues and contains a specific resource for inclusion health groups ('Inclusion health: applying All Our Health'). The Safe Surgeries Initiative was also highlighted as particularly effective for supporting migrants and other inclusion health groups to access healthcare. The expert also described more general approaches that are considered effective in addressing barriers to access, including translation and interpreting services, empathy, building trust, and working with local partners. The importance of acting quickly when a window of opportunity arises was also emphasised when working with marginalised and excluded populations.

Racially minoritized people

The committee also heard evidence from an expert on addressing sexual health inequalities among racially minoritized people in the UK. The testimony highlighted the lack of UK-based evidence on sexual health interventions for minority ethnic groups and emphasised the need for existing interventions to be rigorously assessed and evaluated in order to produce robust evidence that can be used to inform decision making, funding, policy and change. Despite the lack of published literature, the expert discussed anecdotal evidence for several specific projects delivered by a London-based community interest company that have successfully engaged with people from minority ethnic communities, particularly in relation to HIV, PrEP and STI testing. These interventions comprised a range of culturally relevant health promotion services for underserved communities including outreach, web-based interventions, one to one support and peer support, and were projects that aim to address sexual health inequalities in people from Black family backgrounds while also recognising the intersections of race, gender, sexual orientation and HIV status. The expert emphasised that the success of these programs demonstrates the need for sexual health interventions to be culturally appropriate, including using relevant language, imagery, settings and dissemination approaches. It was argued that the best way to do this is by listening to community needs and prioritising community involvement in all aspects of intervention design and delivery so that interventions are co-produced by and for the people they target. The expert also

stressed the importance of sexual health interventions being linked to other services (e.g. mental health, domestic violence, routine health checks) so that providers work in partnership with other local organisations to provide holistic, community-led care.

1.1.11 The committee's discussion of the evidence

This section is presented in section 1.1.8 of the qualitative evidence review (review B), which provides a combined discussion of the quantitative and qualitative evidence.

1.1.12 Recommendations supported by this evidence review

This evidence review supports recommendations 1.1.1 to 1.1.14 and the research recommendations on delivering effective sexual health services as part of other services and on tailoring outreach services.

1.1.13 References – included studies

Studies of Migrants

Peragallo Montano, Nilda, Cianelli, Rosina, Villegas, Natalia et al. (2019) Evaluating a Culturally Tailored HIV Risk Reduction Intervention Among Hispanic Women Delivered in a Real-World Setting by Community Agency Personnel. American journal of health promotion : AJHP 33(4): 566-575

Peragallo, Nilda, Gonzalez-Guarda, Rosa M, McCabe, Brian E et al. (2012) The efficacy of an HIV risk reduction intervention for Hispanic women. AIDS and behavior 16(5): 1316-26

Sanchez, Jesus; De La Rosa, Mario; Serna, Claudia A (2013) Project Salud: Efficacy of a community-based HIV prevention intervention for Hispanic migrant workers in south Florida. AIDS education and prevention: official publication of the International Society for AIDS Education 25(5): 363-75

Studies of homeless people

Tucker, Joan S., D'Amico, Elizabeth J., Ewing, Brett A. et al. (2017) A group-based motivational interviewing brief intervention to reduce substance use and sexual risk behavior among homeless young adults. Journal of Substance Abuse Treatment 76: 20-27

Studies of young people 16-24 years

Calderon, Yvette, Cowan, Ethan, Leu, Cheng-Shiun et al. (2013) A human immunodeficiency virus posttest video to increase condom use among adolescent emergency department patients. The Journal of adolescent health : official publication of the Society for Adolescent Medicine 53(1): 79-84

Champion, Jane Dimmitt and Collins, Jennifer L (2012) Comparison of a theory-based (AIDS Risk Reduction Model) cognitive behavioral intervention versus enhanced 98ounselling for abused ethnic minority adolescent women on infection with sexually transmitted infection: results of a randomized controlled trial. International journal of nursing studies 49(2): 138-50

Gimenez-Garcia, Cristina, Ballester-Arnal, Rafael, Gil-Llario, Maria Dolores et al. (2018) Peer-Led or Expert-Led Intervention in HIV Prevention Efficacy? A Randomized Control Trial Among Spanish Young People to Evaluate Their Role. Health promotion practice 19(2): 277-286

Miller, Melissa K, Catley, Delwyn, Adams, Amber et al. (2021) Brief Motivational Intervention To Improve Adolescent Sexual Health Service Uptake: A Pilot Randomized Controlled Trial In The Emergency Department. The Journal of pediatrics

Morrison-Beedy, Dianne, Jones, Sheryl H, Xia, Yinglin et al. (2013) Reducing sexual risk behavior in adolescent girls: results from a randomized controlled trial. The Journal of adolescent health : official publication of the Society for Adolescent Medicine 52(3): 314-21

Studies of trans people

Garofalo, Robert, Kuhns, Lisa M, Reisner, Sari L et al. (2018) Efficacy of an Empowerment-Based, Group-Delivered HIV Prevention Intervention for Young Transgender Women: The Project LifeSkills Randomized Clinical Trial. JAMA pediatrics 172(10): 916-923

Sevelius, J.M., Neilands, T.B., Dilworth, S. et al. (2019) Sheroes: Feasibility and Acceptability of a Community-Driven, Group-Level HIV Intervention Program for Transgender Women. AIDS and behavior

Studies of people from a Black African or Caribbean family background

Diallo, Dazon Dixon, Moore, Trent Wade, Ngalame, Paulyne M et al. (2010) Efficacy of a single-session HIV prevention intervention for black women: a group randomized controlled trial. AIDS and behavior 14(3): 518-29

Wilson, Tracey E, Gousse, Yolene, Joseph, Michael A et al. (2019) HIV Prevention for Black Heterosexual Men: The Barbershop Talk with Brothers Cluster Randomized Trial. American journal of public health 109(8): 1131-1137

Wingood, Gina M, Card, Josephina J, Er, Deja et al. (2011) Preliminary efficacy of a computer-based HIV intervention for African-American women. Psychology & health 26(2): 223-34

Studies of young people from a Black African or Caribbean family background

Brawner, Bridgette M, Jemmott, Loretta Sweet, Hanlon, Alexandra L et al. (2021) Results from Project GOLD: A pilot randomized controlled trial of a psychoeducational HIV/STI prevention intervention for black youth. AIDS care 33(6): 767-785

Brothers, Jennifer, Hotton, Anna L, Hosek, Sybil G et al. (2016) Young Women Living with HIV: Outcomes from a Targeted Secondary Prevention Empowerment Pilot Trial. AIDS patient care and STDs 30(5): 229-35

Chandler, R., Ross, H., Paul, S. et al. (2019) The HIP LADIES: A Pilot Health Improvement Project for HIV Prevention in Black College Women. The Journal of the Association of Nurses in AIDS Care : JANAC 30(4): 474-487

Crosby, Richard A, Charnigo, Richard J, Salazar, Laura F et al. (2014) Enhancing condom use among Black male youths: a randomized controlled trial. American journal of public health 104(11): 2219-25

DiClemente, R J, Wingood, G M, Rose, E et al. (2010) Evaluation of an HIV/STD sexual risk-reduction intervention for pregnant African American adolescents attending a prenatal clinic in an urban public hospital: preliminary evidence of efficacy. Journal of pediatric and adolescent gynecology 23(1): 32-8

DiClemente, Ralph J, Wingood, Gina M, Sales, Jessica M et al. (2014) Efficacy of a telephone-delivered sexually transmitted infection/human immunodeficiency virus prevention maintenance intervention for adolescents: a randomized clinical trial. JAMA pediatrics 168(10): 938-46

Wingood, Gina M, Diclemente, Ralph J, Robinson-Simpson, Lashun et al. (2013) Efficacy of an HIV intervention in reducing high-risk human papillomavirus, nonviral sexually transmitted infections, and concurrency among African American women: a randomized-controlled trial. Journal of acquired immune deficiency syndromes (1999) 63suppl1: 36-43

Studies of MSM

Brown, Jennifer L, Vanable, Peter A, Bostwick, Rebecca A et al. (2019) A Pilot Intervention Trial to Promote Sexual Health and Stress Management Among HIV-Infected Men Who Have Sex with Men. AIDS and behavior 23(1): 48-59

Cruess, Dean G, Burnham, Kaylee E, Finitsis, David J et al. (2018) A Randomized Clinical Trial of a Brief Internet-based Group Intervention to Reduce Sexual Transmission Risk Behavior Among HIV-Positive Gay and Bisexual Men. Annals of behavioral medicine : a publication of the Society of Behavioral Medicine 52(2): 116-129

Hart, Trevor A, Noor, Syed W, Skakoon-Sparling, Shayna et al. (2021) GPS: A Randomized Controlled Trial of Sexual Health Counseling for Gay and Bisexual Men Living With HIV. Behavior therapy 52(1): 1-14

Mansergh, Gordon, Koblin, Beryl A, McKirnan, David J et al. (2010) An intervention to reduce HIV risk behavior of substance-using men who have sex with men: a two-group randomized trial with a nonrandomized third group. PloS medicine 7(8): e1000329

McKirnan, David J; Tolou-Shams, Marina; Courtenay-Quirk, Cari (2010) The Treatment Advocacy Program: a randomized controlled trial of a peer-led safer sex intervention for HIV-infected men who have sex with men. Journal of consulting and clinical psychology 78(6): 952-63

Mimiaga, M.J., Pantalone, D.W., Biello, K.B. et al. (2019) An initial randomized controlled trial of behavioral activation for treatment of concurrent crystal methamphetamine dependence and sexual risk for HIV acquisition among men who have sex with men. AIDS Care – Psychological and Socio-Medical Aspects of AIDS/HIV 31(9): 1083-1095

Nostlinger, Christiana, Platteau, Tom, Bogner, Johannes et al. (2016) Implementation and Operational Research: Computer-Assisted Intervention for Safer Sex in HIV-Positive Men Having Sex With Men: Findings of a European Randomized Multi-Center Trial. Journal of acquired immune deficiency syndromes (1999) 71(3): e63-72

O'Donnell, Lydia, Stueve, Ann, Joseph, Heather A et al. (2014) Adapting the VOICES HIV behavioral intervention for Latino men who have sex with men. AIDS and behavior 18(4): 767-75

Rhodes, Scott D, Alonzo, Jorge, Mann, Lilli et al. (2017) Small-Group Randomized Controlled Trial to Increase Condom Use and HIV Testing Among Hispanic/Latino Gay, Bisexual, and Other Men Who Have Sex With Men. American journal of public health 107(6): 969-976

Safren, Steven A, O'Cleirigh, Conall M, Skeer, Margie et al. (2013) Project enhance: a randomized controlled trial of an individualized HIV prevention intervention for HIV-infected men who have sex with men conducted in a primary care setting. Health psychology : official journal of the Division of Health Psychology, American Psychological Association 32(2): 171-9

Schwarcz, Sandra K, Chen, Yea-Hung, Murphy, Jessie L et al. (2013) A randomized control trial of personalized cognitive counseling to reduce sexual risk among HIV-infected men who have sex with men. AIDS care 25(1): 1-10

Sikkema, K.J., Hansen, N.B., Kochman, A. et al. (2011) The development and feasibility of a brief risk reduction intervention for newly HIV-diagnosed men who have sex with men. Journal of Community Psychology 39(6): 717-732

Sikkema, Kathleen J, Abler, Laurie, Hansen, Nathan B et al. (2014) Positive choices: outcomes of a brief risk reduction intervention for newly HIV-diagnosed men who have sex with men. AIDS and behavior 18(9): 1808-19

Studies of Young MSM

Hidalgo, Marco A, Kuhns, Lisa M, Hotton, Anna L et al. (2015) The MyPEEPS randomized controlled trial: a pilot of preliminary efficacy, feasibility, and acceptability of a group-level, HIV risk reduction intervention for young men who have sex with men. Archives of sexual behavior 44(2): 475-85

Parsons, Jeffrey T, Lelutiu-Weinberger, Corina, Botsko, Michael et al. (2014) A randomized controlled trial utilizing motivational interviewing to reduce HIV risk and drug use in young gay and bisexual men. Journal of consulting and clinical psychology 82(1): 9-18

Studies of men from a Black African or Caribbean family background who have sex with men

Arnold, Emily A, Kegeles, Susan M, Pollack, Lance M et al. (2019) A Randomized Controlled Trial to Reduce HIV-Related Risk in African American Men Who Have Sex with Men and Women: the Bruthas Project. Prevention science : the official journal of the Society for Prevention Research 20(1): 115-125

Eaton, Lisa A, Kalichman, Seth C, Kalichman, Moira O et al. (2018) Randomised controlled trial of a sexual risk reduction intervention for STI prevention among men who have sex with men in the USA. Sexually transmitted infections 94(1): 40-45

Fernandez, M. Isabel, Hosek, Sybil G., Hotton, Anna L et al. (2016) A Randomized Controlled Trial of POWER: an Internet-Based HIV Prevention Intervention for Black Bisexual Men. AIDS and behavior 20(9): 1951-1960

Harawa, Nina T, Williams, John K, McCuller, W J et al. (2013) Efficacy of a culturally congruent HIV risk-reduction intervention for behaviorally bisexual black men: results of a randomized trial. AIDS (London, England) 27(12): 1979-88

Jemmott, John B 3rd, Jemmott, Loretta Sweet, O'Leary, Ann et al. (2015) On the Efficacy and Mediation of a One-on-One HIV Risk-Reduction Intervention for African American Men Who Have Sex with Men: A Randomized Controlled Trial. AIDS and behavior 19(7): 1247-62

Koblin, Beryl A, Bonner, Sebastian, Powell, Borris et al. (2012) A randomized trial of a behavioral intervention for black MSM: the DiSH study. AIDS (London, England) 26(4): 483-8

Lauby J, Milnamow M, Joseph HA et al. (2018) Evaluation of Project RISE, an HIV Prevention Intervention for Black Bisexual Men Using an Ecosystems Approach. AIDS and behavior 22(1): 164-177

Tobin, K, Kuramoto, SJ, German, D et al. (2013) Unity in diversity: results of a randomized clinical culturally tailored pilot HIV prevention intervention trial in Baltimore, Maryland, for African American men who have sex with men. Health education & behavior 40(3): 286-295

Williams, John K, Glover, Dorie A, Wyatt, Gail E et al. (2013) A sexual risk and stress reduction intervention designed for HIV-positive bisexual African American men with childhood sexual abuse histories. American journal of public health 103(8): 1476-84

Studies of Young men from a Black African or Caribbean family background who have sex with men

Crosby, R.A.; Mena, L.; Vickers Smith, R. (2019) Randomised controlled trial of a brief, clinic-based intervention to promote safer sex among young Black men who have sex with men: Implications for pre-exposure prophylaxis-related counselling. Sexual Health 16(2): 187-191

Crosby, Richard A, Mena, Leandro, Salazar, Laura F et al. (2018) Efficacy of a Clinic-Based Safer Sex Program for Human Immunodeficiency Virus-Uninfected and Human Immunodeficiency Virus-Infected Young Black Men Who Have Sex With Men: A Randomized Controlled Trial. Sexually transmitted diseases 45(3): 169-176

Crosby, Richard A; Mena, Leandro; Smith, Rachel Vickers (2018) Promoting positive condom use experiences among young black MSM: a randomized controlled trial of a brief, clinic-based intervention. Health education research 33(3): 197-204

MSM and transwomen of mixed immigrant status

Rhodes, Scott D, Alonzo, Jorge, Mann-Jackson, Lilli et al. (2020) A peer navigation intervention to prevent HIV among mixed immigrant status Latinx GBMSM and transgender women in the United States: outcomes, perspectives and implications for PrEP uptake. Health education research 35(3): 165-178

Economic

No economic studies were included in this review.

Appendices

Appendix A: Review protocol

Review protocol for interventions to reduce the acquisition and transmission of STIs

ID	Field	Content
1.	Review title	Interventions to reduce STI (including HIV) acquisition or transmission.
2.	Review question	What interventions designed to reduce the acquisition and transmission of STIs, including HIV, are effective and cost effective at preventing STIs in: 1.1a Gay, bisexual and other men who have sex with men 1.1b Young people age 16 to 24 years 1.1c People from a Black African or Caribbean family background 1.1d Trans people 1.1e Migrants communities 1.1f People who are homeless 1.1g Asylum seekers
3.	Objective	This review aims to describe and assess the effectiveness and cost-effectiveness of interventions that aim to prevent the acquisition or transmission of STIs in the specified groups and to identify the interventions associated with effectiveness.
4.	Searches	The following databases will be searched: Cochrane Central Register of Controlled Trials (CENTRAL) Cochrane Database of Systematic Reviews (CDSR) Embase (OVID) Medline (OVID) Medline in Process (OVID) PsycINFO (Ovid) EmCare (OVID) Web of Science (for citation searching* only, if judged to be required) *Citation searching Depending on initial database results, forward citation searching on key papers may be conducted, if judged necessary, using Web of Science (WOS). Only those references which NICE can access through its WOS subscription would be added to the search results. Duplicates would be removed in WOS before downloading. Websites Key websites will be searched for relevant reports or publications (British HIV Association, CDC, PHE, Google) Database functionality will be used, where available, to exclude: Non-English language papers Animal studies Editorials, letters or commentaries

ID	Field	Content
		Conference abstracts or posters Dissertations or theses Duplicates Sources will be searched from 2009 to current. The searches will be re-run 6 weeks before final submission of the review and further studies retrieved for inclusion. The guidance Information Services team at NICE will quality assure the principal search strategy and peer review the strategies for the other databases. Any revisions or additional steps will be agreed by the review team before being implemented. Any deviations and a rationale for them will be recorded alongside the search strategies. A record will be kept of number of records found from each database and of the strategy used in each database. A record will be kept of total number of duplicates found and of total results provided to the Public Health team.
5.	Condition or domain being studied	Sexually transmitted infections including herpes, chlamydia, genital warts, gonorrhoea, syphilis, HIV, mycoplasma genitalium, lymphogranuloma venereum (LGV), trichomonas vaginalis (TV)
6.	Population	Gay, bisexual and other men who have sex with men, people aged 16 to 24 years, people from a Black African or Caribbean family background, trans people, migrant communities, asylum seekers, homeless people. Specific consideration will also be given to subgroup analysis within these populations and people from the groups identified in the EIA (older adults and people with low socioeconomic status).
7.	Intervention/Exposure/Test	Interventions with the primary aim of reducing or preventing STI acquisition or transmission in each of the risk groups identified. Interventions will largely seek to promote the uptake of specific preventative behaviours or to reduce risk behaviours but may also include efforts to improve knowledge or change attitudes and beliefs. Main intervention approaches may include: - Behaviour change approaches (such as goal setting, comparison of outcomes, self-belief, skills building with feedback). - Informational, educational or knowledge-based approaches (raising awareness, providing information and facts about STIs, routes and rates of transmission, risk and protective factors). May also include skills-based information provision (e.g. training in how to use a condom) and testing-focused approaches that are primarily designed to promote, encourage and normalise testing through information provision. May also include normalising condom use. - Relationship focused approaches (such as promoting healthy sexual relationships, negotiating condom use, increasing assertiveness, understanding power and control within relationships, pleasure-based approaches) - Peer to peer approaches. These interventions involve the teaching or sharing of information, values, and behaviours by members of similar age or status group. They are often delivered in community settings and can involve peer supporters who are influential in their networks delivering sexual health advice, information or education to their peer group.

ID	Field	Content
		One to one approach including risk reduction counselling. We will consider single or multi-component interventions that include at least one of the listed approaches. All listed interventions may differ with respect to: Delivery format: (for example, passive or active approaches, remote or in-person approaches, workshops, demonstrations, interactive sessions, traditional media (e.g. posters, leaflets), broadcasting media (e.g. radio and TV), eHealth interventions Delivery location: (e.g. sexual health clinics; GP waiting rooms; gay bars and clubs; sex on premise venues such as saunas; universities and further education colleges, public settings such as posters on public transport) Excluded: Interventions where the primary objective is not specifically to reduce the acquisition or transmission of STIs. Interventions relating to partner notification strategies. Condom distribution schemes. Clinical interventions for the diagnosis, treatment or management of STIs. Interventions delivered in schools.
8.	Comparator/Reference standard/Confounding factors	No intervention Other interventions Other appropriate comparators as described in the study Trials with more than one comparator will be included if at least one of the intervention arms meets the intervention inclusion criteria.
9.	Types of study to be included	Inclusion: Effectiveness studies: RCTs Cluster RCTs Systematic reviews of included study designs Where there is no RCT, we will consider: Controlled before-after studies Prospective cohort studies Exclusion: Cross-sectional studies Case control studies Correlational studies Case series
10.	Other exclusion criteria	Only papers published in the English language will be included. Only full published peer-reviewed comparative effectiveness studies will be included. Only studies carried out in OECD countries will be included
11.	Context	The Department of Health and Social Care in England has asked NICE to update the guideline on sexually transmitted infections and under-18 conceptions: prevention (PH3), published in 2007. Changes in policy and commissioning, financial pressures and new evidence identified through the surveillance process led to the decision to update this guideline. The updated guideline will

ID	Field	Content
		focus solely on the reduction of sexually transmitted infections (STIs), as prevention of under-18 conceptions is covered in other guidelines Data from Public Health England show the overall number of STI diagnoses increased by 5% between 2017 and 2018. STIs can affect personal wellbeing, mental health and relationships and can also lead to serious health problems including pelvic inflammatory disease, ectopic pregnancy or infertility. It is therefore important to address interventions to help prevent or reduce STIs.
12.	Primary outcomes (critical outcomes)	Condom use (including correct use, use at last sexual encounter, proportion of sex acts protected by condoms, frequency and/or consistency of use) Incidence of STIs Changes in sexual health knowledge or attitudes, measured as: STI knowledge such as the prevalence, transmission route, health implications, treatment options for that condition STI testing knowledge such as where to get tested, what testing involves
13.	Secondary outcomes (important outcomes)	Secondary outcomes: Safety or adverse effects Engagement with the intervention Unintended consequences such as reducing stigma Sexual wellbeing such as but not limited to sustainability of healthy relationships, self-efficacy, consent, empowerment, control in relationships
14.	Data extraction (selection and coding)	All references identified by the searches and from other sources will be uploaded into EPPI reviewer and de-duplicated. This review may use the EPPI reviewer priority screening functionality where at least 50% of the identified abstracts will be screened. After this point, screening will only be terminated if a pre-specified threshold is met for a number of abstracts being screened without a single new include being identified. A random 10% sample of the studies remaining in the database when the threshold is met will be additionally screened, to check if a substantial number of relevant studies are not being correctly classified by the algorithm, with the full database being screened if concerns are identified. 10% of the abstracts will be reviewed by two reviewers, with any disagreements resolved by discussion or, if necessary, a third independent reviewer. The full text of potentially eligible studies will be retrieved and will be assessed in line with the criteria outlined above. A standardised template will be used to extract data from studies (this is consistent with the Developing NICE guidelines: the manual section 6.4).
15.	Methodological (quality) assessment	Risk of bias for individual studies will be assessed using the appropriate checklist as described in Developing NICE guidelines: the manual
16.	Strategy for data synthesis	Studies will be grouped by intervention type as appropriate.

ID	Field	Content	
		Data from eligible studies will be meta-analysed (combined) if studies are judged to be similar enough in terms of population, interventions, outcomes, study design or risk of bias. It is anticipated that meta-analysed studies will be heterogeneous. Where appropriate, heterogeneity will be explored by conducting subgroup analyses and incorporated by performing random-effect analyses. If studies are found to be too heterogeneous to be pooled statistically, a narrative approach with sufficient information to make judgements about study effectiveness will be conducted. Where appropriate, the quality or certainty across all available evidence will be evaluated for each outcome using an the 'Grading of Recommendations Assessment, Development and Evaluation (GRADE) toolbox' developed by the international GRADE working group http://www.gradeworkinggroup.org/	
17.	Analysis of sub-groups	Where evidence allows, sub-group analysis will be conducted to include those disproportionately burdened with STIs, including: people with low socioeconomic status people engaging in so-called chemsex people with learning disabilities commercial sex workers people age 65 years and older identified within the high risk groups specified The review will also consider the effectiveness in the groups identified in the EIA. Where evidence allows, sub-group analyses may be used to answer questions about the effectiveness of intervention types, including: Mode of delivery Intervention intensity or duration of provision Whether the intervention includes targeting or tailoring	
18.	Type and method of review	☒	Intervention
		☐	Diagnostic
		☐	Prognostic
		☐	Qualitative
		☐	Epidemiologic
		☐	Service Delivery
		☐	Other (please specify)

Appendix B: Literature search strategies

Search 1: People who are homeless, migrants and asylum seekers

Database name: MEDLINE

Database: Ovid MEDLINE(R) 1946 to March 03, 2020

Search Strategy:

1	(gay adj3 (male* or men)).ti,ab.	3903
2	Homosexuality, Male/	15195
3	"Sexual and Gender Minorities"/	2952
4	Bisexuality/	4028
5	Transgender Persons/	2808
6	Homosexuality/	12282
7	men who have sex with men.ti,ab.	9049
8	(same sex or non heterosexual* or non-heterosexual* or nonheterosexual*).ti,ab.	5776
9	MSM.ti,ab.	7966
10	(transgender* or transexual* or transsexual* or trans man or trans men or trans masculine or (gender adj (queer* or fluid* or variant*)) or nonbinary or non binary or non-binary or genderless or agender or bi-gender or bi gender or neutrois or heteroflexible* or bicurious* or bi-curious* or transpeople* or transperson*).ti,ab.	6310
11	(bisexual* or homosexual* or lgbt).ti,ab.	18466
12	(male adj3 (sex work* or prostitut* or transactional sex or escort*)).ti,ab.	505
13	or/1-12	48551
14	(rough sleep* or runaway*).ti,ab.	1177
15	((homeless* or street or destitut*) adj2 (population or person* or people* or group* or individual* or adult* or shelter* or hostel* or accommodation* or sleep*)).ti,ab.	3515
16	exp Homeless Persons/	8678
17	((temporary or emergency) adj2 (shelter* or accommodation*)).ti,ab.	331
18	(homeless* adj2 (household* or primary or secondary or unshelter* or unhoused or institut*)).ti,ab.	91
19	(homelessness or encampment* or makeshift shelter*).ti,ab.	3673
20	(squatter* or beggar*).ti,ab.	460
21	or/14-20	11882
22	(teen* or youth* or adolescen* or juvenile*).ti,ab.	346195

23	(young adj2 (adult* or person* or individual* or people* or population* or man or men or wom?n or male* or female* or subject*)).ti,ab.	186662
24	student*.ti,ab. or Students/	243445
25	(under adj2 (twenty five or twenty four or twenty three or twenty two or twenty one or twenty or nineteen or eighteen or "25" or "24" or "23" or 22 or 21 or 20 or 19 or 18")).ti,ab.	4068
26	(over adj2 (sixteen* or "16" or eighteen* or "18" or twenty one* or twenty-one* or "21") adj2 (year or years or age or ages or aged)).ti,ab.	5993
27	((15-25 or 16-25 or 17-25 or 18-25 or 19-25 or 20-25 or 21-25 or 22-25 or 23-25 or 24-25 or 16-22) adj2 (year or years or age or ages or aged)).ti,ab.	5129
28	Adolescent/ or Adolescent Behavior/ or Adolescent Health/ or Adolescent Development/	1994181
29	Young Adult/	812054
30	or/22-29	2708562
31	(black* or Afrocaribbean* or caribbean* or african* or African American*).ti,ab.	239417
32	African Continental Ancestry Group/	37418
33	African Americans/	52739
34	or/31-33	263760
35	"Emigrants and Immigrants"/	11695
36	"Emigration and Immigration"/	25004
37	Refugees/	9891
38	"Transients and Migrants"/	11313
39	Undocumented Immigrants/	299
40	Human Migration/	1054
41	(foreigner* or migrant* or immigrant* or emigrant* or refugee*).ti,ab.	42748
42	(asylum seek* or seeking asylum or asylee*).ti,ab.	1440
43	((displaced or alien*) adj2 (people* or person*)).ti,ab.	806
44	(born adj2 overseas).ti,ab.	304
45	foreign born.ti,ab.	2873

46	((marginal* or transient or undocumented) adj1 (people* or population* or communit* or neighbourhood* or neighborhood* or group* or area* or demograph*)).ti,ab.	3112
47	or/35-46	71547
48	13 or 21 or 30 or 34 or 47	2996773
49	Herpes Genitalis/ or Herpes Simplex/	18177
50	((genital* or simplex*) adj3 herpes*).ti,ab.	39297
51	chlamydia*.ti,ab.	25410
52	Chlamydia Infections/ or Chlamydia/ or Chlamydia trachomatis/	20476
53	((genital* or anogenital* or ano-genital* or venereal*) adj3 wart*).ti,ab.	2807
54	Condylomata Acuminata/	5202
55	"condylomata acuminata".ti,ab.	1036
56	Papillomavirus Infections/	25123
57	(papillomavirus adj (human* or infect*)).ti,ab.	3762
58	hpv.ti,ab.	35275
59	Gonorrhea/	13761
60	(Gonorrhea* or Gonorrhoea*).ti,ab.	17454
61	Syphilis/	21667
62	syphilis*.ti,ab.	21453
63	(lymphogranuloma venereum or lgv).ti,ab.	1231
64	Lymphogranuloma Venereum/	1580
65	Trichomonas vaginalis/	3543
66	(trichomonas vaginali* or Trichomoniasi*).ti,ab.	6393
67	Trichomonas Infections/	3242
68	HIV Infections/ or HIV/	198698
69	(hiv or human Immunodeficiency Virus*).ti,ab.	292354
70	(mycoplasma genitalium or Mgen).ti,ab.	1142

71	Mycoplasma genitalium/	694
72	Sexually Transmitted Diseases/	24276
73	((sexually adj2 transmit* adj2 (disease* or infection*)) or sti or std).ti,ab.	34041
74	(venereal* adj2 (disease* or infection*)).ti,ab.	3943
75	or/49-74	488949
76	48 and 75	117227
77	((peer or peers) adj2 (led or support* or intervention* or deliver* or educat* or influenc* or group* or network* or program* or programme* or counsellor* or counselor* or advocate* or behaviour* or behavior* or educat* or base* model*)).ti,ab.	12757
78	role model*.ti,ab.	4604
79	peer group/ or peer influence/	20404
80	or/77-79	31861
81	(counselling or counseling).ti,ab.	77690
82	(motivat* adj2 (interview* or incentive*)).ti,ab.	4107
83	counseling/ or sex counseling/ or Motivational Interviewing/	37678
84	((One-to-one or one to one or 1-1) adj2 intervention*).ti,ab.	159
85	((cognitive or behavio*) adj2 therap*).ti,ab.	23029
86	Cognitive Behavioral Therapy/	24676
87	or/81-86	132258
88	social support*.ti,ab.	31715
89	(self adj2 (belief* or aware*)).ti,ab.	4994
90	(covert adj2 learn*).ti,ab.	10
91	(reward* adj2 threat*).ti,ab.	99
92	Contingency management.ti,ab.	845
93	(repetition* adj2 substitut*).ti,ab.	12
94	(compar* adj2 (outcome* or behaviour* or behavior*)).ti,ab.	59672

95	(natural* adj2 consequence*).ti,ab.	784
96	(shap* adj2 knowledge*).ti,ab.	238
97	(feedback adj2 monitor*).ti,ab.	604
98	(goal* adj2 (plan* or set*)).ti,ab.	6799
99	skill* build*.ti,ab.	794
100	((behavio?r* or lifestyle* or "life style*") and (change* or changing or modification or modify or modifying or therapy or therapies or program* or intervention* or technique* or establish* or individual*)).ti.	33838
101	((behavio?r* or lifestyle* or "life style*") adj2 (change* or changing or modification or modify or modifying or therapy or therapies or program* or intervention* or technique* or establish* or individual*)).ab,kw.	94005
102	Social Support/	69187
103	or/88-102	261817
104	(risk reduc* adj2 (strateg* or counsel* or practice* or agreement* or behaviour* or behavior*)).ti,ab.	2220
105	((monogam* or safe*) adj2 (agreement* or contract* or strateg*)).ti,ab.	2809
106	((selective* or negotiat* or normalis* or normaliz*) adj2 condom*).ti,ab.	406
107	((partner* or sex*) adj2 concurren*).ti,ab.	815
108	(relation* adj2 (dynamic* or focus* or power* or control*)).ti,ab.	9308
109	(educat* adj2 (session* or lesson*)).ti,ab.	3949
110	(pleasur* adj2 approach*).ti,ab.	15
111	Risk Reduction Behavior/	12229
112	or/104-111	31022
113	((universal or population or national* or public health or nationwide* or statewide* or countrywide* or citywide* or national* or nation wide* or state wide* or country wide* or city wide* or government*) adj4 (promotion* or campaign* or intervention* or toolkit* or strateg*)).ti,ab.	34938
114	(rais* adj2 awareness adj4 (promotion* or campaign* or intervention* or toolkit* or strateg*)).ti,ab.	591
115	((poster* or leaflet* or booklet* or presentation* or brochure* or flyer* or newsletter* or advert* or radio or tv or television or article* or factsheet* or magazine* or literature or display* or card* or postcard* or banner* or t-shirt* or blog* or website* or online or social	8014

	media or social market* or facebook or twitter or instagram or snapchat or pinterest* or video* or messag* or email* or text* or sms or smartphone* or mobile* or "tablet computer*" or workshop* or train* or remote or communit* or inform*) adj2 (public health or health promot*)).ti,ab.	
116	Health Promotion/	72299
117	Patient Education as Topic/ or Government Publications as Topic/ or persuasive communication/ or information dissemination/	103670
118	Public Health/	79340
119	Health Knowledge, Attitudes, Practice/ or Text Messaging/ or Electronic Mail/ or Social Media/	120174
120	or/113-119	377761
121	80 or 87 or 103 or 112 or 120	740459
122	76 and 121	25028
123	afghanistan/ or exp africa/ or albania/ or andorra/ or antarctic regions/ or argentina/ or exp asia, central/ or exp asia, northern/ or exp asia, southeastern/ or exp atlantic islands/ or bahrain/ or bangladesh/ or Bhutan/ or bolivia/ or borneo/ or "bosnia and Herzegovina"/ or brazil/ or bulgaria/ or exp central america/ or exp china/ or colombia/ or "Commonwealth of Independent States"/ or croatia/ or "Democratic People's Republic of Korea"/ or ecuador/ or gibraltar/ or guyana/ or exp india/ or indonesia/ or iran/ or iraq/ or jordan/ or kosovo/ or kuwait/ or lebanon/ or liechtenstein/ or macau/ or "macedonia (republic)"/ or exp melanesia/ or moldova/ or monaco/ or mongolia/ or montenegro/ or nepal/ or Netherlands Antilles/ or New Guinea/ or oman/ or pakistan/ or paraguay/ or peru/ or philippines/ or qatar/ or "republic of Belarus"/ or romania/ or exp russia/ or saudi arabia/ or serbia/ or sri lanka/ or suriname/ or syria/ or taiwan/ or exp transcaucasia/ or ukraine/ or uruguay/ or united arab emirates/ or exp ussr/ or venezuela/ or yemen/	1065688
124	"Organisation for Economic Co-Operation and Development"/	240
125	oecd*.ti,ab.	3462
126	"Organisation for Economic Co-operation and Development".ti,ab.	524
127	"Organisation for Economic Cooperation and Development".ti,ab.	137
128	"Organization for Economic Co-operation and Development".ti,ab.	251
129	"Organization for Economic Cooperation and Development".ti,ab.	484
130	australasia/ or exp australia/ or austria/ or exp Baltic States/ or belgium/ or exp canada/ or chile/ or czech republic/ or europe/ or exp france/ or exp germany/ or greece/ or hungary/ or ireland/ or Israel/ or exp italy/ or exp japan/ or korea/ or luxembourg/ or mexico/ or netherlands/ or new zealand/ or north america/ or poland/ or portugal/ or exp "republic of korea"/ or exp "Scandinavian and Nordic Countries"/ or slovakia/ or slovenia/ or spain/ or switzerland/ or turkey/ or exp united kingdom/ or exp united states/	3093254
131	European Union/	15882

132	Developed Countries/	20381
133	or/124-132	3109720
134	123 not (123 and 133)	985039
135	21 or 47	82767
136	122 and 135	1741
137	136 not 134	1206
138	limit 137 to english language	1140
139	limit 138 to yr="2009 -Current"	652
140	limit 139 to (letter or historical article or comment or editorial or news or case reports)	16
141	139 not 140	636
142	Animals/ not (Humans/ and Animals/)	4641346
143	141 not 142	636
144	13 or 30 or 34	2941667
145	122 and 144	24410
146	145 not 134	15152
147	limit 146 to english language	14601
148	limit 147 to yr="2009 -Current"	8054
149	limit 148 to (letter or historical article or comment or editorial or news or case reports)	257
150	148 not 149	7797
151	Animals/ not (Humans/ and Animals/)	4641346
152	150 not 151	7791

Search 2: Young people 16-24 years, trans people, people from a Black African or Caribbean family background, and MSM.

Database name: MEDLINE

Database: Ovid MEDLINE(R) 1946 to March 03, 2020

1	(gay adj3 (male* or men)).ti,ab.	3903
2	Homosexuality, Male/	15195
3	"Sexual and Gender Minorities"/	2952
4	Bisexuality/	4028
5	Transgender Persons/	2808
6	Homosexuality/	12282
7	men who have sex with men.ti,ab.	9049
8	(same sex or non heterosexual* or non-heterosexual* or nonheterosexual*).ti,ab.	5776
9	MSM.ti,ab.	7966
10	(transgender* or transexual* or transsexual* or trans man or trans men or trans masculine or (gender adj (queer* or fluid* or variant*)) or nonbinary or non binary or non-binary or genderless or agender or bi-gender or bi gender or neutrois or heteroflexible* or bicurious* or bi-curious* or transpeople* or transperson*).ti,ab.	6310
11	(bisexual* or homosexual* or lgbt).ti,ab.	18466
12	(male adj3 (sex work* or prostitut* or transactional sex or escort*)).ti,ab.	505
13	or/1-12	48551
14	(rough sleep* or runaway*).ti,ab.	1177
15	((homeless* or street or destitut*) adj2 (population or person* or people* or group* or individual* or adult* or shelter* or hostel* or accommodation* or sleep*)).ti,ab.	3515
16	exp Homeless Persons/	8678
17	((temporary or emergency) adj2 (shelter* or accommodation*)).ti,ab.	331
18	(homeless* adj2 (household* or primary or secondary or unshelter* or unhoused or institut*)).ti,ab.	91
19	(homelessness or encampment* or makeshift shelter*).ti,ab.	3673

20	(squatter* or beggar*).ti,ab.	460
21	or/14-20	11882
22	(teen* or youth* or adolescen* or juvenile*).ti,ab.	346195
23	(young adj2 (adult* or person* or individual* or people* or population* or man or men or wom?n or male* or female* or subject*)).ti,ab.	186662
24	student*.ti,ab. or Students/	243445
25	(under adj2 (twenty five or twenty four or twenty three or twenty two or twenty one or twenty or nineteen or eighteen or "25" or "24" or "23" or 22 or 21 or 20 or 19 or 18")).ti,ab.	4068
26	(over adj2 (sixteen* or "16" or eighteen* or "18" or twenty one* or twenty-one* or "21") adj2 (year or years or age or ages or aged)).ti,ab.	5993
27	((15-25 or 16-25 or 17-25 or 18-25 or 19-25 or 20-25 or 21-25 or 22-25 or 23-25 or 24-25 or 16-22) adj2 (year or years or age or ages or aged)).ti,ab.	5129
28	Adolescent/ or Adolescent Behavior/ or Adolescent Health/ or Adolescent Development/	1994181
29	Young Adult/	812054
30	or/22-29	2708562
31	(black* or Afrocaribbean* or caribbean* or african* or African American*).ti,ab.	239417
32	African Continental Ancestry Group/	37418
33	African Americans/	52739
34	or/31-33	263760
35	"Emigrants and Immigrants"/	11695
36	"Emigration and Immigration"/	25004
37	Refugees/	9891
38	"Transients and Migrants"/	11313
39	Undocumented Immigrants/	299
40	Human Migration/	1054
41	(foreigner* or migrant* or immigrant* or emigrant* or refugee*).ti,ab.	42748
42	(asylum seek* or seeking asylum or asylee*).ti,ab.	1440

43	((displaced or alien*) adj2 (people* or person*)).ti,ab.	806
44	(born adj2 overseas).ti,ab.	304
45	foreign born.ti,ab.	2873
46	((marginal* or transient or undocumented) adj1 (people* or population* or communit* or neighbourhood* or neighborhood* or group* or area* or demograph*)).ti,ab.	3112
47	or/35-46	71547
48	13 or 21 or 30 or 34 or 47	2996773
49	Herpes Genitalis/ or Herpes Simplex/	18177
50	((genital* or simplex*) adj3 herpes*).ti,ab.	39297
51	chlamydia*.ti,ab.	25410
52	Chlamydia Infections/ or Chlamydia/ or Chlamydia trachomatis/	20476
53	((genital* or anogenital* or ano-genital* or venereal*) adj3 wart*).ti,ab.	2807
54	Condylomata Acuminata/	5202
55	"condylomata acuminata".ti,ab.	1036
56	Papillomavirus Infections/	25123
57	(papillomavirus adj (human* or infect*)).ti,ab.	3762
58	hpv.ti,ab.	35275
59	Gonorrhea/	13761
60	(Gonorrhea* or Gonorrhoea*).ti,ab.	17454
61	Syphilis/	21667
62	syphilis*.ti,ab.	21453
63	(lymphogranuloma venereum or lgv).ti,ab.	1231
64	Lymphogranuloma Venereum/	1580
65	Trichomonas vaginalis/	3543
66	(trichomonas vaginali* or Trichomoniasi*).ti,ab.	6393
67	Trichomonas Infections/	3242

68	HIV Infections/ or HIV/	198698
69	(hiv or human Immunodeficiency Virus*).ti,ab.	292354
70	(mycoplasma genitalium or Mgen).ti,ab.	1142
71	Mycoplasma genitalium/	694
72	Sexually Transmitted Diseases/	24276
73	((sexually adj2 transmit* adj2 (disease* or infection*)) or sti or std).ti,ab.	34041
74	(venereal* adj2 (disease* or infection*)).ti,ab.	3943
75	or/49-74	488949
76	48 and 75	117227
77	((peer or peers) adj2 (led or support* or intervention* or deliver* or educat* or influenc* or group* or network* or program* or programme* or counsellor* or counselor* or advocate* or behaviour* or behavior* or educat* or base* model*)).ti,ab.	12757
78	role model*.ti,ab.	4604
79	peer group/ or peer influence/	20404
80	or/77-79	31861
81	(counselling or counseling).ti,ab.	77690
82	(motivat* adj2 (interview* or incentive*)).ti,ab.	4107
83	counseling/ or sex counseling/ or Motivational Interviewing/	37678
84	((One-to-one or one to one or 1-1) adj2 intervention*).ti,ab.	159
85	((cognitive or behavio*) adj2 therap*).ti,ab.	23029
86	Cognitive Behavioral Therapy/	24676
87	or/81-86	132258
88	social support*.ti,ab.	31715
89	(self adj2 (belief* or aware*)).ti,ab.	4994
90	(covert adj2 learn*).ti,ab.	10
91	(reward* adj2 threat*).ti,ab.	99

92	Contingency management.ti,ab.	845
93	(repetition* adj2 substitut*).ti,ab.	12
94	(compar* adj2 (outcome* or behaviour* or behavior*)).ti,ab.	59672
95	(natural* adj2 consequence*).ti,ab.	784
96	(shap* adj2 knowledge*).ti,ab.	238
97	(feedback adj2 monitor*).ti,ab.	604
98	(goal* adj2 (plan* or set*)).ti,ab.	6799
99	skill* build*.ti,ab.	794
100	((behavio?r* or lifestyle* or "life style*") and (change* or changing or modification or modify or modifying or therapy or therapies or program* or intervention* or technique* or establish* or individual*)).ti.	33838
101	((behavio?r* or lifestyle* or "life style*") adj2 (change* or changing or modification or modify or modifying or therapy or therapies or program* or intervention* or technique* or establish* or individual*)).ab,kw.	94005
102	Social Support/	69187
103	or/88-102	261817
104	(risk reduc* adj2 (strateg* or counsel* or practice* or agreement* or behaviour* or behavior*)).ti,ab.	2220
105	((monogam* or safe*) adj2 (agreement* or contract* or strateg*)).ti,ab.	2809
106	((selective* or negotiat* or normalis* or normaliz*) adj2 condom*).ti,ab.	406
107	((partner* or sex*) adj2 concurren*).ti,ab.	815
108	(relation* adj2 (dynamic* or focus* or power* or control*)).ti,ab.	9308
109	(educat* adj2 (session* or lesson*)).ti,ab.	3949
110	(pleasur* adj2 approach*).ti,ab.	15
111	Risk Reduction Behavior/	12229
112	or/104-111	31022
113	((universal or population or national* or public health or nationwide* or statewide* or countrywide* or citywide* or national* or nation wide* or state wide* or country wide* or city wide* or government*) adj4 (promotion* or campaign* or intervention* or toolkit* or strateg*)).ti,ab.	34938

114	(rais* adj2 awareness adj4 (promotion* or campaign* or intervention* or toolkit* or strateg*)).ti,ab.	591
115	((poster* or leaflet* or booklet* or presentation* or brochure* or flyer* or newsletter* or advert* or radio or tv or television or article* or factsheet* or magazine* or literature or display* or card* or postcard* or banner* or t-shirt* or blog* or website* or online or social media or social market* or facebook or twitter or instagram or snapchat or pinterest* or video* or messag* or email* or text* or sms or smartphone* or mobile* or "tablet computer*" or workshop* or train* or remote or communit* or inform*) adj2 (public health or health promot*)).ti,ab.	8014
116	Health Promotion/	72299
117	Patient Education as Topic/ or Government Publications as Topic/ or persuasive communication/ or information dissemination/	103670
118	Public Health/	79340
119	Health Knowledge, Attitudes, Practice/ or Text Messaging/ or Electronic Mail/ or Social Media/	120174
120	or/113-119	377761
121	80 or 87 or 103 or 112 or 120	740459
122	76 and 121	25028
123	afghanistan/ or exp africa/ or albania/ or andorra/ or antarctic regions/ or argentina/ or exp asia, central/ or exp asia, northern/ or exp asia, southeastern/ or exp atlantic islands/ or bahrain/ or bangladesh/ or Bhutan/ or bolivia/ or borneo/ or "bosnia and Herzegovina"/ or brazil/ or bulgaria/ or exp central america/ or exp china/ or colombia/ or "Commonwealth of Independent States"/ or croatia/ or "Democratic People's Republic of Korea"/ or ecuador/ or gibraltar/ or guyana/ or exp india/ or indonesia/ or iran/ or iraq/ or jordan/ or kosovo/ or kuwait/ or lebanon/ or liechtenstein/ or macau/ or "macedonia (republic)"/ or exp melanesia/ or moldova/ or monaco/ or mongolia/ or montenegro/ or nepal/ or Netherlands Antilles/ or New Guinea/ or oman/ or pakistan/ or paraguay/ or peru/ or philippines/ or qatar/ or "republic of Belarus"/ or romania/ or exp russia/ or saudi arabia/ or serbia/ or sri lanka/ or suriname/ or syria/ or taiwan/ or exp transcaucasia/ or ukraine/ or uruguay/ or united arab emirates/ or exp ussr/ or venezuela/ or yemen/	1065688
124	"Organisation for Economic Co-Operation and Development"/	240
125	oecd*.ti,ab.	3462
126	"Organisation for Economic Co-operation and Development".ti,ab.	524
127	"Organisation for Economic Cooperation and Development".ti,ab.	137
128	"Organization for Economic Co-operation and Development".ti,ab.	251
129	"Organization for Economic Cooperation and Development".ti,ab.	484
130	australasia/ or exp australia/ or austria/ or exp Baltic States/ or belgium/ or exp canada/ or chile/ or czech republic/ or europe/ or exp france/ or exp germany/ or greece/ or hungary/ or ireland/ or Israel/ or exp italy/ or exp japan/ or korea/ or luxembourg/ or mexico/ or	3093254

	netherlands/ or new zealand/ or north america/ or poland/ or portugal/ or exp "republic of korea"/ or exp "Scandinavian and Nordic Countries"/ or slovakia/ or slovenia/ or spain/ or switzerland/ or turkey/ or exp united kingdom/ or exp united states/	
131	European Union/	15882
132	Developed Countries/	20381
133	or/124-132	3109720
134	123 not (123 and 133)	985039
135	21 or 47	82767
136	122 and 135	1741
137	136 not 134	1206
138	limit 137 to english language	1140
139	limit 138 to yr="2009 -Current"	652
140	limit 139 to (letter or historical article or comment or editorial or news or case reports)	16
141	139 not 140	636
142	Animals/ not (Humans/ and Animals/)	4641346
143	141 not 142	636
144	13 or 30 or 34	2941667
145	122 and 144	24410
146	145 not 134	15152
147	limit 146 to english language	14601
148	limit 147 to yr="2009 -Current"	8054
149	limit 148 to (letter or historical article or comment or editorial or news or case reports)	257
150	148 not 149	7797
151	Animals/ not (Humans/ and Animals/)	4641346
152	150 not 151	7791

Database name: MEDLINE-in-Process

Database: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations 1946 to March 03, 2020

1	(gay adj3 (male* or men)).ti,ab.	383
2	men who have sex with men.ti,ab.	1411
3	(same sex or non heterosexual* or non-heterosexual* or nonheterosexual*).ti,ab.	717
4	MSM.ti,ab.	1382
5	(transgender* or transexual* or transsexual* or trans man or trans men or trans masculine or (gender adj (queer* or fluid* or variant*)) or nonbinary or non binary or non-binary or genderless or agender or bi-gender or bi gender or neutrois or heteroflexible* or bicurious* or bi-curious* or transpeople* or transperson*).ti,ab.	1451
6	(bisexual* or homosexual* or lgbt).ti,ab.	1603
7	(male adj3 (sex work* or prostitut* or transactional sex or escort*)).ti,ab.	39
8	or/1-7	4996
9	(rough sleep* or runaway*).ti,ab.	422
10	((homeless* or street or destitut*) adj2 (population or person* or people* or group* or individual* or adult* or shelter* or hostel* or accommodation* or sleep*)).ti,ab.	469
11	((temporary or emergency) adj2 (shelter* or accommodation*)).ti,ab.	64
12	(homeless* adj2 (household* or primary or secondary or unshelter* or unhoused or institut*)).ti,ab.	14
13	(homelessness or encampment* or makeshift shelter*).ti,ab.	596
14	(squatter* or beggar*).ti,ab.	46
15	or/9-14	1331
16	(teen* or youth* or adolescen* or juvenile*).ti,ab.	46958
17	(young adj2 (adult* or person* or individual* or people* or population* or man or men or wom?n or male* or female* or subject*)).ti,ab.	25077
18	student*.ti,ab.	36656

19	(under adj2 (twenty five or twenty four or twenty three or twenty two or twenty one or twenty or nineteen or eighteen or "25" or "24" or "23" or 22 or 21 or 20 or 19 or 18")).ti,ab.	518
20	(over adj2 (sixteen* or "16" or eighteen* or "18" or twenty one* or twenty-one* or "21") adj2 (year or years or age or ages or aged)).ti,ab.	907
21	((15-25 or 16-25 or 17-25 or 18-25 or 19-25 or 20-25 or 21-25 or 22-25 or 23-25 or 24-25 or 16-22) adj2 (year or years or age or ages or aged)).ti,ab.	861
22	or/16-21	100203
23	(black* or Afrocaribbean* or caribbean* or african* or African American*).ti,ab.	38999
24	(foreigner* or migrant* or immigrant* or emigrant* or refugee*).ti,ab.	5687
25	(asylum seek* or seeking asylum or asylee*).ti,ab.	257
26	((displaced or alien*) adj2 (people* or person*)).ti,ab.	165
27	(born adj2 overseas).ti,ab.	24
28	foreign born.ti,ab.	323
29	((marginal* or transient or undocumented) adj1 (people* or population* or communit* or neighbourhood* or neighborhood* or group* or area* or demograph*)).ti,ab.	625
30	or/24-29	6644
31	15 or 30	7912
32	8 or 22 or 23	140200
33	((genital* or simplex*) adj3 herpes*).ti,ab.	2010
34	chlamydia*.ti,ab.	1561
35	((genital* or anogenital* or ano-genital* or venereal*) adj3 wart*).ti,ab.	286
36	"condylomata acuminata".ti,ab.	42
37	(papillomavirus adj (human* or infect*)).ti,ab.	297
38	hpv.ti,ab.	4196
39	(Gonorrhea* or Gonorrhoea*).ti,ab.	1375
40	syphilis*.ti,ab.	2824
41	(lymphogranuloma venereum or lgv).ti,ab.	108

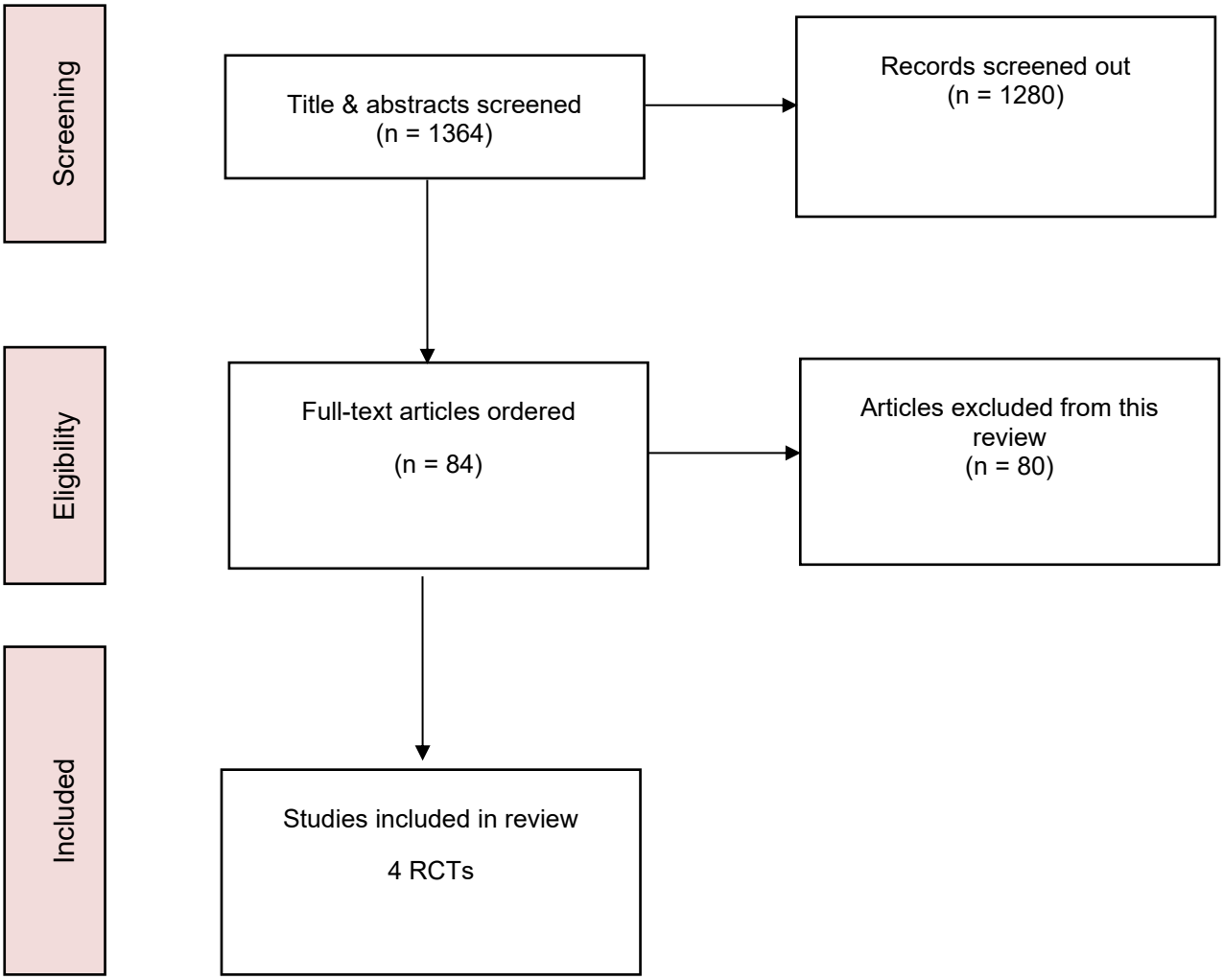
42	(trichomonas vaginali* or Trichomoniasi*).ti,ab.	390
43	(hiv or human Immunodeficiency Virus*).ti,ab.	26764
44	(mycoplasma genitalium or Mgen).ti,ab.	145
45	((sexually adj2 transmit* adj2 (disease* or infection*)) or sti or std).ti,ab.	3323
46	(venereal* adj2 (disease* or infection*)).ti,ab.	621
47	or/33-46	39137
48	((peer or peers) adj2 (led or support* or intervention* or deliver* or educat* or influenc* or group* or network* or program* or programme* or counsellor* or counselor* or advocate* or behaviour* or behavior* or educat* or base* model*)).ti,ab.	2304
49	role model*.ti,ab.	624
50	(counselling or counseling).ti,ab.	10144
51	(motivat* adj2 (interview* or incentive*)).ti,ab.	707
52	((One-to-one or one to one or 1-1) adj2 intervention*).ti,ab.	36
53	((cognitive or behavio*) adj2 therap*).ti,ab.	4073
54	social support*.ti,ab.	4611
55	(self adj2 (belief* or aware*)).ti,ab.	825
56	(covert adj2 learn*).ti,ab.	3
57	(reward* adj2 threat*).ti,ab.	25
58	Contingency management.ti,ab.	115
59	(repetition* adj2 substitut*).ti,ab.	3
60	(compar* adj2 (outcome* or behaviour* or behavior*)).ti,ab.	10376
61	(natural* adj2 consequence*).ti,ab.	188
62	(shap* adj2 knowledge*).ti,ab.	53
63	(feedback adj2 monitor*).ti,ab.	158
64	(goal* adj2 (plan* or set*)).ti,ab.	1172
65	skill* build*.ti,ab.	123

66	((behavio?r* or lifestyle* or "life style*") and (change* or changing or modification or modify or modifying or therapy or therapies or program* or intervention* or technique* or establish* or individual*)).ti.	5597
67	((behavio?r* or lifestyle* or "life style*") adj2 (change* or changing or modification or modify or modifying or therapy or therapies or program* or intervention* or technique* or establish* or individual*)).ab,kw.	16454
68	(risk reduc* adj2 (strateg* or counsel* or practice* or agreement* or behaviour* or behavior*)).ti,ab.	261
69	((monogam* or safe*) adj2 (agreement* or contract* or strateg*)).ti,ab.	509
70	((selective* or negotiat* or normalis* or normaliz*) adj2 condom*).ti,ab.	46
71	((partner* or sex*) adj2 concurren*).ti,ab.	76
72	(relation* adj2 (dynamic* or focus* or power* or control*)).ti,ab.	1581
73	(educat* adj2 (session* or lesson*)).ti,ab.	815
74	(pleasur* adj2 approach*).ti,ab.	5
75	((universal or population or national* or public health or nationwide* or statewide* or countrywide* or citywide* or national* or nation wide* or state wide* or country wide* or city wide* or government*) adj4 (promotion* or campaign* or intervention* or toolkit* or strateg*)).ti,ab.	5761
76	(rais* adj2 awareness adj4 (promotion* or campaign* or intervention* or toolkit* or strateg*)).ti,ab.	138
77	((poster* or leaflet* or booklet* or presentation* or brochure* or flyer* or newsletter* or advert* or radio or tv or television or article* or factsheet* or magazine* or literature or display* or card* or postcard* or banner* or t-shirt* or blog* or website* or online or social media or social market* or facebook or twitter or instagram or snapchat or pinterest* or video* or messag* or email* or text* or sms or smartphone* or mobile* or "tablet computer*" or workshop* or train* or remote or communit* or inform*) adj2 (public health or health promot*)).ti,ab.	1280
78	or/48-77	57504
79	31 and 47 and 78	95
80	limit 79 to english language	95
81	limit 80 to (letter or historical article or comment or editorial or news or case reports)	0
82	80 not 81	95
83	limit 82 to yr="2009 -Current"	86
84	32 and 47 and 78	1033

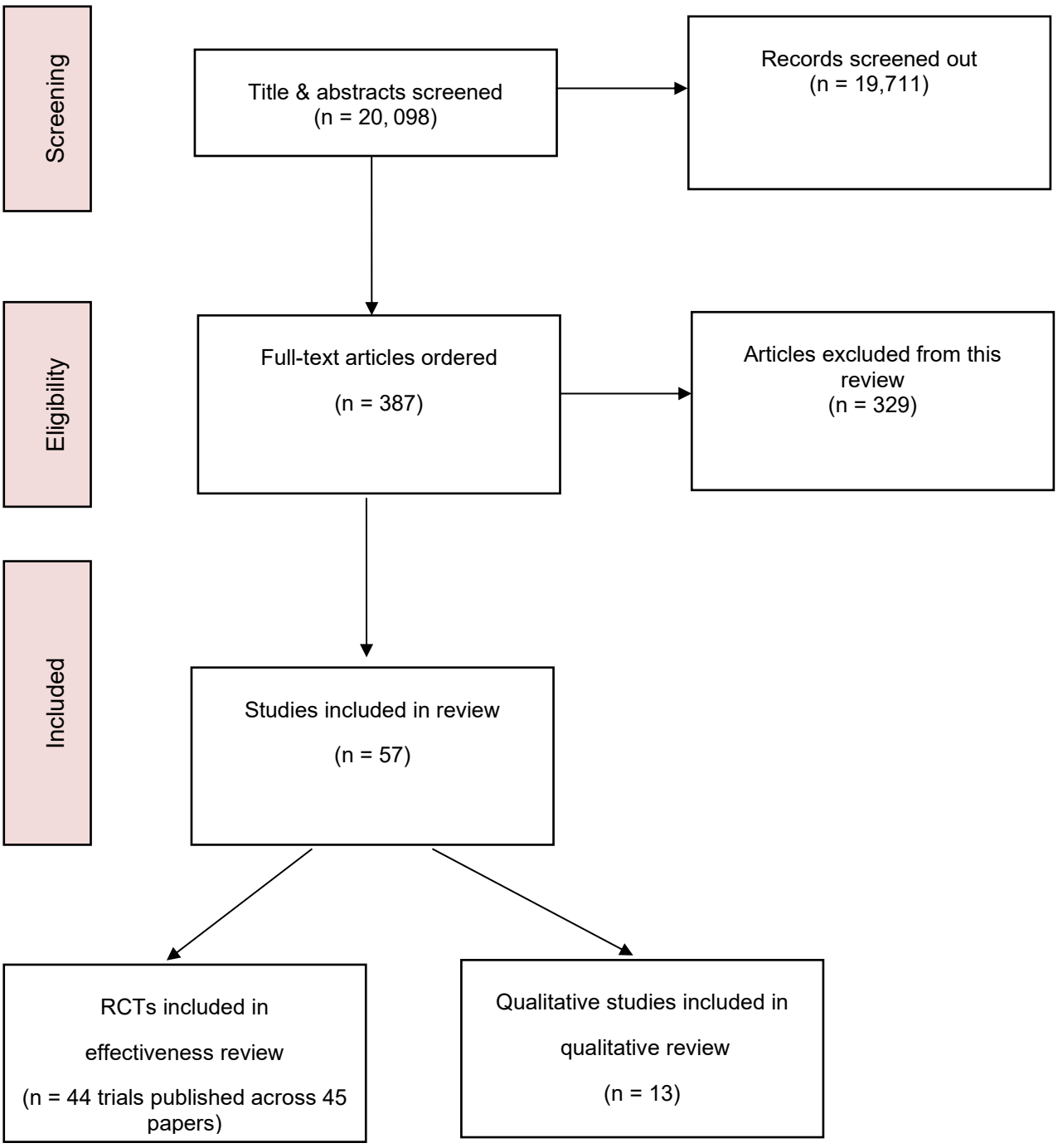
85	limit 84 to english language	1027
86	limit 85 to (letter or historical article or comment or editorial or news or case reports)	14
87	85 not 86	1013
88	limit 87 to yr="2009 -Current"	927

Appendix C: Public health effectiveness evidence study selection

Search 1



Search 2


Screening
Title & abstracts screened
(n = 20, 098)
Records screened out
(n = 19,711)
Eligibility
Full-text articles ordered
(n = 387)
Articles excluded from this review
(n = 329)
Included
Studies included in review
(n = 57)
RCTs included in
effectiveness review
(n = 44 trials published across 45 papers)
Qualitative studies included in
qualitative review
(n = 13)

Appendix D: Public health effectiveness evidence tables

D.1 Effectiveness evidence for Migrants

Peragallo Montano, 2019

Bibliographic Reference	Peragallo Montano, Nilda; Cianelli, Rosina; Villegas, Natalia; Gonzalez-Guarda, Rosa; Williams, Weston O; de Tantillo, Lila; Evaluating a Culturally Tailored HIV Risk Reduction Intervention Among Hispanic Women Delivered in a Real-World Setting by Community Agency Personnel.; American journal of health promotion : AJHP; 2019; vol. 33 (no. 4); 566-575

Study details

Study design	Randomised controlled trial (RCT)
Trial registration number	Not reported
Aim	To evaluate the effectiveness of the SEPA intervention to increase HIV/STI prevention behaviours for Hispanic women delivered in a real-world setting
Country/geographical location	Miami, USA
Setting	Participants were recruited from the Miami Refugee Centre, the Florida Department of Health, and public locations in Miami. Assessment and intervention sessions were conducted in a private room at the University of Miami Hospital as participants were familiar with the site and it could be accessed easily.
Inclusion criteria	- Age 18-50 years - Self-identified as a Hispanic woman

	- Sexual activity within the last 3 months - Not having ever participated in a previous SEPA trial
Exclusion criteria	None reported
Method of randomisation	Participants were randomised using a permuted-block
Method of allocation concealment	Not reported
Unit of allocation	Participant
Unit of analysis	Participant
Statistical method(s) used to analyse the data	- Data analyses were conducted among all participants who completed the baseline survey and at least 1 follow-up survey. - Analyses followed an intention-to-treat protocol so participants were analysed in their original assigned treatment condition regardless of SEPA sessions attended - Participant characteristics including demographics, cultural and relationship attributes were described and differences at baseline by study group were assessed using the Wilcoxon rank sum test for continuous variables, chi squared for proportions, and a negative-binomial model for the rate of sex events with condoms used per the total number of sex events. - Summary measures (means and percentages) were generated for dependent variables by study group and time point - Changes in dependent variables at each follow-up as compared to baseline were assessed in separate models by study group. Log binomial models and negative binomial models were used for dichotomous and count/rate-type dependent variables, respectively. To assess significant differences in changes at follow-up by study group, models including both groups and an interaction term between follow-up and group were also conducted.
Attrition	547 individuals were assessed for eligibility; n = 61 were not eligible and n = 166 could not be contacted, leaving n = 320 participants randomised to groups (n = 160 intervention and n = 160 control).

	In the intervention group, n = 32 participants completed the intervention but did not attend follow-up assessments leaving a final intervention sample of n = 128. In the control group, n = 29 participants did not attend follow-up assessments leaving a final control sample of n = 131. Overall, individuals who did not complete follow-up assessments were older (mean age 35.5 years vs 31.6 for completers), and, among those not born in the US, had been in the country longer (mean 8.2 vs 6.0 years). No other statistically significant differences were observed between completers and non-completers. Intervention session attendance was as follows: 3 sessions = 113 (71%); 2 sessions = 18 (11%); 1 session = 3 (2%); 0 sessions = 26 (16%).
Study limitations (author)	- The comparison group received services that overlapped with those provided as part of the SEPA intervention. Comparison clients were offered HIV testing and counselling, and, if needed, services for IPV, resulting in a comparison between competing interventions. Significant improvements in HIV/STI risk behaviours, HIV knowledge, IPV and condom use self-efficacy were observed in the comparison group, and this receipt of overlapping services limited the ability to draw conclusions regarding differential changes in the SEPA group. - The treatment and comparison group both experienced similar high losses to follow-up, which may limit the external validity of results. - Results were mostly self-reported and possibly subject to recall bias - The sample consisted of a geographically secluded portion of this unique population, which may not lend itself to extrapolate to a larger population - Participants in the intervention group received $20 per session as an incentive; this can represent a potential limitation for future implementation
Study limitations (reviewer)	None to add
Source of funding	This study was funded by the Center of Excellence for Health Disparities Research: El Centro, National Center on minority Health and Health Disparities grant P60MD002266

Study arms

Intervention (N = 128)

HIV testing and counselling plus SEPA (Salud/Health, Educacion/Education, Prevencion/Prevention, Autocuidado/Self-care): a culturally-specific community-based group HIV risk reduction intervention for Hispanic women

Control (N = 131)

HIV testing and counselling only

Characteristics

Study-level characteristics

Characteristic	**Study (N = 320)**
Country of birth	
Cuba	% = 54.7
Nicaragua	% = 9.4
Columbia	% = 9.1
US	% = 4.4
Other countries in Central and South America including Honduras, Dominican Republic and Venezuela	% = 22.4

Arm-level characteristics

Characteristic	**Intervention (N = 128)**	**Control (N = 131)**
Age Mean (SD)	35.23 (8.93)	35.73 (9.32)

Characteristic	Intervention (N = 128)	Control (N = 131)
Gender (Female)	n = 128 ; % = 100	n = 131 ; % = 100
Born outside of the US	% = 96.9	% = 94.7
Years living in the US Mean (SD)	8.29 (7.91)	8.06 (6.97)
Education in years Mean (SD)	13.84 (3.22)	13.35 (3.35)
Employed	% = 29.7	% = 29
Has health insurance	% = 44.5	% = 41.2

Outcomes

Study timepoints

- Baseline
- 6 month
- 12 month

Condom use outcomes

Outcome	Intervention, Baseline, N = 128	Intervention, 6 month, N = 128	Intervention, 12 month, N = 128	Control, Baseline, N = 131	Control, 6 month, N = 131	Control, 12 month, N = 131
% of sex events where condoms were used Mean (SD)	30.97 (44.49)	31.75 (41.52)	38.35 (44.6)	30.98 (42.61)	40.17 (44.8)	42.73 (44.41)

Outcome	Intervention, Baseline, N = 128	Intervention, 6 month, N = 128	Intervention, 12 month, N = 128	Control, Baseline, N = 131	Control, 6 month, N = 131	Control, 12 month, N = 131
Any condom use in past 30 days No of events	n = 45 ; % = 35	n = 57 ; % = 44.4	n = 61 ; % = 47.4	n = 52 ; % = 39.7	n = 64 ; % = 49	n = 71 ; % = 53.9
Number of condomless sex events Mean (SD)	7.51 (8.16)	7.31 (7.82)	5.91 (6.38)	6.86 (7.79)	5.89 (8.3)	6.28 (9.1)
Self-efficacy for condom use 7 items; score denotes number of participants scoring above the median of 3.57) No of events	n = 41 ; % = 32	n = 74 ; % = 57.7	n = 79 ; % = 61.8	n = 44 ; % = 33.6	n = 58 ; % = 43.9	n = 64 ; % = 48.7

% of sex events where condoms were used - Polarity - Higher values are better

Any condom use in past 30 days - Polarity - Higher values are better

Number of condomless sex events - Polarity - Lower values are better

Self-efficacy for condom use - Polarity - Higher values are better

Paper reports % only; n's calculated by analyst

HIV/STI knowledge outcomes

Outcome	Intervention, Baseline, N = 128	Intervention, 6 month, N = 128	Intervention, 12 month, N = 128	Control, Baseline, N = 131	Control, 6 month, N = 131	Control, 12 month, N = 131
HIV Knowledge Scores represent number of participants scoring 80% or above No of events	n = 65 ; % = 50.8	n = 101 ; % = 78.9	n = 106 ; % = 82.7	n = 67 ; % = 51.1	n = 77 ; % = 58.5	n = 99 ; % = 75.6

HIV Knowledge - Polarity - Higher values are better

Paper reports % only; n's calculated by analyst

Study details

Rationale/theory/Goal	Hispanic women have been identified as one of the groups most affected by HIV; in 2014 they were almost 4 times more likely to acquire HIV than their non-Hispanic white counterparts. Among Hispanic women, vulnerability to HIV has been shown to be influenced by factors including cultural values, substance use, depression, and intimate partner violence (IPV). Previous research indicates that cultural norms about gender roles and sexuality among Hispanic people interact with IPV risk among women to disproportionately put them at risk for HIV. The cultural values of machismo and marianismo promote controlling and risk taking behaviours for Hispanic men and modesty and obedience for Hispanic women. These norms make it difficult for Hispanic women to talk about their sexuality with others, often limiting their knowledge regarding HIV risk and prevention, and interfere with their ability to communicate with their partners about safer sexual practices. Gender and culturally specific HIV prevention programs are needed to address the prevention of HIV among Hispanic women (p. 567)
Procedures used	- Participants were recruited from the Miami Refugee Center and the Florida Department of Health, as well as by distribution of flyers and outreach at public locations including grocery stores, churches and community organisations, all in areas with a predominantly Hispanic (70%) population.

	- After participants had provided informed consent, trained bilingual female research staff conducted private interviews in the participants' preferred language (Spanish or English) employing a standardised protocol. - Participants were assessed at baseline and subsequently at 6- and 12-months post-baseline. After each assessment, participants were tested for STIs, received HIV testing and counselling, and any women expressing concerns about IPV were provided with appropriate services. (p. 567-568)
Other details	For each assessment interview, participants were compensated $50. Participants also received $20 for each SEPA session attended (p. 569).

Study arms

Intervention (N = 128)

HIV testing and counselling plus SEPA (Salud/Health, Educacion/Education, Prevencion/Prevention, Autocuidado/Self-care): a culturally-specific community-based group HIV risk reduction intervention for Hispanic women

Brief name	SEPA (Salud/Health, Educacion/Education, Prevencion/Prevention, Autocuidado/Self-care) (p. 565)
Rationale/theory/Goal	The SEPA intervention is based on Bandura's Social Cognitive Model and aims to build on outcome expectancies and self-efficacy, particularly by instructing participants regarding the benefits of condom use and eliciting behaviour change. It also builds on Freire's pedagogy by building an atmosphere that encouraged women to engage actively in discussion and activities during the sessions, and affirms the importance of each participants' contribution to the group. SEPA is also culturally specific to Hispanic women. Prior trials evaluating the SEPA intervention have been delivered in controlled environments with highly trained research staff. In this study, the aim was to test intervention implementation in real world settings by community agency personnel. (p. 567-568).

Materials used	No specific materials reported
Procedures used	- SEPA sessions consisted of group discussions, role plays, negotiation skills, partner communication, and skills building. - Participants chose whether sessions were delivered in Spanish or English according to their preference (p. 568) [More details about the SEPA intervention are provided in the Peragallo 2012 evidence table]
Provider	Sessions were facilitated by bilingual Hispanic bicultural facilitators from the Department of Health. All facilitators possessed a degree in education. None had previous SEPA experience which provided real world context for the study. All facilitators received 3 days training from experienced facilitators and received feedback about implementation. A copyrighted manual was also used during training and intervention implementation (p. 568).
Method of delivery	Face to face small group sessions with 6 to 8 participants (p. 568)
Setting/location of intervention	Sessions were conducted in a private room at the University of Miami Hospital (p. 567)
Intensity/duration of the intervention	Three 2.5 hour sessions per week (p. 568)
Tailoring/adaptation	Not reported
Unforeseen modifications	None reported
Planned treatment fidelity	Implementation fidelity for SEPA was assessed using a SEPA Implementation Fidelity Assessment Checklist, which includes techniques that the facilitators must follow to conduct the intervention properly. Two co-investigators who were also former facilitators conducted fidelity ratings with each facilitator; fidelity was conducted until each facilitator adhered to over 80% of the intervention's required behaviours. Interrater reliability was above 90% (p. 568).
Actual treatment fidelity	Overall assessment of the facilitators was rated as excellent (p. 568)

Control (N = 131)

HIV testing and counselling only

Procedures used	- After completing each assessment, control group participants were offered STI testing, HIV testing and counselling, and, for those expressing concerns regarding IPV, access to appropriate services. - After women in the control group completed their 12 month assessment, they were invited to participate in the SEPA intervention. The 3-session intervention was condensed into 1 day for these participants. (p. 568)

Risk of Bias Assessment

Section	Risk of bias	Reason
Domain 1: Bias arising from the randomisation process	Some concerns	No information on allocation concealment, but no baseline differences between groups
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Some concerns	No information on blinding but deviations from intended intervention unlikely. Intention-to-treat analyses used.
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	Some concerns	Failures in implementing the intervention unlikely, but not all participants completed all sessions (only 71% completed all 3 and 16% did not complete any). Impact of session attendance not assessed
Domain 3. Bias due to missing outcome data	Low	No concerns about missing data
Domain 4. Bias in measurement of the outcome	Some concerns	Unclear whether outcome assessors were blinded
Domain 5. Bias in selection of the reported result	Some concerns	Trial not registered

Section	Risk of bias	Reason
Overall bias and Directness	Some concerns	No information on allocation concealment or whether participants and outcome assessors were blinded. Fairly poor adherence: not all participants completed all sessions (only 71% completed all 3 and 16% did not complete any) and impact of adherence not analysed. Trial not registered
	Overall Directness	Partially applicable (US study of Hispanic migrants)

Peragallo, 2012

Bibliographic Reference	Peragallo, Nilda; Gonzalez-Guarda, Rosa M; McCabe, Brian E; Cianelli, Rosina; The efficacy of an HIV risk reduction intervention for Hispanic women.; AIDS and behavior; 2012; vol. 16 (no. 5); 1316-26

Study details

Study design	Randomised controlled trial (RCT)
Trial registration number	Not reported
Study start date	Jan-2008
Study end date	Apr-2010
Aim	To evaluate the efficacy of SEPA on biological (STI incidence), behavioural and social cognitive risk for HIV in Hispanic women.
Country/geographical location	Miami-Dade and Broward County, USA (neighbourhoods with a high proportion of Hispanic immigrants)
Setting	Community settings
Inclusion criteria	- Self-identifying as Hispanic

	- Between 18 and 50 years old - Reporting sexual activity in the last 3 months
Exclusion criteria	None reported
Method of randomisation	Participants were randomised using a permuted-block randomisation procedure
Method of allocation concealment	Not reported
Unit of allocation	Participant
Unit of analysis	Participant
Statistical method(s) used to analyse the data	- Sample size determination: Most effect sizes from the previous SEPA trial were in the medium to large range, although intervention effects on condom use were smaller (d = 0.17). Assuming a 70% retention rate over the course of the study, N = 548 gives sufficient power (>.80) to detect an effect of this size (d = 0.17). - Each hypothesis was tested in a separate intent-to-treat (ITT) generalised estimating equations (GEE) analysis in SPSS 17, which allowed the inclusion of all data over time, provided estimates robust to correlations from repeated measures using an AR-1 covariance structure, and allowed logistic distributions for outcomes. Goodness of fit between linear change (Time × Condition) and quadratic change (Time squared × Condition) over time was evaluated using the Corrected Quasi-likelihood under Independence Model Criterion.
Attrition	- In total 872 women were screened, 119 of whom were not eligible (14%) and 204 of whom were excluded for various reasons (e.g. could not be reached, did not attend baseline session, had schedule conflict, did not have transportation). A total of 548 women (63%) were randomised: 274 were allocated to the intervention condition and 274 were allocated to the waitlist control. - In the intervention group, 119 (43%) attended 5 sessions; 17 (6%) attended 4 sessions; 8 (3%) attended 3 sessions; 11 (4%) attended 2 sessions; 8 (3%) attended 1 session; and 111 (41%) did not attend any intervention sessions. - In the intervention group, 143 (52%) attended the 3-month follow-up; 171 (62%) attended the 6 month follow-up; and 183 (67%) attended the 12 month follow-up

	- In the control group, 202 (74%) attended the 3-month follow-up; 201 (73%) attended the 6 month follow-up; and 198 (72%) attended the 12 month follow-up
Study limitations (author)	- Data on women's behaviour were self-reported and therefore subject to bias due to poor recall or impression management. - Some measures had lower reliability for this sample of Hispanic women than expected based on past research with HIV risk interventions. Participants tended to respond strongly (either positively or negatively) to items on many measures, which led to the skewed response patterns and the need to dichotomise outcomes. Although use of dichotomous variables avoids violations of analysis assumptions, it does not allow for as rich of an analysis as continuous variables and may attenuate intervention effects. - Assessors were not blinded to the participant assignment. Consequently, assessors may have interpreted and/or scored responses from participants differently based on knowledge of assignment. Assessor trainings addressed this potential source of bias and encouraged assessors to be cautious in committing this error. - Study participants appeared to be at relatively low risk for HIV as indicated by a lower than expected incidence of Chlamydia and a modal number of 1 sexual partner over the previous 3-months at baseline and during the study follow-up period.
Study limitations (reviewer)	Intervention adherence was not factored into any analyses. Only 60% of participants attended at least 1 intervention session and only 43% attended all sessions. The study does not sufficiently address this low uptake.
Source of funding	This research was funded by the National Center on Minority Health and Health Disparities (NCMHD) grant 1P60 MD002266—Center of Excellence for Health Disparities Research: El Centro, (Nilda P. Peragallo, Principal Investigator).

Study arms

Intervention (N = 274) SEPA (Salud/Health, Educacion/Education, Prevencion/Prevention, Autocuidado/Self-care): a culturally-specific community-based group HIV risk reduction intervention for Hispanic women

Control (N = 274) Waitlist control

Characteristics

Study-level characteristics

Characteristic	**Study (N = 548)**
Gender (Female)	n = 548 ; % = 100
Born in Columbia	% = 34
Born in Cuba	% = 13
Born in Peru	% = 8
Born in the US	% = 8
Born in the Dominican Republic	% = 6
Born in other nations	% = 5

Arm-level characteristics

Characteristic	**Intervention (N = 274)**	**Control (N = 274)**
Age Mean (SD)	38.74 (8.32)	38.22 (8.73)
Number of years in the US Mean (SD)	11.84 (10.78)	10.99 (9.88)
Employed	n = 92 ; % = 34	n = 88 ; % = 32
Education in years Mean (SD)	13.62 (3.38)	13.11 (3.51)

Outcomes

Study timepoints

- Baseline
- 3 month
- 6 month
- 12 month

Condom use outcomes

Outcome	Intervention, Baseline, N = 274	Intervention, 3 month, N = 143	Intervention, 6 month, N = 171	Intervention, 12 month, N = 183	Control, Baseline, N = 274	Control, 3 month, N = 202	Control, 6 month, N = 201	Control, 12 month, N = 198
Any condom use Number of participants reporting any condom use in prior 3 months No of events	n = 96 ; % = 35	n = 55 ; % = 39	n = 64 ; % = 37	n = 89 ; % = 49	n = 104 ; % = 38	n = 65 ; % = 32	n = 76 ; % = 38	n = 69 ; % = 35
Behavioural intentions to use a condom Scores represent number of participants scoring in the upper quartile on a 4 item scale assessed on 4-point likert scale No of events	n = 155 ; % = 57	n = 102 ; % = 71	n = 134 ; % = 78	n = 144 ; % = 79	n = 165 ; % = 60	n = 129 ; % = 64	n = 153 ; % = 77	n = 162 ; % = 82

Any condom use - Polarity - Higher values are better

Behavioural intentions to use a condom - Polarity - Higher values are better

STI incidence outcomes

Outcome	Intervention, Baseline, N = 274	Intervention, 3 month, N =	Intervention, 6 month, N = 171	Intervention, 12 month, N = 183	Control, Baseline, N = 274	Control, 3 month, N =	Control, 6 month, N = 201	Control, 12 month, N = 198
Chlamydia incidence No of events	n = 1 ; % = 0	*empty data*	n = 1 ; % = 1	n = 1 ; % = 1	n = 3 ; % = 1	*empty data*	n = 0 ; % = 0	n = 3 ; % = 1

Chlamydia incidence - Polarity - Lower values are better

STI incidence not assessed at 3 month follow-up

HIV/STI knowledge outcomes

Outcome	Intervention, Baseline, N = 274	Intervention, 3 month, N = 143	Intervention, 6 month, N = 171	Intervention, 12 month, N = 183	Control, Baseline, N = 274	Control, 3 month, N = 202	Control, 6 month, N = 201	Control, 12 month, N = 198
HIV Knowledge Scores represent number of participants answering 90% or more questions correctly on a 12 item scale No of events	n = 98 ; % = 36	n = 88 ; % = 62	n = 102 ; % = 60	n = 107 ; % = 59	n = 88 ; % = 32	n = 98 ; % = 49	n = 76 ; % = 38	n = 105 ; % = 53

HIV Knowledge - Polarity - Higher values are better

Study details

Brief name	
Rationale/theory/Goal	Hispanic women in the U.S. are particularly at risk for HIV infection. In 2006 the incidence of HIV infection among Hispanic women was almost four times that of their white female counterparts, with heterosexual intercourse being the most common mode of transmission. Various factors increase HIV risk for Hispanic women, including socioeconomic factors such as high rates of poverty and unemployment, high rates of sexually transmitted infections (STIs), immigration and acculturation stress, and cultural values (e.g., machismo and marianismo) that promote inequitable gender norms that make it difficult for women to negotiate safer sexual practices. This unique configuration for HIV risk among Hispanic women has led to a call for the development and evaluation of gender- and culturally-specific HIV prevention interventions (p. 2).
Procedures used	- Participants were recruited through the distribution of flyers and outreach at public places where Hispanic women go frequently (e.g., churches, supermarkets, community organizations). Recruitment efforts were targeted in areas that had a high proportion of Hispanic immigrants. - After recruitment and informed consent, women were interviewed in their preferred language by trained bilingual (Spanish and English) female research staff using a standardised protocol and a structured interview. - Participants were randomised to either the intervention group or a waitlist control group. - Follow-up assessments were conducted at 3, 6 and 12 months post-baseline. (p. 4)
Setting/location of intervention	Group sessions took place in community sites easily accessible to participants (p.
Other details	Participants were compensated $50 per interview and $20 per SEPA session (p. 4)

Study arms

Intervention (N = 274)

SEPA (Salud/Health, Educacion/Education, Prevencion/Prevention, Autocuidado/Self-care): a culturally-specific community-based group HIV risk reduction intervention for Hispanic women

Brief name	SEPA (Salud/Health, Educación/Education, Promoción/Promotion, y/ and Autocuidado/Self-care) (p. 1)
Rationale/theory/Goal	SEPA is an evidence-based intervention informed by the Social Cognitive Theory of behaviour change and was designed to be consistent with Hispanic cultural values. Culturally ascribed gender roles regarding masculinity (machismo) and femininity (marianismo) can make it difficult for Hispanic women to negotiate condom use with their male partners. For example, culturally desirable values that promote women being like the Virgin Mary (marianismo) and therefore asexual, obedient and submissive, can make the negotiation of condoms socially unacceptable for Hispanic women. The intervention targets changes in an array of beliefs and skills relating to reducing sexual risk, including condom use and condom negotiation (p. 2 & 4).
Materials used	No specific materials reported
Procedures used	- Intervention sessions covered HIV/AIDS in the Hispanic community, STIs, HIV/AIDS prevention (e.g., condom use), negotiation and communication with the partner, IPV and substance abuse. - Group facilitators used multiple approaches: hands-on activities, role playing (e.g., negotiating condom use), skill demonstration (e.g., correct condom use, assertive communication), homework to build self-efficacy (e.g., educating peers about sexual risk and condom use), and direct provision of information (e.g., HIV/ STD knowledge, links between alcohol use and sexual risk). - Intervention delivery also focused on the importance of every individual in the group contributing to the knowledge and skills that were generated during sessions, and providing an atmosphere that encouraged participants to engage in discussions and activities. - Groups were conducted in English or Spanish according to the language with which participants expressed they felt most comfortable.

	- At the 6- month follow-up, women in SEPA were invited to a booster session to discuss topics related to the HIV intervention, although only a small proportion (n=31, 11%) attended these sessions. (p. 5)
Provider	Five bilingual and bicultural Hispanic female facilitators with a range of education (bachelors to doctoral) delivered the intervention (p. 5).
Method of delivery	Face to face small group sessions (M = 4.79 women per session, SD = 1.97) (p. 5)
Intensity/duration of the intervention	Five 2 hour sessions plus one optional booster session (p. 5). Session frequency not reported
Tailoring/adaptation	Not reported
Unforeseen modifications	None reported
Planned treatment fidelity	Fidelity was ensured through a facilitator training, intervention manual and standardised PowerPoint presentations that would assist the facilitator in covering the content and activities during each session. The PI of the study also conducted unannounced visits to groups led by each of the facilitators to assess and address fidelity
Actual treatment fidelity	Not reported

Control (N = 274)

Waitlist control

Materials used	No specific materials reported
Procedures used	The control group received a one-session, condensed version of SEPA after their 12-month assessment (p. 5)

Risk of Bias Assessment

Section	Risk of bias	Reason
Domain 1: Bias arising from the randomisation process	Some concerns	No information on allocation concealment but appropriate randomisation procedures and no baseline differences between groups
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Low	No information on participant blinding but deviations from intended intervention unlikely
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	High	Adherence to the intervention was poor (only 43% attended all sessions and 41% did not attend any session) and the impact of adherence was not assessed
Domain 3. Bias due to missing outcome data	Some concerns	Relatively high attrition (48% at 3-months and 33% at 12 months for intervention group) and no comparison of completers vs those lost to follow-up
Domain 4. Bias in measurement of the outcome	Some concerns	Outcome assessors were not blind to condition. All outcomes were dichotomised due to skewed response patterns which did not allow for as rich of an analysis as if they had been retained as continuous variables, and may attenuate intervention effects
Domain 5. Bias in selection of the reported result	Some concerns	Trial not registered
Overall bias and Directness	High	Adherence to the intervention was very poor and the impact of adherence was not assessed. Relatively high attrition (48% at 3-months and 33% at 12 months for intervention group) and no comparison of completers vs those lost to follow-up. Outcome assessors were not blind to condition. All outcomes were dichotomised due to skewed response patterns which did not allow for as rich of an analysis as if they had been retained as continuous variables, and may attenuate intervention effects. Trial not registered
	Overall Directness	Partially applicable (Hispanic immigrants in the US)

Sanchez, 2013

Bibliographic Reference	Sanchez, Jesus; De La Rosa, Mario; Serna, Claudia A; Project Salud: Efficacy of a community-based HIV prevention intervention for Hispanic migrant workers in south Florida.; AIDS education and prevention : official publication of the International Society for AIDS Education; 2013; vol. 25 (no. 5); 363-75

Study details

Trial registration number	Not reported
Study start date	Nov-2008
Study end date	Mar-2010
Aim	To assess the efficacy of a community-based HIV prevention pilot intervention in reducing risky sexual behaviours and enhancing factors (i.e., HIV knowledge) for HIV preventive behaviours among Latino migrant workers.
Setting	South Florida, USA Recruited by snowball sampling design from neighbourhoods and migrant camps, screened by outreach workers
Inclusion criteria	(1) be of Latino origin; (2) 18 years of age or older; (3) have a “farm card”; (4) self-reported one or more episodes of unprotected sex in the past three months;
Exclusion criteria	Not reported
Method of randomisation	Participants were randomly assigned to the A-SEMI or HPC interventions using a computer-generated randomization table.
Method of allocation concealment	Not reported
Unit of allocation	Individual
Unit of analysis	Individual

Statistical method(s) used to analyse the data	Intervention effects were analysed with logistic regression to compute adjusted odds ratios (AORs) for dichotomous outcomes and linear regression to compute adjusted means and mean differences for continuous variables. Each regression model included the corresponding baseline measure as a covariate in the analysis as well as a measure of intraclass correlation. To assess the A-SEMI intervention effects for the entire 9-month follow-up period, authors used logistic and linear generalized estimating equation regression models to control for repeated within-person measurements. These models incorporated the study conditions as well as covariates and outcomes. Authors adjusted models for the corresponding baseline measure and covariates to obtain AORs and adjusted mean differences. Authors computed the 95% confidence interval (CI) and the corresponding p value. For each model, we calculated adjusted means and standard errors.
Attrition	Of the 290 randomized participants, 145 were allocated to the A-SEMI intervention and the other 145 to the HPC intervention. Data on 12 study participants (4%) were incomplete and therefore not included in data analysis. Results are based on the remaining 278 study participants, of which 140 were assigned to the A-SEMI intervention and 138 to the HPC intervention.
Study limitations (author)	Study did not test participants for HIV and other STIs. Behavioural risk data in the study were self-reported and subject to recall bias but authors attempted to minimize this concern through the use of calendaring techniques designed to maximize recall. Study may not be representative of all LMWs in South Florida but authors attempted to increase the representativeness of the sample by selecting study participants from different neighbourhoods and camps within the Homestead/Florida City area.
Study limitations (reviewer)	Study lacks sufficient information on randomisation. Allocation concealment and blinding were not reported
Source of funding	Research was funded by the National Institute on Minority Health and Health Disparities (Award # P20MD002288).

Study arms

Adapted Stage-Enhanced Motivational Interviewing (A-SEMI) (N = 140) The A-SEMI intervention was culturally adapted in collaboration with the Latino migrant worker (LMW) community. It was guided by the theoretical foundations of social cognitive theory, enhanced with peer education and motivational-enhancing therapy, with the objective of producing a stronger, more sustained HIV risk reduction effect among LMWs.

The Health Promotion Condition (HPC) (N = 138)

The Health Promotion Condition (HPC) served as the comparison condition and targeted specific health issues of special relevance to LMWs, including general health strategies such as hygiene and living in crowded conditions, first aid, and skin problems

Characteristics

Study-level characteristics

	Study (N = 278)
Ethnicity all Latino	

Arm-level characteristics

	Adapted Stage-Enhanced Motivational Interviewing (A-SEMI) (N = 140)	**The Health Promotion Condition (HPC) (N = 138)**
Age Mean/SD	36.6 (4.41)	39.4 (3.91)
Gender		
Male	n = 73; % = 52	n = 78; % = 57
Female	n = 67; % = 48	n = 60; % = 44
Country of origin		
Mexico	n = 62; % = 44.2	n = 58; % = 42
Guatemala	n = 26; % = 18.6	n = 30; % = 21.8
Honduras	n = 52; % = 37.2	n = 50; % = 36.2

	Adapted Stage-Enhanced Motivational Interviewing (A-SEMI) (N = 140)	The Health Promotion Condition (HPC) (N = 138)
Education		
No formal education	n = 40; % = 28.6	n = 37; % = 26.8
Less than high school degree	n = 93; % = 66.4	n = 98; % = 71
Greater than high school degree	n = 7; % = 5	n = 3; % = 2.2
History of sexually transmitted infections (STIs)		
1 Sexual Partner in 90 days prior to Baseline	n = 104; % = 74	n = 112; % = 81
2 or more Sexual Partners in 90 days prior to Baseline	n = 36; % = 26	n = 26; % = 19

Outcomes

Study timepoints	3 (month) Baseline to 3 months assessment 9 (month) 3 to 9 months assessment

Consistent condom use

Self-reported consistent condom use, the primary outcome, was defined as use of a condom during every episode of vaginal intercourse in the 30 days and 90 days prior to baseline and at the 3- and 9-month follow-up assessments.

Authors selected consistent condom use as the primary outcome for the study because of its demonstrated effectiveness against HIV transmission

HIV prevention knowledge

HIV prevention knowledge was measured using an 8-item scale (α = .78), with higher scores indicating greater knowledge about HIV.

Perceived barriers

Perceived barriers to condom use were measured using a 29-item scale (α = .95), with higher scores indicating fewer perceived barriers.

Condom use self-efficacy

Condom use self-efficacy was measured with a 9-item scale (α =.90) reflecting participants' confidence in their ability to properly use condoms, with higher scores indicating greater self-efficacy.

Effects of A-SEMI and HPC Interventions for Latino Migrant Workers on Condom Use Behaviours	**Adapted Stage-Enhanced Motivational Interviewing (A-SEMI)**		**The Health Promotion Condition (HPC)**	
	3 (month)	**9 (month)**	**3 (month)**	**9 (month)**
	N = 140	N = 140	N = 138	N = 138
Consistent condom use in past 90 days				
No of events	n = 63; % = 45.3	n = 54; % = 38.2	n = 24; % = 17.4	n = 21; % = 15.4
Consistent condom use in past 30 days				
No of events	n = 72; % = 51.6	n = 62; % = 44.5	n = 33; % = 23.8	n = 34; % = 24.5
Condom use at last sex				
No of events	n = 83; % = 59.3	n = 70; % = 50.3	n = 44; % = 31.6	n = 48; % = 34.6
Effects of Interventions on Psychosocial Mediators of Preventive Behaviour, Baseline to 9-Month Assessment	**A-SEMI (baseline assessment)**	**HPC (baseline assessment)**	**Baseline to 9-Month Assessment (relative change)**	
	Mean (SD)	Mean (SD)	% (95% CI)	
HIV Prevention Knowledge (Range = 1–8)	6.19 (1.11)	6.34 (1.08)	2.82 (1.65, 4.06), p=0.009	
Perceived Barriers to Condom Use (Range = 29–116)	67.15 (14.86)	65.16 (13.39)	13.03 (8.65, 9.12), p<0.001	

Condom Use Self-Efficacy (Range = 9–27)	20.57 (4.02)	19. 88 (5.13)	9.78 (7.14, 11.66), p<0.001

Outcome on gender roles not extracted for this review

Study details

Brief name	Project Salud: Efficacy of a community-based HIV prevention intervention for Hispanic migrant workers in South Florida
Rationale/theory/Goal	To assess the differential efficacy of an Adapted Stage-Enhanced Motivational Interviewing (A-SEMI) condition compared to a Health Promotion Comparison (HPC) condition for producing reductions in HIV risk and increased health behaviours among LMWs.
Procedures used	The A-SEMI intervention was culturally adapted in collaboration with the Latino migrant worker (LMW) community. Eight focus groups consisting of 83 community members and key community partners were conducted at the offices of the Farmworkers Association of Florida (FWAF) to discuss the factors that increased their HIV risks. Two trained community health workers (CHWs) delivered A-SEMI in Spanish during four 2.5 hour interactive group sessions that took place at the FWAF office in Homestead, Florida, on two consecutive weekends. Based on their schedule, group participants decided whether they wanted to have two sessions—one in the morning and one in the afternoon on the same day (i.e., Sunday) or on different days (i.e., one session on Saturday and another on Sunday). On average, each group was composed of six participants. Session 1 of A-SEMI focused on developing group cohesion and addressing HIV education. Session 2 was devoted to motivational enhancement and goal setting. Study subjects were helped in developing a specific and relevant personal risk-reduction plan that could be realistically accomplished with a sense of mastery and success. Session 3 focused on increasing commitment to and empowerment for safer sex. Session 4 focused on identifying high risk situations and negotiation skills through problem solving, assertiveness, and communication. The Health Promotion Condition (HPC) served as the comparison condition and targeted specific health issues of special relevance to LMWs, including general health strategies such as hygiene and living in crowded conditions, first aid, and skin problems.
Provider	Community health workers (CHWs)
Method of delivery	Adapted Stage-Enhanced Motivational Interviewing (A-SEMI) was an interactive group session composed of: 1) A Peer Counselling Intervention Component (PCIC): Community members—especially in isolated and hard to reach social environments—identify their peers as reliable and preferred sources of information on sexuality-related topics, including sexually transmitted infections and HIV.

	2) Motivational Enhancing Therapy (MET): places great emphasis on actively engaging participants in developing their own risk-reduction strategies and hierarchies of safety, rather than prescribing specific strategies as in more traditional cognitive behavioural interventions.
Setting/location of intervention	Offices of the Farmworkers Association of Florida (FWAF), Florida
Intensity/duration of the intervention	3 and 9 months

Study arms

Adapted Stage-Enhanced Motivational Interviewing (A-SEMI) (N = 140) The design of the A-SEMI intervention was guided by the theoretical foundations of social cognitive theory, enhanced with peer education and motivational-enhancing therapy, with the objective of producing a stronger, more sustained HIV risk reduction effect among Latino migrant workers (LMWs).
The Health Promotion Condition (HPC) (N = 138) The Health Promotion Condition (HPC) served as the comparison condition and targeted specific health issues of special relevance to LMWs, including general health strategies such as hygiene and living in crowded conditions, first aid, and skin problems

Risk of Bias Assessment

Section	Risk of bias	Reason
Domain 1a: Bias arising from the randomisation process	Some concerns	No information on allocation concealment
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Some concerns	There were differences between the groups at baseline on whether they had a primary physician.

Section	Risk of bias	Reason
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	Low	Deviations from intended intervention unlikely
Domain 3. Bias due to missing outcome data	Some concerns	Participants' attendance was high: 88.3% of participants completed all four ASEMI sessions, and 86.2% completed all four HPC sessions, pilot study.
Domain 4. Bias in measurement of the outcome	Low	Appropriate outcome measures used
Domain 5. Bias in selection of the reported result	Low	Trial registered
Overall bias and Directness	Some concerns	Insufficient information on randomisation and allocation concealment
	Overall Directness	Partially Applicable (US Latino migrant workers)

D.2 Effectiveness evidence for people who are homeless

Tucker, 2017

Bibliographic Reference Tucker, Joan S.; D'Amico, Elizabeth J.; Ewing, Brett A.; Miles, Jeremy N.V.; Pedersen, Eric R.; A group-based motivational interviewing brief intervention to reduce substance use and sexual risk behavior among homeless young adults; Journal of Substance Abuse Treatment; 2017; vol. 76; 20-27

Study details

Study design	Randomised controlled trial (RCT)
Trial registration number	Not reported

Aim	To conduct a pilot trial of AWARE, a brief group-based motivational interviewing intervention addressing sexual risk behaviour and alcohol and drug use among homeless young adults.
Country/geographical location	Hollywood and Venice, Los Angeles, USA
Setting	Two drop-in centres for homeless youth
Inclusion criteria	- Age 18-25 years - Seeking services at one of the two drop-in centres - Planned to be in the study area for the next month - Could be reached by email or phone for follow-up
Exclusion criteria	None reported
Method of randomisation	Group randomisation. The field period was divided into four 16-week phases and individuals were assigned to groups in each of these phases based on the drop-in centre where they were present during recruitment hours. The two drop-in centres alternated across phases in serving as the “intervention site” or “control site,” with each drop-in centre having a total of two intervention phases and two control phases. An individually randomized trial design was initially considered for this study, with individuals randomly assigned to condition within drop-in centre. However, implementation challenges did not make this design a feasible option and there was concern about contamination across conditions. A group-randomized design for this evaluation has distinct advantages, and the comparability of the intervention and control groups was maximised by having each drop-in centre serve as both intervention and control site on an alternating basis (with a wash-out period between the intervention and control phases within site) and using the same procedures at each drop-in centre to identify and recruit participants.
Method of allocation concealment	N/A
Unit of allocation	Study site (drop-in centre)
Unit of analysis	Participant

Statistical method(s) used to analyse the data	- The treatment and control groups were compared at baseline on demographic characteristics and the outcome of interest using t-tests for continuous variables and chi squared tests for categorical variables. - For each outcome, the overall difference in the treatment and control groups was evaluated at follow-up using a multivariable regression model, which controlled for covariates (such as age, race, sexual orientation, and treatment site) and the baseline value of the outcome being evaluated. A generalised linear modelling approach was used for continuous outcomes. - A secondary analysis was conducted on the main sex-related outcome of interest, proportion of unprotected sex in the past 3 months, restricting the sample to individuals who were sexually active at both assessments. Paired t-tests were used to evaluate changes from baseline to follow up on two subsamples of participants: those with 1 partner at both assessments, and those with 2+ partners at both assessments.
Attrition	Of the 214 individuals screened for eligibility, 2 were ineligible, 1 refused participation, and 11 were identified as repeater, resulting in a final sample of n = 200. Of the intervention participants, 21% attended one AWARE session, 27% attended 2 sessions, 4% attended 3 sessions and 48% attended all 4 sessions. Extensive tracking and locator information was obtained from participants at baseline and follow-up surveys were completed with 91% of participants overall. There was a higher follow up rate among intervention participants (95%) than control participants (86%); p = .032.
Study limitations (author)	- The study relied on self-reported behaviour, the limitations of which are well-known (although possibly exaggerated; Chan, 2008). - Although the evaluation was conducted in agencies located in two distinct areas of Los Angeles County, it is unclear whether results would generalize to other agencies located in other geographic regions. - The sample size for this pilot study of 100 per group resulted in insufficient power to detect smaller, but nonetheless potentially important group differences.

	- Another limitation is the 3 month follow-up period; further research is needed to determine whether the short-term effects that were found are sustained over a longer period of time. - In this pilot study, several potential outcomes and models were assessed and therefore there is risk of type I error rate inflation. Thus, p-values should be treated with the appropriate degree of caution, and replication in a larger sample would provide more confidence in the results.
Study limitations (reviewer)	None to add
Source of funding	Grant R34 DA034813 from the National Institute on Drug Abuse (PI: Joan Tucker)

Study arms

Intervention (N = 100)

Usual care plus AWARE; a brief, innovative, group motivational interviewing intervention designed to reduce alcohol and other drug use (AOD) and sexual risk behaviour among homeless young adults aged 18-25 years.

Control (N = 100)

Usual care

Characteristics

Study-level characteristics

Characteristic	**Study (N = 200)**
Age Mean (SD)	21.81 (1.87)
Gender (Male)	% = 73
Non-Hispanic white	% = 31
African American	% = 25

Characteristic	Study (N = 200)
Hispanic	% = 24
Multiracial / other	% = 21
Heterosexual	% = 79

Outcomes

Study timepoints

- Baseline
- 3 month

Condom use outcomes

Outcome	Intervention, Baseline, N = 100	Intervention, 3 month, N = 95	Control, Baseline, N = 100	Control, 3 month, N = 86
Proportion of unprotected sexual events In the prior 3 months Mean (SD)	0.47 (0.46)	0.42 (0.45)	0.44 (0.45)	0.41 (0.47)
Condom use self-efficacy Mean (SD)	2.15 (0.7)	2.44 (0.56)	2.18 (0.7)	2.31 (0.63)

Proportion of unprotected sexual events - Polarity - Lower values are better

Condom use self-efficacy - Polarity - Higher values are better

Study details

Rationale/theory/Goal	Rates of HIV infection among homeless youth range from around 3-25% across US studies (Medlow et al 2014), and 40-70% of homeless youth report engaging in unprotected sexual intercourse (Tucker et al 2012; Valente & Auerswald 2013). Alcohol and drug (AOD) use is associated with increased sexual activity and risk sex among homeless youth. Given the interrelated nature of AOD use and risky sex, interventions will likely be more effective if they simultaneously address both types of behaviour than either one alone. Risk reduction programs for homeless youth are needed that address both AOD use and sexual risk behaviour, are evidence based, and can be feasibly delivered in the settings where these youth typically seek services (p. 2).
Procedures used	- Participants in both conditions were recruited by advertising the study at the drop-in centres and soliciting volunteers. - At each recruitment visit to the drop-in centre, a sign-up sheet was used for individuals to indicate their interest in participating. - Depending upon the number of sign-ups, individuals were randomly selected from the sign-up sheet until the recruitment goal for the visit was met. - Individuals were then screened for eligibility, and those who were eligible were asked to provide written consent and complete the baseline survey. - Recruitment of intervention group participants occurred once a week, on the day when the program was being delivered at the drop-in centre. - Because each AWARE session was designed to be free standing, and individuals could attend the sessions in any order, those in the intervention condition attended their first AWARE session shortly after completing the baseline survey. All recruitment was completed during the first half of each 16-week phase in order to give participants at least two opportunities to complete each of the four sessions. - All screened individuals received written information on HIV prevention and a resource guide that listed free and low-cost services for homeless youth in the study area. - Participants completed self-administered baseline and 3 month follow-up assessments; research staff were available to participants who needed assistance.

	(p. 6)
Other details	Participants received $20 for completing the baseline survey and $30 for completing the follow up survey. Intervention participants received $5 for each of the 4 sessions and an additional $15 for attending all 4 sessions. Free snacks and condoms were available at each session.

Study arms

Intervention (N = 100)

Usual care plus AWARE; a brief, innovative, group motivational interviewing intervention designed to reduce alcohol and other drug use (AOD) and sexual risk behaviour among homeless young adults aged 18-25 years.

Brief name	AWARE (p. 1)
Rationale/theory/Goal	AWARE was designed to address the substantial need for risk reduction interventions for homeless youth that are both intensive enough to address the multiple and interrelated risk behaviours that most homeless youth exhibit and feasible to integrate into settings such as drop-in resource centres where these young people routinely seek services (p. 3). The AWARE intervention is based on Social Learning Theory, Decision Making Theory, and Self-Efficacy Theory. It includes components that have been utilised in effective programs for homeless and other at-risk youth such as targeting multiple, interrelated behaviours, using interactive techniques that allow for active learning, reinforcing skills, providing personalized feedback, delivering the curriculum in a group format which allows the facilitator to capitalise on prosocial processes (e.g., reinforcement for behaviour change, norm change, vicarious learning), and presenting the materials using a motivational interviewing approach. The AWARE curriculum involves sharing basic information on HIV/STI transmission and the effects of AOD use on the brain; providing condom use skills training; providing normative feedback on AOD use and HIV-risk behaviour among young adults; discussing unrealistic beliefs about AOD use and HIV risk; discussing potential benefits of both cutting down and stopping risky behaviours; and discussing risky situations and coping strategies (e.g., avoiding certain high-risk

	situations, protecting yourself when drinking or having sex). All sessions include discussion of the connection between AOD use and risky sexual behaviour. All AWARE participants also had access to 'usual care' at the drop-in centre in terms of all basic services, case management, and other programs that were available at the time of the study. (p. 5)
Materials used	No specific materials reported
Procedures used	No information on procedures specific to intervention sessions
Provider	Two project staff, not affiliated with the drop-in centres, delivered the intervention sessions. One was a Bachelor level facilitator who delivered the curriculum and the other provided assistance (e.g. distributing materials). Facilitator training included a one-day workshop on MI and practice sessions for each of the four sessions (p. 6)
Method of delivery	Face to face group sessions
Setting/location of intervention	Two drop-in centres for homeless youth (p. 4)
Intensity/duration of the intervention	Four x 45 minute sessions that rotated on a weekly basis throughout a 16 week study period (p. 5).
Tailoring/adaptation	None reported
Unforeseen modifications	None reported
Planned treatment fidelity	Sessions were recorded and all session recordings were reviewed by the first 2 authors to determine adherence to protocol content and provide weekly supervision to the facilitator. Using standard fidelity procedures, twenty-eight percent (n = 16) of the sessions were coded using the Motivational Interviewing Treatment Integrity scale (MITI 3.1; Moyers, Martin, Manuel, Miller & Ernst, 2010) to measure MI adherence in delivering the protocol content, with one quarter of these sessions (n = 4) being independently coded by two coders (p. 8).
Actual treatment fidelity	Average global scores across sessions on the MITI were all over 4 (competent), with all double-coded global scores within one point of each other. Adherence to protocol content across sessions was 93.7% (p. 9).

Control (N = 100)

Usual care

Materials used	No specific materials reported
Procedures used	The control group received usual care which included access to all of the basic services (e.g. food, hygiene), case management, and programs that were available at the drop in centre at the time of the study (p. 5)
Provider	Not reported
Setting/location of intervention	Two drop-in centres for homeless youth (p. 4)
Intensity/duration of the intervention	Not reported
Tailoring/adaptation	N/A
Unforeseen modifications	N/A
Planned treatment fidelity	N/A

Risk of Bias Assessment

Section	Risk of bias	Reason
Domain 1: Bias arising from the randomisation process	Some concerns	This was a crossover RCT so participants were randomly allocated to intervention or control group depending on which of 2 services were accessed at which time
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Some concerns	No information on blinding; unclear whether participants attending one service could also access services at the other site

Section	Risk of bias	Reason
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	Some concerns	Intervention adherence was low: only 48% attended all 4 sessions and 48% attended only 1 or 2 sessions. Impact of intervention attendance on outcomes was not assessed
Domain 3. Bias due to missing outcome data	Some concerns	Overall follow-up rates were high (91%) but follow-up was significantly higher in the intervention group (95%) than the control group (86%)
Domain 4. Bias in measurement of the outcome	Low	Appropriate assessment procedures and outcome assessments were self-administered
Domain 5. Bias in selection of the reported result	Some concerns	Trial not registered
Overall bias and Directness	High	Randomised cross-over trial with no information on blinding. Intervention adherence was low and impact of intervention attendance on outcomes was not assessed. Overall follow-up rates were high (91%) but follow-up was significantly higher in the intervention group (95%) than the control group (86%). Trial not registered
	Overall Directness	Partially applicable (US study)

D.3 Effectiveness evidence for Young People

Calderon, 2013

Bibliographic Reference	Calderon, Yvette; Cowan, Ethan; Leu, Cheng-Shiun; Brusalis, Christopher; Rhee, John Y; Nickerson, Jillian; Leider, Jason; Bauman, Laurie J; A human immunodeficiency virus posttest video to increase condom use among adolescent emergency department patients.; The Journal of adolescent health : official publication of the Society for Adolescent Medicine; 2013; vol. 53 (no. 1); 79-84

Study details

Trial registration number	www.clinicaltrials.gov (identifier NCT00851539).
Study start date	Nov-2009
Study end date	Jun-2010
Aim	To compare the effectiveness of a theory-based HIV post-test educational video tool with in-person post-test HIV counselling in promoting safer sex behaviours among adolescent patients of an urban Emergency Department (ED).
Country/geographical location	New York, US
Setting	Emergency Department of a hospital in New York
Inclusion criteria	- Sexually active - Aged 15–21 years - Proficient in English.
Exclusion criteria	- Medically unstable or in obvious pain - Unable to understand the consent process, - Did not speak English - Were known to be HIV-positive, or had been tested within the past 6 months
Method of randomisation	Randomisation was conducted using a computer-generated block randomisation scheme obtained from http://www.randomization.com.
Method of allocation concealment	The randomisation scheme was kept in an opaque envelope that was not opened until patients signed informed consent.

Unit of allocation	Participants
Unit of analysis	Participants
Statistical method(s) used to analyse the data	Descriptive statistics of baseline characteristics were generated separately for counselling and video treatment groups. To compare the difference between the two study groups on the baseline characteristics, a t-test was used for continuous variables and chi-square test for categorical variables. The primary analyses compared the effect of the video intervention with in-person counselling on three primary outcomes: intention to use condom, condom use self-efficacy, and condom outcome expectancies using the generalized linear model with identity link function. To account for the within-subject correlation owing to multiple assessments on the same participant, the generalized estimating equation method was used with independent working correlation to estimate the regression coefficients and standard errors. The independent variables included in each regression model were the video intervention indicator (versus in-person counselling), post-intervention time indicator (versus preintervention), and the interaction of time and intervention indicator. The Stage of Change variable was included in the model because it showed a difference at baseline between groups. The regression coefficient corresponding to the interaction term was used to test the intervention effect; it represents the differential mean improvement between groups (i.e., video intervention and in-person counselling). The Holm step-down procedure was used to adjust for multiple comparisons.
Uptake	Of 215 eligible participants identified, 203 (94.4%) agreed to participate
Attrition	Not reported but note that pre- and post-intervention assessments were done within the same session.
Study limitations (author)	The intervention effects are limited to youth from the Bronx. There was a statistically significant difference in the 'Stage of Change' assessment at baseline, although this was controlled for in the primary analysis.
Study limitations (reviewer)	The post-test assessment was immediately after the intervention and there are limitations to repeated assessment with the same measures in a short time period.
Source of funding	Funding for this study was provided by U.S. National Institutes of Health Institute of Child Health and Human Development grant 5K23-HD054315.

Study arms

Intervention Video (N = 102)

A brief HIV prevention video focusing on condom use, negotiating condom use, and how to use a male condom, female condom and dental dam. It also included a video tailored to the participants' stage of change (as assessed at baseline) and focused on either negative consequences of risky sexual behaviours or positive consequences of consistent condom use.

Control Counselling (N = 101)

In-person HIV post-test counselling delivered by a trained HIV counsellor.

Characteristics

Arm-level characteristics

	Intervention Video (N = 102)	**Control Counselling (N = 101)**
Age Age < 18 years	20.6%	25.7%
Gender (female)	60.8%	55.4%
Ethnicity		
Hispanic	59.8%	57.4%
American Indian	1%	1%
Asian	2.9%	1%
Black	34.3%	42.6%
White	8.8%	3%

	Intervention Video (N = 102)	Control Counselling (N = 101)
Other	52.9%	52.5%
Vaginal sex in the past year	97.1%	96%

Outcomes

Study timepoints	Immediately post-intervention

Condom use outcomes

	Intervention Video	Control Counselling
	Post-intervention	**Post-intervention**
	N = 102	N = 101
Condom use self-efficacy Adjusted mean improvement; adjustment for baseline stage of change Adapted from Dilorio et al *Polarity: Higher values are better*	.23	-.03

TIDieR Checklist

Study details

Procedures used	Eligible youth attending the adult (aged 18-21 years) or paediatric (aged 15-17 years) Emergency Department were invited to participate. All participants completed a baseline questionnaire then viewed a validated HIV pre-test educational video, after which they were offered an optional HIV test. Participants were then randomised to one of two groups. For participants who accepted HIV

	testing, the intervention or control procedures were delivered after testing while they were waiting for their results. For participants who declined HIV testing, the intervention or control procedures were delivered immediately. All participants then competed the post-intervention measures. After completing post-intervention measures, those in the intervention group who had accepted testing also received standard in-person post-test counselling when they received their results.
Provider	Trained research assistants completed recruitment and assessment procedures. Trained HIV counsellors provided in-person counselling for participants in the control counselling group and for intervention group participants post-intervention.
Setting/location of intervention	Adult and paediatric ED

Study arms

Video Intervention (N = 102)

Rationale/theory/Goal	Based on the Theory of Reasoned Action and the Stages of Change (SOC) theory. Assumes that individuals are at different stages of a continuum when making decisions to change behaviours: precontemplation, contemplation, preparation for action, action, and maintenance. The intervention is tailored to the persons' stage of change to ensure they are most open to risk-reduction messages.
Materials used	A series of youth-friendly post-test HIV prevention videos
Procedures used	After the HIV testing session, participants randomised to the video intervention group were shown a series of three video vignettes. For intervention group participants who declined HIV testing (15.7%), they were shown the videos immediately after completing baseline assessments. The first video was shown to all intervention participants and depicted an adolescent couple discussing whether to use condoms and was designed to model how to advocate for using couples with one's partner. The second video was tailored toward the participants SOC as assessed at baseline. Those in the “pre-contemplation” and “contemplation” stages viewed a video on the negative consequences of risky behaviours. The video depicted a pair of teens ending their relationship after discovering that they both had contracted HIV. Participants in the “preparation,” “action,” or “maintenance” stages viewed a video that reinforced the positive consequences of consistent condom use. The third video demonstrated how to use a male condom, a female condom, and a dental dam and was shown to all intervention participants.
Intensity/duration of the intervention	3 videos each lasting 2 to 3 minutes.
Tailoring/adaptation	The first and third videos in the sequence remained the same for all participants, but the second video was tailored with respect to target message content and style, depending on the participants' stage of change which was determined through pre-intervention measures.

Unforeseen modifications	None reported; unlikely
Planned treatment fidelity	Not reported
Actual treatment fidelity	Not reported

Counselling Control (N = 101)

Rationale/theory/Goal	Standard HIV post-test counselling
Procedures used	After the HIV testing session, participants randomised to the counselling control group received standard in-person, age appropriate, culturally sensitive HIV prevention counselling while waiting for their test results. For control group participants who declined HIV testing (15.9%), they received counselling immediately after completing baseline assessments. As part of the counselling, participants were given information on how to interpret HIV test results, partner notification, and condom use.
Provider	Trained HIV counsellors provided in-person counselling for participants in the control counselling group.
Method of delivery	Face to face
Tailoring/adaptation	None reported
Unforeseen modifications	None reported; unlikely
Planned treatment fidelity	Not reported
Actual treatment fidelity	Not reported

Risk of Bias Assessment

Section	Risk of bias	Reason
Domain 1a: Bias arising from the randomisation process	Low	RCT, allocation concealment described, no baseline differences between groups.
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Low	Deviations from the intended intervention not described. Participants and assessors unaware of allocation, appropriate analysis.
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	Low	Deviations from the intended intervention were unlikely and participants were analysed in the groups to which they were assigned
Domain 3. Bias due to missing outcome data	Low	No concern over missing outcome data
Domain 4. Bias in measurement of the outcome	Low	Measurement was the same across arms. Outcome assessment not aware of the interventions received by study participants.
Domain 5. Bias in selection of the reported result	Low	Trial registered
Overall bias and Directness	Low	
	Overall Directness	Partially applicable (US study)

Champion, 2012

Bibliographic Reference Champion, Jane Dimmitt; Collins, Jennifer L; Comparison of a theory-based (AIDS Risk Reduction Model) cognitive behavioral intervention versus enhanced counseling for abused ethnic minority adolescent women on infection with sexually transmitted infection: results of a randomized controlled trial.; International journal of nursing studies; 2012; vol. 49 (no. 2); 138-50

Study details

Trial registration number	ClinicalTrials.gov Identifier: NCT01387646
Study start date	Jul-2005
Study end date	Mar-2008
Aim	To evaluate the effects of a theory based (AIDS Risk Reduction Model) cognitive behavioural intervention versus enhanced counselling for abused ethnic minority adolescent women on STI infection at 6- and 12-months follow-up.
Country/geographical location	Southwestern US
Setting	Community-based clinics
Inclusion criteria	- Ethnic minority women - Aged 14-18 years - History of STI or abuse (emotional, physical or sexual)
Exclusion criteria	Not reported
Method of randomisation	Participant selection of “intervention” start-times from several dates within two weeks of enrolment, blinded to group status. Intervention and control group “intervention” start-times were pre-assigned to dates randomized and balanced during the enrolment period across time of day, days of the week, weeks of the month, and months of the year.
Method of allocation concealment	Not reported
Unit of allocation	Participant
Unit of analysis	Participant

Statistical method(s) used to analyse the data	Analyses of intervention effects were performed on an intent-to-treat basis. In secondary analyses the effect of participation in any or no intervention session was examined. Prior to fitting multivariate models, dichotomous analyses were conducted to evaluate the relationship between study group and STI infection. After achieving a thorough understanding of the important relationships observed in the data, analyses proceeded using multivariate modelling of the intervention impact. Multivariable logistic models were fit, controlling for confounders based on theoretical considerations and relationships observed in bivariate data analyses. Separate longitudinal analyses were conducted for the 0-6, 6-12 and 0-12 month follow-ups, to assess the changing impact of the intervention over time. Previous analyses identified substance use and abuse history as powerful predictors of STI infection risk so the present analyses evaluated these variables as effect modifiers and confounders. All models examining the association between study group and STI infection tested for effect modification by age, ethnicity, any substance use (alcohol, drugs or cigarettes) and physical or sexual abuse history. Current school attendance, history of runaway and emotional abuse history were initially included in these analyses however were removed due to insignificant contributions to the model. Effect modification was considered to be present based on a nominal global p-value of .05. The analytic package used for statistical analysis was PASW Statistics, Version 18.
Uptake	N=1150 potential participants were provided an information sheet about the study. N=231 were excluded for not meeting inclusion criteria. N=43 declined to participate and n=317 were excluded for other reasons (not reported in paper).
Attrition	Participants were randomized into intervention (n=199, 48.7%) and control (n=210, 51.3%) arms. High follow-up rates were achieved at 6- (93.0%) and 12-month (93.7%) follow-ups. These adjusted rates account for participants that could not be contacted because they had moved out of the city/state, had no contact numbers/addresses or were incarcerated at 6 (16.4%) or 12 (15.4%) month follow-ups. Unadjusted rates at follow-up for 6- (78%) and 12- (81%) months were high.
Study limitations (author)	Study limitations include those inherent in efficacy trials of behavioural interventions. These include the homogeneity of the study sample and controlled conditions of the randomized controlled trial. These characteristics of efficacy trials limit effectiveness in translation of interventions to a heterogeneous population on a community level.
Study limitations (reviewer)	None to add
Source of funding	National Institute on Drug Abuse R01DA19180

Study arms

Intervention (N = 199)

Project IMAGE, a behavioural intervention for ethnic minority adolescents with a history of STIs and abuse. Includes workshops, support group sessions and individual risk reduction counselling sessions.
Control (N = 210) Waitlist control.

Characteristics

Arm-level characteristics

	Intervention (N = 199)	**Control (N = 210)**
Age; mean	16.5	16.42
Gender; female	100%	100%
Ethnicity		
Mexican-American	n = 171 ; % = 85.9	n = 171 ; % = 81.4
African-American	n = 28 ; % = 14.1	n = 39 ; % = 18.6

Outcomes

Study timepoints	6 (month) 12 (month)

STI infection outcomes

	Intervention		Control	
	6 (month)	**12 (month)**	**6 (month)**	**12 (month)**
	N = 155	N = 166	N = 163	N = 167
STI infection *Polarity: Lower values are better*	n = 0 ; % = 0	n = 6 ; % = 3.6	n = 11 ; % = 6.6	n = 13 ; % = 7.8

TIDieR Checklist

Study details

Procedures used	African-American and Mexican-American adolescent women seeking health care at a health district clinic were provided with an information sheet concerning the study. Those indicating interest were assessed for eligibility and informed consent procedures were completed. Baseline assessments were conducted using face to face questionnaires. Following this, a physical examination, HIV/STI screening, pregnancy testing and a pap smear was performed. All study participants were encouraged to return to the research clinic during the course of the study for contraception, pregnancy testing and examination and treatment of suspected STI. Should study participants receive physical examinations or treatment for STI or pregnancy at other health care providers during the 12-month study interval, a request for these medical records was made after obtaining appropriate permission from the participant. Participants were compensated $50 for their time for initial, 6- and 12- month follow-ups.
Provider	Female research clinicians who were nurse practitioners and received extensive training on interviewing and intervention procedures.
Method of delivery	Face to face small group sessions (4-8 people) and one to one counselling sessions
Setting/location of intervention	Community based research clinics

Intensity/duration of the intervention	2 workshop sessions lasting 3-4 hours each, 3-5 support group sessions and 2 or more individual counselling sessions.
Tailoring/adaptation	Not reported
Unforeseen modifications	None reported
Planned treatment fidelity	Not reported
Actual treatment fidelity	Not reported

Study arms

Intervention (N = 199)

Brief name	ProjectIMAGE
Rationale/theory/Goal	Adolescent women with a history of abuse are more likely than those without to engage in sexual risk behaviour and experience STI, necessitating an additional intervention focus. Project IMAGE is an adaptation of Project SAFE, an evidence based culturally relevant intervention based on the AIDS Risk Reduction Model. Project IMAGE is modified in order to meet the needs of young women with a history of abuse. It is based on a culturally informed conceptualisation of behaviour change and considers the importance of male-female power relationships in African- and Mexican-American culture. The impact of violence and history of abuse is also considered, alongside situational factors such as education, employment, poverty and substance abuse.
Procedures used	The intervention involves workshops, support group sessions and individual counselling sessions. Workshop sessions begin 1-3 weeks after study entry and are led by a facilitator in round table format using principles of motivational interviewing. Session 1 covers Awareness and Perception of Risk and focuses on helping participants to understand their risk of infection. It addresses disease transmission, provides information about STIs and their symptoms and consequences, raises awareness that minorities are disproportionately affected by HIV/STIs, explains how people get STIs, discusses issues around partner selection, and increases awareness of personal risk. Session 2 covers Strategies to Reduce Risk Behaviours and focuses on ways of

	preventing HIV/STIs such as abstinence, monogamy, condom use and STI testing. Conversations with potential partners about sexual history are discussed and consideration is given to romantic relationships (e.g. signs of an unhealthy relationship, how to avoid conflict, violence). This session also covers condom use including application and barriers to use. Support group sessions begin approximately 1 week after completing both workshops and are conducted by a facilitator using motivational interviewing techniques. Support group topics are generated by the group but largely include sexual risk behaviour, treatment compliance, GU symptomatology, interpersonal relationships and contraceptive use. Individual counselling sessions are initiated by the participant and focus on any expressed needs.
Control (N = 210)	
Brief name	Control group
Procedures used	Control group participants received the intervention at study completion. The workshop and support group sessions were identical to those provided to the intervention group and were conducted by the same facilitator.

Risk of Bias Assessment

Section	Risk of bias	Reason
Domain 1a: Bias arising from the randomisation process	Some concerns	Random allocation and participant blinding procedures described. Some differences between groups at baseline (intervention participants were more likely to have experienced abuse than control participants (83% vs 71%) and were more likely to have run away from home (63% vs 46%).
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Low	No deviations from the intended intervention reported. Appropriate analyses used.
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	Low	Intervention adherence generally high – 249 of the 271 allocated received the intervention

Section	Risk of bias	Reason
Domain 3. Bias due to missing outcome data	Low	Follow up rates at 6 months considered high (unadjusted 78-81%, adjusted 93-94%)
Domain 4. Bias in measurement of the outcome	Low	Appropriate outcome assessments used and although participants were not blinded, group status did not appear on interviews or clinic records; participants were only asked their group status at the end of follow-up interviews.
Domain 5. Bias in selection of the reported result	Low	Trial registered
Overall bias and Directness	Low	
	Overall Directness	Partially applicable (US study of adolescent women with a history of sexual or physical abuse)

Gimenez-Garcia, 2018

Bibliographic Reference	Gimenez-Garcia, Cristina; Ballester-Arnal, Rafael; Gil-Llario, Maria Dolores; Salmeron-Sanchez, Pedro; Peer-Led or Expert-Led Intervention in HIV Prevention Efficacy? A Randomized Control Trial Among Spanish Young People to Evaluate Their Role.; Health promotion practice; 2018; vol. 19 (no. 2); 277-286

Study details

Trial registration number	Not reported
Aim	To examine the effectiveness of peer facilitators and expert facilitators for a HIV prevention program aimed at Spanish young people.

Country/geographical location	Valencia region, Spain
Setting	University
Inclusion criteria	- 18 to 25 years old - Spanish speaker - No previous experience of STI prevention programs
Exclusion criteria	None reported
Method of randomisation	Not reported
Method of allocation concealment	Not reported
Unit of allocation	Participant
Unit of analysis	Participant
Statistical method(s) used to analyse the data	To analyse differences between both groups, Student's t test was conducted for "HIV information" as well as Cohen's d to evaluate the effect size (Cohen, 1992). For safe sex, chi-square analysis was carried out to examine differences and Cramer's V to evaluate the effect size (Ellis, 2010). To examine the differences for each group at evaluation moments, repeated measures analyses of variance were used for "HIV information" and Cochran's Q test for "safe sex behavior." Finally, the generalized estimating equation was performed to evaluate the role of facilitator in risk variables, as well as the possible influence of age and gender in these results. The statistical software used for these analyses was SPSS 22.
Uptake	Outreach activities related to sexual risk prevention and advertisements located in education centres in the Valencia region resulted in 250 young people visiting the University meeting room to receive information about the study. 90% of them (n=225) provided informed consent to participate in the study.
Attrition	n=225 participants completed the baseline assessment.

	n=218 (96.89%) completed the post-intervention assessment (1 week after the intervention). n=190 (84.44%) completed the 1-month follow-up n=166 (73.77%) completed the 4-month follow-up Rates of attrition by group were not reported.
Study limitations (author)	The sample was not large enough to generalize these results and most of the participants were women.
Study limitations (reviewer)	The peer facilitators had not met the participants previously, which may differ from other peer-based interventions which are led by facilitators who are known to their peers or have close relationships with them. There was no assessment of facilitators' adherence to the intervention protocol across the two groups. The study would have benefited from a no-intervention control group.
Source of funding	Not reported

Study arms

Peer facilitator IMB (N = 114) An Information-Motivation-Behavioural Skills (IMB) based intervention delivered by a peer facilitator. Main components were (1) improving information about HIV prevalence, risk transmission routes and condom use to promote healthy decision making, (2) facilitating positive attitudes toward condom use and self-efficacy, and (3) promoting behavioural skills to negotiate condom use and put it on appropriately. Structured content and activities, videos, role plays, group discussions.
Expert facilitator IMB (N = 111) Same intervention delivered by expert facilitator.

Characteristics

Study-level characteristics

	Study (N = 225)
Age	
Range	18 to 25
Mean/SD	20.9 (1.97)
Gender	
Male	n = 58 ; % = 25.8
Female	n = 167 ; % = 74.2
Sexually active	
Male	n = 48 ; % = 82.8
Female	n = 129 ; % = 77.2

Outcomes

Study timepoints	Baseline 1 (month) 4 (month)

STI Knowledge outcomes

	Peer facilitator IMB			Expert facilitator IMB		
	Baseline	**1 (month)**	**4 (month)**	**Baseline**	**1 (month)**	**4 (month)**
	N = 114	N = 97	N = 82	N = 111	N = 93	N = 84
HIV transmission knowledge; Mean/SD Addition of 13 dichotomous items about different HIV transmission modes *Polarity: Higher values are better*	10.05 (1.83)	11.4 (1.46)	11.8 (1.39)	10.29 (1.83)	11.3 (1.46)	11.73 (1.17)

Condom use outcomes

Condom use was measured using Likert scale items ranging from 0 (never use condoms) to 3 (always use condoms). This variable was transformed into a dichotomous measure: 1 for safe sex (using condoms always) or 0 for risky sexual behaviour (using condoms never, rarely or sometimes).

	Peer facilitator IMB			Expert facilitator IMB		
	Baseline	**1 (month)**	**4 (month)**	**Baseline**	**1 (month)**	**4 (month)**
	N = 114	N = 97	N = 82	N = 111	N = 93	N = 84
Condom use for vaginal sex *(Values are n and % reporting Always)* *Polarity: Higher values are better*	n = 70 ; % = 61.4	n = 77 ; % = 79.8	n = 72 ; % = 87.7	n = 79 ; % = 71.2	n = 79 ; % = 84.7	n = 72 ; % = 85.6
Condom use for anal sex *(Values are n and % reporting Always)* *Polarity: Higher values are better*	n = 84 ; % = 73.7	n = 89 ; % = 92.1	n = 75 ; % = 91.2	n = 90 ; % = 81.1	n = 89 ; % = 95.5	n = 82 ; % = 98.2

TIDieR Checklist

Study details

Rationale/theory/Goal	Some studies support the effectiveness of peer facilitators for sexual risk prevention. Shared social status (e.g. gender, age, social class) may facilitate behaviour change and peers can become healthy models of safe sexual habits. They may also provide a supportive atmosphere for discussing sexuality issues. Other studies support the effectiveness of expert facilitators, because specific abilities and technical education may improve credibility and intervention delivery. It is not clear which type of facilitator is most effective for HIV prevention interventions for young people.

Study arms

Peer facilitator IMB (N = 114)

Brief name	Peer facilitator HIV prevention intervention
Procedures used	Trained peer facilitators led the intervention delivery for this condition. They were small group sessions with 7 young people and one facilitator. The intervention was based on the IMB skills model. The main components were (1) improving information about HIV prevalence, risk transmission routes, and condom use to promote healthy decision-making; (2) generating positive attitudes toward condom use and their own self-efficacy; and (3) promoting behavioural skills to negotiate condom use and to put it on appropriately. The contents were divided in four sections: HIV transmission routes, beliefs about HIV and condom use, behavioural intention to prevent HIV, and preventive behaviours. The behavioural intervention techniques were based on participatory learning such as an attitudinal discussion related to HIV risk and condom use, a short video about HIV-AIDS consequences, and roleplays for negotiating condom use. The structure of intervention was divided in three phases: (1) an introduction to create confidence and to explain the intervention, (2) behavioural intervention techniques to cover sexual risk–taking behaviours, and (3) the conclusion.
Provider	Trained peer facilitators. They were one of two Psychology students aged between 20 and 21 years old and were selected for having knowledge of the target social context, communication skills to manage groups, and interest in developing the HIV prevention program. They received training in the contents, activities and development of the intervention sessions from an expert psychologist in HIV prevention. Training lasted 15 hours and the same training was delivered to both peer and expert facilitators.
Method of delivery	Face to face small group sessions.
Setting/location of intervention	University meeting rooms
Intensity/duration of the intervention	A single 1 hour session

Tailoring/adaptation	None reported
Unforeseen modifications	None reported; unlikely
Planned treatment fidelity	Not reported
Actual treatment fidelity	Not reported

Expert facilitator IMB (N = 111)

Brief name	Expert facilitator HIV prevention intervention
Procedures used	Expert facilitators led the intervention delivery for this condition. They were small group sessions with 7 young people and one facilitator. The intervention was based on the IMB skills model. The main components were (1) improving information about HIV prevalence, risk transmission routes, and condom use to promote healthy decision-making; (2) generating positive attitudes toward condom use and their own self-efficacy; and (3) promoting behavioural skills to negotiate condom use and to put it on appropriately. The contents were divided in four sections: HIV transmission routes, beliefs about HIV and condom use, behavioural intention to prevent HIV, and preventive behaviours. The behavioural intervention techniques were based on participatory learning such as an attitudinal discussion related to HIV risk and condom use, a short video about HIV-AIDS consequences, and roleplays for negotiating condom use. The structure of intervention was divided in three phases: (1) an introduction to create confidence and to explain the intervention, (2) behavioural intervention techniques to cover sexual risk–taking behaviours, and (3) the conclusion.
Provider	Two trained expert facilitators selected for their experience in HIV prevention. They were 40 years old and worked as associate professors. They had 10 years experience in sexual risk prevention and health promotion. They received training in the contents, activities and development of the intervention sessions from an expert psychologist in HIV prevention. Training lasted 15 hours and the same training was delivered to both peer and expert facilitators.
Method of delivery	Face to face small group sessions
Setting/location of intervention	University meeting rooms

Intensity/duration of the intervention	A single 1 hour session
Tailoring/adaptation	Not reported
Unforeseen modifications	None reported; unlikely
Planned treatment fidelity	Not reported
Actual treatment fidelity	Not reported

Risk of Bias Assessment

Section	Risk of bias	Reason
Domain 1a: Bias arising from the randomisation process	High	*RCT, limited information on randomisation and allocation concealment; potential differences between groups at baseline not reported*
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Some concerns	*No information on participant blinding*
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	Some concerns	*No information on adherence*
Domain 3. Bias due to missing outcome data	Some concerns	*Rates of missing data not reported or analysed, attrition by group not analysed but percentages by group do not appear to differ substantially*
Domain 4. Bias in measurement of the outcome	Low	*Appropriate outcome measurement and procedures the same for both groups*

Section	Risk of bias	Reason
Domain 5. Bias in selection of the reported result	Some concerns	*Trial not registered*
Overall bias and Directness	High	No information on participant blinding, baseline differences between groups, adherence to intervention regimen or impact of attrition. Trial was not registered.
	Overall Directness	Directly Applicable

Miller, 2021

Bibliographic Reference Miller, Melissa K; Catley, Delwyn; Adams, Amber; Staggs, Vincent S; Dowd, M Denise; Stancil, Stephani; Miller, Elizabeth; Satterwhite, Catherine L; Bauermeister, Jose; Goggin, Kathy; Brief Motivational Intervention To Improve Adolescent Sexual Health Service Uptake: A Pilot Randomized Controlled Trial In The Emergency Department.; The Journal of pediatrics; 2021

Study details

Study design	Randomised controlled trial (RCT)
Trial registration number	ClinicalTrials.gov NCT03341975
Study start date	10-Nov-2017
Study end date	14-Sep-2019
Aim	To examine whether a motivational sexual health intervention (SexHealth) for sexually active adolescents would increase health service uptake, condom use attitudes and intentions, and sexual and care-seeking behaviours. Note that outcomes relating to health service uptake were not outcomes of interest for this review so were not extracted.

Country/geographical location	Midwestern USA
Setting	Paediatric emergency department of a children's hospital
Inclusion criteria	- English fluency - Aged 14-19 years - Any previous lifetime sexual activity
Exclusion criteria	- Critical illness or cognitive impairment - Receiving clinical care from a study author - Seeking care for acute suicidal ideation or sexual assault / abuse
Method of randomisation	Participants were stratified based on the present of genitourinary symptoms and allocated to groups using a computer-generated randomisation sequence.
Method of allocation concealment	Sequentially numbered, opaque sealed envelopes.
Unit of allocation	Participant
Unit of analysis	Participant
Statistical method(s) used to analyse the data	- Sample size calculations were based on data from medical record review and a previous open trial. A simulation study using estimates from these data indicated a sample size of 76 adolescents provided 89% power to detect a difference in health service completion of 35 percentage points between arms (i.e., 15% vs 50%). - Preliminary efficacy was assessed using an intention-to-treat analysis. - Between-arm differences in rates of sexual behaviours assessed at 6 months were compared using Fisher exact tests.

	- For attitudes, each participant's change from baseline to postintervention and change from baseline to 6-month follow-up were computed. Differences in average change score between arms were tested using nonparametric permutation tests. - R software (R Foundation for Statistical Computing) was used for analyses
Attrition	303 people were assessed for eligibility; n = 109 did not meet inclusion criteria and n = 89 declined eligibility screening. A further n = 14 declined enrolment in the trial, leaving 91 participants randomised. In the intervention group (n = 44), n = 23 (53%) completed the 2 month follow up, n = 22 (50%) completed the 4 month follow up, and n = 19 (43%) completed the 6 month follow up. In the control group (n = 47), n = 20 (43%) completed the 2 month follow up, n = 18 (38%) completed the 4 months follow up, and n = 18 (38%) completed the 6 month follow up. Participants lost to follow up were more likely to have private insurance (65% vs 35%, P = .03), to be male (54% vs 35%, P = .16), to be Hispanic (56% vs 37%, P = .19), and to report non-Black race (57% vs 33%, P = 04). Intervention and control participants were generally similar across baseline characteristics. A greater percentage of control arm participants reported using a condom during their last sexual encounter (47% vs 32%) but this difference was not statistically significant (p = 0.22).
Study limitations (author)	- This was a pilot study conducted at a single site. Findings may not be generalisable to all EDs or to adolescents who differ from than those enrolled in this study. - Some outcomes of interest were documented by the educator and potentially subject to bias, although some of these data were validated with electronic medical record review. - Participant behaviours were self-reported, although computerised assessments were used to reduce bias. - Many participants were lost to follow-up, limiting the ability to evaluate for longer-term behavioural and attitudinal changes.
Study limitations (reviewer)	None to add

Source of funding	Supported in part by the Eunice Kennedy Shriver National Institute of Child Health and Human Development/ National Institutes of Health (NIH) Career Development Awards (K23HD083405 [to M.M.]), NIH Clinical and Translational Science Award (UL1TR002366 [to the University of Kansas]), and Eunice Kennedy Shriver National Institute of Child Health and Human Development/NIH Training Award (T32 HD069038 [to S.S.]).

Study arms

Intervention (N = 44)

The SexHealth Intervention, a brief motivational interviewing intervention delivered by health educators in paediatric emergency departments.

Control (N = 47)

Printed materials which included a brochure on safer sex practices and a list of local resources for sexual and mental health care.

Characteristics

Study-level characteristics

Characteristic	**Study (N = 91)**
Age Range	14 to 19
Age Mean (SD)	16.9 (1)

Arm-level characteristics

Characteristic	**Intervention (N = 44)**	**Control (N = 47)**
Gender (Female)	n = 31 ; % = 70	n = 34 ; % = 72

Characteristic	Intervention (N = 44)	Control (N = 47)
Race / Ethnicity		
Black	n = 28 ; % = 63	n = 30 ; % = 64
White	n = 10 ; % = 23	n = 10 ; % = 21
Other / unknown	n = 6 ; % = 14	n = 7 ; % = 15
Hispanic	n = 7 ; % = 16	n = 11 ; % = 23

Outcomes

Study timepoints

- Baseline
- 6 month

Condom use outcomes

Outcome	Intervention, Baseline, N = 44	Intervention, 6 month, N = 19	Control, Baseline, N = 47	Control, 6 month, N = 18
Condom attitudes (3 items; 6 point Likert scale) Mean (SD)	1.85 (1.08)	1.81 (1.44)	2.08 (1.26)	2.13 (1.38)

Outcome	Intervention, Baseline, N = 44	Intervention, 6 month, N = 19	Control, Baseline, N = 47	Control, 6 month, N = 18
Condom use intention (1 item; 4 point likert scale) In next 3 months Mean (SD)	3.41 (0.87)	2.74 (1.28)	3.24 (0.85)	3.28 (0.96)
Confidence in condom use (1 item; 5 point Likert scale) Mean (SD)	4.3 (*empty data*)	4.16 (1.46)	4 (1.1)	4.11 (1.23)

Condom attitudes - Polarity - Higher values are better

Condom use intention - Polarity - Higher values are better

Confidence in condom use - Polarity - Higher values are better

Condom use outcomes

Outcome	Intervention, Baseline, N = 44	Intervention, 6 month, N = 10	Control, Baseline, N = 47	Control, 6 month, N = 14
Condom use at last sex Sample size	n = 14 ; % = 32	n = 4 ; % = 40	n = 22 ; % = 47	n = 8 ; % = 57

Condom use at last sex - Polarity - Higher values are better

Separate table as denominators differ

TIDier Checklist

Study details

Rationale/theory/Goal	Adolescents' limited access to preventive care is associated with increased risk for sexually transmitted infections (STIs) and HIV infection. Adolescents make 19 million ED visits annually, with those who seek ED care evidencing elevated rates of STIs (up to 6-7 times greater) compared with the general population of adolescents. Studies have demonstrated the feasibility and acceptability of single session, ED-based interventions for adolescents targeting STI/HIV testing and contraception use, and while RCT evidence has shown these ED-based interventions hold promise for increasing testing, without the accompanying provision of behavioural counselling to increase preventive behaviours, their use is unlikely to reduce STIs/HIV. The study builds on this research by coupling brief behavioural counselling with provision of health services, personalised for the diverse range of sexual health behaviours reported by adolescents (p. 1-2).
Materials used	
Procedures used	Participants were recruited from the ED department of a Midwestern children's hospital across a wide range of hours (10am to 11pm). Trained research team members identified potential participants and asked the treating clinician about suitability for recruitment. Adolescents were screened and consented participants were then randomised and completed a pre-intervention assessment. Participants then received their assigned treatment, followed by a post-intervention assessment. All assessments were completed using a computerised survey in a private room. Where required, electronic medical records were accessed to verify key information. Participants also completed follow-up assessments at 2, 4 and 6 months via telephone or web link (p. 2).
Setting/location of intervention	Emergency Department of a children's hospital
Other details	Participants received $35 for completing the baseline assessment, and $10, $10 and $25 for completing the 2, 4 and 6 month follow-up assessments, respectively (p. 2).

Study arms

Intervention (N = 44)

The SexHealth Intervention, a brief motivational interviewing intervention delivered by health educators in paediatric emergency departments.

Brief name	The SexHealth intervention (p. 1)
Rationale/theory/Goal	The Theory of Planned Behaviour informed intervention content and the Social Ecological Model informed the delivery approach. Motivational Interviewing principles guided the counselling (p. 3).
Materials used	The intervention included tablet-based components including short, publicly available educational video clips and a computerised sexual health screening that fed directly into a clinical decision support system to generate tailored service recommendations and a condom skills training video. Participants in the intervention arm also received the same health brochure and list of resources as controls (p. 3)
Procedures used	Health educators delivered the intervention using a tablet, intermittently sharing the screen with the participant. Educators first worked to build rapport and used open ended questions to engage the adolescent in discussion of their sexual behaviours, then aimed to facilitate enhancement of motivation for safer behaviours. Participants could choose from a menu of topics such as number of partners, taking a break from sex, condom use, safer sex. All participants received condom skills training and patient-centred tailored risk reduction counselling (p. 3).
Provider	Two female health educators delivered study treatments; both were Master of Public Health students with training in health behaviour change. Educators received an intervention manual developed for the project that included a detailed description of the intervention, screen shots, and sample scripts. They received 30 hours of training, including an 8-hour workshop to develop and practice techniques central to Motivational Interviewing as well as role-playing and direct observation. Educators demonstrated proficiency in practice sessions prior to intervening with participants (p. 3).
Method of delivery	Face to face 1-to-1 sessions (p. 3)
Intensity/duration of the intervention	Brief single session. The mean intervention duration was 24.6 minutes (p. 4)
Tailoring/adaptation	Participants completed a computerised sexual health screen that fed directly into a clinical decision support system to generate tailored service recommendations such as STI testing, treatment, emergency contraception, pregnancy testing, or referral to adolescent clinic (p. 4-5).
Unforeseen modifications	None reported
Planned treatment fidelity	All sessions were audio recorded, 30% of recordings were monitored to ensure fidelity and a member of the Motivational Interviewing Network of Trainers regularly reviewed recordings with educators to provide feedback and address questions (p. 3).
Actual treatment fidelity	Educators maintained high fidelity to content (delivered all core content in >94% of sessions) and MI principles (mean score on overall summary item was 6.3 (SD = 0.7); scored from 1 [poor] to 7 [excellent] (p. 4).

Control (N = 47)

Printed materials which included a brochure on safer sex practices and a list of local resources for sexual and mental health care.

Materials used	Control participants were offered a commercially available printed brochure describing safer sex behaviours and a printed list of local resources for sexual and mental health care (p. 2).
Procedures used	Control participants were offered printed information (see 'materials' above) then were referred back to their ED clinician (p. 2).
Provider	Health educators (p. 2)
Method of delivery	Face to face (p. 2)
Setting/location of intervention	Emergency Department of a children's hospital (p. 2)
Intensity/duration of the intervention	N/A
Tailoring/adaptation	None reported
Unforeseen modifications	None reported
Planned treatment fidelity	Not reported
Actual treatment fidelity	Not reported

Risk of Bias Assessment

Section	Risk of bias	Reason
Domain 1a: Bias arising from the randomisation process	Low	Appropriate randomisation procedures. Greater number of control participants reported using a condom at last sex (47%) compared to

Section	Risk of bias	Reason
		intervention participants (32%) but this difference did not reach statistical significance
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Low	Unclear whether participants were blinded but deviations from intended intervention unlikely. ITT used.
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	Low	Failures in intervention implementation unlikely and single session 1-to-1 format likely ensured participants' adherence to intervention
Domain 3. Bias due to missing outcome data	Some concerns	High attrition (only 40.6% completion at 6 months) but no differential attrition by group
Domain 4. Bias in measurement of the outcome	Low	Appropriate measures used and assessments were self-administered using computerised survey
Domain 5. Bias in selection of the reported result	Low	Trial registered and analyses completed in line with prespecified plan
Overall bias and Directness	Some concerns	High attrition (only 40.6% completion at 6 months) but no differential attrition by group. Small final sample size (n = 37)
	Overall Directness	Partially applicable (US study delivered in paediatric ED setting)

Morrison-Beedy, 2013

Bibliographic Reference Morrison-Beedy, Dianne; Jones, Sheryl H; Xia, Yinglin; Tu, Xin; Crean, Hugh F; Carey, Michael P; Reducing sexual risk behavior in adolescent girls: results from a randomized controlled trial.; The Journal of adolescent health : official publication of the Society for Adolescent Medicine; 2013; vol. 52 (no. 3); 314-21

Study details

Trial registration number	The trial was registered at ClinicalTrials.gov (NCT 00161343).

Aim	To evaluate the efficacy of a sexual risk reduction intervention, supplemented with post-intervention booster sessions, targeting low-income, urban, sexually active teenage girls.
Country/geographical location	New York, US
Setting	Community settings including youth development centres, adolescent health services and school-based health centres.
Inclusion criteria	- Female age 15 to 19 years - Able to participate in an English-speaking intervention - Unmarried - Not pregnant or had not given birth in the past 3-months - Sexually active within the past 3-months
Method of randomisation	Block randomisation
Method of allocation concealment	Condition assignment was known only to the project director until each group was filled and facilitators assigned
Unit of allocation	Participant
Unit of analysis	Participant
Statistical method(s) used to analyse the data	We followed intent-to-treat principle and included all girls randomized to groups in the analyses. Analyses controlled for age, ethnicity, race, and poverty as well as baseline status of the dependent measure. To test the study hypotheses, we used regression analyses. Zero-inflated Poisson (ZIP) regression analyses were used for count data (frequency of sexual behaviour) with substantial numbers of zeroes. For ZIP models, two regression equations were estimated simultaneously: (a) a logistic regression model to predict whether specific types of sexual behaviour occurred (e.g., reported protected vaginal sex), and (b) a Poisson regression model to predict the values of episodes of that sexual activity. Prior to assessing the primary hypotheses, cases with missing data were evaluated to assess potential biases on the outcomes. The ZIP model was evaluated with 3, 6, and 12 month post-intervention data for each outcome, controlling for the baseline value of the variable and six covariates: age, white race, multi-racial, other ethnicity, Hispanic, free lunch, and treatment condition. We modelled each follow-up visit separately.

Uptake	Of 1178 potential participants screened, 765 (43%) did not meet eligibility criteria. Among eligible participants (n=1013), 73% (n=738) consented to participate. Most who declined cited lack of time due to work or school.
Attrition	639 participants were randomised to the intervention (n = 329) or control groups (n = 310). 537 (84.0%) completed the 3-month follow up; 539 (84.4%) completed the 6 month follow up; and 484 (75.7%) completed the 12 month follow up (intervention n = 249; control n = 235). Group assignment was not associated with attrition. The only baseline characteristic associated with attrition was age: older participants were more likely to be lost to follow up than younger participants.
Study limitations (author)	Study limitations included sampling from a single city, limiting generalizability to other population subgroups with different demographic characteristics, and the use of self-report data, which are vulnerable to cognitive and social biases. Sampling bias was also an issue as the sample was comprised only of individuals who, meeting the criteria, voluntarily agreed to participate.
Source of funding	National Institute of Nursing Research (R01 NR008194).

Study arms

Intervention (N = 329) A sexual risk reduction intervention guided by the Information-Motivation-Behavioural skills model, supplemented with post-intervention booster sessions, targeting low-income, urban, sexually active teenage girls.
Control (N = 310) Attention-matched control groups with health promotion content.

Characteristics

Arm-level characteristics

	Intervention (N = 329)	**Control (N = 310)**
Age; Mean/SD	16.41 (1.24)	16.43 (1.24)

	Intervention (N = 329)	Control (N = 310)
Gender; Female	n = 329 ; % = 100	n = 310 ; % = 100
Ethnicity		
Hispanic	n = 57 ; % = 17	n = 44 ; % = 14
Not Hispanic	n = 272 ; % = 83	n = 266 ; % = 86
Race		
Black / African-American	n = 243 ; % = 74	n = 220 ; % = 71
White/Caucasian	n = 19 ; % = 6	n = 29 ; % = 9
Mixed/multiracial	n = 43 ; % = 13	n = 28 ; % = 9
Other	n = 27 ; % = 7	n = 33 ; % = 11

Outcomes

Study timepoints	Baseline 3 (month) 6 (month) 12 (month)

Condom based outcomes

	Intervention				Control			
	Baseline	**3 (month)**	**6 (month)**	**12 (month)**	**Baseline**	**3 (month)**	**6 (month)**	**12 (month)**
	N = 324	N = 278	N = 284	N = 249	N = 309	N = 259	N = 262	N = 235
Unprotected vaginal sex Any episodes (% yes) *Polarity: Lower values are better*	n = 216 ; % = 66.7	n = 162 ; % = 58.3	n = 154 ; % = 54.2	n = 170 ; % = 68.3	n = 211 ; % = 68.3	n = 162 ; % = 62.5	n = 176 ; % = 67.2	n = 171 ; % = 72.8
Unprotected vaginal sex Number of episodes; Mean/SD *Polarity: Lower values are better*	6.68 (9.95)	4.47 (7.03)	5.13 (8.26)	7.03 (11.13)	6.37 (9.31)	5.17 (7.49)	6.1 (8.83)	8.09 (11.04)

STI incidence outcomes were also reported for this trial but it was unclear what the denominator was for the STI infection rates so the data could not be extracted.

TIDier Checklist

Study details

Procedures used	All participants completed an audio computer-assisted self-interview (ACASI), reporting on demographics, health behaviours and sexual behaviours. Following completion of the intervention period, at 3, 6 and 12 months participants returned to complete ACASI. Both intervention and control group sessions were implemented in small groups of 6 to 8 girls. Facilitators began each program with a description of how the sessions would function, overall goals and a request for confidentiality within the group. Both groups employed a variety of learning modalities, including verbal, visual, experiential and repeated exposure to important information. Course content was presented in concrete, explicit terms and included colloquial jargon, language, and mannerisms familiar to the adolescent girls in this study. Participants in both groups received a payment for attendance as well as refreshments; girls received $15 per session and $10 at data collection (this information was taken from Morrison-Beedy 2013b).

Study arms

Intervention (N = 329)	
Brief name	Sexual risk reduction intervention
Rationale/theory/Goal	Teenage girls, particularly in low-income urban settings, often become sexually active at early ages and are at elevated risk for HIV and STIs. Teen interventions based on the Information Motivation Behavioural skills model (IMB) can reduce risk but interventions to facilitate long term maintenance of behaviour change are needed. Including 'booster sessions' to address behavioural patterns that may occur over time as they age may be efficacious.
Procedures used	The intervention was guided by the Information Motivation Behavioural Skills (IMB) Model and provided HIV information, increased readiness to reduce risk behaviours (motivation), and instructed, modelled, and allowed girls to practice interpersonal and self-management skills facilitating SRR and condom use. The intervention addressed concerns such as how to persuade a partner to use a condom, how to obtain condoms and how fertility could be jeopardised by risky sexual behaviour. There were also communication skills components. The structure and content of the intervention included developmentally appropriate strategies such as games, interactive group activities, and skits. Initial sessions involved practicing basic skills. As sessions progressed, scenarios became more challenging and drew upon participants' experiences. Booster sessions at 3 and 6 months post-intervention provided additional reinforcement of intervention components, including reviewing health behaviours and goal setting.
Provider	Session facilitators were randomly selected pairings of fifteen women diverse in age, race, ethnicity, discipline, and experience, trained to facilitate the manualised intervention.
Method of delivery	Face to face small group sessions
Setting/location of intervention	The intervention was delivered in the recruitment sites which included urban reproductive and general health care clinics and youth development programs
Intensity/duration of the intervention	Four, 120 minute sessions delivered weekly for 4 weeks, followed by two 90 minute booster sessions at 3 and 6 months post-intervention.
Tailoring/adaptation	The authors state the intervention was tailored to adolescent girls. No adaptations reported
Unforeseen modifications	None reported; unlikely
Planned treatment fidelity	Sessions were audiotaped and rated with respect to manual adherence and motivational approach. A review of every session for the first month of study was conducted; then a random selection of 25% from both groups were reviewed to determine intervention fidelity.

	From Morrison-Beedy (2013b): Fidelity of this intervention was facilitated by: 1) extensive training of facilitators; 2) random observation of groups by the intervention leaders; 3) random review and ratings of audiotapes from group sessions (all sessions were audio-taped); 4) weekly meetings between facilitators and team leaders; 5) monthly team meetings; 6) self-evaluation forms completed by facilitators directly after every session relating to the meetings' session goals and amount of participation by each of the girls; 7) group guidelines of confidentiality to prevent cross-contamination between the groups, and 8) guidelines pertaining to appropriate responses if girls enrolled in the control intervention ask about HIV-related topics. Feedback from ratings was provided to facilitators throughout the program to enhance the delivery of intervention content.
Actual treatment fidelity	Independent raters scored group facilitators at 97% fidelity to content and process.

Control (N = 310)

Brief name	Health promotion control group
Procedures used	The structurally equivalent health promotion condition had the same number of sessions and was led by the same facilitators to reduce the chance that intervention effects could be attributed to factors such as total contact time, group interaction or support, or facilitator attention. This control group consisted of general health promotion topics such as nutrition, breast health and anger management. As with the intervention group, IMB constructs were used as determinants of general health behaviours so the group sessions provided information, motivational strategies to change specific behaviors, and assertive communication and negotiation skills exercises. From Morrison-Beedy (2013b): The control group booster sessions had a structure identical to the intervention booster sessions but emphasised the health promotion issues presented in the control sessions and reinforced the social norms developed during control group sessions.
Provider	Session facilitators were randomly selected pairings of fifteen women diverse in age, race, ethnicity, discipline, and experience, trained to facilitate the manualised control group procedures.
Method of delivery	Face to face small group sessions
Setting/location of intervention	The sessions were delivered in the recruitment sites which included urban reproductive and general health care clinics and youth development programs
Intensity/duration of the intervention	Four, 120 minute sessions delivered weekly for 4 weeks, followed by two 90 minute booster sessions at 3 and 6 months post-intervention.

Planned treatment fidelity	Intervention procedures for ensuring fidelity were also applied to the control group

Risk of Bias Assessment

Section	Risk of bias	Reason
Domain 1a: Bias arising from the randomisation process	Low	Appropriate randomisation procedures and no baseline differences between groups
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Some concerns	No information on participant blinding but deviations from intended intervention unlikely
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	Some concerns	No information on session adherence
Domain 3. Bias due to missing outcome data	Some concerns	76% completed 12 month follow-up; no analyses of completers vs. those lost to follow up
Domain 4. Bias in measurement of the outcome	Low	Appropriate outcome measurement using ACASI
Domain 5. Bias in selection of the reported result	Low	Trial registered and analyses completed in line with protocol, although analysis plan also indicates HIV knowledge outcomes would be assessed but not reported in this study
Overall bias and Directness	Some concerns	No information on participant blinding, intervention adherence. 24% lost to follow-up and no attrition analyses.
	Overall Directness	Partially applicable (US study)

D.4 Effectiveness Evidence for Trans People

Garofalo, 2018

Bibliographic Reference	Garofalo, Robert; Kuhns, Lisa M; Reisner, Sari L; Biello, Katie; Mimiaga, Matthew J; Efficacy of an Empowerment-Based, Group-Delivered HIV Prevention Intervention for Young Transgender Women: The Project LifeSkills Randomized Clinical Trial.; JAMA pediatrics; 2018; vol. 172 (no. 10); 916-923

Study details

Study design	Randomised controlled trial (RCT)
Trial registration number	NCT01575938
Study start date	26-Mar-2012
Study end date	15-Aug-2016
Aim	To assess the effectiveness of a culturally specific, empowerment-based, behavioural intervention to reduce the risk of HIV acquisition and transmission in sexually active young transgender women
Country/geographical location	Boston, Massachusetts, and Chicago, Illinois, USA
Setting	Delivery setting is not reported. Recruitment was via outreach and other community venues
Inclusion criteria	- 16 - 29 years of age - Assigned male sex at birth and now self-identify as female, transgender women, or on the transfeminine spectrum - English-speaking - No plans to move from the local area during the 12-month study period - Self-reported sexual risk in the preceding 4 months

	- Written informed consent was obtained for each participant with parental consent waived for minors (aged 16-17 years).
Exclusion criteria	None reported
Method of randomisation	• Initially participants were allocated to 3 conditions. The 3rd condition (not reported here) was an attention control focusing on diet and nutrition. However this was abandoned due to poor feasibility of accrual to the control group, on the advice of the Data, Safety,and Monitoring Board and the findings were not included in the analyses. • Initially randomisation was by cohort in blocks of 5 (2:2:1) to each of the 3 conditions • After 6 cohorts this was revised to assignment of cohorts to 2 modalities (Lifeskills versus standard care or Lifeskills versus attention control,) on a 1:1 basis. • Within each of the 2 modalities there was a nested individual assignment to one of the two possible conditions • Randomisation at both cohort and individual level was computer generated in blocks of 2(1:1) or 3(2:1)
Method of allocation concealment	Randomisation scheme was concealed from both participants and researchers until it was revealed at the randomisation visits after each complete cohort had been assembled.
Unit of allocation	Individual in cohorts
Unit of analysis	Individual
Statistical method(s) used to analyse the data	Power analysis aimed to detect a 40% (or greater) change in the rate of condomless sex acts (anal or vaginal) between groups. Based on these data, with a power of 80% and α = .05, a target of 107 completers was set per group. There was low feasibility for randomisation to the attention control arm and low statistical power, so that group was not included in the final analyses; a modified intent-to-treat approach was therefore used. To ascertain difference in the rate of change for the outcomes variables, a mixed-effects model was used with a participant-level random intercept to allow the baseline outcome measure (e.g. condomless sex acts) to vary across participants and account for within-participant correlation. Intraclass correlation for condomless sex acts was 0.49, suggesting that, for each individual, the outcome measures were moderately correlated across time points. A Poisson distribution and log link were specified, for outcome measures which were count variables. This allowed improved modelling of count variables in which the variance increases with the mean, values are discrete, and values have a lower bound of 0. The models contained terms for intervention group assignment, time, and their interaction; with a significant effect for the interaction indicating differences in the change of the outcomes from baseline to follow-up for the intervention groups. For outcomes that did not have a significant effect for the interaction, the interaction term was removed and assessed whether there were overall changes across study follow-up that could not be accounted for by the intervention (ie, a significant effect for time).

	For each outcome, means (SEs) produced for each time point. Complete-case analyses were conducted; therefore, no data were imputed. Missing data for the primary outcome at each time point ranged from 12.1% to 13.7%. Analyses were conducted with SAS, version 9.4 (SAS Institute Inc) and Stata, version 15 (StataCorp). Two-sided P < .05 denoted statistical significance.
Uptake	N=487 individuals assessed for eligibility. N=65 were excluded due to not meeting inclusion criteria. N=122 dropped out before enrolment.
Attrition	• In the Lifeskills group 115 of the 116 randomised received the intervention. All 74 of those randomised to standard care received the intervention • At 4 months 99.1% (N=115) of the Lifeskills group and 79.7% (n = 66) of the standard care group were followed up • At 8 months 86.2% (n = 66) of the Lifeskills group and 90.5% (n=67) of the standard care group were followed up • At 12 months 87.1% (n=101) of the Lifeskills group and 85.1% (n=63) of the standard care group were followed up • Intention to treat analysis Percentages calculated by reviewer.
Study limitations (author)	• Conducted in only 2 geographic locations n the USA which may limit generalisability • Content was specific to the process of medical gender transition and may not resonate with young women who either have completed transition process or do not intend to initiate the process. • Study was powered on the basis of behavioural outcomes rather than HIV infection incidence, which would be a stronger indicator of effect but would have required several thousand participants • The intervention curriculum was written before the advent of PrEP, a biomedical prevention strategy that should be integrated into behavioural interventions like lifeskills • It is reported that deviation from the original randomisation plan resulted in an imbalance between groups but that there were no statistically meaningful imbalances between conditions
Study limitations (reviewer)	None to add
Source of funding	Supported by award R01MH094323 from the National Institute of Mental Health of the National Institutes of Health and in part by the Northwestern University Clinical and Translational Science Institute and grant UL1TR000150 (Clinical and Translational Sciences Award, a registered trademark of the US Department of Health and Human Services) from the National Center for Advancing Translational Sciences .

Study arms

Project Lifeskills (N = 116)

Empowerment based HIV prevention intervention for young transgender women

Standard care (N = 74)

Standard care - HIV/sexually transmitted infections testing and counselling

Characteristics

Arm-level characteristics

	Project Lifeskills (N = 116)	**Standard care (N = 74)**
Age; Mean/SD	23.6 (3.5)	23 (3.4)
Ethnicity Primary race/ethnicity		
White	n = 30 ; % = 25.9	n = 17 ; % = 23
Black /African American	n = 53 ; % = 45.7	n = 30 ; % = 40.5
Hispanic or Latina	n = 14 ; % = 12.1	n = 11 ; % = 14.9
Other	n = 19 ; % = 16.4	n = 16 ; % = 21.6
Sexual identity		
Gay/homosexual	n = 31 ; % = 26.7	n = 18 ; % = 24.3
Lesbian	n = 6 ; % = 5.2	n = 4 ; % = 5.4
Bisexual	n = 25 ; % = 21.6	n = 13 ; % = 17.6

	Project Lifeskills (N = 116)	Standard care (N = 74)
Sample Size		
Straight/heterosexual	n = 42 ; % = 36.2	n = 31 ; % = 41.9
Other	n = 12 ; % = 10.3	n = 8 ; % = 10.8
HIV infected at baseline	n = 23 ; % = 19.8	n = 17 ; % = 23
STI diagnosis at baseline	n = 3 ; % = 2.7	n = 1 ; % = 1.4

Outcomes

Study timepoints	Baseline 4 (month) follow up 8 (month) Follow up 12 (month) follow up

Condom use outcomes

	Project Lifeskills				Standard care			
	Baseline	**4 (month)**	**8 (month)**	**12 (month)**	**Baseline**	**4 (month)**	**8 (month)**	**12 (month)**
	N = 116	N = 116	N = 116	N = 116	N = 74	N = 74	N = 74	N = 74
Condomless sex acts Standardised Mean/SE *Polarity: Lower values are better*	2.26 (0.4)	1.22 (0.22)	0.66 (0.12)	0.71 (0.13)	2.69 (0.59)	2.1 (0.47)	1.09 (0.25)	1.4 (0.32)

TIDier Checklist

Study arms

Project Lifeskills (N = 116)

Empowerment based HIV prevention intervention for young transgender women

Brief name	Project Lifeskills - Empowerment based HIV prevention intervention for young transgender women.
Rationale/theory/Goal	The prevalence of HIV is very high among transgender women in the USA, including among young transgender women. Condomless anal sex is the primary risk for acquisition and transmission of HIV though it may also be acquired or transmitted through condomless vaginal sex. Few interventions have focussed on reducing risk in transgender women and authors report those that have as being of low quality. This study aimed to address the safe sex challenges specific to young transgender women. The primary aim of the intervention was to test the effectiveness of the LifeSkills intervention in reducing the risk of HIV acquisition and transmission among young transgender women in a randomised trial. (Page 917)
Materials used	None reported
Procedures used	Participants were recruited (until 300 were enrolled) via various approaches, including outreach to community-based organisations and other venues. Participants attended a baseline study visit that included a standardised quantitative assessment via computer-assisted self-interviewing and preventive screening for HIV infection and urogenital gonorrhoea and chlamydia infections. together with pre and post-test counselling. Intervention participants underwent the LifeSkills Project which was developed through a community participatory approach to address the life circumstances of transgender women. It takes a empowerment based approach. and covers issues such as finding employment, safe housing,and accessing medical care. Topics were delivered through a curriculum of 6 modular or stand-alone sessions and included: • basic HIV-related information (e.g. transmission modes and related risks), • developing the motivation to protect oneself

	• behavioural skills (e.g. condom use and sexual partner communication and negotiation) Further assessments were conducted at follow up visits at 4-, 8-, and 12-months, with additional HIV/sexually transmitted infection screening at the 4- and 12-month visits. (Pages 917-918 and page 921)
Provider	Peer educators (Page 921)
Method of delivery	Small group sessions (Page 918)
Setting/location of intervention	Not reported
Intensity/duration of the intervention	2 hour sessions delivered twice weekly over 3 consecutive weeks (Page 918)
Tailoring/adaptation	None reported
Unforeseen modifications	None reported
Planned treatment fidelity	Fidelity of intervention delivery was supported using approaches recommended by the Treatment Fidelity Workgroup of the National Institutes of Health Behavior Change Consortium. 19 Fidelity ratings were used for each session and included 18 items reflecting content delivery, process, and professionalism. (Page 918)
Actual treatment fidelity	Attendance at intervention sessions was 80.3% (559 of 696 sessions attended) across cities and intervention cohorts. In Chicago, the attendance was 83.9% (282 of 336 sessions attended) and in Boston was 76.9% (277 of 360).

	The LifeSkills intervention was delivered to approximately 3 to 4 individuals per cohort in each city (mean [SD], 3.5 [1.0] in Chicago and 3.5 [1.3] in Boston). Mean (SD) intervention fidelity was 34.1 (2.1) of 36 fidelity items (94.8%) across sites and cohorts. (Page 920)
Other details	Participants were offered incentives. These were $25 for the initial visit and $50 per visit thereafter. For group participation they were offered $10 per session, with an additional $10 per week for perfect attendance. (Page 918)

Standard Care (N = 74)

Standard care - HIV/sexually transmitted infections testing and counselling

Brief name	Standard care
Rationale/theory/Goal	Not applicable
Materials used	None reported
Procedures used	Participants were recruited (until 300 were enrolled) via various approaches, including outreach to community-based organisations and other venues. Participants attended a baseline study visit that included a standardised quantitative assessment via computer-assisted self-interviewing and preventive screening for HIV infection and urogenital gonorrhoea and chlamydia infections. together with pre and post-test counselling. Standard care participants received standard care - HIV/sexually transmitted infections testing and counselling. Further assessments were conducted at follow up visits at 4-, 8-, and 12-months, with additional HIV/sexually transmitted infection screening at the 4- and 12-month visits.

	(Page 917-918)
Provider	Not reported
Method of delivery	Not reported
Setting/location of intervention	Mot reported
Intensity/duration of the intervention	Not reported
Tailoring/adaptation	Not reported
Unforeseen modifications	Not reported
Planned treatment fidelity	Not reported
Actual treatment fidelity	Not reported
Other details	None to add

Risk of Bias Assessment

Section	Risk of bias	Reason
Domain 1a: Bias arising from the randomisation process	Some concerns	There was a change in randomisation approach after the first 6 cohorts were randomised

Section	Risk of bias	Reason
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Some concerns	One arm of the trial stopped and not analysed due to difficulty in accruing to that arm. Changes to the randomisation procedure caused some (non-significant) differences between the groups
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	Some concerns	Due to original third arm of the trial being abandoned
Domain 3. Bias due to missing outcome data	Low	Missing data for the primary outcome at each time point ranged from 12.1% to 13.7%.
Domain 4. Bias in measurement of the outcome	Low	Appropriate outcome measurement using CASI
Domain 5. Bias in selection of the reported result	Some concerns	Trial not registered
Overall bias and Directness	Some concerns	Due to the change in the randomisation process part way through and abandoning the 3rd attention control arm of the trial
	Overall Directness	Partially Applicable (US study)

Sevelius, 2019

Bibliographic Reference Sevelius, J.M.; Neilands, T.B.; Dilworth, S.; Castro, D.; Johnson, M.O.; Sheroes: Feasibility and Acceptability of a Community-Driven, Group-Level HIV Intervention Program for Transgender Women; AIDS and behavior; 2019

Study details

Study design	Randomised controlled trial (RCT)

Trial registration number	Not reported
Aim	To carry out a pilot randomised controlled trial (RCT) to determine the feasibility and acceptability of the Sheroes intervention and to examine preliminary data on the effectiveness of Sheroes on reducing sexual risk behaviour and increasing social support.
Country/geographical location	San Francisco, USA
Setting	Delivery setting not reported. Participants were recruited from community-based venues such as transgender-serving community-based organisations, clinics, and social venues.
Inclusion criteria	• Self-identified transgender women • At least 18 years of age • Reported condomless sex in the past 3 months • Provided informed consent
Exclusion criteria	None reported
Method of randomisation	• Once enrolled participants were stratified by HIV status and randomised by computer to either intervention or control conditions. • Randomisation was stratified by HIV status via SAS 9.4 using block randomisation with block sizes of two.
Method of allocation concealment	Participants were not blinded to their allocation. It is not reported if the researchers were blinded.
Unit of allocation	Individual
Unit of analysis	Individual
Statistical method(s) used to analyse the data	• Assessments consisted of computer-assisted self-administered quantitative surveys using RedCAP and were completed at baseline and 3 and 6 months post randomisation. • Descriptive statistics were calculated using SAS v9.4. • Analyses used an intent-to-treat approach and were performed using generalised linear mixed models (GLLMs) in Stata v15.1 stratified by HIV serostatus, containing fixed effects for group (control, intervention), time (baseline, 3 month follow up, 6 month follow up), and their interaction.

	• Counts of numbers of sex partners outcomes were modelled using a negative binomial distribution and log-link • Mean level of continuous social support was modelled using a normal distribution and identity link. • Count outcome models estimated the mean numbers of sex partners as a function of the fixed effects model plus random intercepts via maximum likelihood whereas the continuous social support mean level was estimated as a function of the fixed effects using restricted maximum likelihood (REML) with an unstructured covariance matrix of the residuals andKenward-Roger denominator degrees of freedom. • Pre-specified simple main effects compared outcomes on time points within each group. • All effects were evaluated at alpha = .05. • Cases with partial outcome data were included in the analysis with incomplete data assuming to arise from either a missing-completely-at-random(MCAR) or a missing-at-random (MAR) missingness mechanism via the maximum likelihood estimation approach used in the mixed models analyses.
Uptake	Not reported
Attrition	• 17.9% (n= 7/ 30) of those randomised to the intervention did not receive the intervention. 82% (n=32/39) attended at least one session. • 12% (n=16/38) of those randomised to the control condition did not receive the intervention. 57.9% attended at least one session. • 61.5% (n= 24/39) of those randomised to the intervention group were included in the analyses • 60.5% (n=23/38) of those randomised to the control condition were included in the analyses • Intention to treat analyses were carried out Percentages calculated by reviewer
Study limitations (author)	• Study was carried out in an urban area of San Francisco USA and may not be generalisable to other countries/ geographical areas • Primary outcomes were self reported and may be subject to bias • Negotiated safety was not measured and so the risk level of reported condomless sex cannot be determined • The study was conducted at around the same time as PrEP was being introduced and so this was not included in the Sheroes curriculum, but should be in future studies in terms of content and outcomes
Study limitations (reviewer)	• This was a small pilot study and it was noted that it was not powered to test the efficacy of the intervention. • It is noted that the outcome of interest for this data extraction (mean number of condomles sex partners) is reported for HIV negative participants only.

Source of funding	Not reported

Study arms

Sheroes (N = 39) Reducing risk of HIV through gender affirmation by empowering transgender women and building social support.
Time attention control (N = 38) Movie nights

Characteristics

Arm-level characteristics

	Sheroes (N = 39)	**Time attention control (N = 38)**
Age; Standardised Mean/SD	40.1 (10.9)	37.8 (10.2)
Race/Ethnicity		
African American/Black	n = 18 ; % = 46.2	n = 20 ; % = 52.6
White	n = 7 ; % = 18	n = 9 ; % = 23.7
Latina	n = 4 ; % = 10.3	n = 4 ; % = 10.5
Other	n = 10 ; % = 26.6	n = 5 ; % = 13.2
Gender identity		

	Sheroes (N = 39)	Time attention control (N = 38)
Female	n = 21 ; % = 53.9	n = 15 ; % = 39.5
Transgender female	n = 17 ; % = 43.6	n = 19 ; % = 50
Other	n = 1 ; % = 2.6	n = 4 ; % = 10.5
HIV positive	n = 18 ; % = 46.2	n = 17 ; % = 44.7
Years living with HIV; Mean/SD	14.3 (8.3)	12.4 (8.5)

Outcomes

Study timepoints	Baseline 3 (month) follow up 6 (month) follow up

Condom use outcomes

	Sheroes			Time attention control		
	Baseline	**3 (month)**	**6 (month)**	**Baseline**	**3 (month)**	**6 (month)**
	N = 39	N = 39	N = 39	N = 38	N = 38	N = 38
Condomless sex partners Standardised Mean/SE *Polarity: Lower values are better*	4.6 (1.55)	1.91 (0.86)	1.15 (0.56)	3.39 (1.16)	1.62 (0.76)	1.57 (0.82)

Study arms

Sheroes (N = 39)

Reducing risk of HIV through gender affirmation by empowering transgender women and building social support.

Brief name	Sheroes
Rationale/theory/Goal	Transgender women are experience high rates of discrimination, stigma and violence and the prevalence of HIV is high particularly among African American transgender women. Transgender women frequently under-estimate the risk of acquiring or transmitting HIV despite reporting multiple sexual risk behaviours including unprotected anal sex with multiple partners. There are few culturally specific interventions for transgender women and no group-based interventions reported. Sheroes is based on the Model of Gender Affirmation, which contextualises risk behaviours among transgender women of colour. This theorises that stigma and social oppression decreases access to gender affirmation, while psychological distress increases the need for gender affirmation, together leading to identity threat. Attempts to decrease the threat to identity happen in high risk contexts leading to risky behaviours. Sheroes aims to decrease identity threat by increasing access to gender affirmation, by for example, improving access to health care, including that related to transition (e.g. surgery, hormone therapy), HIV prevention and treatment and social support. The intervention aims to increase social support through a] empowering approach and by building community support (a sisterhood) among transgender women who have completed the intervention. (Background section)
Materials used	None reported
Procedures used	A screening survey to assess eligibility served as a baseline assessment and included demographics, sexual risk behaviour, HIV status, mental health, and substance use. Once enrolled and randomised participants were given a schedule of sessions The 5 sessions consisted of group discussions and interactive group activities and covered the following topics • Gender pride - Positive role models with a focus on trans women of colour. Self-care and its relationship with self-worth. Self care in terms of sexual health, HIV status, safer sex.

	• Looking good, feeling good - Gender affirmation and how it relates to self-image, self-care , negotiating sexual behaviours. Transition related health care and physical health care (sleep nutrition etc) • Let's talk about sex - Information session on rates and risk of HIV in transgender women, protecting self and others, getting tested • Taking back the power - discusses the impact of transphobia on one's sense of power, assertiveness skills, negotiating safer sexual behaviours, communicating with health professionals, self-defence and coping with harassment and violence • Surviving and thriving - knowing ones HIV status, getting treated, coping with transphobia, resources and support for substance use and mental health. Celebration of oneself and reinforcement of gender pride Assessments were made at 3 and 6 months post randomisation and consisted of computer-assisted self-administered quantitative surveys using RedCAP (Methods and Background sections, Table 1 intervention content)
Provider	Sessions were conducted by two trained peer co-facilitators who were transgender women of colour and who had received 25 hours of initial training in the Sheroes intervention together with ongoing supervision (Background section), Methods section)
Method of delivery	Group sessions of 6-8 participants (Background section)
Setting/location of intervention	Not reported
Intensity/duration of the intervention	5 sessions conducted weekly (Background section)
Tailoring/adaptation	None reported
Unforeseen modifications	None reported

Planned treatment fidelity	Fidelity was monitored using checklists completed at the end of each session by the peer facilitators. This indicated whether all components of the session were implemented. Sections of audio recordings of the sessions were reviewed at random by the supervisor to ensure fidelity and support ongoing training for the peer facilitators. (Measures section)
Actual treatment fidelity	• 82% (n=32) attended at least one session and 67% (n=26) attended all five sessions. • There was high implementation fidelity, with only two sessions not being implemented as planned due to unexpected external events (one fire alarm and one emergency unrelated to the intervention implementation). (Results section)
Other details	Participants received $40 cash for their participation in each assessment visit. An additional $40 bonus incentive was offered to participants who completed all 5 sessions. (Methods section)

Time attention control (N = 38)

Movie nights

Brief name	Time attention control - Movie nights
Rationale/theory/Goal	Not applicable
Materials used	None reported
Procedures used	Control participants underwent a time and attention matched control that consisted of movie nights, matched to the intervention sessions by number and length of sessions and group size. They watched a standardised set of movies that were deemed by the Community Advisory Board to be of interest but without content that overlapped with the Sheroes intervention. A brief facilitated discussion followed each movie night session, but avoided content that overlapped with the intervention. (Methods section)
Provider	Not reported

Method of delivery	Small group (Methods section)
Setting/location of intervention	Not reported
Intensity/duration of the intervention	Matched to the intervention condition - 5 weekly sessions
Tailoring/adaptation	None reported
Unforeseen modifications	None reported
Planned treatment fidelity	Not reported
Actual treatment fidelity	Not reported
Other details	Participants received $40 cash reimbursement for their participation in each assessment visit. An additional $40 bonus incentive was offered to participants who completed all 5 sessions. (Methods section).

Risk of Bias Assessment

Section	Risk of bias	Reason
Domain 1a: Bias arising from the randomisation process	Low	Appropriate randomisation procedures and no baseline differences between groups

Section	Risk of bias	Reason
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Some concerns	Participants were not blinded
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	Low	82% of intervention participants attended at least one session and 67% attended all five sessions. There was high implementation fidelity
Domain 3. Bias due to missing outcome data	Some concerns	Relatively high attrition but rates were similar across groups: 61.5% of those randomised to the intervention group were included in the analyses and 60.5% of those randomised to the control condition were included in the analyses. Intention to treat analyses were carried out
Domain 4. Bias in measurement of the outcome	Low	Appropriate outcome measures assessed using CASI
Domain 5. Bias in selection of the reported result	Low	Trial registered
Overall bias and Directness	Some concerns	Due to lack of participant blinding and relatively high attrition
	Overall Directness	Partially Applicable (US study)

D.5 Effectiveness evidence for people from a Black African or Caribbean family background

Diallo, 2010

Bibliographic Reference

Diallo, Dazon Dixon; Moore, Trent Wade; Ngalame, Paulyne M; White, Lisa Diane; Herbst, Jeffrey H; Painter, Thomas M; Efficacy of a single-session HIV prevention intervention for black women: a group randomized controlled trial.; AIDS and behavior; 2010; vol. 14 (no. 3); 518-29

Study details

Trial registration number	ClinicalTrials.gov (number NCT00362375)
Study start date	Mar-2006
Study end date	Jun-2007
Aim	To evaluate the efficacy of a single-session HIV prevention intervention, the Healthy Love Workshop (HLW), for increasing HIV-related protective behaviours and reducing sexual risk behaviours of Black women.
Country/geographical location	Atlanta, USA
Setting	Intervention workshops took place at locations of the women's choosing, including college campuses, churches, participants' homes, and community centres.
Inclusion criteria	- Women who self-identified as Black (i.e. African American, African or Caribbean) - > 18 years old - Not pregnant or planning to become pregnant during the next 6 months - English speaking
Exclusion criteria	- Had participated in a group-level HIV prevention intervention during the last 6 months - Had religious beliefs that prohibited the use of male or female condoms
Method of randomisation	Group-randomised design. Groups of women, such as university dormitory residents, church groups, friendship groups, neighbours or other affinity groups, were pair matched according to group type. One group from each matched pair was then randomly assigned to receive the intervention or control, via a coin toss.
Method of allocation concealment	Not reported
Unit of allocation	Group
Unit of analysis	Individuals

Statistical method(s) used to analyse the data	All analyses controlled for clustering that could result from the group-level randomisation process. Initial analyses compared baseline characteristics and attrition by group using cluster-adjusted chi squares and t tests. Intervention effects on behavioural and psychosocial outcomes were analysed by comparing proportions or mean values from HLW and comparison participants at the 3- and 6-month follow-up assessments. Multivariate analyses used generalized estimating equations (GEE) to assess intervention efficacy and adjusted the standard errors of coefficients to account for intra-cluster correlations of data. Each GEE model controlled for baseline levels of the outcome variable. Dichotomous outcomes (e.g., condom use and unprotected vaginal sex) were assessed using a logit link function with a binomial distribution to derive robust estimates of odds ratios (OR). Condom use at last sex was assessed using cluster adjusted chi-squared analyses. Psychosocial outcomes were assessed using an identity link function with a Gaussian distribution to derive robust estimates of regression coefficients. The analysis of behavioural outcomes was conducted based on the initial random assignment of participants' groups to the HLW or HIV101 comparison condition, and regardless of whether individual participants actually completed their respective workshops. Significance tests were based on alpha = 0.05, and analyses were performed using STATA statistical software.
Uptake	58 groups of women were screened for eligibility and initially agreed to participate in the study. 30 groups progressed to randomisation. The remaining 28 groups did not participate for logistical reasons, including a lack of follow-up by group contact persons to finalise arrangements (10 groups), failure of group members to arrive for the workshop (7 groups), and too few women to meet the minimum workshop size (6 groups). Five groups did not participate because of insufficient interest by their members in receiving either workshop.
Attrition	For the intervention group, 15 groups (n = 161) completed baseline assessments; n = 116 (72%) completed 3-month follow up and n = 121 (75.2%) completed 6-month follow up. For the comparison group, 15 groups (n = 152) completed baseline assessments; n = 116 (76.3%) completed 3-month follow up and n = 117 (77%) completed 6-month follow up. Retention rates at 3- and 6-month follow up were comparable for both groups. Analyses of attrition indicated that women who did not return for the 3-month follow-up assessment were more likely to have children than women who completed the 3-month follow-up ($p < .05$). Women who did not return for the 6-month follow up assessment were more likely to report being sexually active, engaging in sex while under the influence of drugs or alcohol, and having spent 30 or more days in jail than women who completed the 6-month follow-up ($p's < .05$).
Study limitations (author)	- Findings are based on self-reported risk and protective behaviours. It would have been preferable to also collect data from participants on biological outcomes (e.g., incident STD infections). - The choice of a comparison condition that also provided HIV prevention information rather than a general health promotion condition may have reduced the magnitude of observed differences between the HLW and comparison workshops - The relatively small number of groups in this study may have reduced the statistical power needed to detect significant intervention effects on certain outcomes. - Intervention efficacy was evaluated based on a non-probability sample of groups of Black women that may limit the generalizability of study findings.

	- The women enrolled in this study reported fairly low levels of behavioural risk at baseline. This included low rates of alcohol and drug use, and high rates of condom use and abstinence. Interventions may be less effective when levels of risk behaviours are already relatively low.
Study limitations (reviewer)	None to add
Source of funding	Funding for this study was provided by the Centers for Disease Control and Prevention (CDC) to Sister-Love, Inc. (a community-based organisation) under cooperative agreement U65/CCU424514.

Study arms

Intervention (N = 161) Healthy Love Workshop (HLW), a highly interactive, single session HIV prevention intervention for pre-existing groups of Black women.
Control (N = 152) Comparison workshop on STIs and HIV facts; similar information to intervention but delivered in lecture style format rather than interactive approach

Characteristics

Arm-level characteristics

	Intervention (N = 161)	**Control (N = 152)**
Age, Mean/SD	29.1 (10.1)	33.7 (12.7)
Gender, Female	n = 161 ; % = 100	n = 152 ; % = 100
Ethnicity, African American	n = 155 ; % = 96.9	n = 146 ; % = 96.1
HIV Positive at baseline	n = 13 ; % = 8.1	n = 10 ; % = 6.6

Outcomes

Study timepoints	Baseline 3 (month) 6 (month)

Condom use outcomes

These outcomes are reported for all study participants.

Although data for unprotected sex with a primary male partner were extracted, analyses only used data for unprotected sex with any male partner as this was considered a more comprehensive assessment of unprotected sex. Furthermore, where there is no concurrency (for both the participant or their male partner) and both individuals have received negative STI test results, unprotected sex in this context may be safe so may not be a useful indicator of risky sexual behaviour.

	Intervention (HLW)			**Control (HIV 101)**		
	Baseline	**3 (month)**	**6 (month)**	**Baseline**	**3 (month)**	**6 (month)**
	N = 161	N = 93	N = 120	N = 152	N = 94	N = 117
Unprotected vaginal sex with any male partner In prior 3 months *Polarity: Lower values are better*	n = 58 ; % = 36.3	n = 35 ; % = 37.6	n = 37 ; % = 30.8	n = 67 ; % = 44.1	n = 34 ; % = 36.2	n = 37 ; % = 31.6
Unprotected vaginal sex with a primary male partner In prior 3 months *Polarity: Lower values are better*	n = 56 ; % = 34.8	n = 32 ; % = 34.4	n = 34 ; % = 28.3	n = 65 ; % = 42.8	n = 32 ; % = 34	n = 35 ; % = 29.9

Condom use outcomes

These condom use outcomes are restricted to women who were sexually active at the assessment points

Although data for unprotected sex with a primary male partner were extracted, analyses only used data for unprotected sex with any male partner as this was considered a more comprehensive assessment of unprotected sex. Furthermore, where there is no concurrency (for both the participant or their male partner) and both individuals have received negative STI test results, unprotected sex in this context may be safe so may not be a useful indicator of risky sexual behaviour.

	Intervention (HLW)			Control (HIV 101)		
	Baseline	**3 (month)**	**6 (month)**	**Baseline**	**3 (month)**	**6 (month)**
	N = 108	N = 59	N = 70	N = 108	N = 53	N = 67
Condom use during vaginal sex with any male partner *Polarity: Higher values are better*	n = 55 ; % = 50.9	n = 35 ; % = 59.3	n = 38 ; % = 54.3	n = 51 ; % = 47.2	n = 21 ; % = 39.6	n = 30 ; % = 44.1
Condom use during vaginal sex with primary male partner *Polarity: Higher values are better*	n = 45 ; % = 41.7	n = 33 ; % = 55.9	n = 37 ; % = 52.9	n = 46 ; % = 42.6	n = 19 ; % = 35.8	n = 28 ; % = 41.2
Condom use at last vaginal, oral or anal sex with any partner *Polarity: Higher values are better*	n = 59 ; % = 54.7	n = 42 ; % = 71	n = 48 ; % = 67.8	n = 55 ; % = 50.5	n = 26 ; % = 49.5	n = 33 ; % = 48.6

TIDier Checklist

Study details

Rationale/theory/Goal	Given the disproportionate impact of HIV/AIDS on Black women in general and the limited availability of culturally appropriate, evidence based interventions for delivery to this population, there is an urgent need for innovative approaches to prevent HIV designed by and for Black women (p. 519).
Procedures used	Information about the HIV prevention study was disseminated through the use of print media, public service announcements on local radio stations, electronic communication (e.g., e-mail, listservs and social network sites), and informational mailings to local AIDS service organizations, county health departments, medical clinics, and community centres. Outreach was used to recruit groups of women affiliated with faith-based organizations and CBOs serving African immigrants, at college health fairs and community events,

	and at SisterLove-sponsored activities. Groups responded to the recruitment efforts described above and indicated that her group was interested in participating. Groups were screened against eligibility criteria then matched with another similar group, assigned to HLW or comparison group, and a date and preferred location for the workshop was arranged. All eligible women who agreed to participate provided written informed consent, completed a self-administered baseline survey, and then participated in the HLW or comparison workshop. Ineligible women, or those who did not wish to participate in the evaluation, were allowed to attend the workshop. At the termination of both workshops, all participants received male and female condoms, dental dams, HIV risk reduction brochures, and information on where to obtain HIV counselling and testing services (p. 520-521). Incentives used to retain women in the study included $20 for completing the baseline survey, $25 for the 3-month survey and $30 for the 6-month survey (p. 521).

Study arms

Intervention (N = 161)

Healthy Love Workshop (HLW), a highly interactive, single session HIV prevention intervention for pre-existing groups of Black women.

Brief name	Healthy Love Workshop (HLW) (p. 519)
Rationale/theory/Goal	The intervention is based on principles of the Health Belief Model, the Transtheoretical Model, and Social Cognitive Theory. It uses approaches that are respectful of women's abilities to empower themselves and the belief that Black women's collective wisdom and lived experiences provide important learning opportunities (p. 520). It delivers HIV prevention information and teaches condom-use skills in a highly interactive, festive and non-judgemental manner. It eroticises safer sex and aims to create a safe space in which Black women can connect with their sexuality in ways that are positive and self-loving rather than shameful or degrading (p. 519). The intervention is designed to increase consistent use of condoms and other latex barriers, reduce unprotected sex with male partners, and reduce the number of sex partners (p. 520).
Materials used	At the termination of the workshops, participants received male and female condoms, dental dams, HIV risk reduction brochures and information on where to obtain HIV counselling and testing services (p. 521).

Procedures used	The Healthy Love Workshop is a single session intervention delivered to pre-existing groups of 4-15 women. It is designed to change participants behaviours by improving their knowledge about the transmission and prevention of STIs including HIV; their ability to assess personal risk of contracting HIV; their attitudes about condom use and HIV testing; and their self-efficacy to engage in protective behaviours including condom use. The HLW includes components providing basic information on HIV/AIDS and STIs (e.g. facts and information about common STIs, symptoms, how they are spread; prevalence) and the circumstances or behaviours that can increase a woman's risk of contracting or transmitting HIV. Other components address attitudes, beliefs and feelings around sex and sexuality, and the societal influences that can trivialise or denigrate women's sexuality. Remaining components are interactive activities that include a personal sexual risk assessment, condom use demonstrations, and negotiating condom use with partners. Throughout the session there is a keen sensitivity to women's unequal treatment and status as females and as Blacks in the South, and addresses issues around internalised sexual oppression or their empowerment and rights. The intervention provides current information concerning the impacts of HIV/AIDS on Black women in a way that helps participants situate known risk factors in their lives and communities, while maintaining an affirming, Black woman-centred, sex-positive focus on ways of avoiding or eliminating some of those risks. (p. 520, 522).
Provider	The HLW was delivered by a trained Black female facilitator (p. 521).
Method of delivery	Face to face group sessions (P. 520)
Setting/location of intervention	The HLW is delivered in locations selected by the groups of women, including college campuses, churches, participants homes, and community centres (p. 519).
Intensity/duration of the intervention	Single session lasting 3-4 hours (p. 520).
Tailoring/adaptation	None reported
Unforeseen modifications	None reported; unlikely
Planned treatment fidelity	Not reported

Actual treatment fidelity	Not reported

Control (N = 152)

Comparison workshop on STIs and HIV facts; similar information to intervention but delivered in lecture style format rather than interactive approach

Brief name	HIV 101 comparison workshop (p. 521)
Materials used	At the termination of the workshop, all participants received male and female condoms, dental dams, HIV risk reduction brochures, and information on where to obtain HIV counselling and testing services (p. 521).
Procedures used	The comparison workshop was delivered as a single session to groups of women about the same size and in settings similar to those used for the HLW. The HIV101 workshop consists of an opening component to describe the purpose of the workshop and establish ground rules, one module containing the same three HIV/STI related components as the HLW, and a closing component to give participants opportunities to ask questions and provide workshop feedback. The presentation of all information used a didactic, lecture-style format, as opposed to the interactive approach used to deliver the HLW (p. 521-522).
Provider	A trained Black female facilitator (p. 521)
Method of delivery	Face to face group sessions (p. 521)
Setting/location of intervention	Locations selected by the groups of women, including college campuses, churches, participants homes, and community centres (p. 519).
Intensity/duration of the intervention	A single session lasting 2-3 hours (p. 521)
Tailoring/adaptation	None reported
Unforeseen modifications	None reported; unlikely

Planned treatment fidelity	None reported
Actual treatment fidelity	None reported

Risk of Bias

Domain	Risk of bias	Reason
1a: Bias arising from the randomisation process	Some concerns	*Random allocation and no baseline differences between groups but no allocation concealment*
1b. Bias arising from the timing of identification and recruitment of individual participants in relation to timing of randomisation	Low	
2. Bias due to deviations from intended interventions	Low	
3. Bias due to missing outcome data	Low	*Acceptable retention rates which were comparable across groups. No differences in attrition by group or baseline characteristics*
4. Bias in measurement of the outcome	Low	*All assessments conducted using self-administered surveys. Controlled for clustering.*
5. Bias in selection of the reported result	Low	
Overall bias and Directness	Low	
	Overall Directness	Partially applicable (*US study)*

Wilson, 2019

Bibliographic Reference	Wilson, Tracey E; Gousse, Yolene; Joseph, Michael A; Browne, Ruth C; Camilien, Brignel; McFarlane, Davin; Mitchell, Shawn; Brown, Humberto; Urraca, Nelson; Romeo, Desmond; Johnson, Steven; Salifu, Moro; Stewart, Mark; Vavagiakis, Peter; Fraser, Marilyn; HIV Prevention for Black Heterosexual Men: The Barbershop Talk with Brothers Cluster Randomized Trial.; American journal of public health; 2019; vol. 109 (no. 8); 1131-1137

Study details

Trial registration number	ClinicalTrials.gov identifier: NCT01980771
Study start date	Nov-2012
Study end date	Jul-2016
Aim	To test the effectiveness of the Barbershop Talk with Brothers (BTWB) intervention for Black heterosexual men living in areas of high risk for heterosexual HIV infection.
Country/geographical location	Brooklyn, New York. Specifically, neighbourhoods with a high prevalence of HIV infection attributable to heterosexual behaviour.
Setting	The intervention was introduced to men through barbershop partnerships. Sessions were intended to be held in barbershops but as a result of space and time constraints, sessions took place in private settings at the State University of New York and the Arthur Ashe Institute of Urban Health.
Inclusion criteria	- Reports of at least 2 sexual partners in the preceding 6 months - Reports of at least 1 episode of condomless sex in the preceding 6 months - 18 years or older - Identified as Black or African American
Exclusion criteria	- Those reporting using injection drugs

	- Those reporting having sex with other men in the preceding 5 years - Those with HIV positive serostatus - Men unable to understand spoken English - Those reporting participation in another HIV or substance use study in the preceding 6 months
Method of randomisation	This was a cluster randomised study. Barbershops located within high-risk neighbourhoods were randomly allocated to intervention or control groups using permuted block randomisation conducted via a computerised number generator, with 1:1 allocation typically performed in block sizes of 4.
Method of allocation concealment	Computerised number generator
Unit of allocation	Barbershop
Unit of analysis	Participant
Statistical method(s) used to analyse the data	The Chi square test (for categorical variables) and independent samples t-test (for group differences in continuous variables) were used to assess study characteristics across groups and in relation to condomless sex. Generalized linear mixed-effects models were used to estimate between-group differences at the participant level taking into account the hierarchical data structure, with men clustered by barbershop. Differences between the BTWB intervention and control groups in terms of changes in outcomes were analysed on an intention-to-treat basis. SAS PROC GLIMMIX version 9.4 (SAS Institute, Cary, NC) was used to analyse the data.
Uptake	Sixty-two barbershop owners agreed to participate; 53 shops received training and were randomised (24 BTWB intervention, 29 control). Of the 9 excluded shops, 2 lost interest in participating and withdrew before study activities began, 1 went out of business, 2 did not have barbers willing or available to be trained, and the others yielded no recruits after 1 week of attempts.
Attrition	N = 860 participants completed baseline assessments (n = 436 intervention; n = 424 control). N = 650 participants provided complete follow-up data at 6 months (n = 347 intervention; n = 303 control). Follow-up was higher in the BTWB group (79.6%) than in the control group (71.5%; p =.006). Among the 650 men with outcome data, there were no differences detected in baseline-reported condomless sex as a function of completing follow-up or in the covariates of living with a partner, insurance status, nativity, housing stability, marijuana use, alcohol use, other drug use, incarceration history, or age (all Ps > .05). Follow-up was higher among men who were not employed (79.7%) than among those who were working (71.4%; P = .005); it was also higher among men with lower educational attainment (69.7%) than among those with at least the equivalent of a high school education (77.4%; P = .03).

Study limitations (author)	- Generalisability is limited to patrons of barbershops situated in neighbourhoods with large HIV disparities. - Concealment of treatment allocation was not plausible except at the level of data analysis. The inability to blind could have led to bias. - The primary outcome was self-reported as more objective measures, such as STI incidence, were not feasible in this research context. - There were shifts toward safer sex over time in both the experimental and control groups. These shifts could be due to a number of factors, including the potential intervention effect of condom distribution at both experimental and control shops, regression to the mean, inflated baseline risks reported by participants to gain entry into the study, or a contamination effect across shop personnel or study participants. - Loss to follow-up differed as a function of baseline education and employment but not by condom use or other model covariates. These differences could have biased the findings, particularly given that education was associated with condom use at follow-up.
Study limitations (reviewer)	- There were significant baseline differences between the groups: At baseline, men recruited from BTWB intervention barbershops were younger, more likely to be in stable housing, less likely to have health insurance, less likely to be currently employed, less likely to report illicit substance use, less likely to report lifetime criminal justice system involvement, and less likely to have been born in the United States than were men recruited from control barbershops (all Ps < .05).
Source of funding	This study was supported by the National Institute on Minority Health and Health Disparities (grant P20MD006875).

Study arms

Intervention (N = 436) Barbershop Talk with Brothers (BTWB), a single small-group peer-led session focused on HIV risk reduction skills and motivation, community health empowerment, and personal communication skills.
Control (N = 424) Attention control group focused on prostate cancer screening

Characteristics

Study-level characteristics

	Study (N = 860)
Age Range Mean/SD	 18 to 76 33 (11)
Gender, Male	n = 860 ; % = 100
Ethnicity	
Born in the United States	n = 557 ; % = 64.8
Born outside of the United States	n = 303 ; % = 35.2
Ethnicity of men born outside of US	
Haitian	% = 47.9
Jamaican	% = 9.4
Guyanese	% = 8.1
Trinidad and Tobago	% = 3.9
Other Caribbean	% = 5.9
Africa	% = 8.8
Other countries	% = 14.7
Did not respond	% = 1.3
History of incarceration	n = 447 ; % = 52

Outcomes

Study timepoints	Baseline 6 (month)

Condom use outcomes

	Intervention		Control	
	Baseline	**6 (month)**	**Baseline**	**6 (month)**
	N = 436	N = 352	N = 424	305
No condomless sex Number of participants reporting no condomless vaginal or anal sex in previous 90 days *Polarity: Higher values are better*	n = 240 ; % = 55	n = 228 ; % = 64.8	n = 206 ; % = 48.7	n = 164 ; % = 53.8
Condomless sex Number of participants reporting condomless vaginal or anal sex in previous 90 days	n = 196 ; % = 45	n = 124 ; % = 35.2	n = 218 ; % = 51.3	n = 141 ; % = 46.2

Condomless sex outcome calculated by analyst; reverse of no condomless sex outcome.

TIDier Checklist

Study details

Rationale/theory/Goal	BTWB aims to address risk factors associated with HIV risk among heterosexual Black men, such as social determinants (poor socioeconomic status, greater income inequality) and the impact of sex roles and conceptualisations of normative male and female behaviour on partner concurrency, condom use and HIV stigma. The intervention focuses on leveraging the strong connections and

	frequent interactions that barbers have with members of this priority population. Barbershops represent a trusted community venue for Black men, and they are regular points of contact for men who might not have regular access to prevention education (p. 1131-1132).
Materials used	Participants, regardless of study condition, were provided $20 for taking part in the program along with a roundtrip subway/bus fare card, a T-shirt with the project logo, and a referral guide for local free or low-cost health and social services. In addition, condoms were periodically distributed at all shops (p. 1133).
Procedures used	Partnerships were formed with barbershops located in high-risk neighbourhoods for heterosexually transmitted HIV infection. All participating barbershops were trained on strategies to promote referral of customers to the program (intervention and control). Study staff were introduced to customers by their barber; they then described the study and interested customers completed screening questions via audio computer-assisted self-interviewing (ACASI) on a laptop with privacy screen and headphones. Eligible participants completed a baseline interview, engaged in intervention activities consistent with their group assignment, and completed a 6 month follow-up assessment (p. 1132).

Study arms

Intervention (N = 436)

Barbershop Talk with Brothers (BTWB), a single small-group peer-led session focused on HIV risk reduction skills and motivation, community health empowerment, and personal communication skills.

Brief name	Barbershop Talk with Brothers (BTWB)
Rationale/theory/Goal	The BTWB program is informed by social cognitive theory; community- and individual-level empowerment theory; and an assets- and strengths-based perspective on health promotion. This strengths-based approach emphasises individual and environmental resources, capacities, values, and competencies (p. 1132).
Materials used	Each participant received a workbook and supporting educational materials, including a pamphlet and information on sites where PrEP and HIV testing could be attained (p. 1133).
Procedures used	The BTWB program involved a combination of educational messages, role-play activities, self-evaluation activities, and a strengths-based lens on men and masculinity to support several goals on the pathway to sustained sexual risk reduction (p. 1132). Core elements of the intervention focused on promoting attitudes, self-efficacy and perceived norms supporting reduced risk behaviour; increasing effective communication strategies for condom use with sexual partners; and developing increased personal

	responsibility and commitment to improving community health by empowering men with skills and motivation to co-educate people in their social networks about sexual risk reduction (p. 1132-1133). Participants also developed a set of achievable behavioural change goals associated with their own sexual behaviour (p. 1133).
Provider	Barbers, managers and shop owners supported recruitment activities. Intervention sessions were provided by group facilitators - Black men, most of whom lived or worked in the prioritised geographic area. Minimum qualifications were a bachelor's degree in a health- or science-related field or having prior experience working in the field of HIV prevention (p. 1132).
Method of delivery	Small group sessions; presumed face to face (p. 1131).
Setting/location of intervention	Participants were recruited from barbershops. Intervention sessions were originally intended to be held during off hours at participating barbershops; as a result of space and time constraints, however, sessions took place in private settings at SUNY Downstate and the Arthur Ashe Institute for Urban Health (p. 1132).
Intensity/duration of the intervention	Single session (p. 1131). Session duration not reported.
Tailoring/adaptation	None reported
Unforeseen modifications	None reported.
Planned treatment fidelity	Study investigators conducted a checklist-guided review of audiotapes of intervention sessions to ensure that all core components were delivered, and provided ongoing individualised feedback to interventionists on delivery of content areas (p. 1132).
Actual treatment fidelity	Not reported.

Control (N = 424)

Attention control group focused on prostate cancer screening.

Procedures used	Control group participants received a curriculum focused on prostate cancer screening and detection. The protocol for the control group activity was adapted early in the data collection process to be administered in a similar group format to the BTWB program, to be moderated by a staff member, and to involve a time commitment for participation similar to that associated with the BTWB intervention (p. 1133).
Provider	Study staff members (p. 1133).
Method of delivery	Small group sessions (p. 1131); presumed face to face.
Setting/location of intervention	Participants were recruited from barbershops. Intervention sessions were originally intended to be held during off hours at participating barbershops; as a result of space and time constraints, however, sessions took place in private settings at SUNY Downstate and the Arthur Ashe Institute for Urban Health (p. 1132).
Intensity/duration of the intervention	Single session (p. 1131). Session duration not reported.
Tailoring/adaptation	None reported
Unforeseen modifications	None reported
Planned treatment fidelity	Not reported
Actual treatment fidelity	Not reported

Risk of Bias Assessment

Domain	Risk of bias	Reason
1a: Bias arising from the randomisation process	Some concerns	*Multiple significant baseline differences, including age, housing instability, health insurance, employment status, substance use, criminal justice system involvement, and whether born in US*
1b. Bias arising from the timing of identification and recruitment of individual participants in relation to timing of randomisation	Some concerns	*Limited information concerning timings of recruitment and randomisation*
2. Bias due to deviations from intended interventions	Some concerns	*Participants and people delivering the interventions were not blinded. Only blinding of statistical analyst was possible.*
3. Bias due to missing outcome data	Some concerns	*Differential attrition by group but generally low attrition overall*
4. Bias in measurement of the outcome	Low	*Staff conducting intervention sessions were different from staff conducting assessments*
5. Bias in selection of the reported result	Low	*Analyses match those planned in the trial registration*
Overall bias and Directness	High	*Baseline difference between groups on key variables; differential attrition by group, no blinding*
	Overall Directness	Partially applicable (*US study; conducted in barbershops)*

Wingood, 2011

Bibliographic Reference	Wingood, Gina M; Card, Josephina J; Er, Deja; Solomon, Julie; Braxton, Nikia; Lang, Delia; Seth, Puja; Cartreine, Jim; Diclemente, Ralph J; Preliminary efficacy of a computer-based HIV intervention for African-American women.; Psychology & health; 2011; vol. 26 (no. 2); 223-34

Study details

Trial registration number	Not reported
Study start date	Apr-2006
Study end date	Mar-2007
Aim	To evaluate the preliminary efficacy of SAHARA to enhance HIV protective sexual behaviours and mediators among African-American women over a 3-month follow-up period.
Country/geographical location	Atlanta, USA
Setting	Planned Parenthood services in Atlanta (nonprofit organisation that provides sexual health care in the United States and globally)
Inclusion criteria	- African American women - 21-29 years - Reporting unsafe sex with a male sexual partner in prior 3 months - Seeking services at Planned Parenthood Atlanta
Exclusion criteria	- Being married or living with their partner - Not sexually active - Using condoms 100% of the time
Method of randomisation	Prior to enrolment, a randomisation scheme was generated using computer-generated block randomisation. As participants completed baseline assessments, sealed opaque envelopes were used to execute assignments.
Method of allocation concealment	Sealed opaque envelopes

Unit of allocation	Participant
Unit of analysis	Participant
Statistical method(s) used to analyse the data	Analysts were blind to intervention arm. Analyses were performed using an intent-to-treat protocol in which participants were analysed in their assigned treatment conditions irrespective of the number of treatment sessions attended. At baseline, descriptive statistics were calculated for sociodemographic variables, mediators and sexual behaviours. Differences between conditions were assessed using Student's t-tests for continuous variables and chi-square analyses for categorical variables. Variables for which differences between study conditions approached statistical significance ($p<0.05$) and which were theoretically or empirically identified as potential confounders were included as covariates in subsequent logistic regression and ANCOVA analyses. The computer-based HIV intervention effects analysis from baseline to the 3-month follow-up used logistic regression to compute adjusted odds ratios (ORs) for dichotomous outcomes (consistent condom use) and used linear regression to compute adjusted means for continuous outcomes (proportion condom use). An indicator for the time period was included in the model to model any unaccounted temporal effects and an indicator for cohort was included in the model to adjust for unaccounted group effects (clustering). This approach yields adjusted OR which assess the effect of the intervention on dichotomous outcomes (consistent condom use) and adjusted mean differences to assess the effects of the intervention on continuous outcomes (proportion condom use). The 95% confidence intervals (95% CI) around the adjusted ORs and the adjusted means and the corresponding p-values were also computed. Analyses were performed using STATA statistical software, version 8 (StataCorp, College Station, TX, USA).
Uptake	N=506 potential participants were screened for eligibility. N=346 were not eligible. An additional n=25 were eligible but did to participate (n=10 not interested; n=14 unreachable; n=1 no childcare to attend sessions).
Attrition	135 participants were randomised into the study; 67 (49.7%) in the computer-based HIV intervention and 68 (50.3%) in the general health condition. Of the 67 participants allocated to the computer-based HIV intervention, 58 (87%) completed the 3-month follow-up assessment. 60 (89.6%) received both intervention sessions. Of the 68 participants allocated to the general health condition, 58 (85%) completed the 3-month follow-up assessment.
Study limitations (author)	Limitations of the study include reliance on self-report data, a small sample size and short-study follow-up. While this study is primarily a computer-based HIV intervention, the intervention includes a 15-minute group delivered component which could limit its feasibility for dissemination

	Participants in the computer-based HIV intervention condition received a greater amount of contact time compared to participants in the control condition.
Study limitations (reviewer)	It is not clear why one of the reasons for participants not being eligible included living with a partner.
Source of funding	This study was supported by an SBIR grant from the National Institute of Mental Health (R43 MH077212).

Study arms

Intervention (N = 67) SISTAs Accessing HIV/AIDS Resources at a Click (SAHARA) - a computer-based HIV prevention intervention with small group sessions
Control (N = 68) General health intervention including discussion of HIV prevention

Characteristics

Arm-level characteristics

	Intervention (N = 67)	**Control (N = 68)**
Age, Mean/SD	24.06 (2.24)	24.1 (2.35)
Gender, Female	n = 67 ; % = 100	n = 68 ; % = 100
Ethnicity, African-American	n = 67 ; % = 100	n = 68 ; % = 100

Outcomes

Study timepoints	Baseline 3 (month)

Condom use outcomes

	Intervention		Control	
	Baseline	**3 (month)**	**Baseline**	**3 (month)**
	N = 67	N = 58	N = 68	N = 58
Proportion of condom-protected sex acts In prior 90 days Mean/SD *Polarity: Higher values are better*	0.48 (0.41)	0.85 (0.1)	0.54 (0.41)	0.53 (0.1)
Condom use self-efficacy Mean/SD 9 items rated on 5 point likert scale *Polarity: Higher values are better*	27.71 (6.09)	30.81 (0.52)	28.44 (5.55)	28.96 (0.51)

STI knowledge outcomes

	Intervention		Control	
	Baseline	**3 (month)**	**Baseline**	**3 (month)**
	N = 67	N = 58	N = 68	N = 58
STI/HIV prevention knowledge Mean/SD 10 true or false items	8.62 (0.97)	9.45 (0.09)	8.66 (1.04)	8.99 (0.09)

	Intervention		Control	
	Baseline	**3 (month)**	**Baseline**	**3 (month)**
	N = 67	N = 58	N = 68	N = 58
Polarity: Higher values are better				

TIDier Checklist

Study details

Rationale/theory/Goal	Computer-based interventions have the potential to provide greater access and exposure to effective HIV prevention programs, and to ultimately affect significant reductions in risk behaviours and HIV infection (p. 224).
Procedures used	Eligible participants were recruited by study staff and randomised to the HIV prevention or health promotion conditions. Once a cohort of 6 participants was identified, they were randomised to relevant group sessions. Data collection occurred at baseline and 3-month follow-up. Assessments were administered via audio computer-administered survey interview (ACASI). To enhance confidentiality, codes rather than names were used. Participants in both conditions were compensated $50 for attending study sessions (p. 225-226).

Study arms

Intervention (N = 67)

SISTAs Accessing HIV/AIDS Resources at a Click (SAHARA) - a computer-based HIV prevention intervention with small group sessions

Brief name	SISTAs Accessing HIV/AIDs Resources At a click (SAHARA)

Rationale/theory/Goal	SAHARA is an adaptation of a CDC-defined evidence-based HIV intervention for young adult African-American women known as SISTA. The adaptations primarily accommodate the five, 2-hour group based SISTA sessions into 2 shorter computer-based sessions. The SISTA HIV intervention is guided by Social Cognitive Theory and the Theory of Gender and Power. It emphasises ethnic and gender pride by discussing attributes and accomplishments of African-American women. It also builds HIV risk reduction knowledge and seeks to enhance communication, condom use and relationship skills by modelling the skills, allowing for role play of the skills in different scenarios, and enhancing norms of supportive partner involvement in safer sex (p. 226-227). Small group sessions were also used to support the computer-based intervention because coupling CBIs with small group sessions has been shown to enhance health promoting behaviours relative to CBI alone (p. 227).
Materials used	A laptop for delivering the computer-based sessions (p. 227).
Procedures used	The first computer based session focused on enhancing ethnic and gender pride. Participants watched vignettes of people discussing the joys and challenges of being an African-American woman and watched female models read poetry by African-American female poets. Participants were asked to identify African-American female role models and to prioritise their personal values. The first part of this session was designed to enhance the cultural congruence of HIV prevention efforts for African-American women. Additionally, this session highlighted the proportion of African-American women living with HIV in Atlanta and discussed the HIV risk factors prevalent among African-American women. The second computer-based session offers communication skills and realistic choices in sexual decision making. The importance of consistent condom use is discussed and modules illustrating correct condom use skills and assertive communication approaches are included in this session. Examples of interactive vignettes include activities that allow participants: to provide responses to true and false statements on HIV prevention, to select female models who demonstrate negotiating safer sex using assertive communication as opposed to passive or aggressive communication, to select female models who use condoms correctly on a dildo, to choose components of relationships characterised as healthy (i.e. trust and respect), to identify high-risk sexual behaviours that enhance women's HIV vulnerability and to choose hypothetical male partners who they would be interested in dating. After completing the computer-based sessions, participants took part in a small group session which provided an opportunity for participants to role play and receive feedback on condom use and communication skills. (p. 227).
Provider	The small group sessions were implemented by an African-American female health educator (p. 227).

Method of delivery	2 computer-based sessions and 1 small group face to face session (p. 227)
Setting/location of intervention	Participating Planned Parenthood clinics (p. 227).
Intensity/duration of the intervention	Two 60-minute computer-based sessions and one 15-minute group session (p. 227).
Tailoring/adaptation	None reported
Unforeseen modifications	None reported; unlikely
Planned treatment fidelity	Not reported
Actual treatment fidelity	Not reported

Control (N = 68)

General health intervention including discussion of HIV prevention

Brief name	General health comparison intervention (p. 226)
Materials used	A 30-minute video on the importance of HIV prevention for African-American women, produced by the CDC. Participants also received brochures on proper nutrition and HIV prevention for African-American women (p. 228)
Procedures used	Control group participants received a 1-hour group session which consisted of 15 minutes general health information and a 30-minute video on the importance of HIV prevention for African-American women. For 15 minutes, the facilitator answered questions participants had pertaining to the HIV prevention video. All participants in this condition also received brochures on proper nutrition and HIV prevention for African-American women. The control condition was designed to represent usual care regarding clients typical exposure to HIV prevention education at Planned Parenthood (p. 228).

Provider	The control group was facilitated by a trained African-American female facilitator (this facilitator was different than the facilitator who implemented the computer-based HIV intervention) (p. 228).
Method of delivery	Face to face (p. 228).
Setting/location of intervention	Participating Planned Parenthood clinics (p. 227).
Intensity/duration of the intervention	1 hour (p. 228).
Tailoring/adaptation	None reported
Unforeseen modifications	None reported; unlikely
Planned treatment fidelity	Not reported
Actual treatment fidelity	Not reported

Risk of Bias Assessment

Section	Risk of Bias	Reason
Domain 1: Bias arising from the randomisation process	Some concerns	*Appropriate randomisation procedures but baseline differences between groups (financial dependence on partner; current relationship status)*
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Low	

Section	Risk of Bias	Reason
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	Some concerns	*Intervention adherence not assessed. 7 participants (10.4%) did not attend both intervention sessions*
Domain 3. Bias due to missing outcome data	Low	*Low attrition overall and no group differences in attrition*
Domain 4. Bias in measurement of the outcome	Low	*ACASI used for outcome assessments; standardised measures*
Domain 5. Bias in selection of the reported result	Some concerns	*Trial not registered*
Overall bias and Directness	Risk of bias judgement: Some concerns	*Impact of intervention adherence not assessed; 10.4% did not attend both intervention sessions. Trial not registered.*
	Overall Directness	Partially applicable *(US study)*

D.6 Effectiveness evidence for young people from a Black African or Caribbean family background

Brawner, 2021

Bibliographic Reference	Brawner, Bridgette M; Jemmott, Loretta Sweet; Hanlon, Alexandra L; Lozano, Alicia J; Abboud, Sarah; Ahmed, Charisse; Wingood, Gina; Results from Project GOLD: A pilot randomized controlled trial of a psychoeducational HIV/STI prevention intervention for black youth.; AIDS care; 2021; vol. 33 (no. 6); 767-785

Study details

Study design	Randomised controlled trial (RCT)

Trial registration number	Not reported
Study start date	Aug-2014
Study end date	Dec-2016
Aim	To pilot test the efficacy of a psychoeducational intervention designed to address the role of mental illness and emotion regulation in HIV/STI risk among heterosexually active Black youth aged 14-17 years.
Country/geographical location	Philadelphia, USA
Setting	Department of Family and Community Health, University of Pennsylvania School of Nursing
Inclusion criteria	Not reported Participants were heterosexually active Black youth
Exclusion criteria	Exclusionary mental health diagnoses were active psychosis and schizophrenia
Method of randomisation	The permuted-block randomisation technique was used with a block size of 4 and a 1:1 allocation ratio. A biostatistician generated the randomisation list using a pseudo-randomiser computer program. Participants were stratified based on their Patient Health Questionnaire (PHQ-9) total scores (none/moderate depression versus moderately severe/severe depression) and gender.
Method of allocation concealment	The research coordinator implemented the treatment allocation protocol; investigators were blinded.
Unit of allocation	Participant
Unit of analysis	Participant
Statistical method(s) used to analyse the data	- Descriptive statistics were used to characterise the study variables at each time point, and their changes from baseline by intervention condition. - Since all continuous variables were not normally distributed, non-parametric exact Wilcoxon rank-sum tests were used to examine differences in rank-sum scores across the two conditions. Comparisons of categorical variables relied on Fisher’s exact tests.

	- As this was a small pilot study, the focus was on estimation of effect and not formal hypothesis testing. Effect sizes were based on η2 (eta-squared) for continuous variables (small [0.01], medium [0.06], and large [>0.14]) and Cramer's V for categorical variables (small [0.10–0.29], medium [0.30–0.50], and large [>0.50]). - Statistical significance was taken at the 0.05 level and did not adjust for multiplicity given the pilot nature of this study. - All analyses were performed using SAS, version 9.4 (SAS Institute Inc., Cary, NC). - Pairwise deletion (available-case analysis) was used to handle missing data.
Attrition	The original intent was to complete 3, 6 and 12 month follow ups, however due to study delays and a fixed end date, the majority of participants could only be scheduled for the 3 month follow up. 109 participants were randomised at baseline (n=52 intervention, n=57 control). In the intervention group, n = 39 completed the 3 month follow up, and in the control group, n = 38 completed the 3 month follow up. At 6 months, n = 25 intervention participants were eligible for follow up, of which n = 17 completed it; and n = 33 control participants were eligible for follow up, of which n = 24 completed it. At 12 months, n = 19 intervention participants were eligible for follow up, of which n = 11 completed it; and n = 22 control participants were eligible for follow up, of which n = 13 completed it. Overall completion rates for the intervention group were 39/47 (83%) at 3 months, 17/25 (68%) at 6 months, and 11/19 (58%) at 12 months. For the control group they were 38/52 (73%) at 3 months, 24/33 (73%) at 6 months, and 13/22 (59%) at 12 months. Prominent causes for attrition were loss to follow up, placement in residential treatment, incarceration and withdrawal. Those who dropped out were slighter younger than those retained (M = 15.5 vs. 16, p = 0.0052). Compared to intervention participants, control participants had statistically significantly more: sexual partners in the past three months (Median = 2 vs. 1, p = 0.04), same month sexual partner concurrency (57% vs. 35%, p = 0.02) and past 30-day alcohol use (Median = 2 [1–3 times last month] vs. 1 [never], p = 0.01, η2 = 0.13).

Study limitations (author)	- The sample was small, the fixed end date meant fewer participants completed the 6- and 12-month follow-ups, and there was considerable attrition. This reduced power for the behavioural outcomes, limited detection of effects and increases uncertainty in the findings. - The outcomes were self-reported and thus susceptible to bias; participants did undergo HIV/STI testing but there were too few cases to include in the analyses. - The intent was to test an intervention for youth experiencing mental illness and emotion regulation, yet depressive symptoms were low in the sample – PHQ-9 scores less than four indicate minimal depression. However, depressive symptoms were only one of many symptoms participants experienced (e.g., anxiety) and they reported difficulties regulating anger and sadness, thus the overall objective was still achieved.
Study limitations (reviewer)	The study aimed to recruit a sample of young people receiving outpatient mental health treatment, but due to delays and accrual difficulties, the protocol was expanded to include youth in the general community, resulting in a combined sample that included n = 58 youth from the community who were not receiving any mental health treatment at the time of screening, and n = 50 youth who were currently receiving outpatient mental health treatment. The needs and risk profiles of these groups may differ in unknown ways, but separate analyses were not performed for these two population groups within the sample.
Source of funding	This research was funded by the Centers for Disease Control and Prevention grant # U01PS003304 awarded to Dr Bridgette M. Brawner. The research was also supported by a grant from the Penn Mental Health AIDS Research Center (PMHARC), a National Institute of Mental Health-funded program (P30MH097488), to Dr Brawner.

Study arms

Intervention (N = 52)

Project GOLD: a psychoeducational STI/HIV prevention intervention designed to address the role of mental illness and emotion regulation in sexual risk among heterosexually Black youth.

Control (N = 56)

General health comparison condition (diet and exercise based content)

Characteristics

Study-level characteristics

Characteristic	Study (N = 109)
Age Range	14 to 17
Age Mean (SD)	15.78 (0.97)
Male	n = 67 ; % = 62
Female	n = 41 ; % = 38

Outcomes

Study timepoints

- Baseline
- 3 month
- 6 month
- 12 month

Condom use outcomes

Outcome	Intervention, Baseline, N = 30	Intervention, 3 month, N = 21	Intervention, 6 month, N = 9	Intervention, 12 month, N = 5	Control, Baseline, N = 36	Control, 3 month, N = 20	Control, 6 month, N = 12	Control, 12 month, N = 9
Proportion of condom use for vaginal sex In past 3 months	0.64 (0.42)	0.77 (0.37)	0.58 (0.43)	0.73 (0.44)	0.67 (0.39)	0.64 (0.38)	0.72 (0.35)	0.91 (0.19)

Outcome	Intervention, Baseline, N = 30	Intervention, 3 month, N = 21	Intervention, 6 month, N = 9	Intervention, 12 month, N = 5	Control, Baseline, N = 36	Control, 3 month, N = 20	Control, 6 month, N = 12	Control, 12 month, N = 9
Mean (SD)								

Proportion of condom use for vaginal sex - Polarity - Higher values are better

Condom use outcomes

Outcome	Intervention, Baseline, N = 47	Intervention, 3 month, N = 37	Intervention, 6 month, N = 17	Intervention, 12 month, N = 11	Control, Baseline, N = 51	Control, 3 month, N = 31	Control, 6 month, N = 18	Control, 12 month, N = 10
Condom use self-efficacy Mean (SD)	4.14 (0.61)	4.26 (0.56)	4.33 (0.51)	4.4 (0.55)	4.15 (0.46)	3.95 (0.57)	4.12 (0.64)	4.15 (0.61)

Condom use self-efficacy - Polarity - Higher values are better

Separate tables for each outcome because n's are different

Condom use outcomes

Outcome	Intervention, Baseline, N = 50	Intervention, 3 month, N =	Intervention, 6 month, N = 17	Intervention, 12 month, N = 11	Control, Baseline, N = 55	Control, 3 month, N =	Control, 6 month, N = 18	Control, 12 month, N = 12
Condom use knowledge Mean (SD)	0.67 (0.28)	*empty data*	0.84 (0.2)	0.84 (0.25)	0.69 (0.27)	*empty data*	0.79 (0.23)	0.75 (0.32)

Condom use knowledge - Polarity - Higher values are better

Separate tables because n's are different

STI/HIV knowledge outcomes

Outcome	Intervention, Baseline, N = 50	Intervention, 3 month, N = 36	Intervention, 6 month, N = 17	Intervention, 12 month, N = 11	Control, Baseline, N = 55	Control, 3 month, N = 30	Control, 6 month, N = 18	Control, 12 month, N = 12
STI/HIV knowledge Mean (SD)	0.64 (0.22)	0.73 (0.21)	0.76 (0.21)	0.77 (0.19)	0.63 (0.21)	0.57 (0.27)	0.72 (0.18)	0.7 (0.24)

STI/HIV knowledge - Polarity - Higher values are better

TIDier Checklist

Study details

Rationale/theory/Goal	The HIV/STI epidemic in the US disproportionately affects Black youth and HIV/STI incidence and prevalence in this group remains high. Numerous interactive effects across individual, social and structural domains impact vulnerability, including racism, discrimination, and neighbourhood disadvantage. Gender role norms, mental illness, and emotion regulation are mediators of HIV/STI risk-related behaviours, as they can contribute to some youth engaging in risk behaviours such as condomless sex to cope with feelings such as sadness or inferiority. Targeting these mediators may reduce HIV/STI risk, for example interventions that incorporate affect management and emotion regulation could address the affective components of the sexual decision making process (p. 767-768).
Procedures used	- Participants were recruited from outpatient mental health treatment programs or general community settings via community partner referrals, face-to-face encounters, flyers and social media. - All participants provided written informed consent. - After initial screening for preliminary eligibility, participants underwent an interviewer-administered structured clinical interview using the MINI International Neuropsychiatric Inventory (van Vliet & de Beurs, 2007) to determine mental health

	diagnoses and rule out exclusionary conditions (e.g., active psychosis, schizophrenia). The most frequent diagnoses were substance use disorders (15%), obsessive-compulsive disorder (7%) and post-traumatic stress disorder (6%). - Participants were randomised to either the intervention or control group, and the study design included a pre-test, immediate post-test, 3-, 6- and 12-month follow up assessments. At the baseline and follow-ups, participants completed a computer-assisted personal interview (CAPI) and were also tested for HIV (oral swab) and Chlamydia and Gonorrhoea (urine sample). - The study had a fixed completion date of December 2016 so many participants were only scheduled to complete the 3-month follow up. (p. 768-769)
Setting/location of intervention	All research activities took place at the University of Pennsylvania School of Nursing (p. 768)
Other details	Although participants were tested for HIV (oral swab) and Chlamydia and Gonorrhoea (urine sample) at baseline and follow up assessments, the paper reports that the number of positive HIV/STI cases was too small to include in effect estimations (p. 769) No information on remuneration

Study arms

Intervention (N = 52)

Project GOLD: a psychoeducational STI/HIV prevention intervention designed to address the role of mental illness and emotion regulation in sexual risk among heterosexually Black youth.

Brief name	Project GOLD: We are Kings and Queens (p. 768)

Rationale/theory/Goal	The intervention was designed to enhance culturally and contextually relevant, developmentally and psychologically appropriate sexual health promotion programs for Black youth. The intervention drew from psychology, developmental and behaviour change theories, and was embedded in a social determinants of health framework (p. 769).
Materials used	No specific materials reported
Procedures used	Intervention sessions included content on emotion regulation, such as meditation skills, which was used to explore alternatives to using sex as a coping strategy. The intervention also addressed the way emotions such as anger and sadness can affect decisions about sex. Other activities were used to highlight social determinants of sexual behaviours such as financial independence and stability, navigating parental conflict and residential instability, and dealing with daily stressors such as racism (p. 769).
Provider	Sessions were delivered by facilitators who underwent 16 hours of training (p. 769)
Method of delivery	Face to face. Unclear from paper whether this was 1-to-1 or group sessions, but no details provided on group sizes or format so presumed individual sessions.
Intensity/duration of the intervention	6 hours: 2 x 3 hour sessions (p. 769)
Tailoring/adaptation	None reported
Unforeseen modifications	None reported
Planned treatment fidelity	Facilitators rated activity adherence after each session (p. 769)
Actual treatment fidelity	Reported fidelity was 98% (p. 769)

Control (N = 56): General health comparison (diet and exercise content)

Materials used	No specific materials reported
Procedures used	Limited information provided. Paper states it was a general health control condition (i.e. diet, exercise) (p. 769)
Provider	Sessions were delivered by facilitators who underwent 16 hours of training (p. 769)

Method of delivery	Face to face (p. 769)
Intensity/duration of the intervention	Unclear; assumed same duration as intervention group (2 x 3 hour sessions) but no information provided
Tailoring/adaptation	None reported
Unforeseen modifications	None reported
Planned treatment fidelity	Facilitators rated activity adherence (p. 769)
Actual treatment fidelity	Reported fidelity was 98% (p. 769)

Risk of Bias Assessment

Section	Risk of Bias	Reason
Domain 1: Bias arising from the randomisation process	Some concerns	Randomisation and allocation concealment procedures appropriate but baseline differences between groups on some key variables: control participants had significantly more sexual partners at baseline, more same month partner concurrency, and higher past 30-day alcohol use than intervention participants
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Low	Deviation from intended interventions unlikely
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	Low	Intervention was 1-to-1 session with trained facilitator so intervention adherence likely to be high. Intervention fidelity reported as 98%
Domain 3. Bias due to missing outcome data	Some concerns	Significant attrition for 6- and 12-month follow ups but this was due to fixed study completion date so participants that were recruited late to the study were unable to complete follow-ups beyond 3 months. Attrition from baseline to 3-month follow-up was 17% in the intervention group and 27% in the control group, although there

Section	Risk of Bias	Reason
		was no significant difference in attrition between groups. Participants who dropped out were younger than completers (M = 15.5 vs 16; *p* = 0.005)
Domain 4. Bias in measurement of the outcome	Low	Appropriate measures used and outcome assessments completed using CASI.
Domain 5. Bias in selection of the reported result	Some concerns	Trial not registered
Overall bias and Directness	Some concerns	Baseline differences between groups, high attrition and trial not registered
	Overall Directness	Partially applicable *(US study)*

Brothers, 2016

Bibliographic Reference Brothers, Jennifer; Hotton, Anna L; Hosek, Sybil G; Harper, Gary W; Fernandez, M Isabel; Young Women Living with HIV: Outcomes from a Targeted Secondary Prevention Empowerment Pilot Trial.; AIDS patient care and STDs; 2016; vol. 30 (no. 5); 229-35

Study details

Trial registration number	Not reported
Aim	A pilot RCT to assess the preliminary efficacy of the EVOLUTION intervention to reduce sexual risk for young women living with HIV.
Country/geographical location	Baltimore, Maryland; Chicago, Illinois; and Tampa, Florida; USA
Setting	3 participating Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN) clinical sites in Maryland, Illinois and Florida.

Inclusion criteria	- Young women living with HIV - Age 16-24 - Receiving medical care at one of the 3 participating sites or their community partners - Able to understand written and spoken English - Free of any active, serious psychiatric symptoms that would impair their ability to meet study requirements - Not intoxicated at the time of enrolment
Exclusion criteria	None reported
Method of randomisation	Participants were randomised at each study site to one of the two study arms in a 1:1 ratio (EVOLUTION intervention or HEALTH/LIFE SKILLS control). No information on method of randomisation.
Method of allocation concealment	Not reported
Unit of allocation	Participant
Unit of analysis	Participant
Statistical method(s) used to analyse the data	Participant characteristics were compared at baseline using Pearson chi-square tests for categorical variables and t-tests or Wilcoxon rank-sum tests for continuous variables. Fisher's exact chi-square tests were used for comparison of categorical variables with cell sizes <5. Analysis of intervention efficacy was based on an intent-to-treat approach. Effects of the intervention on each of the primary and secondary outcomes were evaluated using generalized estimating equations (GEE) to account for correlation among repeated measures, with link functions as appropriate based on the distribution of the outcome variable. Models were fit that included an indicator for group, time, and a group by time interaction to assess whether the intervention and control groups differed in response to the intervention over time. In the absence of a significant interaction, average group differences across the entire follow-up period were also assessed. Effect estimates from the models presented reflect average group differences from baseline and immediate postintervention and the 3-month post-intervention follow-up, and are represented as odds ratios for binary outcomes, rate ratios for count outcomes, and mean differences for continuous outcomes. Adjusted models included an indicator for time, age at baseline, and the value of the outcome at baseline. Other potential confounders that were considered empirically or conceptually important and those for which baseline comparisons yielded $p < 0.2$ (including ATN site, age, and number of sex partners) were assessed in multivariable models but were not included in

	the final models because they were not statistically significantly associated with the outcome and did not alter the intervention effect estimates significantly. Results were similar when participants who never attended a group session (n = 4) or who withdrew from the trial (n = 2) were excluded. Findings presented here are based on the intent-to-treat analysis. The data were also analysed using ANOVA with mean differences for continuous outcomes and yielded similar results. Therefore, it was decided to present the data using GEE, while recognizing the limitation of the small sample size. Data were analysed using SAS software version 9.3 (SAS Institute, Cary, NC).
Uptake	Not reported
Attrition	Of 43 young women who were enrolled into the trial, 36 (84%) women completed the baseline, immediate post and 3-month post assessments; 1 completed the baseline and immediate post assessments but not the 3-month assessment; 2 completed only the baseline and 3-month post assessments; and 4 completed only the baseline assessment. There were no statistically significant differences by intervention group or patient characteristics between women who completed all three of the assessments compared to those who did not, although those who completed all three assessments tended to be older (median age 21 vs. 17, p = 0.111) and more likely to be taking antiretroviral therapy at baseline (64% vs. 29%, p = 0.110) than those who did not complete all three assessments.
Study limitations (author)	Although the small sample size was appropriate for the objectives of a feasibility trial, the sample size was too limited to conduct a robust or theory driven analysis and therefore limited the interpretation of the data and the intervention's relationship to the theory that guided it. Efficacy of this intervention could not be determined from this small trial. Young women in the trial reported far fewer sexual risks and higher empowerment and self-efficacy scores at baseline than anticipated from our initial pilot and from existing literature. A little over half of the young women in the trial did not report any vaginal intercourse in the 3 months prior to baseline and 25% reported having no male sexual partners in the last 3 months. Alongside these observed low rates of HIV risk behaviour, at baseline the young women in both groups scored very high on the self-efficacy scales and questionnaires, leaving very little room for significant change in outcomes such as self-efficacy for limiting HIV risk behaviour. It is unclear whether the young women in the trial are representative of young women living with HIV in the general population or if this phenomenon is a product of sample selection from the clinical sites where young women are already engaged and retained in care.
Study limitations (reviewer)	There was a significant difference in HIV transmission risk behaviours at baseline: 43% of women in the intervention group reported having 2 or more sex partners in the prior 3 months, compared to 29% of women in the control group (p = 0.094).
Source of funding	This study was supported by The Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN) from the National Institutes of Health [U01 HD 040533 and U01 HD 040474] through the National Institute of Child Health and Human Development (Lee Kapogiannis), with supplemental funding from the National Institutes on Drug Abuse (Kahana Davenny) and Mental Health (Allison Brouwers).

Study arms

Intervention (N = 22)

"EVOLUTION: Young Women Taking Charge and Growing Stronger." This intervention provided young women with sexual HIV risk reduction education along with behavioural and cognitive skills building activities to reduce the risk of transmitting HIV to others and lead healthier lives.

Control (N = 21)

HEALTH/LIFE SKILLS; an attention-matched control arm focusing on health, nutrition, exercise and life skills.

Characteristics

Arm-level characteristics

	Intervention (N = 22)	Control (N = 21)
Age; MedianIQR	21 (19 to 23)	20 (17 to 22)
Gender, female	n = 22 ; % = 100	n = 21 ; % = 100
Ethnicity		
African-American / non-Hispanic	n = 19 ; % = 86.4	n = 16 ; % = 76.2
White/Hispanic/other race/ethnicity	n = 3 ; % = 13.6	n = 5 ; % = 23.8
Sexual orientation		
Heterosexual	n = 19 ; % = 86.4	n = 15 ; % = 71.4
Bisexual	n = 3 ; % = 13.6	n = 6 ; % = 28.6

	Intervention (N = 22)	Control (N = 21)
Time since HIV diagnosis < 12 months	n = 2 ; % = 9.1	n = 3 ; % = 14.3
Taking ARV medications	n = 13 ; % = 59.1	n = 12 ; % = 57.1

Outcomes

Study timepoints	Baseline Immediate post-test (immediately after all intervention sessions had been completed; ~9 weeks) 3 (month)

Condom use outcomes - sexually active participants

Analyses were restricted to those reporting 1 or more sex partners at each time point

	Intervention			Control		
	Baseline	**Post-test**	**3 (month)**	**Baseline**	**Post-test**	**3 (month)**
	N = 17	N = 15	N = 12	N = 13	N = 15	N = 13
Unprotected vaginal or anal intercourse Number and % of participants reporting any episodes in prior 3 months *Polarity: Lower values are better*	n = 7 ; % = 41.2	n = 3 ; % = 20	n = 6 ; % = 50	n = 7 ; % = 53.9	n = 5 ; % = 33.3	n = 6 ; % = 46.2

Condom use outcomes - all participants

Not restricted to sexually active participants

	Intervention			Control		
	Baseline	**Post-test**	**3 (month)**	**Baseline**	**Post-test**	**3 (month)**
	N = 19	N = 18	N = 18	N = 19	N = 18	N = 18
Condom use self-efficacy; Mean/SD Assessed with 28 item scale *Polarity: Higher values are better*	4.67 (0.34)	4.47 (0.56)	4.58 (0.45)	4.32 (0.6)	4.36 (0.53)	4.15 (0.52)

TIDier Checklist

Study details

Rationale/theory/Goal	There is a need for continued prevention work among young women living with HIV, but the literature on how best to reduce sexual risk and increase the health and well-being of young women living with HIV is scarce. Publications on the topic of secondary prevention among young women living with HIV is limited (p. 229).
Procedures used	Potential participants were approached by research staff members at each clinical site to explain the study, gauge interest in participation, and gather written informed consent for those interested and eligible. A waiver of parental permission was granted by each IRB. All participants completed a baseline behavioural assessment using audio computer-assisted self-interview (ACASI). Participants were then randomized at each site to one of the two study arms in a 1:1 ratio: (1) the EVOLUTION intervention or (2) a HEALTH/LIFE SKILLS focused time and attention matched control condition. Participants returned for post-intervention assessments via ACASI immediately after the intervention sessions. They were also completed at 3 months postintervention. Participants were compensated for their time as determined by each site's IRB (p. 230).

Study arms

Intervention (N = 22)

"EVOLUTION: Young Women Taking Charge and Growing Stronger." This intervention provided young women with sexual HIV risk reduction education along with behavioural and cognitive skills building activities to reduce the risk of transmitting HIV to others and lead healthier lives.

Brief name	EVOLUTION: Young Women Taking Charge and Growing Stronger (p. 229).
Rationale/theory/Goal	The intervention is guided by the Theory of Gender and Power and developed based on data collected from focus groups held with young women living with HIV, alongside a review of existing interventions. It attempts to address the moderating factors of young women's sexual risk behaviour such as gender roles, cultural norms, perceived control over sexual relationships, social support, and self-efficacy and self-confidence (p. 230).
Materials used	No specific materials reported
Procedures used	The intervention comprised 9 sessions: 7 group and 2 individual sessions. Each group comprised of 6-8 young women. Session activities were designed to empower the young women with the knowledge, skills and tools to accurately identify and assess their social environment and emotional state. Activities aimed to develop life goals and gain power over their actions in order to reduce the risk of transmitting HIV to others. Session topics included traditional HIV risk reduction education and sexual negotiation skills, as well as forgiveness, emotional regulation, communication and relationships. Themes of sexuality, what it means to be a woman with HIV, healthy and unhealthy relationships, self-esteem, and becoming a healthy sexual being were embedded throughout the program. (p. 230)
Provider	Trained facilitators who attended a 3-day training session led by the Principal Investigator and Project Director. The training included protocol and data management procedures, group facilitator expectations, group facilitation techniques, intervention fidelity monitoring, and a session-by-session walk-through of the intervention manual. The facilitators then practiced delivering both intervention conditions during the training. Interventionists were given feedback based upon their knowledge of the material, their ability to maintain fidelity to the intervention manual while building rapport with mock participants (p. 230).
Method of delivery	Small group sessions and individual sessions (p. 230)
Setting/location of intervention	Participating clinic sites (p. 230)

Intensity/duration of the intervention	9 sessions, each lasting 2-3 hours, taking place approximately weekly for 9 weeks (p. 230)
Tailoring/adaptation	None reported
Unforeseen modifications	None reported; unlikely
Planned treatment fidelity	Once the trial was launched, interventionists recorded every session and sent it to the Project Director for review. The recorded sessions were compared to the manuals and feedback to interventionists was provided during weekly supervision calls (p. 231).
Actual treatment fidelity	Not reported

Control (N = 21)

HEALTH/LIFE SKILLS; an attention-matched control arm focusing on health, nutrition, exercise and life skills.

Brief name	HEALTH/LIFE SKILLS control arm (p. 230)
Materials used	No specific materials reported
Procedures used	This was a time and attention matched control group, consisting of 9 sessions (7 group and 2 individual). Each group comprised 6-8 women. The HEALTH/LIFE SKILLS control arm aimed to build life skills. Activities focused on topics such as health, internet safety, nutrition, and exercise, as well as life skills needed to manage finances and prepare for the workforce (p. 230).
Provider	Trained facilitators (p. 230)
Method of delivery	Face to face; 7 small group sessions and 2 individual sessions (p. 230)
Setting/location of intervention	Participating medical clinics (p. 230)

Intensity/duration of the intervention	9 sessions, each lasting 2-3 hours, taking place approximately weekly for 9 weeks (p. 230)
Tailoring/adaptation	None reported
Unforeseen modifications	None reported; unlikely
Planned treatment fidelity	Once the trial was launched, interventionists recorded every session and sent it to the Project Director for review. The recorded sessions were compared to the manuals and feedback to interventionists was provided during weekly supervision calls (p. 231).
Actual treatment fidelity	Not reported

Risk of Bias Assessment

Section	Risk of Bias	Reason
Domain 1: Bias arising from the randomisation process	High	Limited information on randomisation procedure or allocation concealment. No baseline differences in sociodemographic characteristics but baseline differences in HIV transmission risk behaviours.
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Low	Deviation from intended interventions unlikely; ITT analysis used
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	Some concerns	Intervention adherence not assessed. 4 participants did not attend any intervention sessions but were retained in analyses.
Domain 3. Bias due to missing outcome data	Low	Low level of missing data and no group differences in attrition

Section	Risk of Bias	Reason
Domain 4. Bias in measurement of the outcome	Low	Standardised outcome assessments conducted via ACASI
Domain 5. Bias in selection of the reported result	Some concerns	Trial not registered, pilot study
Overall bias and Directness	Risk of bias judgement: High	Limited information on randomisation; baseline differences between groups; intervention adherence not assessed; trial not registered
	Overall Directness	Partially applicable *(US study)*

Chandler, 2019

Bibliographic Reference	Chandler, R.; Ross, H.; Paul, S.; Shittu, A.; Lescano, C.; Hernandez, N.; Morrison-Beedy, D.; The HIP LADIES: A Pilot Health Improvement Project for HIV Prevention in Black College Women; The Journal of the Association of Nurses in AIDS Care : JANAC; 2019; vol. 30 (no. 4); 474-487

Study details

Trial registration number	Trial not registered
Study start date	Jan-2014
Study end date	Oct-2014
Aim	To pilot-test a manualised HIV prevention intervention for Black college women (HIP LADIES) compared to an educationally equivalent program about health promotion (COST).

Country/geographical location	Florida, USA
Setting	A research-intensive Traditionally White Institution (TWI) and a teaching-focused Historically Black College/University (HBCU) in Florida
Inclusion criteria	- Female - Age 18–24 years - Able to read and speak in English - Self-report race as Black African American and/or Black Hispanic - Not pregnant or actively trying to become pregnant and no births within the past 6 months - Sexually active with a male partner in the past 3 months
Exclusion criteria	None reported
Method of randomisation	The research coordinator at each study site used a permutated block randomisation procedure to maintain a balanced mix of intervention and control groups.
Method of allocation concealment	The prescribed randomisation sequence remained secure through the use of a card and envelope system that kept the assignments concealed until the time of enrolment.
Unit of allocation	Participant
Unit of analysis	Participant
Statistical method(s) used to analyse the data	Descriptive statistics of the study population (demographic and sexual behaviour factors) were delineated as M (SD) for continuous variables and frequencies (percentages) for categorical variables. T-tests/chi-square tests were initially conducted to determine statistically significant differences between program intervention and control baseline characteristics. Preliminary effectiveness of the intervention was assessed using analysis of covariance (i.e., whether the postintervention means differed between the two groups after adjusting for baseline scores). Data were also adjusted for variation due to site. A measure of effect size was calculated as the standardised difference between the adjusted group means post-intervention. The effect size for the various outcomes were classified as <0.3 = small, 0.3–0.5 = medium, and. >0.5 = large (Cohen, 1988). A significance level of p = .05 was used for hypothesis testing. SPSS 23 was used for data management and statistical analysis.
Uptake	Not reported

Attrition	Thirty-six participants were assigned to the intervention and control groups. For the intervention group, 29 (81%) completed pre-test measures and 25 (69%) completed all intervention sessions and 3-month post-test assessments. For the control group, 28 (78%) completed pre-test measures and 21 (58%) completed all sessions and 3-month post-test assessments. Data analyses were restricted to those completing all sessions and pre- and 3-month follow up assessments (intervention n = 25; control n = 21). Paper did not report whether attrition significantly differed by group.
Study limitations (author)	The study was implemented at a teaching-focused institution and a research-intensive institution. Success at the latter academic institution was reflected in participant familiarity with standard research procedures (e.g. enrolment, study attendance) and preparedness to engage in this study. The teaching-focused institution required more human resources to ensure that study procedures were congruent with those in the research institution. It was not possible to use objective measures to substantiate behavioural outcomes.
Study limitations (reviewer)	Participants were recruited from either a Traditionally White Institution (TWI; where 57% of enrolled students self-identify as White) or a Historically Black College/University (HBCU; where more than 80% of enrolled students self-identify as Black). There may be important differences between Black women attending these different institutions but no analyses by study site were reported. Pilot study with small participant numbers.
Source of funding	This study was funded by the National Institutes of Health, National Institute of Nursing Research (NINR). Mentored Research Scientist Development Award (KO1) KO1NR013435-01A1 (PI: Rasheeta Chandler).

Study arms

Intervention (N = 29) Health Improvement Project for LADIES (HIP LADIES): a manualised small-group HIV prevention intervention based on the IMB model and designed for Black college women
Control (N = 28) College-Oriented Safety Topics (COST): a structurally equivalent intervention addressing college health and safety topics such a breast health, nutrition and sleep.

Characteristics

Study-level characteristics

	Study (N = 57)
Gender Female	n = 57 ; % = 100
Ethnicity Black African-American / Black Hispanic	n = 57 ; % = 100

Arm-level characteristics

	Intervention (N = 29)	Control (N = 28)
Age Mean/SD	20.7 (1.4)	20.1 (1.2)

Outcomes

Study timepoints	3 (month)

Condom use outcomes

Paper reports mean/SE; SDs calculated by analyst

	Intervention	Control
	3 (month)	**3 (month)**
	N = 24	N = 21
Condom use self-efficacy; Mean/SD Assessed using 7-item scale	21.03 (5.78)	19.71 (5.77)

	Intervention	Control
	3 (month)	**3 (month)**
	N = 24	N = 21
Polarity: Higher values are better		

STI Knowledge outcomes

Paper reports mean and SE; SDs calculated by analyst.

Mean HIV knowledge scores at follow-up were adjusted for baseline scores

	Intervention	Control
	3 (month)	**3 (month)**
	N = 25	N = 21
HIV Knowledge; Mean/SD Assessed using 18-item HIV Knowledge Questionnaire *Polarity: Higher values are better*	18.13 (2.2)	15.06 (2.02)

TIDier Checklist

Study details

Rationale/theory/Goal	College campuses are pertinent microenvironments when considering young Black women's vulnerability to HIV and the potential for HIV/STI transmission in Black college students is high. Despite the availability of HIV and STI information, many other sociocultural

	factors contribute to the persistence of sexual behaviours that put young Black women at risk for HIV. Effective HIV prevention interventions need to focus on sociocultural as well as information barriers (p. 474).
Procedures used	Electronic flyer distribution (e.g., campus media) and in-person recruitment were used at the TWI. HBCU recruitment strategies included in-person pre-screening and on-campus flyer distribution at a number of student organisations and campus landmarks, which were identified as high traffic areas for the study population. One-hour enrolment appointments were scheduled for participants at both sites; participants also received e-mail and telephone reminders for upcoming appointments. Baseline, 1-week and 3-month surveys were conducted using audio computer-assisted self-interview (ACASI) and participants were able to navigate the survey at their own pace. A brief tutorial for operating the ACASI program was provided. At enrolment appointments, students were introduced to the principal investigator and study coordinator. The study coordinator provided an overview of the study purpose and schedule. It was explained that participants were expected to meet for a total of seven times. The first session included consent, enrolment, and baseline assessment (in a 1-hr enrolment appointment). Sessions 2–5 represented 4 consecutive weekly intervention sessions where, each week, participants would meet with their assigned groups at the specified dates, times, and locations. Sessions 6 (1-week postintervention) and 7 (3-month follow-up) served as data collection sessions and required a 1-hr appointment for time to complete assessments. For each completed session, participants received a $15 cash incentive (maximum 7 sessions = $105 USD). To promote session attendance at each site, e-mail reminders were sent 2 days before the weekly sessions, and telephone contact was attempted 1 day before each session. To schedule assessments, correspondence was made through e-mail and by phone. (p. 479-480)

Study arms

Intervention (N = 25)

Health Improvement Project for LADIES (HIP LADIES): a manualised small-group HIV prevention intervention based on the IMB model and designed for Black college women

Brief name	Health Improvement Project for LADIES (HIP LADIES) (p. 475)

Rationale/theory/Goal	Qualitative research and feedback was used to refine a pre-existing HIV prevention intervention, HIP TEENS, for implementation in the Black college female population. The HIP LADIES intervention was based on the Information Motivation Behavioural skills model (IMB).
Materials used	Powerpoint presentations with audio and video files embedded (p. 478)
Procedures used	The intervention sessions presented information components about HIV transmission, prevention and safe sex behaviours. Sessions then addressed factors influencing immediate (behaviour-focused) motivations and broader motivation regarding life goals. These were (a) gender-specific, (b) considered personal and community values, and (c) engaged other germane situational contexts. Intervention components addressing behavioural skills were focused on improving assertiveness, self-efficacy, use of condoms or other risk reduction practices with partners, and identification of high-risk situations. Behavioural skill elements also helped prepare participants to counter negative perceptions about condoms and included a condom application demonstration for male and female condoms. Sessions included role-playing and positive feedback from facilitators and other participants. Sessions were constructed using a multimodal, interactive, and paired-facilitator approach to program delivery. PowerPoint presentations served as the primary information delivery method; embedded audio and video files were added for content variability. Interactive activities were strategically placed within certain modules to address or reinforce relevant objectives and to strengthen group discussions and support. (p. 475-476)
Provider	Intervention peer facilitators were African American, largely graduate or doctoral-level students at their respective institutions, and represented diverse academic majors such as public health (e.g., prevention, promotion, administration), social work, and psychology. Facilitators received 2 consecutive days of training approximately 1 month before study implementation (p. 476).
Method of delivery	Face to face small group sessions containing 6 participants (p. 480)
Setting/location of intervention	Colleges in Florida: either a research-intensive Traditionally White Institution (TWI) or a teaching-focused Historically Black College/University (HBCU) (p. 475)
Intensity/duration of the intervention	4 consecutive weekly intervention sessions lasting 90 minutes each (p. 478)
Tailoring/adaptation	None reported

Unforeseen modifications	None reported; unlikely
Planned treatment fidelity	Fidelity of program delivery was established across the participating institutions by randomly attending at least 50% of all HIP LADIES sessions in person, supplemented by digital recordings of all sessions. Facilitators were scored using two benchmarks, adherence and competence, rated on a 5-point scale from 1 (very well) to 5 (not very well). Evaluation forms were designed to follow each module within the scheduled session. Checklists were used to assess adherence to program content (e.g., information, activities); as well as facilitator delivery styles and content proficiency (competence) (p. 476).
Actual treatment fidelity	The total mean scores for adherence and competence were 1.5 (Very well/well) for the intervention program (p. 476).

Control (N = 21)

College-Oriented Safety Topics (COST): a structurally equivalent intervention addressing college health and safety topics such a breast health, nutrition and sleep.

Brief name	College-Oriented Safety Topics (COST) (p. 476)
Materials used	Powerpoint presentations with audio and video files embedded (p. 478)
Procedures used	C.O.S.T. module topics included breast health, nutrition, collegiate stress management, and body augmentation. The sessions covered issues such as breast cancer screening, breast cancer risk, risk sensitisation, healthy eating, menu planning, assertive communication, goal setting and self-empowerment (p. 476 and p. 478). As with intervention sessions, control sessions were constructed using a multimodal, interactive, and paired-facilitator approach to program delivery. PowerPoint presentations served as the primary information delivery method; embedded audio and video files were added for content variability. Interactive activities were strategically placed within certain modules to address or reinforce relevant objectives and to strengthen group discussions and support (p. 476).
Provider	Intervention peer facilitators were African American, largely graduate or doctoral-level students at their respective institutions, and represented diverse academic majors such as public health (e.g., prevention, promotion, administration), social work, and psychology. Facilitators received 2 consecutive days of training approximately 1 month before study implementation (p. 476).
Method of delivery	Face to face small group sessions containing 6 participants (p. 480)

Setting/location of intervention	Colleges in Florida: either a research-intensive Traditionally White Institution (TWI) or a teaching-focused Historically Black College/University (HBCU) (p. 475)
Intensity/duration of the intervention	4 consecutive weekly intervention sessions lasting 90 minutes each (p. 478)
Tailoring/adaptation	None reported
Unforeseen modifications	None reported; unlikely
Planned treatment fidelity	Fidelity of program delivery was established across the participating institutions by randomly attending at least 50% of all COST sessions in person, supplemented by digital recordings of all sessions. Facilitators were scored using two benchmarks, adherence and competence, rated on a 5-point scale from 1 (very well) to 5 (not very well). Evaluation forms were designed to follow each module within the scheduled session. Checklists were used to assess adherence to program content (e.g. information, activities); as well as facilitator delivery styles and content proficiency (competence) (p. 476).
Actual treatment fidelity	The total mean scores for adherence and competence were 1.5 (Very well/well) for the control program (p. 476).

Risk of Bias Assessment

Section	Risk of Bias	Reason
Domain 1: Bias arising from the randomisation process	Low	*Randomisation procedures appropriate; no baseline differences between groups*
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Low	*Participants and people delivering the interventions were blind to condition*
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	Some concerns	*Intervention implementation assessed and adequate but adherence not assessed*

Section	Risk of Bias	Reason
Domain 3. Bias due to missing outcome data	Some concerns	*Moderate attrition and paper did not report whether attrition significantly differed by group*.
Domain 4. Bias in measurement of the outcome	Low	*Appropriate measures used; assessments were standardised and conducted using ACASI. Pilot study*
Domain 5. Bias in selection of the reported result	Some concerns	*Trial not registered*
Overall bias and Directness	Risk of bias judgement: Some concerns	*Intervention adherence not assessed; trial not registered*
	Overall Directness	Partially applicable *(US study)*

Crosby, 2014

Bibliographic Reference Crosby, Richard A; Charnigo, Richard J; Salazar, Laura F; Pasternak, Ryan; Terrell, Ivy W; Ricks, JaNelle; Smith, Rachel V; Taylor, Stephanie N; Enhancing condom use among Black male youths: a randomized controlled trial.; American journal of public health; 2014; vol. 104 (no. 11); 2219-25

Study details

Trial registration number	Not reported
Study start date	2010
Study end date	2012

Aim	To test the efficacy of a brief clinic-based sex-positive intervention to promote correct and consistent condom use among Black male youths attending STI clinics.
Country/geographical location	3 southern US cities: New Orleans, LA; Baton Rouge, LA; and Charlotte, NC.
Setting	Private rooms in STI clinics
Inclusion criteria	- Male aged 15-23 years - Self-identifying as Black - Engaging in penetrative sexual intercourse at least once in the prior 2 months - Not knowingly HIV positive
Exclusion criteria	None reported
Method of randomisation	Participants were randomised with a computer-generated algorithm.
Method of allocation concealment	The allocation technique was concealed. The randomised sequence was transposed to separate index cards which were placed in sealed envelopes. The envelopes were placed in pre-packaged and ID-numbered enrolment folders. For each newly enrolled participant, project staff used the next available ID number and folder. Envelopes were only opened after baseline survey completion.
Unit of allocation	Participant
Unit of analysis	Participant
Statistical method(s) used to analyse the data	An intent-to-treat design was used; there were no cases of crossover between groups. First, to identify statistically relevant covariates, bivariate associations were tested between group assignment and various demographic measures and potential confounders for significance. Except where otherwise indicated, groups were compared on nominal and ordinal variables with the Chi squared or Fisher exact test and on interval and ratio variables with the t test. After unadjusted group comparisons were performed on the primary dependent behavioural variable, logistic regression models were fit to examine group differences in correct and consistent use at 2 months and at 6 months, with adjustment for correct and consistent use at baseline, history of CT or GC, age, and treatment group. A logistic regression model with generalized estimating equations was also fit to estimate the adjusted association of correct and consistent use with each covariate over both follow-up visits. Finally, a nonparametric rank sum test was used to determine whether change scores (baseline to 2 months and baseline to 6 months) significantly differed by group assignment for correct and consistent use as well as whether change scores (history to 6 months) significantly differed by group assignment for CT or GC. Data analyses were performed with SPSS version 20.0 (IBM, Armonk, NY) and SAS version 9.4 (SAS Institute Inc, Cary, NC).

Uptake	Not reported
Attrition	702 participants were recruited at baseline. Retention at the 2-month assessment was comparable between intervention (70.8%) and control (73.9%) conditions (p = .35). Similarly, no significant differences in retention were observed at the 6 month assessment for intervention (78.5%) and control (73.9%) groups (p = .16).
Study limitations (author)	As is true for all sexuality research, findings were limited by the validity of self-report. The use of a convenience sample limited the generalizability of the findings to other populations of Black male youths. Randomization did not produce pre-test equivalence between study arms. Although there was no reason to believe that these differences were not attributable to chance, baseline differences were controlled for in the analyses and still found significant effects.
Study limitations (reviewer)	The study does not explicitly state that this is a one-to-one intervention. There is no evidence that this is a group-based intervention so it is presumed to be one-to-one, but the paper does not specifically state this. For participants younger than 18 years, only those who provided details of a parent or guardian who could provide in-person parental consent were eligible to participate. This group may not be representative of all sexually active males aged 15-18 years. There were baseline differences on key variables: intervention participants were significantly less likely to report correct and consistent condom use, and were more likely to report a history of STIs. Although controlled for in the analyses, these baseline differences indicate the potential for key unassessed differences in sexual behaviour that may influence intervention efficacy.
Source of funding	This study was funded by the National Institute of Mental Health (grant R01MH083621).

Study arms

Intervention (N = 349) Adapted version of Focus on the Future (FoF): a sex positive intervention focusing on correct and consistent condom use
Control (N = 353) Attention-equivalent control condition including slides focused on basic STI knowledge and prevention

Characteristics

Arm-level characteristics

	Intervention (N = 349)	Control (N = 353)
Age; Mean/SD	19.8 (1.8)	19.5 (2)
Gender Male	n = 349 ; % = 100	n = 353 ; % = 100
Ethnicity Self-identifying as Black	n = 349 ; % = 100	n = 353 ; % = 100
Ever incarcerated	n = 119 ; % = 42.7	n = 121 ; % = 42.5
Sexual identification		
Heterosexual	n = 291 ; % = 83.4	n = 298 ; % = 84.4
Bisexual	n = 22 ; % = 6.3	n = 17 ; % = 4.8
Homosexual or gay	n = 26 ; % = 7.4	n = 17 ; % = 4.8
Sexual partners, lifetime Mean/SD	19.8 (20.2)	17 (17.9)
Sexual partners, past 2 months Mean/SD	3.3 (7.2)	2.8 (5.1)

Outcomes

Study timepoints	Baseline 2 (month) 6 (month)

Condom use outcomes

Correct and consistent condom use is defined as condom use 100% of the time and no condom use errors (slippage during intercourse, slippage during withdrawal, breakage, late application, or early removal).

	Intervention			Control		
	Baseline	**2 (month)**	**6 (month)**	**Baseline**	**2 (month)**	**6 (month)**
	N = 349	N = 349	N = 349	N = 353	N = 353	N = 353
Correct and consistent condom use Number and % of participants *Polarity: Higher values are better*	n = 59 ; % = 16.9	n = 187 ; % = 53.5	n = 180 ; % = 51.5	n = 95 ; % = 26.9	n = 175 ; % = 49.6	n = 166 ; % = 46.9

Paper reports that the 6-month multivariable model for the dependent behavioural variable (correct and consistent condom use) had data from 420 participants. After adjustment for age, history of chlamydia or gonorrhoea, and baseline levels of the outcome variable, the model yielded an EOR of 1.63 (95% CI = 1.07, 2.49; P = .02), which supported intervention efficacy.

STI Incidence outcomes

STI incidence not assessed at the 2-month follow-up

	Intervention		Control	
	Baseline	**6 (month)**	**Baseline**	**6 (month)**
	N = 349	N = 349	N = 353	N = 353
STI incidence (CT or GC) No of events *Polarity: Lower values are better*	n = 65 ; % = 19.1	n = 33 ; % = 9.4	n = 53 ; % = 16.3	n = 26 ; % = 7.4

Study details

Rationale/theory/Goal	Most behavioural interventions addressing STIs have focused solely on young women or MSM; few have focused on young Black men who have sex with women. The primary method of preventing disease acquisition and transmission among young Black men is the consistent and correct use of male latex condoms but these are vastly underused. Overcoming barriers to condom use may prevent STIs (p. 2219).
Procedures used	Recruitment procedures were standard across all study sites. After a potentially eligible patient completed his medical exam, clinic staff notified a research staff member. Researchers used a private exam room to screen for eligibility. Persons younger than 18 years were asked whether they had a parent or guardian who would be able to provide in-person parental consent for enrolment. After an eligible person assented, he was asked for permission to contact 1 parent or guardian to obtain consent. All others provided written informed consent. After enrolment, an audio computer-assisted self-interview was administered in a private area. After the survey, participants were randomised using a computer-generated algorithm. Next, participants provided a urine sample for gonorrhea and chlamydia testing. They received results within 2 weeks. Research staff contacted those testing positive to return to the clinic for prompt treatment. Contact information was collected and participants were compensated with a $50 gift card. Participants were frequently recontacted to return for follow-up assessments (occurring ~2 months and ~6 months after baseline). $50 gift cards were also provided at these follow-up assessments. The 6-month follow-up assessment included retesting for gonorrhea and chlamydia (p. 2219). In both conditions, participants were given free access to a wide variety of condoms and lubricants and told them to take as many as they could fit into a bag we provided We provided condoms and lubricants in an identical manner at the 2- and 6-month follow-up assessments. We also informed all participants that condoms could be obtained at the clinic at any time (p. 2220)
Setting/location of intervention	Private rooms in STI clinics in the southern United States (p. 2219)

Study arms

Intervention (N = 349)

Focus on the Future (FoF): a sex positive intervention focusing on correct and consistent condom use, plus free access to condoms and lubricants

Brief name	Focus on the Future (FoF) (p. 2219).
Rationale/theory/Goal	The intervention is an adapted version of FoF which was previously used for Black men aged 18-29 years testing positive for an STI. The adapted version was more suitable for use with younger males 15-23 years and could be used regardless of STI diagnosis. The

	program is designed to overcome barriers to condom use for Black male youths. Established barriers include perceived reduction in sexual pleasure and ability to perform; problems with condom fit and feel; and reduced self-efficacy to use condoms. The FoF intervention is pleasure focused and seeks to address and overcome these barriers (p. 2220).
Materials used	Slides, posters and graphs for visual presentations. Condoms, lubricants and anatomical models for condom use demonstrations. All participants were given free access to a wide variety of condoms and lubricants to take away. (p. 2220).
Procedures used	FoF sessions comprise a number of objectives, including making participants aware that Black males experience a disproportionate share of AIDS cases and other STIs; having conversations about the participants' prior positive condom use or other positive sexual behaviour; discussing any issues the participant may have with using condoms; achieving satisfactory fit and feel; providing guided practice in the correct application and use of condoms using an anatomical model; discussing lubricants; discussing condom negotiation skills and using role play to demonstrate how to communicate about condom use; and explaining how planning and negotiating condom use is critical to HIV prevention (p. 2220).
Provider	Trained health educators (p. 2220)
Method of delivery	Face to face sessions; assumed 1-to-1 (p. 2220).
Intensity/duration of the intervention	1 hour sessions (average session time was 54.1 minutes) (p. 2220)
Tailoring/adaptation	Paper reports this was a tailored intervention and states that intervention objectives were addressed in various sequences according to individual needs (p. 2220).
Unforeseen modifications	None reported; unlikely
Planned treatment fidelity	Not reported
Actual treatment fidelity	Not reported

Control (N = 353)

Attention-equivalent control including slides on basic STI knowledge and prevention. Plus free access to condoms and lubricants

Brief name	Attention-equivalent control (p. 2220)
Materials used	40 PowerPoint slides for visual presentations. All participants were given free access to a wide variety of condoms and lubricants to take away. (p. 2220).
Procedures used	Participants viewed a PowerPoint presentation focused on male and female reproductive anatomy, basic knowledge of various STIs, and 1 slide on prevention. Health educators specifically refrained from elaborating on the content of these slides unless participants asked direct questions, in which case the educators answered in 1 or 2 sentences. Participants were also given access to a wide variety of condoms and lubricants (p. 2220).
Provider	Trained health educators (p. 2220).
Method of delivery	Face to face sessions, assumed 1-to-1 (p. 2220).
Intensity/duration of the intervention	1 hour session (average length of time to deliver this condition was 48.5 minutes) (p. 2220).
Tailoring/adaptation	None reported
Unforeseen modifications	None reported; unlikely
Planned treatment fidelity	Not reported
Actual treatment fidelity	Not reported

Risk of Bias Assessment

Section	Risk of Bias	Reason
Domain 1: Bias arising from the randomisation process	Some concerns	*Appropriate randomisation and allocation concealment but baseline differences between groups on key variables (correct and consistent condom use; history of CT or GC)*
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Low	
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	Low	*No information on intervention adherence but 1-to-1 sessions with trained health educator so deviations unlikely*
Domain 3. Bias due to missing outcome data	Low	
Domain 4. Bias in measurement of the outcome	Low	*Appropriate measures used; assessments conducted via ACASI*
Domain 5. Bias in selection of the reported result	Some concerns	*Trial not registered*
Overall bias and Directness	Risk of bias judgement: Some concerns	*Baseline differences between groups on key variables (condom use and history of STIs). Trial not registered.*
	Overall Directness	Partially applicable *(US study)*

DiClemente, 2010

Bibliographic Reference DiClemente, R J; Wingood, G M; Rose, E; Sales, J M; Crosby, R A; Evaluation of an HIV/STD sexual risk-reduction intervention for pregnant African American adolescents attending a prenatal clinic in an urban public hospital: preliminary evidence of efficacy.; Journal of pediatric and adolescent gynecology; 2010; vol. 23 (no. 1); 32-8

Study details

Trial registration number	Not reported
Study start date	Apr-1999
Study end date	Jun-2000
Aim	To test the efficacy of a peer-delivered behavioral intervention designed to enhance safer sex practices among pregnant African American adolescents residing in the Southern U.S.
Country/geographical location	Georgia, USA
Setting	A large prenatal clinic at a public hospital serving low-income minority residents of Atlanta, Georgia
Inclusion criteria	- Unmarried African American females - 14-20 years - Less than 21 weeks gestation - Having vaginal sex in the previous 2 months - Planned to deliver at the hospital where they were seeking prenatal care (to facilitate follow-up)
Exclusion criteria	None reported
Method of randomisation	Not reported
Method of allocation concealment	Not reported but paper confirms concealment of allocation techniques were used to ensure the integrity of randomisation.
Unit of allocation	Participant

Unit of analysis	Participant
Statistical method(s) used to analyse the data	Analyses were performed only on pre-specified hypotheses using an intention-to-treat protocol with participants analysed in their assigned study conditions irrespective of the number of sessions attended. At baseline, descriptive statistics were calculated to summarise sociodemographic variables, psychosocial mediators, and sexual behaviours between study conditions. Differences between study conditions at baseline were assessed using Student's t-tests for continuous variables and chi-square analyses for categorical variables. Variables in which differences between study conditions approached statistical significance, or which were theoretically or empirically identified as potential confounders, were included as covariates in the intervention efficacy analyses. To examine intervention effects, logistic regression was used to compute adjusted odd ratios (AOR) for dichotomous behavioural outcomes (i.e., the two measures of condom use), and repeated measures ANCOVA was used for continuous outcomes (i.e., the psychosocial mediators). The corresponding baseline measure for the specific outcome was included as a covariate in each analysis.
Uptake	Of the 311 adolescents screened, 183 met eligibility criteria. Of those not eligible to participate in the study (n=128), most reported they had not engaged in sex during the previous two months, were unable to attend the intervention, or did not complete the baseline assessment.
Attrition	Among the 170 participants completing baseline assessments and randomised to study conditions, 137 (80.5%) were eligible to complete the follow-up assessment - across both conditions, 30 participants delivered at another hospital and 3 experienced stillbirth. Of the 137 eligible participants, 86 completed the follow-up assessment (47 in the intervention group and 39 in the control groups). Attrition analyses indicate no difference between those completing the follow-up assessment and those unavailable for follow-up assessment. Separate analyses, by study condition, also observed no difference between those completing the follow-up and those unavailable for follow-up assessment.
Study limitations (author)	• The findings may not be applicable to pregnant African American adolescents with different sociodemographic characteristics or risk profiles (e.g., injecting drug users). Additionally, whether the findings are generalizable to other geographic regions of the U.S. is undetermined. • Another methodological concern is the reliability of self-reported outcome measures (i.e., sexual behaviours and psychosocial scales). • The comparison condition was not a true control as all participants received prenatal counselling which included HIV/STI prevention education. Thus, the provision of HIV/STI risk reduction education may have reduced the study's capacity to detect significant changes in participants' condom use and psychosocial mediators. • The findings are also limited by attrition, despite statistical assurances that attrition bias did not occur. Furthermore, the small sample size reduces precision of effect estimates and confidence intervals. Larger studies, conducted in other regions with improved retention rates are needed to corroborate these findings. • Data were not collected to determine whether these behavioural changes were sustained post-partum.

Study limitations (reviewer)	None to add
Source of funding	This study was funded by a grant to the first author from the Center for Mental Health Research on AIDS, National Institute of Mental Health (1R01 MH54412) and the Office of AIDS Research.

Study arms

Intervention (N = 85) Peer-educator intervention comprising two 4-hour sessions enhancing self-concept and self-worth; heightening HIV/STI risk reduction knowledge; and teaching preventive skills including condom use and negotiation.
Control (N = 85) Enhanced standard-of-care healthy nutrition comparison condition

Characteristics

Arm-level characteristics

	Intervention (N = 85)	**Control (N = 85)**
Age; Mean/SD	17.9 (1.6)	17.8 (1.7)
Gender; Female	n = 85 ; % = 100	n = 85 ; % = 100
Ethnicity; African American	n = 85 ; % = 100	n = 85 ; % = 100
Number of weeks pregnant at enrolment; Mean/SD	10.74 (3.63)	10.89 (3.57)

Outcomes

Study timepoints	6 (month)

Paper does not specify follow-up period. It states that data collection was conducted during initial visit (mean = 10 weeks gestation) and again 2 weeks prior to scheduled delivery. Assuming delivery at 38 weeks, 2 weeks prior is 36 weeks. Follow up period is therefore ~26 weeks so categorised as 6-month follow-up.

Condom use outcomes

	Intervention vs Control
	6 (month)
	N1 = 47, N2 = 39
Condom use at last intercourse; Odds ratio/95% CI *Polarity: Higher values are better*	3.9 (1 to 15.71)
Consistent condom use; Odds ratio/95% CI Over previous 30 days *Polarity: Higher values are better*	7.9 (1 to 56.7)

TIDier Checklist

Study details

Rationale/theory/Goal	Research suggests that pregnant adolescents, including African Americans, may be less likely to use condoms than their non-pregnant counterparts. While a number of interventions have been developed to reduce HIV/STI risk behaviours among adolescents, including African American adolescents, pregnant African American adolescents remain a vulnerable subgroup; understudied, underserved and at increased risk for HIV/STIs. Pregnancy represents a critical window of opportunity to intervene with African American adolescents to reduce HIV/STI associated sexual behaviours (p. 2).
Procedures used	Project recruiters screened a consecutive sample of pregnant African American adolescents from a large prenatal clinic. Eligibility criteria were assessed and eligible participants were enrolled into the study. Dall collection was conducted at

	the clinic during the initial visit and again 2 weeks prior to scheduled delivery. A trained interviewer assessed self-reported sexual behaviour and a self-administered survey was used to assess sociodemographic and psychosocial mediators (p. 2-3). All adolescents seeking pre-natal care receive HIV/STI prevention education as part of standard-of-care prenatal services (p. 2). Adolescents were reimbursed $50 for completing each of the baseline and follow-up assessments (p. 3).
Setting/location of intervention	A large prenatal clinic at a public hospital in Atlanta, Georgia (p. 2).

Study arms

Intervention (N = 85)

Peer-educator intervention comprising two 4-hour sessions enhancing self-concept and self-worth; heightening HIV/STI risk reduction knowledge; and teaching preventive skills including condom use and negotiation.

Brief name	HIV/STI risk reduction intervention (p. 1).
Rationale/theory/Goal	The intervention, based on Social Cognitive Theory and the Theory of Gender and Power, was an adapted version of a CDC-defined evidence-based HIV/STD intervention for African American female adolescents 14–18 years of age attending community clinics (DiClemente, 2004). The original intervention was adapted to be appropriate for the current population, pregnant African American adolescents (p. 3).
Materials used	No specific materials reported
Procedures used	The two 4-hour group intervention sessions were conducted with 5-7 participants and focused on enhancing adolescents' self-worth and self-concept. It was also designed to heighten awareness of HIV/STI risk reduction knowledge, specifically the adverse consequences of STIs on themselves and their unborn child. It reinforced the importance of condom use when having sex during pregnancy. It also taught HIV/STI preventive skills such as condom use, negotiation skills, and skills associated with refusing risky sex (p. 4).

	All study participants also received HIV/STI prevention education as part of standard-of-care prenatal services (p. 2).
Provider	Trained African American female health educators and an African American peer educator (p. 3). To enhance realism of the interactive role play scenarios, an African American male peer health educator participated in a few specific intervention activities (p. 4).
Method of delivery	Face to face small group sessions (p. 4).
Intensity/duration of the intervention	Two 4-hour sessions conducted on consecutive Saturdays (p. 4).
Tailoring/adaptation	None reported.
Unforeseen modifications	None reported; unlikely
Planned treatment fidelity	Not reported.
Actual treatment fidelity	Not reported.

Control (N = 85)

Enhanced standard-of-care healthy nutrition comparison condition

Brief name	Enhanced standard-of-care healthy nutrition comparison (p. 4).
Materials used	A 'Good Nutrition during Pregnancy' video (p. 4).
Procedures used	Control participants received a 2-hour group session consisting of a 'Good Nutrition during Pregnancy' video and a brief question and answer session (p. 4).

Provider	Not reported
Method of delivery	Not reported but assumed face-to-face.
Intensity/duration of the intervention	One 2-hour group session (p. 4).
Tailoring/adaptation	None reported.
Unforeseen modifications	None reported
Planned treatment fidelity	None reported
Actual treatment fidelity	None reported

Risk of Bias Assessment

Section	Risk of Bias	Reason
Domain 1: Bias arising from the randomisation process	Low	*Appropriate randomisation and allocation concealment procedures; no group differences at baseline*
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Low	*Deviation from interventions unlikely, ITT protocol used*
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	Low	*Intervention adherence not assessed but sessions were delivered by trained facilitators*
Domain 3. Bias due to missing outcome data	Some concerns	*High attrition rate (~50%) but no differential attrition by group and no difference in study*

Section	Risk of Bias	Reason
		characteristics between those who completed follow-up assessments and those who did not
Domain 4. Bias in measurement of the outcome	Some concerns	*Standardised assessment via self-administered survey for psychosocial outcomes but behavioural outcomes were assessed by trained interviewers and study does not report whether interviewers were blind to condition*
Domain 5. Bias in selection of the reported result	Some concerns	*Trial not registered but study reports analyses were conducted on pre-specified hypotheses only. Data not reported on results of analyses.*
Overall bias and Directness	Risk of bias judgement: Some concerns	*High attrition; unclear whether outcome assessors were blind to condition; trial not registered but analyses conducted according to pre-specified plan*
	Overall Directness	Partially applicable *(US study; pregnant women)*

DiClemente, 2014

Bibliographic Reference DiClemente, Ralph J; Wingood, Gina M; Sales, Jessica M; Brown, Jennifer L; Rose, Eve S; Davis, Teaniese L; Lang, Delia L; Caliendo, Angela; Hardin, James W; Efficacy of a telephone-delivered sexually transmitted infection/human immunodeficiency virus prevention maintenance intervention for adolescents: a randomized clinical trial.; JAMA pediatrics; 2014; vol. 168 (no. 10); 938-46

Study details

Trial registration number	Clinicaltrials.gov Identifier: NCT00279799
Study start date	01-Jun-2005

Study end date	16-Jun-2007
Aim	To evaluate the efficacy of a maintenance intervention using brief telephone contacts to support STI/HIV-preventive behaviors and reduce STIs among African American adolescent girls.
Country/geographical location	Atlanta, Georgia, USA
Setting	Intervention sessions delivered in 3 sexual health clinics; PMI sessions delivered by telephone calls
Inclusion criteria	- Self-identifying as African American - Age 14-20 years at enrolment - Reporting at least 1 episode of unprotected vaginal sex in the past 6 months
Exclusion criteria	- Adolescents were excluded if they were married, pregnant or attempting to become pregnant
Method of randomisation	A computer-generated algorithm was used to generate a random allocation sequence.
Method of allocation concealment	The random allocation sequence was placed in opaque envelopes and staff executed treatment assignment subsequent to baseline assessment.
Unit of allocation	Participant
Unit of analysis	Participant
Statistical method(s) used to analyse the data	A treatment effect of 20% reduction in incident chlamydial infections during the 36-month follow-up period was estimated. Using methods outlined by Rochon for repeated measurements and assuming a 20% correlation for within-person measurements, 80% participation at 6-, 12-, 18-, 24-, 30-, and 36-month assessments, and setting the type I error rate at .05 for a 2-tailed test, 700 participants were needed to detect the hypothesized reduction with 80% power.

	Analyses of prespecified hypotheses were carried out using an intention-to-treat protocol with participants analysed in their assigned treatment conditions irrespective of number of completed telephone contacts. Descriptive statistics summarised sociodemographic and study variables and bivariate analyses examined differences between conditions using t tests for continuous variables and $\chi 2$ tests for categorical variables. Variables in which differences approached statistical significance ($P < .10$) or in which differences were theoretically and empirically associated with study outcomes were included as covariates in multivariate models. To assess intervention effects for the entire 36-month follow-up period, random effects (per person) were estimated and generalized estimating equation models (with exchangeable correlation) to control for within-subject correlated measurements. Fitted models were adjusted for the corresponding baseline measure and covariates to estimate adjusted risk ratios (RRs) for treatment effects on dichotomous biological outcomes and adjusted mean differences of treatment effects on continuous behavioural outcomes. Indicators for site and cohort were included to adjust for clustering; no time-dependent variables affected by treatment were included. The 95% confidence intervals for adjusted RRs and mean differences, and corresponding P values, were also computed. To assess intervention effects specifically on the behavioural outcomes at the 36-month follow-up, the most rigorous assessment of the PMI's efficacy in sustaining behaviour change, adjusted means and mean differences for outcomes were calculated from an estimated linear regression model. Each of these models adjusted for the corresponding baseline measure for the specific outcome, sociodemographic variables observed to differ across study conditions, and theoretically or empirically relevant variables. All analyses were performed using Stata version 12 statistical software (StataCorp LP).
Uptake	Of the 746 eligible adolescents, 701 (94%) enrolled, completed baseline assessments and were randomised.
Attrition	For inclusion in analyses, participants must have completed at least 1 follow-up assessment. Overall, 89.7% of participants completed at least 1 follow-up assessment. No differences were observed between the conditions in the number of participants completing at least 1 follow-up, with 309 (90.4%) of the experimental group and 318 (88.6%) of the comparison group completing at least 1 follow-up and therefore included in analyses of the primary outcomes. At the 6-month follow-up, differences in attrition were observed, with higher retention in the intervention condition (81%) compared to the control condition (75%). No differences in attrition were observed at the 12-month, 18-month, 24-month, 30-month or 36-month follow ups. By the 36-month follow up, retention rates were 62% (n=213) for the intervention group and 60% (n=216) for the control group. No differences in sociodemographic characteristics or baseline variables were observed at any time point for participants retained in the trial compared to those unavailable for follow-up.
Study limitations (author)	The findings may not be applicable to African American adolescent girls with different sociodemographic characteristics or STI/HIV risk profiles.

	Other methodological concerns are the reliability of self-reported outcomes and the fact that the study had increasing attrition across 36 months. Not with standing that attrition levels were substantial (and every effort in future studies should aim to decrease attrition), investigations determined that inference from analyses on imputed data did not differ from analyses on complete data. The study design means it is not possible to ascertain the effects of the maintenance intervention from those of the primary intervention. Future research should focus on ascertaining the efficacy of telephone counselling alone in achieving reductions in sexual risk behaviours and STIs among this population. While an increased proportion of condom-protected sexual acts may partially explain the difference in STIs, there is the possibility that other unmeasured variables (eg, partner risk factors, STI density in certain geographical or neighbourhood settings) may also contribute to differences in STIs.
Study limitations (reviewer)	A large number of adolescent girls in this sample reported a history of abuse: approximately 56% for emotional abuse and approximately 39% for physical abuse. This high level of abuse history was not addressed in the paper. There was a significant difference between groups in the mean (SD) number of supplementary calls received: intervention 10.78 (5.44); control 9.86 (5.22), p = 0.02.
Source of funding	This work was supported by grants 5R01 MH070537 from the National Institute of Mental Health and P30 AI050409 from the Center for AIDS Research, Emory University and by the Office of Behavioral and Social Science Research, National Institutes of Health.

Study arms

Intervention (N = 342) HORIZONS, a group-based intervention for African American adolescent girls designed to enhance HIV/STI preventive attitudes, sexual negotiation and refusal skills, and preventive behaviours. Plus a telephone counselling prevention maintenance intervention (PMI)
Control (N = 359) HORIZONS plus a time- and dose-consistent PMI focused on general health

Characteristics

Study-level characteristics

	Study (N = 701)
STI infection at baseline	
Chlamydial infection	% = 17.1
Gonococcal infection	% = 6.3

Arm-level characteristics

	Intervention (N = 342)	**Control (N = 359)**
Age; Mean/SD	17.55 (1.62)	17.73 (1.72)
Gender; Female	n = 342 ; % = 100	n = 359 ; % = 100
Ethnicity; African American	n = 342 ; % = 100	n = 359 ; % = 100
Current boyfriend	n = 276 ; % = 80.7	n = 281 ; % = 78.3
History of abuse		
Emotional abuse	n = 198 ; % = 57.9	n = 194 ; % = 54
Physical abuse	n = 137 ; % = 40.1	n = 139 ; % = 38.7

Outcomes

Study timepoints	36 (month)

Condom use outcomes

Behavioural outcomes relating to condom use were adjusted by baseline variables: clinic, family aid index (receipt of government assistance), years in school, partner communication frequency, unprotected vaginal sex in the past 90 days, history of emotional or physical abuse, depression, perceived partner concurrency, corresponding baseline level of the outcome variable, and dose of telephone contacts.

Paper reports mean and SE; SDs calculated by analyst.

	Intervention	Control
	36 (month)	**36 (month)**
	N = 213	N = 216
Proportion of condom-protected sex acts in the past 90 days; Mean/SD *Polarity: Higher values are better*	0.5 (0.29)	0.41 (0.29)
Proportion of condom protected sex acts in the past 6 months; Mean/SD *Polarity: Higher values are better*	0.51 (0.29)	0.42 (0.29)

STI incidence outcomes

Percentage of participants detected with a laboratory-confirmed incident chlamydial infection and percentage detected with a laboratory-confirmed incident gonococcal infection at the 6-, 12-, 18-, 24-, 30- or 36-month assessment. Therefore total intervention participants with one or more follow-up included in the analyses (n = 309) and total control participants with one or more follow-up included in the analyses (n = 318)

	Intervention	Control
	During the 36 month follow-up	**During the 36 month follow up**
	N = 309	N = 318
Chlamydial infection *Polarity: Lower values are better*	n = 94; % = 30.4%	n = 104; % = 32.7

	Intervention	Control
	During the 36 month follow-up	**During the 36 month follow up**
	N = 309	N = 318
Gonococcal infection *Polarity: Lower values are better*	n = 48; % = 15.5	n = 54; % = 17

Percentages calculated by analyst. Note that the paper reports different percentages; not possible to determine which denominator was used.

TIDier Checklist

Study details

Rationale/theory/Goal	Recent reviews indicate that behavioural interventions are effective in enhancing shorter-term (i.e. <12 months) adoption of STI/HIV preventive behaviours among adolescents, including African American girls. However, continuation of HIV/STI preventive behaviours during longer periods is less common. In the absence of maintenance strategies, changes in preventive behaviours progressively diminish. Thus, development of innovative strategies to enhance maintenance of STI/HIV preventive behaviours remains a public health priority. Telephone counselling maintenance interventions may be a promising strategy (p. 2-3).
Materials used	No specific materials reported
Procedures used	An African American female recruiter approached adolescents in clinic waiting areas, described the study, solicited participation, and assessed eligibility. Adolescents meeting inclusion criteria and interested in participating were scheduled to return to the clinic to complete informed consent procedures and baseline assessments and be randomised to trial conditions. Written informed consent was obtained from all adolescents. Parental consent was waived for those younger than 18 years owing to the confidential nature of clinic services. Data collection occurred at baseline, prior to randomisation, and at 6, 12, 18, 24, 30, and 36 months following participation in the primary treatment, HORIZONS. At each assessment, participants provided self-collected vaginal swab specimens for STI assessment and completed an audio computer-assisted self-administered interview (ACASI). Participants were trained, using an anatomical model, to self-collect vaginal swab specimens.

	All study participants received as their primary treatment a Centers for Disease Control and Prevention (CDC)-defined evidence-based STI/HIV intervention for African American adolescent girls. HORIZONS is a group-based intervention designed to enhance STI/HIV-preventive attitudes, sexual negotiation and refusal skills, safer sex norms, and preventive behaviors. In the current study, HORIZONS was implemented in a single group session with, on average, 7 or 8 participants per group. (p. 3-4).
Provider	2 trained African American health educators (p. 4)
Method of delivery	Face to face group session with 7-8 participants (p. 4)
Setting/location of intervention	Sexual health clinics (p. 3).
Intensity/duration of the intervention	1 group session (duration not reported) (p. 4).
Tailoring/adaptation	None reported
Unforeseen modifications	None reported; unlikely
Planned treatment fidelity	Not reported
Actual treatment fidelity	Not reported
Other details	Participants were compensated for travel and childcare to complete assessments. Specifically, participants received $75 for completing the baseline assessment and group session, $20 for completing each of the 6-, 12-, 18-, 24-, 30-, and 36-month follow-ups, and $10 for each of the 18 individual telephone sessions (p. 3).

Study arms

Intervention (N = 342)

HORIZONS, a group-based intervention for African American adolescent girls designed to enhance HIV/STI preventive attitudes, sexual negotiation and refusal skills, and preventive behaviours. Plus a telephone counselling prevention maintenance intervention (PMI)

Brief name	HORIZONS plus a telephone counselling prevention maintenance intervention (PMI) (p. 4)
Rationale/theory/Goal	A telephone counselling PMI may work to boost initial intervention content and help to reinforce or maintain HIV/STI prevention behaviours over a longer term (p. 3).
Procedures used	The PMI was a 10-minute, health educator-administered telephone contact guided by a risk appraisal that identified participants' STI/HIV risks and prioritised STI/HIV prevention strategies to reduce their risk. For the risk appraisal procedure, participants were asked to prioritise risk factors related to sexual risk behaviour engagement (e.g., partners resistant to using condoms). Health educators used the prioritised list to tailor telephone counselling strategies to address identified risk factors (p. 4).
Provider	Health educators (p. 4)
Method of delivery	Telephone sessions (p. 4)
Setting/location of intervention	Remote
Intensity/duration of the intervention	Brief 10-minute telephone contacts every 8 weeks for 36 months (p. 2). The mean number of PMI telephone contacts received was 10.78 (SD=5.44). The minimum number of telephone contacts was 0 (2.6% received 0 calls) and the maximum was 18 (9.6% received all 18 calls) (p. 6-7).
Tailoring/adaptation	Health educators tailored the telephone counselling sessions in response to identified risk factors (e.g. having a partner resistant to condoms) (p. 4).
Planned treatment fidelity	Not reported

Control (N = 359)

HORIZONS plus a time- and dose-consistent PMI focused on general health

Brief name	HORIZONS plus a General health promotion comparison telephone calls (p. 4).
Rationale/theory/Goal	Control group participants received a time- and dose-equivalent telephone counselling placebo, designed to reduce the likelihood that the effects of the PMI are attributable to differences in exposure to staff contact (p. 4).
Procedures used	The telephone sessions focused on nutrition and physical activity goals set by the participants and barriers she may encounter / have encountered toward achieving her goals (p. 4)
Provider	Health educators (p. 4)
Method of delivery	Telephone sessions (p. 4).
Setting/location of intervention	Remote
Intensity/duration of the intervention	Brief 10-minute telephone contacts every 8 weeks for 36 months (p. 2). The mean number of comparison telephone contacts received was 9.86 (SD=5.22). The minimum number of telephone contacts was 0 (2.2% received 0 calls) and the maximum was 18 (5.8% received all 18 calls) (p. 6-7).

Risk of Bias Assessment

Section	Risk of Bias	Reason
Domain 1: Bias arising from the randomisation process	Low	*Appropriate randomisation and allocation concealment; no baseline differences on any study variables*
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Some concerns	*No information on participant blinding*
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	Some concerns	*Some variation in the number of telephone sessions received by participants; intervention group received significantly more telephone contacts than controls*

Section	Risk of Bias	Reason
Domain 3. Bias due to missing outcome data	Some concerns	*High attrition but no evidence of differential attrition and long follow-up period (36 months)*
Domain 4. Bias in measurement of the outcome	Low	
Domain 5. Bias in selection of the reported result	Low	*Data analysed in line with pre-specified plan*
Overall bias and Directness	Risk of bias judgement: Some concerns	*No information on blinding; intervention group received more phone sessions than control; high attrition*
	Overall Directness	Partially applicable *(US study)*

Wingood, 2013

Bibliographic Reference Wingood, Gina M; Diclemente, Ralph J; Robinson-Simpson, Lashun; Lang, Delia L; Caliendo, Angela; Hardin, James W; Efficacy of an HIV intervention in reducing high-risk human papillomavirus, nonviral sexually transmitted infections, and concurrency among African American women: a randomized-controlled trial.; Journal of acquired immune deficiency syndromes (1999); 2013; vol. 63suppl1; 36-43

Study details

Trial registration number	Not reported
Study start date	Oct-2004
Study end date	Oct-2007
Aim	To evaluate the efficacy of an HIV intervention that sought to reduce concurrency, other HIV sexual behaviours, and incident STIs among African-American women in the Southern US.

Country/geographical location	Atlanta, Georgia, USA
Setting	Kaiser Permanente health centres
Inclusion criteria	- Self-identified African American woman - Age 18-29 years - Sexually active in the prior 6 months - A member of one of 3 Kaiser Permanente centres in Atlanta
Exclusion criteria	- Reported using condoms 100% of the time - Want to become pregnant in the next year - Live outside the state
Method of randomisation	Prior to enrolment a computer-generated randomisation scheme was developed. As participants completed baseline assessments, sealed opaque envelopes were used to execute assignments. Participants were randomly assigned to the HIV intervention condition or the health promotion control condition using a 2:1 intervention-to-comparison ratio to provide increased power. However, 50 sibling pairs were randomised together in the intervention leading to a 2.5:1 randomisation ratio.
Method of allocation concealment	Computer generated randomisation scheme
Unit of allocation	Individual
Unit of analysis	Individual
Statistical method(s) used to analyse the data	Given enrolment of 848 participants assigned to treatment with a 2:1 randomization allocation ratio, we estimated accruing 568 participants to the intervention and 280 to the comparison. Baseline prevalence was estimated at 17% such that a 25% reduction would correspond to a post-treatment incidence of 12.8%. Following Rochon, we assumed a within-participant correlation of 5% and an attrition rate of 20%, yielding approximately 70% power to detect a 25% reduction in STI incidence.

	Data analysts were blind to study conditions. Analyses were performed only on pre-specified hypotheses using an intention-to-treat protocol in which participants were analysed in their assigned conditions. Differences between conditions were assessed using t-tests for continuous variables and chi square analyses for categorical variables. Variables for which differences between conditions approached (P< 0.15) and which were identified as potential confounders were considered covariates. The effectiveness of the intervention was analysed over the 12-month period (from baseline to 12 month assessment) using population generalized estimating equations (GEE) for logistic and linear regression models. Statistical models included a time-independent variable (study condition) and time-dependent variables (covariates and outcomes). Models included the corresponding baseline measure of the outcome of interest as well as the theoretically important covariates such as history of forced sex and receipt of public assistance. An indicator for the time period was included in the model to capture any unaccounted temporal effects. An indicator for cohort was included in the model to adjust for unaccounted group effects. This yields adjusted odds ratios (OR) which assess intervention effects on dichotomous outcomes, and adjusted mean differences to assess intervention effects on continuous outcomes over the 12-month period. The 95% confidence intervals were computed using two-tailed statistical testing. For fitted models adjusted means were calculated and standard errors were estimated.
Uptake	N=4080 women were mailed letters inviting them to participate in the study. Of these, 2510 (61.5%) were not eligible due to study exclusion criteria and 591 (14.5%) were not available to participate (i.e. they could not attend both sessions of the intervention due to school or work conflicts).
Attrition	Of the 848 participants randomized, 605 were allocated to the HIV intervention and 243 to the comparison condition. Of the 605 participants allocated to the HIV intervention condition, 441 (72.9%) completed the 6-month assessment and 452 (74.7%) completed the 12-month assessment. Of the 243 participants allocated to the comparison condition, 194 (79.8%) completed the 6-month assessment and 183 (75.3%) completed the 12-month assessment. 727 (86%) participants were retained for at least one follow-up; 511 (84%) participants in the HIV intervention and 216 (89%) in the comparison. No differences were observed between conditions with participants retained and lost to follow-up at the 6-month assessment (27.10% [n = 441] versus 20.20% [n = 194]) or 12-month assessment (25.30% [n = 452] versus 24.7% [n = 183]).
Study limitations (author)	This study may not be generalizable to women who are not African American, who have a different risk profile (drug users), who engage in concurrency defined differently than in this study, or who are not Health Maintenance Organisation (HMO) members.

	While the comparison was not time matched to the intervention, the provision of STI testing and counselling with minimal health education was delivered to represent the usual STI services participants may receive at a clinic. Siblings were not randomized to avoid contamination; they were assigned as a pair to the intervention which may introduce bias.
Study limitations (reviewer)	None to add
Source of funding	This study was supported by a grant from the National Institute of Mental Health (R01 MH62717, MH8428905), the National Institute of Drug Abuse (DA8429360) with additional support provided by the Emory Center for AIDS Research (P30 A1050409).

Study arms

Intervention (N = 605) HIV intervention consisting of two 4-hour group sessions that sought to reduce sexual concurrency and other HIV risk behaviours among African American women
Control (N = 243) Attention matched control - health promotion condition emphasising nutrition education

Characteristics

Arm-level characteristics

	Intervention (N = 605)	**Control (N = 243)**
Age; Mean/SD	21.99 (3.65)	22.15 (3.65)
Gender; Female	n = 605 ; % = 100	n = 243 ; % = 100
Ethnicity; African American	n = 605 ; % = 100	n = 243 ; % = 100

	Intervention (N = 605)	Control (N = 243)
STI diagnosis at baseline	n = 99 ; % = 16.4	n = 45 ; % = 18.5

Outcomes

Study timepoints	Baseline 6 (month) 12 (month)

Condom use outcomes

Note that this study reports outcome data for condom use for oral sex, but it was not possible to determine the denominator (n and % reported did not align with given numbers of participants in intervention and control groups). The data could not be used for analyses so was not extracted.

Percentage condom use for vaginal sex in past 30 days was reported at baseline but no follow up data were provided so could not be extracted.

	Intervention			Control		
	Baseline	**6 (month)**	**12 (month)**	**Baseline**	**6 (month)**	**12 (month)**
	N = 605	N = 441	N = 452	N = 243	N = 194	N = 183
Condom use self-efficacy; Mean/SD *Polarity: Higher values are better*	28.82 (5.39)	30.83 (4.39)	16.76 (3.68)	28.21 (5.88)	29.11 (5.34)	17.21 (3.7)

STI incidence outcomes

Non-viral STIs

For non-viral STIs, self-administered vaginal swabs were collected and assessed for STIs (Chlamydia, CT; gonorrhoea, GC; or trichomoniasis, TV) using polymerase chain reaction nucleic acid amplification assays.

	Intervention			Control		
	Baseline	**6 (month)**	**12 (month)**	**Baseline**	**6 (month)**	**12 (month)**
	N = 605	N = 441	N = 452	N = 243	N = 194	N = 183
Non-viral STIs (CT, GC, TV) *Polarity: Lower values are better*	n = 99 ; % = 16.4	n = 27 ; % = 6.1	n = 42 ; % = 9.5	n = 45 ; % = 18.5	n = 19 ; % = 9.7	n = 22 ; % = 12

HPV incidence

HPV incidence only assessed at 12 month follow-up. Incident high-risk HPV infection was defined as a laboratory-confirmed test for HPV type 16 or 18 at the 12 month assessment after testing HPV negative at baseline. Participants provided a self-administered vaginal swab; swabs were tested by polymerase chain reaction (PCR)/reverse blot strip assay. Low risk PHV types were not assessed.

	Intervention	Control
	12 (month)	**12 (month)**
	N = 153	N = 61
HPV incidence *Polarity: Lower values are better*	n = 36 ; % = 23.5	n = 24 ; % = 39.3

Note different n's for 12 month follow up. Unclear from paper but reports that 38.9% (n=259) tested positive for high risk HPV at baseline and 12-month HPV incidence was only assessed in those testing HPV negative at baseline, therefore 12 month follow-up sample likely limited.

STI knowledge outcomes

	Intervention			Control		
	Baseline	**6 (month)**	**12 (month)**	**Baseline**	**6 (month)**	**12 (month)**
	N = 605	N = 441	N = 452	N = 243	N = 194	N = 183
HIV/STI knowledge; Mean/SD Assessed using 7 true/false items *Polarity: Higher values are better*	5.46 (1.1)	6.29 (0.93)	6.39 (0.87)	5.34 (1.17)	5.7 (1.08)	5.74 (1.1)

TIDier Checklist

Study details

Rationale/theory/Goal	HIV is the leading cause of death among African American women ages 25 to 34 years. Southern African American women's HIV risk may be attributed to the higher prevalence of other sexually transmitted infections (STIs) among African Americans in the South, vaginal douching, which is much more prevalent among African American women in the Southern US, and having a higher prevalence of concurrent sexual partnerships among African Americans. Interventions tailored to address sexual concurrency are warranted (p. 2).
Procedures used	During the recruitment period, the Kaiser Permanente subscriber database was used to randomly select women from the three Kaiser Permanente Centers having the greatest number of African-Americans. Eligible women were sent letters inviting them to participate in the study (p. 2). All eligible participants completed a 40-minute Audio Computer-Assisted Survey Interview (ACASI) that collected psychosocial and sexual behaviour data at baseline, 6- and 12-months follow up. At each assessment self-administered vaginal swabs were also collected (p. 3). Participants were compensated $50 for their time in participating in baseline and follow-up assessments (p. 2).

Study arms

Intervention (N = 605)

HIV intervention consisting of two 4-hour group sessions that sought to reduce sexual concurrency and other HIV risk behaviours among African American women

Brief name	HIV intervention (p. 1)
Rationale/theory/Goal	Social Cognitive Theory informed HIV intervention content by seeking to enhance participants' attitudes and skills in abstaining from sexual intercourse, practicing low-risk sexual behaviours (i.e. outercourse), avoiding untreated STIs, using condoms consistently, and refraining from having multiple and concurrent sexual partners. HIV intervention content was also informed by the Theory of Gender and Power, which examines economic forces, power imbalances, gender-related factors, and biological influences affecting women's HIV risk (p. 3).
Materials used	None reported
Procedures used	Theoretically informed session content sought to enhance women's awareness of power imbalances, such as relationships that threaten their safety, and by teaching women about economic forces which may reduce their self-sufficiency, such as dating male partners who desire pregnancy. There was also content that educated participants' about gender-related HIV prevention strategies, such as refraining from vaginal douching and enhancing sexual communication. Sessions also aimed to educate women about biological influences which could reduce HIV risk, such as encouraging participants to have their male sexual partners seek STI testing and treatment if necessary. Session content regarding avoiding concurrency emphasised valuing one's body, perceiving one's body as a temple (a culturally appropriate connotation), informing participants of the heightened risk of STIs, including HIV, when women engage in concurrency, and discussing partner selection strategies that encouraged monogamy (for both the female participant and their male sexual partners) (p. 3).
Provider	Sessions were provided by two trained African-American female health educators (p. 3)
Method of delivery	Face to face group sessions containing an average of 10 people (p. 3)
Setting/location of intervention	Kaiser medical centres (p. 3)
Intensity/duration of the intervention	Two 4-hour group sessions, delivered on consecutive Saturdays (p. 3)

Tailoring/adaptation	None reported
Unforeseen modifications	None reported; unlikely
Planned treatment fidelity	Not reported
Actual treatment fidelity	Not reported

Control (N = 243)

Attention matched control - health promotion condition emphasising nutrition education

Brief name	Health promotion condition (p. 3)
Materials used	None reported
Procedures used	The health promotion condition emphasised nutrition education (p. 3)
Provider	The session was implemented by two trained African-American female health educators (p. 3)
Method of delivery	Face to face group sessions (p. 3)
Setting/location of intervention	Kaiser medical centres (p. 3)
Intensity/duration of the intervention	One 4-hour session (p. 3)
Tailoring/adaptation	None reported

Unforeseen modifications	None reported
Planned treatment fidelity	Not reported
Actual treatment fidelity	Not reported

Risk of Bias Assessment

Section	Risk of Bias	Reason
Domain 1: Bias arising from the randomisation process	Low	*Random allocation with concealed sequence; no baseline differences between groups*
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Low	
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	Low	
Domain 3. Bias due to missing outcome data	Low	*~75% completed follow ups. No differential attrition by group*
Domain 4. Bias in measurement of the outcome	Low	*Outcomes assessed using ACASI and ACASI monitors were blind to condition*
Domain 5. Bias in selection of the reported result	Some concerns	*Trial was not registered and results for unprotected vaginal sex were listed as outcomes but not reported*
Overall bias and Directness	Some concerns	Trial not registered
	Overall Directness	Partially applicable *(US study; limited to members of HMO)*

D.7 Effectiveness evidence for MSM

Brown, 2019

Bibliographic Reference	Brown, Jennifer L; Vanable, Peter A; Bostwick, Rebecca A; Carey, Michael P; A Pilot Intervention Trial to Promote Sexual Health and Stress Management Among HIV-Infected Men Who Have Sex with Men.; AIDS and behavior; 2019; vol. 23 (no. 1); 48-59

Study details

Trial registration number	Not reported
Aim	To pilot-test a two-session group delivered HIV secondary prevention intervention designed to improve stress management and coping skills while also addressing key motivational and skills-based barriers to sexual risk reduction.
Country/geographical location	Northeastern US city
Setting	Outpatient HIV clinics at an academic medical centre
Inclusion criteria	- Male - HIV-infected - reported having oral or anal sex with a man during the past year - medically, cognitively and psychologically capable of participation (as determined by clinic staff) - able to read and converse in English
Exclusion criteria	None reported

Method of randomisation	Not reported
Method of allocation concealment	Not reported
Unit of allocation	Participant
Unit of analysis	Participant
Statistical method(s) used to analyse the data	- Descriptive statistics calculated for demographic characteristics, self-reported HIV health status variables, and baseline levels of the outcome measures for full sample and by intervention condition. - Chi square and univariate ANOVA analyses to examine equivalency between the two conditions on demographic characteristics, self-reported HIV health status variables, and baseline levels of the outcome measures. - Independent samples t test compared number of intervention sessions attended between study conditions. - Analyses of covariance (ANCOVAs) to examine if participants in immediate treatment condition (who attended one or both of the intervention sessions) reported changes in 3-month assessment outcomes compared to delayed treatment participants, accounting for baseline levels of functioning. For each ANCOVA, partial eta2 calculated as measure of effect size.
Attrition	**<u>Uptake</u>** Approached by clinic staff: n = 179 Declined screening: n = 38 Met eligibility criteria: n = 107 Eligible but did not participate (reasons include schedule conflicts, transportation issues): n = 27 **<u>Attrition</u>**

	Randomised: n = 80 (but 1 immediate intervention participant died before attending intervention) Immediate intervention group (n=39) 72% (28/39) attended workshop 1 and 72% (28/29) attended workshop 2. 92% (36/39) completed post-intervention assessment 100% (39/39) completed 3 month assessment Delayed intervention group (n=40) 88% (35/40) completed pre-intervention assessment 58% (23/40) attended workshop 1 and 55% (22/40) attended workshop 2 78% (31/40) completed post-intervention assessment 83% (33/40) completed 3 month assessment Overall, 65% of participants attended the first workshop; 63% attended the second, and 57% attended both. The number of intervention sessions attended did not differ between immediate intervention group (M=1.4; SD=.82) and the delayed intervention group (M=1.1; SD=.94).
Study limitations (author)	- The small sample size limited our ability to conduct analyses examining dynamics of condom use within different partnerships (e.g., seroconcordant versus serodiscordant partners) associated with differing levels of HIV transmission risk (e.g., ARV medication use and adherence use within partnerships). - The analyses did not account for level of engagement in the supplemental social support sessions. - The small sample size precluded analyses examining potential moderators of intervention efficacy (e.g., participant characteristics, relationship status, adherence to ARV medications) and analyses examining potential dose effects based on number of intervention sessions attended.

	- This study was conducted with a small sample of HIV-infected MSM living in a medium-sized Northeastern US city, so caution is warranted generalizing study findings to other HIV-infected MSM.
Study limitations (reviewer)	None to add
Source of funding	This study was funded by R21MH65865 to Peter A. Vanable. Jennifer L. Brown received support from R03DA037786 from the National Institute on Drug Abuse.

Study arms

Intervention (N = 40)

Two-session group delivered intervention to promote sexual health and stress management skills for HIV-infected MSM

Control (N = 40)

Waitlist control

Characteristics

Arm-level characteristics

Characteristic	Intervention (N = 40)	Control (N = 40)
Age Mean (SD)	39.4 (8.1)	41.9 (7.8)
Gender Male	n = 40 ; % = 100	n = 40 ; % = 100

Characteristic	Intervention (N = 40)	Control (N = 40)
Ethnicity		
Caucasian	n = 26 ; % = 66.7	n = 23 ; % = 59
African American	n = 7 ; % = 17.9	n = 13 ; % = 33.3
Asian	n = 1 ; % = 2.6	n = 0 ; % = 0
American Indian	n = 0 ; % = 0	n = 1 ; % = 2.6
Multiracial	n = 4 ; % = 10.3	n = 2 ; % = 5.1
Other	n = 1 ; % = 2.6	n = 0 ; % = 0
Primary partner; live together	n = 13 ; % = 33.3	n = 13 ; % = 32.5
Primary partner; live separately	n = 6 ; % = 15.4	n = 5 ; % = 12.5
No primary partner	n = 20 ; % = 51.3	n = 22 ; % = 55
Undetectable (<50 copies/mL)	n = 17 ; % = 45.9	n = 18 ; % = 46.2
Detectable (>50 copies/mL)	n = 11 ; % = 29.7	n = 14 ; % = 35.9
Does not know most recent viral load	n = 9 ; % = 24.3	n = 7 ; % = 17.9
No prior AIDs diagnosis	n = 30 ; % = 76.9	n = 27 ; % = 67.5
Prior AIDS diagnosis	n = 9 ; % = 23.1	n = 13 ; % = 32.5

Outcomes

Study timepoints

- Baseline
- 3 month

Condom use outcomes

Outcome	Intervention, Baseline, N = 40	Intervention, 3 month, N = 39	Control, Baseline, N = 40	Control, 3 month, N = 33
Frequency of unprotected anal sex During past 3 months Mean (SD)	2.7 (5.2)	0.18 (0.31)	5.9 (15.4)	0.27 (0.29)
Frequency of unprotected anal or oral sex During past 3 months Mean (SD)	17.4 (37.9)	0.51 (0.56)	16.7 (31)	0.76 (0.08)

Frequency of unprotected anal sex - Polarity - Lower values are better

Frequency of unprotected anal or oral sex - Polarity - Lower values are better

Values are presented as adjusted means and SEs at 3 month follow up adjusting for baseline values. SEs converted to SDs by analyst.

STI Knowledge outcomes

Outcome	Intervention, Baseline, N = 40	Intervention, 3 month, N = 39	Control, Baseline, N = 40	Control, 3 month, N = 33
HIV transmission knowledge 23-item measure Standardised Mean (SD)	11.1 (3.5)	13.8 (2.25)	12.2 (2.5)	11.7 (1.78)

HIV transmission knowledge - Polarity - Higher values are better

Values are presented as adjusted means and SEs at 3 month follow up adjusting for baseline values. SEs converted to SDs by analyst.

TIDier Checklist

Study details

Rationale/theory/Goal	Sexual risk reduction interventions involving HIV-infected MSM have shown mixed success and interest in participating in interventions that focus exclusively on sexual behaviour change is relatively low. Interventions that address a broader set of needs relating to mental and physical health interest HIV-infected MSM more. A significant proportion of HIV-infected people report difficulties in coping with HIV and other stressors, alongside the experience of stigma associated with both sexual minority status and HIV serostatus. Thus, an intervention approach with a combined focus on coping with sexual minority status, HIV-related stressors, and sexual health may offer more promise than a stand-alone intervention focusing exclusively on sexual risk reduction (p. 49).
Procedures used	Male patients were recruited during outpatient HIV medical visits. Staff described the study during their regularly scheduled appointments. After obtaining informed consent, participants were randomly assigned to an immediate intervention condition or a time delayed intervention control condition. All participants received $20 for each assessment, $20 for each intervention session they completed, and $5 for attending additional support group sessions (p. 49).

Study arms

Intervention (N = 40) Two-session group delivered intervention to promote sexual health and stress management skills for HIV-infected MSM

Brief name	Sexual health and stress management intervention (p. 48)
Rationale/theory/Goal	The intervention was informed by Coping Effectiveness Training, and the Information, Motivation, Behavioural Skills model. It sought to address the combined stress management and health behaviour challenges faced by HIV infected MSM by integrating content designed to improve stress management and coping skills while also addressing key motivational and skills-based barriers to sexual risk reduction (p. 49).
Materials used	No specific materials reported
Procedures used	The intervention comprised two group sessions that addressed motivational, behavioural skills and HIV transmission information tailored to HIV infected MSM, coupled with stress management training. Session 1: Program overview, focus on healthy living, coping effectiveness training, and stress management Provided latest information on HIV epidemiology and HIV treatment among MSM; taught skills to manage the stress of being HIV-infected; identified core strategies for problem and emotion focused coping; addressed challenges associated with social support and disclosure. Session 2: Healthy relationships Addressed issues relating to healthy relationships and intimacy; strengthened assertiveness and negotiation skills; identify personal triggers and manage risk; practice how to correctly use a condom and increase comfort with condom use.

	After completing the intervention workshops, all men were invited to participate in support group sessions led by intervention facilitators. These groups served as a supportive forum for participants and to reinforce the stress management and sexual risk reduction strategies covered by the intervention. (p. 51)
Provider	Intervention sessions were led by two MSM facilitators who had prior work experience in HIV risk reduction counselling and in addressing psychosocial aspects of HIV (p. 51).
Method of delivery	Face to face group sessions with approximately 10 participants (p. 51).
Setting/location of intervention	Not reported but assumed sessions were conducted in the clinics from which participants were recruited.
Intensity/duration of the intervention	Two 4 hour sessions. Participants were also invited to participate in additional support group sessions lasting 2 hours (p. 51). 37% of participants elected to attend one or more support group sessions (p. 54).
Tailoring/adaptation	Not reported
Unforeseen modifications	None reported
Planned treatment fidelity	Not reported
Actual treatment fidelity	Not reported
Other details	Participants rated their satisfaction with the intervention program and group facilitators using a four-point Likert scale with higher values indicating greater satisfaction. Overall, participants who attended one or both intervention sessions indicated a high level of comfort in the workshops (M = 3.8, SD = .51). Participants found the workshops to be interesting (M = 3.8, SD = .54) and would recommend the intervention to a friend (M = 3.8, SD = .52). Most participants were satisfied with the information provided in the groups (M = 3.8, SD = .58), believed the information to be important (M = 3.8, SD = .54), and felt that the intervention content met their needs (M = 3.4, SD = .65). Participants also expressed satisfaction with the group facilitators. Responses indicated that they found the facilitators to be friendly (M = 3.9, SD = .14), likeable (M = 3.9, SD = .23), helpful (M = 3.9, SD = .26), caring (M = 3.9, SD = .19), and knowledgeable (M = 3.9, SD = .19) (p. 54).

Control (N = 40)

Brief name	Waitlist control
Procedures used	Participants completed the same intervention after a 3 month delay (p. 49).

Risk of Bias Assessment

Section	Risk of Bias	Reason
Domain 1: Bias arising from the randomisation process	Some concerns	No information on randomisation or allocation concealment. No baseline differences between groups on demographic characteristics or HIV health status variables but those in the immediate intervention group reported significantly more favourable attitudes towards condoms than the delayed intervention group
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Low	All participants received the same intervention, delivered by the same facilitators, the only difference was immediate or delayed timing of the intervention
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	Some concerns	Only 57% of participants attended both intervention workshops. Low attendance at additional group support sessions (37%). Analyses did not account for level of adherence to all intervention components
Domain 3. Bias due to missing outcome data	Low	
Domain 4. Bias in measurement of the outcome	Some concerns	Outcomes assessed using validated scales or yes/no self-report items. Unclear whether participants completed questionnaires or whether assessors were used
Domain 5. Bias in selection of the reported result	Some concerns	Trial not registered
Overall bias and Directness	Risk of bias judgement: Some concerns	No information on randomisation or allocation concealment; low intervention attendance (57%) and impact of adherence not included in analyses; trial not registered.
	Overall Directness	Partially applicable (US study)

Cruess, 2018

Bibliographic Reference	Cruess, Dean G; Burnham, Kaylee E; Finitsis, David J; Goshe, Brett M; Strainge, Lauren; Kalichman, Moira; Grebler, Tamar; Cherry, Chauncey; Kalichman, Seth C; A Randomized Clinical Trial of a Brief Internet-based Group Intervention to Reduce Sexual Transmission Risk Behavior Among HIV-Positive Gay and Bisexual Men.; Annals of behavioral medicine : a publication of the Society of Behavioral Medicine; 2018; vol. 52 (no. 2); 116-129

Study details

Study design	Randomised controlled trial (RCT)
Trial registration number	ClinicalTrials.gov number is NCT#02887508
Study start date	May-2012
Study end date	Jan-2014
Aim	To test a newly developed, brief, exclusively online sexual risk reduction intervention for HIV positive gay and bisexual men, called the HIV Internet Sex (HINTS) study.
Country/geographical location	Specific location not reported. Participants were recruited using online and offline methods. Research team from the USA.
Setting	Online
Inclusion criteria	- At least 18 years old - Self-identifying as gay or bisexual - Living with HIV/AIDS - Reporting at least one instance of using the Internet to meet a potential sex partner

	- Reporting at least one instance of condomless anal sex with a male partner
Exclusion criteria	None reported
Method of randomisation	Computer-generated randomisation program. Participants were blind to randomisation status.
Method of allocation concealment	Not reported
Unit of allocation	Participant
Unit of analysis	Participant
Statistical method(s) used to analyse the data	- Baseline characteristics, including demographic, health, psychosocial, and sexual behavior variables for intervention and control groups were compared to assess the success of randomization. - Missing data was minimal (6%) at follow-up. - Standard power analyses confirmed sufficient sample size to test main hypotheses. - All analyses carried out using SPSS, version 21.0. - Incidence of CAS was operationalised as count data, which tend to exhibit a strong positive skew and over dispersion. As a result, a negative binomial distribution was applied to analyze CAS with (a) all male sex partners and then (b) seronegative/unknown male sex partners and (c) seropositive male sex partners. - Multivariate analyses were conducted analysing effects of study condition (intervention vs. control), and controlling for baseline sexual behavior, and a priori psychosocial covariates (e.g., age, depression, alcohol use).
Attrition	**Uptake** Of n=249 eligible participants, n=195 provided consent: n=50 did not consent and n=4 declined to participate. **Attrition**

	167 participants completed baseline assessments and were randomised. Of the n=85 participants randomised to the intervention, n=70 (82%) completed the 6 month follow up Of the n=82 participants randomised to the control, n=70 (85%) completed the 6 month follow up No significant differences in attrition were observed between groups.
Study limitations (author)	- The sample was drawn primarily from the East Coast and the Midwest due to logistical difficulties associated with running groups in different time zones. - Participants' sexual behavior data must be interpreted with some caution, as it was collected online via self-report, which may have resulted in biased reporting (although prompts were incorporated to help ensure valid data collection). - Use of biomedical prevention strategies (e.g., TasP or PrEP) by participants' partners was not evaluated in this study. HIV treatment is a critical component of recent primary and secondary prevention efforts, and should be incorporated into the development of future risk reduction strategies. - This study also examined only gay and bisexual men, and therefore cannot be generalised to all MSM, women, transgender individuals, or other people living with HIV. Similarly, the HINTS intervention was specifically developed using input from gay and bisexual men living with HIV and was designed to address transmission risk factors relevant to this group, so it is unclear how effective it would be in other populations affected by HIV infection.
Study limitations (reviewer)	None to add
Source of funding	This study was funded by an NIMH research grant (R34MH087120). This research was also partially supported by an NIMH training grant (T32MH074387).

Study arms

Intervention (N = 85)

HIV Internet Sex (HINTS); a brief, exclusively online, group-based sexual risk reduction intervention for sexual minority men living with HIV

Control (N = 82)

Healthy Living comparison condition; followed the same format as HINTS but sessions addressed nonsexual health-related topics such as nutrition, exercise and stress reduction.

Characteristics

Arm-level characteristics

Characteristic	Intervention (N = 85)	Control (N = 82)
Age Mean (SD)	43.7 (11.4)	45.7 (10.1)
Male gender identification	n = 84 ; % = 99	n = 81 ; % = 99
Transgender	n = 1 ; % = 1	n = 1 ; % = 1
Ethnicity		
White	% = 55	% = 60
Black/African American	% = 25	% = 24
Hispanic/Latino	% = 14	% = 13
Asian/Pacific islander	% = 4	% = 0
Biracial/Mixed ethnicity	% = 2	% = 2
Gay or homosexual	% = 88	% = 96
Bisexual	% = 12	% = 4

Characteristic	Intervention (N = 85)	Control (N = 82)
Married or living with partner	% = 20	% = 21
Years since HIV diagnosis Mean (SD)	12.4 (9.7)	11.7 (9.1)
Most recent CD4 cell count Mean (SD)	643.7 (271.9)	646.1 (242.6)
Currently taking HIV medications	% = 93	% = 94
Undetectable viral load at baseline	% = 73	% = 76

Outcomes

Study timepoints

- Baseline
- 6 month

Condom use outcomes

Outcome	Intervention, Baseline, N = 85	Intervention, 6 month, N = 70	Control, Baseline, N = 82	Control, 6 month, N = 70
Condomless anal sex - all partners Number of times during past 6 months Mean (SD)	9.34 (16.4)	6.4 (14.8)	11.32 (19.1)	8.9 (18.1)

Outcome	Intervention, Baseline, N = 85	Intervention, 6 month, N = 70	Control, Baseline, N = 82	Control, 6 month, N = 70
Condomless anal sex - HIV-/unknown serostatus Number of times during past 6 months Mean (SD)	3.7 (6.33)	1.54 (4.1)	5.31 (11.2)	3.58 (13.3)
Condomless anal sex - HIV+ Number of times in past 6 months Mean (SD)	7.17 (16)	4.86 (13.4)	8.02 (17.3)	5.32 (12)

Condomless anal sex - all partners - Polarity - Lower values are better

Condomless anal sex - HIV-/unknown serostatus - Polarity - Lower values are better

Condomless anal sex - HIV+ - Polarity - Lower values are better

CAS with sexual partners without HIV or whose HIV-status was unknown (serodiscordant) was measured to assess HIV transmission risk behaviour as an outcome measure. CAS with sexual partners with HIV (seroconcordant) was measured to assess the extent of serosorting as an outcome measure. This method of dichotomising sexual behaviour by partner serostatus followed convention used in previous research on sexual risk behaviour.

TIDier checklist

Study details

Rationale/theory/Goal	Secondary prevention strategies for MSM with HIV have tended to adopt a risk reduction approach. Two commonly endorsed behavioral strategies to reduce transmission risk among MSM include serosorting practices (limiting condomless sexual encounters to partners of the same serostatus) and condom use. Despite these risk reduction

	strategies, many MSM with HIV continue to engage in sexual behaviours associated with high risk of transmission (e.g. condomless anal intercourse with serodiscordant partners). Reducing sexual risk behaviours in this population has been an important target for secondary prevention efforts. The Internet may offer a unique venue for providing interventions to reduce HIV transmission risk behaviour, particularly because several studies have documented the increased frequency with which MSM seek sex partners online, and more recently through mobile applications (apps). Other studies have found increased rates of condomless anal intercourse among MSM meeting partners online; and have shown that online interventions delivered to young MSM are feasible and acceptable (p. 117).
Procedures used	Men were recruited using online and offline methods. Recruitment ads instructed potential participants to call the HINTS screening phone line. Study staff conducted a brief phone call with interested participants to assess eligibility. Eligible participants were then provided with information about the study. If they agreed to participate, they received emails containing study-related information and relevant links to the baseline survey, their online groups sessions and the 6 month follow-up assessment (p. 118).

Study arms

Intervention (N = 85) HIV Internet Sex (HINTS); a brief, exclusively online, group-based sexual risk reduction intervention for sexual minority men living with HIV

Brief name	The HIV Internet Sex (HINTS) study (p. 118)
Rationale/theory/Goal	Based on the Information Motivation Behavioural Skills (IMB) model and developed using focus groups and individual interviews with gay and bisexual men living with HIV, the HINTS intervention aims to improve information, motivational skills and behavioural strategies relevant to HIV transmission risk reduction for sexual minority men living with HIV (p. 118).
Materials used	All participants were sent a free headset to better participate in the online groups (p. 118).
Procedures used	Participants randomised to the HINTS intervention participated in 4 online group sessions: <u>Session 1:</u>

	- Introductions and overview of intervention - Meeting people, including sexual partners, via the internet. - Discussion of own experiences and whether they had encountered deceptive person or profile online Main goal of session: to highlight the possibility that potential sex partners might misrepresent their personal information (including serostatus) online. <u>Session 2:</u> - Covered HIV serostatus disclosure with partners met online. - How and when to address serostatus with potential sex partners - How to manage possible rejection following disclosure of HIV status Main goal of session: to enhance motivation and behavioral strategies for engaging in a productive dialogue about HIV serostatus. <u>Session 3:</u> - Condom negotiation and condom use with partners met online - When to discuss condom use preferences with a potential partner and how to make condom use more enjoyable - How best to maintain sexual health Main goal of session: to increase motivation and discuss behavioural skills to effectively engage sex partners in using condoms <u>Session 4:</u>

	- Safety when actually meeting potential sex partners met online - Strategies for maintaining safety, e.g. meeting in public, letting a friend know where meeting, having an 'escape plan' Main goal of session: reinforce the topics presented in earlier sessions and how to put them into practice in real life settings Each session ended with an assignment to complete before the next session, and the subsequent sessions began with a brief review of that assignment. Sessions included relevant video clips to promote discussion, and group interaction included a combination of voice chat and typed chat with facilitators. (p. 118-120)
Provider	Group facilitators included two clinical psychology graduate students and two community-based counsellors, all of whom had specialised training for working with populations affected by HIV. All facilitators were female (p. 118)
Method of delivery	Online group sessions (p. 118)
Setting/location of intervention	Online (p. 118)
Intensity/duration of the intervention	Four 45 minute sessions, twice per week over 2 consecutive weeks (p. 118).
Tailoring/adaptation	None reported
Unforeseen modifications	None reported
Planned treatment fidelity	Group sessions were recorded and reviewed by the principal investigator, a licensed psychologist, and the project manager, a social worker, to monitor intervention fidelity. The study team met weekly to discuss any pertinent issues regarding intervention delivery (p. 118-119).
Actual treatment fidelity	Not reported

Control (N = 82) Healthy Living comparison condition; followed the same format as HINTS but sessions addressed nonsexual health-related topics such as nutrition, exercise and stress reduction.

Brief name	Healthy Living control (p. 118)
Materials used	All participants were sent a free headset to better participate in the online groups (p. 118).
Procedures used	The Healthy Living comparison condition followed the same format as the HINTS intervention: facilitators presented information, motivational skills, and behavioral skills strategies, but sessions were tailored to address nonsexual health-related topics relevant to individuals living with HIV: (a) nutrition and healthy eating, (b) portion control, (c) exercise and staying active, (d) stress reduction to maintain health. As with the HINTS sessions, videos and poll questions were integrated to stimulate discussion during the groups. All control sessions were time-matched with the intervention group sessions (p. 120).
Provider	Not specifically reported but assumed to be the same facilitators as HINTS sessions.
Method of delivery	Online group sessions (p. 120)
Setting/location of intervention	Online (p. 120)
Intensity/duration of the intervention	Time-matched with intervention group sessions (four 45 minute sessions, twice per week for 2 consecutive weeks) (p. 120)
Tailoring/adaptation	None reported
Unforeseen modifications	None reported
Planned treatment fidelity	Not reported
Actual treatment fidelity	Not reported

Risk of Bias Assessment

Section	Risk of Bias	Reason
Domain 1: Bias arising from the randomisation process	Low	Computer generated randomisation; no baseline differences between groups
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Low	All participants were blinded and analysed in the group they were assigned to
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	Low	Modal number of sessions attended was 4 (out of 4). Sessions were led by experienced facilitators who could encourage intervention adherence
Domain 3. Bias due to missing outcome data	Low	Low amount of missing data; 82% and 85% retention in intervention and control groups; no differential attrition.
Domain 4. Bias in measurement of the outcome	Low	Outcomes assessed using self-completed surveys and using the same measures for both groups
Domain 5. Bias in selection of the reported result	Low	Trial registered and data analysed in accordance with prespecified plan
Overall bias and Directness	Low	
	Overall Directness	Partially applicable (US study)

Hart, 2021

Bibliographic Reference	Hart, Trevor A; Noor, Syed W; Skakoon-Sparling, Shayna; Lazkani, Samer N; Gardner, Sandra; Leahy, Bob; Maxwell, John; Julien, Rick; Simpson, Scott; Steinberg, Malcolm; Adam, Barry D; GPS: A Randomized Controlled Trial of Sexual Health Counseling for Gay and Bisexual Men Living With HIV.; Behavior therapy; 2021; vol. 52 (no. 1); 1-14

Study details

Study design	Randomised controlled trial (RCT)

Trial registration number	Not reported
Aim	To evaluate the efficacy of GPS, a community-based and peer-delivered sexual health promotion MI-based intervention for HIV+ GBM who engaged in CAS in the past 2 months.
Country/geographical location	Toronto and Vancouver, Canada
Setting	Community settings
Inclusion criteria	Eligible participants identified as (a) male (cisgender or transgender) (b) at least 18 years of age (c) having engaged in condomless anal sex (CAS) with a man in the past 3 months (d) HIV + serostatus (e) able to speak and understand English (f) being able to attend all workshops (g) willing to participate in program monitoring and evaluation
Exclusion criteria	Participants were excluded from the study if their ability to respond to study measures could be compromised by (a) a central nervous system condition (e.g., dementia) (b) acute psychotic or mood dysregulation (c) debilitative physical conditions

Method of randomisation	Participants were randomly assigned (2 participants per arm for each block of 4 participants) to either the intervention or the TAU arm. Randomisation was stratified by site to balance enrolment at each location across time. No further information on method of randomisation
Method of allocation concealment	No information
Unit of allocation	Participant
Unit of analysis	Participant
Statistical method(s) used to analyse the data	- Based on a power analysis of data, it was estimated that a sample size of 72 individuals per arm (i.e., intervention and control) would be needed to achieve 80% power (α = .05, two-sided) to detect an effect size of a 36% reduction in the prevalence of CAS with HIV-negative or unknown HIV status partners at 2-month follow-up, assuming baseline prevalence at 56% for both arms, and at 2-month follow-up a prevalence of 36% for the intervention arm, and 56% for the control arm. After adjusting for a 35% attrition rate, the aim was to enrol a final sample of 180 participants (90 per arm). - Demographic characteristics of the sample were examined using the mean, standard deviation, and normality assumptions of the measures. - The primary hypothesis was tested by comparing intervention arm and TAU arm participants' relative change in prevalence of serodiscordant CAS from the baseline to 3-month follow-up. - To account for group and city-specific clustering and nonindependence of data across timepoints, a three level (individual, group, and city) random-intercept random-coefficient nested regression model was built using gllamm in STATA. Likelihood ratio (LR) tests were used to build the most parsimonious model. Beta estimates were calculated for continuous measures, incident risk ratios (IRR) for count outcomes and odds ratios (OR) for binary outcomes. - All participants were included in the analyses following intent-to-treat protocol and maximum likelihood estimation was used to address nonresponse across time points. - Treatment effect sizes (Cohen's d and h) were calculated for all measures, considering an effect size of 0.20 = small, 0.50 = moderate, and 0.80 = large. - All statistical tests were two-tailed, and all analyses were conducted in Stata13 (StataCorp., 2014).

Attrition	89 participants were allocated to the intervention group. At the 3 month follow-up, n = 3 did not respond to attempts to schedule 3- or 6-month follow up data collection appointments. N = 28 discontinued the intervention, citing poor health (n=3) or unstable living situation (n=1), or did not attend the group sessions (n=24). 94 participants were allocated to the control group. N = 32 were lost to follow-up. Intervention and control participants did not differ on any demographic characteristics at baseline.
Study limitations (author)	- Given that data collection ended in 2018, which was before the local availability of PrEP, the present trial was unable to examine whether GPS would have an effect on CAS with HIV-negative partners using PrEP. - The present study is limited by its use of self-report measures, including self-report of sexual behaviour and viral load. This method, therefore, precludes confirmation of participants' actual viral load and assessment of biological outcomes such as contraction of sexually transmitted infections. - The study is also limited by its short-term follow-up.
Study limitations (reviewer)	None to add
Source of funding	This research was supported in part by a grant from the Canadian Institutes of Health Research (Operating Grant # 258818) and CIHR Canadian HIV Trials Network (CTN #271) as well as the Ontario HIV Treatment Network (Award ID: 921).

Study arms

Intervention (N = 89)

Gay Poz Sex (GPS), a sex positive, community based, peer delivered sexual health promotion intervention based on motivational interviewing and behavioural strategies, for HIV+ gay and bisexual men (GBM)

Control (N = 94)

Treatment as usual

Characteristics

Arm-level characteristics

Characteristic	Intervention (N = 89)	Control (N = 94)
Age Mean (SD)	40.82 (10.7)	40.77 (11.37)
Gender Male	n = 89 ; % = 100	n = 94 ; % = 100
Race / Ethnicity		
White	n = 58 ; % = 69.88	n = 60 ; % = 66.67
Black	n = 6 ; % = 7.23	n = 4 ; % = 4.44
East / Southeast Asian	n = 5 ; % = 6.02	n = 7 ; % = 7.78
Aboriginal / Metis / Inuit	n = 1 ; % = 1.2	n = 3 ; % = 3.33
Latin American / Hispanic	n = 7 ; % = 8.43	n = 3 ; % = 3.33
Middle Eastern / North African	n = 2 ; % = 2.41	n = 3 ; % = 3.33
South Asian	n = 1 ; % = 1.2	n = 3 ; % = 3.33
Mixed Race	n = 3 ; % = 3.61	n = 7 ; % = 7.78

Characteristic	Intervention (N = 89)	Control (N = 94)
HIV viral load		
Detectable	n = 8 ; % = 9.88	n = 14 ; % = 15.91
Non-detectable	n = 73 ; % = 90.12	n = 74 ; % = 84.09
Sexual orientation		
Gay/homosexual	n = 79 ; % = 92.94	n = 85 ; % = 94.44
Bisexual	n = 6 ; % = 7.06	n = 5 ; % = 5.56

Outcomes

Study timepoints

- Baseline
- 3 month (This follow-up is 3 months from baseline, so is actually an immediate-post test follow up)
- 6 month (This follow-up is 6 months from baseline, so is actually a 3-month post-intervention follow up)

Condom use outcomes

Outcome	Intervention, Baseline, N = 89	Intervention, 3 month, N = 89	Intervention, 6 month, N = 89	Control, Baseline, N = 94	Control, 3 month, N = 94	Control, 6 month, N = 94
Serodiscordant condomless anal sex with a male partner No of events	n = 61 ; % = 68.54	n = 45 ; % = 50	n = 35 ; % = 39.29	n = 56 ; % = 59.57	n = 46 ; % = 49.38	n = 45 ; % = 48
Serodiscordant condomless anal sex with casual male partner No of events	n = 56 ; % = 62.92	n = 41 ; % = 46.55	n = 32 ; % = 35.71	n = 50 ; % = 53.19	n = 39 ; % = 41.98	n = 40 ; % = 42.67
Condom use self efficacy Mean (SD)	10.15 (3.06)	10.6 (3.09)	10.78 (2.99)	9.88 (3.12)	10.53 (3.35)	10.75 (2.99)

Serodiscordant condomless anal sex with a male partner - Polarity - Lower values are better

Serodiscordant condomless anal sex with casual male partner - Polarity - Lower values are better

Condom use self efficacy - Polarity - Higher values are better

Paper reports % only; n's calculated by analyst

TIDier Checklist

Study details

Rationale/theory/Goal	Gay, bisexual, and other men who have sex with men (GBM) continue to have high rates of HIV and sexually transmitted infections, including syphilis. The rapidly developing landscape of biomedical HIV prevention via TasP and PrEP allows for greater opportunities for reducing the transmission of HIV among GBM, although they do not protect against other

	STIs such as syphilis. Mental health problems such as depression, loneliness, sexual compulsivity and fear of being rejected also disproportionately affect GBM, and can be a barrier to sexual risk reduction. Sexual risk reduction interventions that include attention to mental health problems are warranted. Given the shortage of credentialed mental health providers working in HIV and STI prevention, such as psychologists, psychiatrists, and social workers, there has also been increasing interest in delivering sexual health and mental health counselling via non-credentialed lay workers, including peers in the community and other community-based organisations (p. 2).
Procedures used	- Participants were recruited using notices posted in LGBTQ + friendly locations in the Toronto and Vancouver metropolitan areas (e.g., bars, coffee shops, community centres, and HIV/AIDS service organisations) as well as in online spaces (e.g., social media, web-based magazines and newspapers that serve the gay community in Vancouver and Toronto, and on websites targeting gay men). - Potential participants were invited to complete a brief interview at the study site in order to determine eligibility. Eligible participants were invited to a 1-hour in-person session in order to provide written informed consent for the study and to complete a computer-assisted self-interview (CASI) questionnaire in order to collect baseline demographic information. - Participants were then randomly assigned to the intervention arm or were referred to the TAU arm and placed on the waitlist for the intervention. - After intervention participants completed the GPS program, they completed an immediate post-test CASI questionnaire and at 3 months following intervention completion. To maintain the same assessment periods, control participants completed the same assessments at 3- and 6-months after baseline. (p. 4-5)
Setting/location of intervention	Community settings (p. 3)
Other details	After completing each assessment session, participants in both arms received an honorarium of CAD$30, transit passes to offset the cost of travel to the study site, and a list of community resources (e.g. mental health and substance use counselling services).

Study arms

Intervention (N = 89): Gay Poz Sex (GPS), a sex positive, community based, peer delivered sexual health promotion intervention based on motivational interviewing and behavioural strategies, for HIV+ gay and bisexual men (GBM)

Brief name	Gay Poz Sex (GPS) (p. 3)
Rationale/theory/Goal	The use of non-credentialed lay workers to provide services previously provided by credentialed health providers is known as task shifting. Within behaviour therapy, there have been calls to train non-psychologists to do evidence-supported therapies in order to extend the reach of behavioural therapy (McQuillin et al., 2019). Community-based organizations are well-positioned to provide many task-shifted behavioural intervention services, as they already offer a wide range of services to individuals living with HIV who are otherwise hard to reach or have low trust in the standard healthcare system. Motivational interviewing combined with behavioural strategies may be an effective method for providing sexual health and mental health counselling in community settings (p. 2-3). The GPS intervention takes a sex positive orientation, where the focus is not on reducing CAS or reducing sexual behaviour, but instead on promoting sexual health and well-being. It also emphasises choice and encourages HIV+ GBM to choose their own sexual behaviour goals (p. 9-10).
Materials used	No specific materials reported
Procedures used	- The first two sessions of the GPS program were informational in nature: groups engaged in interactive activities to discuss information on topics such as HIV transmission, sexually transmitted infections (STIs), strategies to promote sexual health, and psychosocial problems that impact sexual health. - In Sessions 2–8, facilitators worked with participants to identify areas of inconsistent or conflicting motivations. These sessions were designed to help participants identify their personal sexual health goals and discuss their current sexual health behaviours. - Starting in Session 4 and continuing through Session 8, facilitators worked with participants to develop behavioural skills relevant to each participant’s personal sexual health goals, such as learning how to assert oneself in sexual situations, how to meet other gay and bisexual men outside of sexual situations so a participant does not need to have sex to avoid loneliness, and how to manage cues that may trigger maladaptive substance use that leads to undesired sexual behaviour (p. 5).

Provider	Sessions were led by 2 peer facilitators who were HIV+ gay men and non-credentialed lay workers who were trained in the GPS protocol by a clinical psychologist (p. 4).
Method of delivery	Face to face small group sessions of 5-8 men (p. 4)
Intensity/duration of the intervention	Eight weekly 2-hour group sessions (p. 4)
Tailoring/adaptation	None reported
Unforeseen modifications	None reported
Planned treatment fidelity	Counsellors provided information to the study office after each session confirming if they followed protocol for each session. Motivational Interviewing (MI) session fidelity was scored by three trained MI counsellors using the most recent version available at the beginning of data collection of the Motivational Interviewing Treatment Integrity coding system (MITI 3.1.1; Moyers, Martin, Manuel, Miller, & Ernst, 2010). MITI assessments were conducted for a random 15% of sessions in 20-minute increments, via in-person (in Toronto) or telephone fidelity assessments (in Vancouver). A proficient-level of fidelity is suggested by a score of at least 3.5 on the global ratings, 50% open questions/total questions, 40% complex reflections/total reflections, 1 reflection per 1 question, and 90% MI-adherent behaviours (p. 7)
Actual treatment fidelity	Counsellors reported adherence to the study protocol for each session. Within the intervention arm, the average global rating across the five domains of adherence to MI suggested a proficient fidelity to MI spirit, mean = 3.88, standard deviation = 0.55. Specific counsellor behaviour counts also suggested proficiency, with an average of 73.09% open questions/total questions, 42.18% complex reflections/total reflections, mean = 1.87 (standard deviation = 2.26) reflections per 1 question asked, and 97% (standard deviation = 13%) MI-adherent behaviours/total behaviours (p. 7-8)

Control (N = 94): Treatment as usual

Materials used	No specific materials reported
Procedures used	Control participants were placed on a waitlist for the GPS intervention. During their time on the waitlist, they were given treatment as usual and were permitted to continue whatever treatments they were already receiving through other means, such as referrals to mental health or sexual health services already found at local community-based organisations and clinics (p. 3-4).
Provider	N/A

Method of delivery	N/A
Intensity/duration of the intervention	N/A
Tailoring/adaptation	N/A
Unforeseen modifications	N/A
Planned treatment fidelity	N/A
Actual treatment fidelity	N/A

Risk of Bias Assessment

Section	Risk of Bias	Reason
Domain 1: Bias arising from the randomisation process	Some concerns	Limited information on randomisation method and no information on allocation concealment
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Low	No information on blinding but deviations from intended interventions unlikely and ITT used
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	Low	Intervention sessions were delivered face-to-face by trained facilitators so non-adherence unlikely
Domain 3. Bias due to missing outcome data	Low	Some missing data but ITT used and no difference in missing data by arm
Domain 4. Bias in measurement of the outcome	Low	Appropriate outcome assessment using CASI
Domain 5. Bias in selection of the reported result	Some concerns	Trial not registered
Overall bias and Directness	Some concerns	Limited information on randomisation method, no information on allocation concealment or participant blinding; trial not registered

Section	Risk of Bias	Reason
	Overall Directness	Partially applicable (Canadian study)

Mansergh, 2010

Bibliographic Reference	Mansergh, Gordon; Koblin, Beryl A; McKirnan, David J; Hudson, Sharon M; Flores, Stephen A; Wiegand, Ryan E; Purcell, David W; Colfax, Grant N; Project MIX Study, Team; An intervention to reduce HIV risk behavior of substance-using men who have sex with men: a two-group randomized trial with a nonrandomized third group.; PLoS medicine; 2010; vol. 7 (no. 8); e1000329

Study details

Study design	Randomised controlled trial (RCT) This was a three-arm trial with two randomised groups (intervention and attention-control) and one non-randomised group (standard care). The standard care arm was excluded from this review because participants were not randomised to this group, so no data was extracted for this arm.
Trial registration number	ClinicalTrials.gov NCT00153361
Study start date	Oct-2004
Study end date	Apr-2008
Aim	To test the efficacy of a group-based, cognitive-behavioral intervention to reduce risk behavior of substance-using MSM, compared to a randomised attention-control group and a non-randomised standard HIV testing group (note that the non-randomised arm was not extracted for this review).
Country/geographical location	Chicago, Los Angeles, New York City and San Francisco, USA
Setting	Unclear; assumed clinic-based.

Inclusion criteria	Men were eligible to participate if they reported (1) being drunk or ‘‘buzzed’’ on alcohol two or more times, or high on non-injection drugs at least once, during (or 2h before) anal sex in the past 6 mo, and (2) at least one unprotected anal sex episode in the past 6 months with a male partner whose HIV serostatus was unknown or different from their own.
Exclusion criteria	Men were ineligible if they: - reported only marijuana or use of erectile dysfunction medications soon before or during anal sex in the past 6 mo - reported injecting drugs other than steroids, hormones, prescribed medications, or methamphetamine in the past 6 mo - had known for less than 6 mo that they were HIV-positive - were currently participating in another HIV behavioural intervention trial.
Method of randomisation	Using laptop computer program. A minimum of 10 (5 per group) and maximum of 20 (10 per group) men were needed for randomisation. On-site computerised randomisation was blocked by HIV serostatus so that where possible the intervention and attention-control group each contained at least two men who were HIV-positive and at least two men who were HIV-negative.
Method of allocation concealment	Computerised randomisation
Unit of allocation	Participant
Unit of analysis	Participant
Statistical method(s) used to analyse the data	- Sample size was based on 80% statistical power to detect an approximate 25% change in behaviour (e.g., unprotected anal sex) from baseline to follow-up, which is consistent with findings from meta-analyses of HIV behavioural intervention trials. - Bivariate comparisons of outcomes and predictors at each follow-up wave were performed with chi-square tests; 95% confidence intervals (CIs) for raw proportions were calculated with asymptotic standard errors and a continuity correction. - Primary outcomes were dichotomous variables focused on participant behaviour during the most recent anal sex encounter with a nonprimary partner.

	- For longitudinal analyses, a generalised linear mixed model was used to evaluate dichotomous outcomes. A random intercept for each participant was incorporated into the model to control for any correlation within participants in the four follow-up waves. - A multiple imputation approach with adaptive rounding for binary variables was used to impute missing outcome variables. Ten imputations were aggregated for the results and drug use covariates were incorporated into the imputation procedure to increase the efficiency of the imputed observations. Models were also run on the raw, nonimputed data. Inferences for the trial arm, wave, and interaction between trial arm and wave did not differ between the analyses of the raw and multiply imputed data. - Rates of reduction were calculated from population-averaged rates, which control for all other covariates in the multivariable model. - Models were calculated by using the GLIMMIX and MIANALYZE procedures in Statistical Analysis Software (SAS), version 9.2, and model fit was evaluated by diagnostic statistics and residual plots.
Attrition	**<u>Uptake</u>** N=7370 completed an initial screen, of which n=4777 were ineligible, n=186 declined or refused to participate, n=485 passively declined, n=160 did not attend for the second screen, and n=35 had other reasons for not proceeding. **<u>Attrition</u>** N=1206 were enrolled and randomly assigned to the intervention group (n=599) or the control group (n=607). For both groups, session attendance ranged between 73% and 100% across the 6 sessions. For follow-up assessments, retention did not significantly differ between groups and was as follows: *Intervention*

	3 months: n=524 (87%) 6 months: n=520 (87%) 12 months: n=537 (90%) *Control* 3 months: n=537 (88%) 6 months: n=538 (89%) 12 months: n=542 (89%)
Study limitations (author)	- The use of self-report (although ACASI was used to minimize this bias) - The potential of behavioural regression to the mean over time; this may especially be the case with the very high-risk enrolment criteria in this study (i.e., greater potential for regression to the mean at follow-up relative to less-risky samples). - Not all of the outcome variables are entirely exclusive from one another (e.g., UA with a discordant partner is subsumed in UA overall).
Study limitations (reviewer)	None to add
Source of funding	This work was funded by cooperative agreements from the Division of HIV/AIDS Prevention, CDC, USA (http://www.cdc.gov), award numbers: U65/ CCU522209 (Chicago); U65/CCU922215 (Los Angeles); U65/CCU222309 (New York); U65/CCU922213 (San Francisco).

Study arms

Intervention (N = 599)

Group CBT sessions focused on reducing substance use and sexual risk behaviour

Control (N = 607)

Attention-control comparison focusing on MSM community issues unrelated to substance, sexual risk and HIV/AIDS.

Characteristics

Arm-level characteristics

Characteristic	Intervention (N = 599)	Control (N = 607)
18-24 years	n = 70 ; % = 12	n = 56 ; % = 9
25-34 years	n = 158 ; % = 26	n = 162 ; % = 27
35-44 years	n = 239 ; % = 40	n = 265 ; % = 44
45 years and older	n = 132 ; % = 22	n = 124 ; % = 20
Gender Male	n = 599 ; % = 100	n = 607 ; % = 100
Ethnicity		
Black	n = 200 ; % = 33	n = 194 ; % = 32

Characteristic	Intervention (N = 599)	Control (N = 607)
Hispanic/Latino	n = 120 ; % = 20	n = 102 ; % = 17
White	n = 225 ; % = 38	n = 241 ; % = 40
Other	n = 54 ; % = 9	n = 70 ; % = 11
HIV Status		
Positive	n = 307 ; % = 51	n = 300 ; % = 49
Negative	n = 248 ; % = 42	n = 272 ; % = 45
Unknown	n = 44 ; % = 7	n = 35 ; % = 6
Gay/homosexual	n = 501 ; % = 84	n = 508 ; % = 84
Bisexual/other	n = 98 ; % = 16	n = 99 ; % = 16

Outcomes

Study timepoints

- Baseline
- 3 month
- 6 month
- 12 month

Condom use outcomes

Outcome	Intervention, Baseline, N = 599	Intervention, 3 month, N = 524	Intervention, 6 month, N = 520	Intervention, 12 month, N = 537	Control, Baseline, N = 607	Control, 3 month, N = 537	Control, 6 month, N = 538	Control, 12 month, N = 542
Unprotected anal sex During most recent anal sex encounter with a non-primary partner No of events	n = 401 ; % = 67	n = 225 ; % = 43	n = 224 ; % = 43	n = 215 ; % = 40	n = 413 ; % = 68	n = 236 ; % = 44	n = 226 ; % = 42	n = 206 ; % = 38
HIV-discordant unprotected anal sex During most recent anal sex encounter with a non-primary partner whose HIV serostatus was unknown or different from participant No of events	n = 234 ; % = 39	n = 100 ; % = 19	n = 88 ; % = 17	n = 97 ; % = 18	n = 231 ; % = 38	n = 113 ; % = 21	n = 97 ; % = 18	n = 108 ; % = 20
Drug use soon before or during unprotected anal sex with any non-primary partner No of events	n = 270 ; % = 45	n = 136 ; % = 26	n = 140 ; % = 27	n = 118 ; % = 22	n = 261 ; % = 43	n = 129 ; % = 24	n = 124 ; % = 23	n = 103 ; % = 19
Drug use soon before or during unprotected anal sex with any non-primary partner of different or unknown HIV serostatus No of events	n = 150 ; % = 25	n = 63 ; % = 12	n = 52 ; % = 10	n = 54 ; % = 10	n = 146 ; % = 24	n = 64 ; % = 12	n = 48 ; % = 9	n = 60 ; % = 11

Unprotected anal sex - Polarity - Lower values are better

HIV-discordant unprotected anal sex - Polarity - Lower values are better

Drug use soon before or during unprotected anal sex with any non-primary partner - Polarity - Lower values are better

Drug use soon before or during unprotected anal sex with any non-primary partner of different or unknown HIV serostatus - Polarity - Lower values are better

Paper reports % only; number of events calculated by analyst

TIDier checklist

Study details

Rationale/theory/Goal	Alcohol and non-injection substance use is associated with sexual risk behaviour in MSM, and sexual risk increases when substances are used soon before or during sexual encounters. Although interventions have been tested with substance-abusing MSM in drug treatment settings, few interventions have been tested with substance-using MSM not in treatment. Interventions to address sexual risk taking among out-of-treatment substance-using MSM are needed (p. 1-2).
Procedures used	Participants were recruited through street and MSM venue outreach, agency/business-based posters and flyers, ads in print media, and word of mouth. Each city (Chicago, Los Angeles, New York City and San Francisco) tailored its recruitment campaigns to the local population. Potential participants were initially screened by telephone; eligible participants were then scheduled for a baseline appointment. At the baseline assessment, all men were rescreened for eligibility, provided written informed consent, and completed the ACASI in a private location. All participants received standard HIV risk reduction counselling. HIV-negative and unknown serostatus men were administered a rapid HIV test. Contact information was collected and their intervention or control group sessions where scheduled. Follow-up assessment waves were completed at 3-, 6- and 12-months after the final group session; participants completed the same ACASI at each assessment (p. 2-3).
Other details	Participants were reimbursed for their time and travel as determined by each study site (range $25-$40 for baseline assessment and range $25-$50 for each follow-up assessment) (p. 2 and p. 3).

Study arms

Intervention (N = 599) Group CBT sessions focused on reducing substance use and sexual risk behaviour

Brief name	Group CBT
Rationale/theory/Goal	The intervention is based on cognitive behavioural techniques and relevant skills building approaches including modelling and behavioural rehearsal (p. 2).
Materials used	No specific materials reported
Procedures used	Intervention sessions contained specific modules to help participants analyse their substance abuse and sexual risk patterns, identify situational triggers for risky behaviour, develop behavioural alternatives and negotiation strategies, and plan for change. Behaviour change attempts during the intervention period allowed for feedback and positive reinforcement on a weekly basis (p. 2).
Provider	Trained facilitators who were specifically trained to lead intervention exercises and discussions, emphasising the primary messages (p. 3)
Method of delivery	Face to face group-sessions (p. 2)
Setting/location of intervention	Unclear from paper but assumed clinic based
Intensity/duration of the intervention	Six weekly sessions lasting 2 hours with a 10-minute break in the middle of each session (p. 2)
Tailoring/adaptation	Not reported
Unforeseen modifications	None reported
Planned treatment fidelity	Intervention sessions were taped and 2 of the 6 sessions were reviewed and scored to ensure all material in the facilitator manuals was covered (p. 3).
Actual treatment fidelity	Adherence to the manual during the 6 sessions averaged 94% (p. 3)

Control (N = 607) Attention-control comparison focusing on MSM community issues unrelated to substance, sexual risk and HIV/AIDS.

Brief name	Attention-control group (p. 1)
Materials used	Videos focused on MSM-related issues (p. 2)
Procedures used	Modules for the attention-control group consisted of videos and group discussion focused on MSM-related issues unrelated to substance abuse, sexual risk behaviour and HIV. Topics included relationships, spirituality and racism. Each module consisted of a video followed by a discussion of the video and two modules were presented at each session (p. 3)
Provider	Trainer facilitators specifically trained to subtly redirect discussion away from substance use, sexual risk behaviour and HIV/AIDS (p. 3).
Method of delivery	Face to face group sessions (p. 2).
Setting/location of intervention	Unclear from paper but assumed clinics
Intensity/duration of the intervention	Six weekly 2 hour sessions with a 10-minute break in the middle of each session (p. 3)
Tailoring/adaptation	Not reported
Unforeseen modifications	None reported
Planned treatment fidelity	Attention-control group sessions were taped and 2 out of 6 were reviewed and scored to ensure all material was covered (p. 3)
Actual treatment fidelity	Any intervention content was to be avoided; unintended discussion of intervention topics related to HIV, substance use or sexual risk behaviours occurred in 3% of sessions and was redirected by facilitators (p. 3).

Risk of Bias Assessment

Section	Risk of Bias	Reason
Domain 1: Bias arising from the randomisation process	Low	Adequate randomisation procedures and no baseline differences between groups

Section	Risk of Bias	Reason
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Low	No information on blinding but deviations from intended interventions unlikely
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	Some concerns	Acceptable adherence (~75% attendance at all sessions) but impact of intervention adherence not assessed
Domain 3. Bias due to missing outcome data	Low	87-90% retention at each follow-up, low rates of missing data
Domain 4. Bias in measurement of the outcome	Low	Outcome assessment the same for both groups and used ACASI
Domain 5. Bias in selection of the reported result	Low	Trial registered and data analysed in accordance with prespecified plan
Overall bias and Directness	Low	
	Overall Directness	Partially applicable (US study)

McKirnan, 2010

Bibliographic Reference	McKirnan, David J; Tolou-Shams, Marina; Courtenay-Quirk, Cari; The Treatment Advocacy Program: a randomized controlled trial of a peer-led safer sex intervention for HIV-infected men who have sex with men.; Journal of consulting and clinical psychology; 2010; vol. 78 (no. 6); 952-63

Study details

Study design	Randomised controlled trial (RCT)
Trial registration number	www.clinicaltrials.gov Trial Number NCT0016433

Study start date	May-2004
Study end date	May-2006
Aim	To test the efficacy of the Treatment Advocacy Program (TAP), a 4-session, primary-care-based, individual counselling intervention led by HIV-positive MSM “peer advocates” in reducing unprotected sex with HIV-negative or unknown partners.
Country/geographical location	Chicago, USA
Setting	Three Chicago-area clinics that reflected a range of primary care settings: a well-established gay/lesbian health centre, a public clinic, and a private medical centre.
Inclusion criteria	- Received an HIV diagnosis at least 3 months prior to screening - Were enrolled in primary care at one of the three target clinics - MSM sexual activity within the previous year
Exclusion criteria	- Intended to move within the next year - Did not speak English
Method of randomisation	Randomly assigned participant identification numbers generated by a central research office; the assigned identification number coded participants as intervention or comparison.
Method of allocation concealment	Randomly assigned participant numbers were generated by a central research office
Unit of allocation	Participant
Unit of analysis	Participant
Statistical method(s) used to analyse the data	All intervention effects were tested by the general estimating equation procedure in SAS. The Type III Wald chi-square with an autoregressive correlation structure was used to test the interaction of group (intervention vs. comparison) by follow-up period for each outcome. Interactions were tested with the main effects entered as prior terms in the model. Simple contrasts were conducted to test the interactions of group by (a) baseline versus 6 months, (b) baseline versus 12 months, and (c) baseline versus the mean of 6 and 12 months. All these analyses tested linear effects of group

	differences on risk levels across wave. For all analyses, clinic, age, ethnicity, income, and education were entered as covariates prior to the terms coding group and follow-up period. Core analyses used an intent-to-treat, listwise missing value procedure, wherein all participants who had data for all waves (n = 251 [comparison n = 120, intervention n = 131]; 80% of participants) were analysed. These results were compared with analyses in which missing values among participants with at least one follow-up wave (n = 297; 95% of participants) were imputed. The target sample size (n = 225 at follow-up) had 90% power (two-tail p < .05) to detect a 15% decrease in the percentage of men in the intervention group who reported UAI at one follow-up wave.
Attrition	- Participants were recruited from a screening pool sample of 945 HIV+ MSM attending the three target clinics. Of this patient population, 581 patients (61%) were screened, of whom 411 (71% of the screening pool) met the eligibility requirements. - Of these men, 317 (77%) agreed to enrol and were randomised to the comparison group (n=151) or intervention group (n=166). - Four participants were dropped from the analyses sample because of death during the study, for a final sample of 313 (intervention n=163, comparison n=150). - At the 6 month follow-up, retention was 80% (n=133) in the intervention group and 82% (n=122) in the comparison group. At the 12 month follow-up, retention was 92% (n=152) in the intervention group and 94% (n=139) in the comparison group. - A total of 251 participants had data available for all three assessment waves (intervention n=131, comparison n=120). - Intervention and comparison groups did not differ in initial enrollment rate or in retention at any wave; and did not differ on any demographic or clinical variables at baseline.
Study limitations (author)	- Behavioural interventions may be most effective if begun early after diagnosis. The study did not have sufficient statistical power to test that hypothesis here, but anecdotal reports have suggested that participants who had been living with HIV-and having characteristic sexual patterns-for many years may have been more resistant to change.

	- The range of clinics and patients also limits these results. Participants were not randomly sampled and were therefore prey to unmeasurable sampling bias. In particular, the ability to show intervention effects may have been suppressed by lower than expected baseline risk behaviour. In addition, the standard of care at the participating clinics was very high, potentially higher than in HIV clinics more generally. Thus, stronger effects may have been seen among riskier, more recently diagnosed men who were being compared with men receiving a more typical standard of HIV care. - There was a trend for the intervention group participants to report more risk at baseline than did the comparison group. Although this group difference was not statistically significant, it does raise the prospect that some of the observed behavioural change in the intervention group was due to a regression to the mean. The randomisation procedure was rigorously followed by screening staff and was unlikely to have been biased. Nonetheless, these baseline differences warrant caution in consideration of these results, as the groups could have differed at baseline by chance in ways that were not captured by randomisation checks.
Study limitations (reviewer)	None to add
Source of funding	This research was funded by Centers for Disease Control and Prevention Grant PA 01190.

Study arms

Intervention (N = 165)

Treatment Advocacy Program (TAP): a peer-based counselling intervention for sexual safety and general coping among MSM with HIV.

Control (N = 148)

Standard HIV primary care

Characteristics

Study-level characteristics

Characteristic	Study (N = 313)
Age	
18-29 years	n = 41 ; % = 13
30–39 years	n = 94 ; % = 30
40–49 years	n = 137 ; % = 44
50+	n = 41 ; % = 13
Ethnicity	
African American	n = 98 ; % = 31
Latino	n = 54 ; % = 17
White	n = 147 ; % = 47
Asian/Other	n = 14 ; % = 5
Time since diagnosis	
<3 years	n = 100 ; % = 32
4-9 years	n = 93 ; % = 30
10+ years	n = 120 ; % = 38
Clinical status	
On medications	n = 225 ; % = 72
Discontinued medications	n = 32 ; % = 10
Medication naive	n = 56 ; % = 18
CD4 t-cell counts <350	n = 94 ; % = 30
‘Out’ as MSM to social network	
Half or less	n = 98 ; % = 31

Characteristic	Study (N = 313)
Most of social network	n = 133 ; % = 43
Completely 'out'	n = 82 ; % = 26

Outcomes

Study timepoints

- Baseline
- 6 month
- 12 month

Transmission risk behaviour (UAI with HIV- or unknown status partners)

Outcome	Intervention, Baseline, N =	Intervention, 6 month, N = 131	Intervention, 12 month, N = 131	Control, Baseline, N =	Control, 6 month, N = 120	Control, 12 month, N = 120
Number of participants reporting UAI with HIV- or unknown status partners in prior 6 months No of events	% = 33.6	% = 20 n = 26	% = 20 n = 26	% = 23	% = 24 n = 29	% = 23 n = 28
Number of transmission risk partners Mean only (SD not reported)	0.74	Not reported	0.42	0.55	Not reported	0.43

Number of participants reporting UAI with HIV- or unknown status partners in prior 6 months - Polarity - Lower values are better

Number of transmission risk partners - Polarity - Lower values are better

For number of participations reporting UAI, paper reports % only; n's calculated by analyst

TIDier Checklist

Study details

Rationale/theory/Goal	Many HIV+ MSM continue to engage in unprotected sex. The development of effective interventions for HIV risk reduction has increasingly become a public health priority. While previous interventions among HIV+ individuals have generally been successful, they have proven less so for HIV+ MSM. The effectiveness of some peer-based interventions may have been limited by their group structure: risky participants may have influenced otherwise safer men. It was proposed that an individual intervention using CBT and motivational interviewing based approaches may be effective (p. 2).
Procedures used	- Trained research assistants approached all HIV-positive men attending their regular medical provider visits at the target clinics. -The same procedures and structured screening forms were used in each of the clinics to assess patients' interest in the program and the entry criteria. When a patient screened eligible and accepted enrolment, the research assistant scheduled the consent and baseline interview and completed randomisation procedures. Informed consent and baseline assessments were generally conducted immediately after enrolment, unless time constraints required that a participant come in for a later visit. - Participants were introduced to the ACASI in a private interview room by a research assistant. The assistant left the room during the actual interview, although the assistant remained just outside to provide assistance. - After the interview, the participant was told his group assignment and was scheduled for his next visit. - Intervention participants were scheduled for their TAP sessions in the 4-6 weeks post-enrolment and additional coping follow-up sessions were conducted at 6- and 12-months. - All participants completed full ACASI follow-up assessments at 6- and 12-months.

	- Where possible, all intervention and follow-up sessions were conducted during participants' regular primary care visit. (p. 4).
Other details	All participants received $25 for completing the baseline and 6-month visits, and $40 for completing the 12- month assessments. Intervention participants also received $10 for each of the coping follow-up sessions at 6- and 12-months (p. 4).

Study arms

Intervention (N = 165)

Treatment Advocacy Program (TAP): a peer-based counselling intervention for sexual safety and general coping among MSM with HIV.

Brief name	Treatment Advocacy Program (TAP) (p. 1)
Rationale/theory/Goal	The theoretical model drew on basic coping and self-regulation frameworks, particularly in relation to coping with a chronic disease. In the case of HIV, the difficult behavioural demands of this condition were acknowledged, including sexual safety and adherence to a treatment regimen, which can be emotionally aversive, particularly for those with diminished self-efficacy for coping. The resultant negative affect or cognitive avoidance may compromise both general coping and specific adherence to sexual safety demands. It was therefore hypothesised that sexual safety among HIV-positive men would be facilitated by improving self-efficacy and skills for enhancing social support and coping with HIV, modulating negative affect, enhancing HIV disclosure, and enhancing information and motivation around sexuality. Given the importance of alcohol and drug use to sexual risk and avoidant coping generally, content on substance use harm reduction was also considered important. The use of peer advocates was intended to provide coping models and to decrease the isolation that may accompany an HIV diagnosis (p. 2-3).
Materials used	Intervention sessions were structured around a menu-driven Powerpoint program with slides using text or images as prompts (p. 6).
Procedures used	- The intervention consisted of one-to-one sessions with treatment advocates. - Advocates and clients met with a computer open on a desk. Advocates clicked through each intervention module using text or images as prompts for information, attitude or motivation change, or skills building. Each slide typically began with

	a “cardinal” question addressing general motivations and goals (e.g., “How has being infected changed your relationship[s] or sex life?”) and was followed by increasingly structured prompts to facilitate specific behavioural plans. - The intervention content combined motivational interviewing and cognitive behavioural techniques to motivate men to participate in active health behaviour change and to inculcate skills and self-efficacy in initiating and maintaining behavioural change. - Skills and self-efficacy were facilitated by tailored goals and plans and by personal feedback; each module concluded with a specific behavioural planning exercise. - The intervention comprised eight modules: Three were used during the initial three sessions then during Session 4, the counsellor and participant chose one of five “focus” modules. **Session 1: HIV coping and basic medication skills.** This module contained information stressing the importance of sexual safety and medication adherence; framed active HIV coping in terms of mindful sexuality and intimacy, drug and alcohol use reduction, regulating negative affect, and social support; and used cognitive-behavioural techniques to inculcate self-efficacy for basic adherence skills, e.g. the use of cue controls, pill boxes and medication monitoring, and communication with the provider. **Session 2: Advanced medication and coping skills.** The advocate helped the participant articulate his values and goals for coping with HIV, assessed current adherence levels, and used cognitive-behavioural strategies to articulate the contexts that challenge adherence goals such as periods of negative affect, alcohol or drug use, sexual settings, and challenging social settings. A concluding “coping analysis” was used to develop a written behavioural plan sheet for behavioural rehearsal over the next week. **Session 3: Intimacy and sexuality.** The advocate first presented systematic information about the continuing risks of unprotected sex for HIV infected men. He then conducted a motivational interview to articulate the participants’ sexual values and goals, current satisfactions and dissatisfactions regarding intimacy and sexuality, and commitment to change areas. This led to a cognitive-behavioural analysis of sexual risks vis-à-vis social settings, high-risk partners, moods and feelings, drugs and alcohol, avoidant coping, and communication. “Hot buttons” in each content area linked to skills or coping exercises when appropriate. The advocate and participant then developed a concrete, written behavioural change plan for each target skill area.

	Session 4: Focused safety skills. One of five modules was selected based on an analysis and discussion of behavioural plans from previous sessions: (a) HIV transmission information, (b) basic safety skills, (c) HIV communication, (d) alcohol and drug use, and (e) moods and feelings. **Coping follow-up visits:** These were completed at 6- and 12-months and used the same structure and computer based approach as the core intervention. Participants responded to structured probes to report recent sexual risks, adherence to medications, social support, alcohol or drug use, negative affect, and general coping with HIV. Responses indicating difficulties in any area linked them to the appropriate intervention content, typically replicating content from the core intervention modules. (p. 6-8)
Provider	Six ethnically diverse, HIV-positive MSM peer counsellors (treatment advocates) delivered the intervention. Ages ranged from 24 to 40 years. Treatment advocates were recruited through providers or case managers, and they received 40 hr of training on motivational interviewing and cognitive-behavioural techniques for sexual safety and HIV coping, non-judgmental communication, confidentiality, research and counselling ethics, and referral resources. Ongoing supervision was provided via weekly meetings with doctoral- and master's-level licensed therapists (p. 6).
Method of delivery	Face to face individual sessions (p. 6).
Setting/location of intervention	Primary care clinics (p. 5)
Intensity/duration of the intervention	Four 60-90 minute intervention sessions; 3 month "check-in" phone calls, and 6- and 12-month coping follow-up sessions which lasted around 15-20 minutes for those coping well and up to 90 minutes for those with continued risk or coping difficulties (p. 3, p. 8).
Tailoring/adaptation	Participants and advocates together selected on of 5 modules for the final intervention session, tailored to the participants' needs (p. 8).
Unforeseen modifications	None reported
Planned treatment fidelity	20% of intervention sessions were recorded to audit them for compliance to key elements of the intervention protocol (p. 6)
Actual treatment fidelity	Compliance averaged over 85% for all advocates (p. 6)

Control (N = 148)

Standard care

Procedures used	The comparison was a 12-month waitlist during which participants received standard HIV primary care at their respective clinics. Standard of care was very high at all 3 participating clinics in terms of the quality of the healthcare and available social supports (p. 3).
Provider	Not reported
Method of delivery	Face to face care
Setting/location of intervention	Primary care clinics (p. 3)
Intensity/duration of the intervention	N/A
Tailoring/adaptation	N/A
Unforeseen modifications	N/A
Planned treatment fidelity	N/A
Actual treatment fidelity	N/A

Risk of Bias Assessment

Section	Risk of Bias	Reason
Domain 1: Bias arising from the randomisation process	Low	Adequate randomisation procedures and no baseline differences between groups
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Low	Deviations from intended interventions unlikely

Section	Risk of Bias	Reason
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	Low	Acceptable adherence
Domain 3. Bias due to missing outcome data	Low	
Domain 4. Bias in measurement of the outcome	Low	
Domain 5. Bias in selection of the reported result	Some concerns	Trial registered but registration number not found on clinicaltrials.gov so cannot check analysis protocol
Overall bias and Directness	Low	
	Overall Directness	Partially applicable (US study)

Mimiaga, 2019

Bibliographic Reference Mimiaga, M.J.; Pantalone, D.W.; Biello, K.B.; Hughto, J.M.W.; Frank, J.; O'Cleirigh, C.; Reisner, S.L.; Restar, A.; Mayer, K.H.; Safren, S.A.; An initial randomized controlled trial of behavioral activation for treatment of concurrent crystal methamphetamine dependence and sexual risk for HIV acquisition among men who have sex with men; AIDS Care - Psychological and Socio-Medical Aspects of AIDS/HIV; 2019; vol. 31 (no. 9); 1083-1095

Study details

Study design	Randomised controlled trial (RCT)
Trial registration number	Not reported

Study start date	Jan-2013
Study end date	Jun-2016
Aim	To test the efficacy of an intervention integrating sexual risk reduction counselling and behavioural activation approaches for MSM with crystal methamphetamine dependence.
Country/geographical location	Boston, Massachusetts, USA
Setting	The Fenway Institute, a large health centre caring for sexual and gender minority populations (see Safren, 2013).
Inclusion criteria	- Age 18 or older - Self-identified a male biological birth sex - HIV-uninfected (verified via antibody test on at baseline) - Self-reported having condomless anal sex (CAS; receptive or insertive) with a non-monogamous male sexual partner within the context of crystal methamphetamine use (either a few hours prior to or during sex) in the past three months - Met DSM-IV diagnostic criteria for crystal methamphetamine abuse or dependence (Note: All participants enrolled met DSM-IV diagnostic criteria for crystal methamphetamine dependence, even though they could have met for either abuse or dependence).
Exclusion criteria	None reported
Method of randomisation	No information
Method of allocation concealment	No information
Unit of allocation	Participant
Unit of analysis	Participant

Statistical method(s) used to analyse the data	- Sample size was determined using the mean change data from an open pilot trial (Mimiaga et al., 2012). Assuming at least a 30% or greater decline in the experimental condition, with 40 participants randomized, there would be an 80% chance of detecting a significant difference at a two-sided, .05 alpha level. - Means for continuous variables and frequencies for categorical variables were calculated to describe sociodemographic characteristics of the participants at baseline, overall, and stratified by intervention condition. T-tests and chi-square tests were used to examine differences by study condition and assess balance on key variables with respect to randomization. - The impact of the intervention on key outcomes (CAS acts, including in the context of meth use) was assessed at acute post intervention (3 months) and 6-month post intervention assessments. Because number of condomless anal sex acts is count data and was not normally distributed, mean counts were estimated and intervention effects were tested by specifying a Poisson distribution and log link. All analyses were conducted in SAS (version 9.4).
Attrition	**Uptake** Of n=46 eligible participants enrolled into the study, n=3 did not attend the pre-randomisation visit and were withdrawn from the study. **Attrition** Of the n=21 participants assigned to the intervention group, n=2 did not attend the 3-month assessment visit. All 21 participants attended the 6 month assessment visit. Of the n=20 participants assigned to the control group, n=3 did not attend the 3-month assessment visit. N=19 attended the 6 month assessment visit. 98% retention across both groups.
Study limitations (author)	- The relatively small sample size limits efficacy testing and the extent to which the results can be generalized to the wider target population, although significant differences were found between treatment groups in spite of the small sample size, indicating promise for future full scale efficacy trial.

	- Long-term follow up past 6 months was beyond the scope of the current trial, so data examining sustained (up to 12-months) intervention effects were not collected. - Enrollment for the current study was restricted to MSM who were HIV-uninfected and, thus, the current findings do not extent to HIV-infected MSM.
Study limitations (reviewer)	Not clear whether control group sessions reflected standard care.
Source of funding	This work was supported by National Institute on Drug Abuse: [Grant Number K24DA040489 (PI: Steven Safren), R34DA031028 (PI: Matthew Mimiaga)

Study arms

Intervention (N = 21)

Behavioural Activation and Sexual Risk Reduction counselling (BA-SRR).

Control (N = 20)

2 sessions of sexual risk reduction counselling

Characteristics

Arm-level characteristics

Characteristic	**Intervention (N = 21)**	**Control (N = 20)**
Age Range	25 to 65	25 to 65

Characteristic	Intervention (N = 21)	Control (N = 20)
Age Mean (SD)	39.7 (13.2)	39.9 (10.1)
Gender	n = 21 ; % = 100	n = 20 ; % = 100
White	n = 18 ; % = 85.7	n = 14 ; % = 70
Racial/ethnic minority	n = 3 ; % = 14.3	n = 6 ; % = 30
Sexual orientation		
Gay	n = 16 ; % = 76.2	n = 13 ; % = 65
Not gay	n = 5 ; % = 23.8	n = 7 ; % = 35
Any prior crystal meth treatment		
Yes	n = 10 ; % = 47.6	n = 5 ; % = 25
No	n = 11 ; % = 52.4	n = 15 ; % = 75
Route of crystal meth administration		
Smoked	n = 19 ; % = 90.5	n = 19 ; % = 95
Snorted	n = 5 ; % = 23.8	n = 4 ; % = 20
IDU ("slam")	n = 13 ; % = 61.9	n = 10 ; % = 50
Rectally inserted ("booty bump")	n = 6 ; % = 28.6	n = 7 ; % = 35

Outcomes

Study timepoints

- Baseline
- 3 month (Classed as 'acute post-intervention' because the assessment was completed immediately after the 13-week intervention sessions were completed, 3 months after baseline.)
- 6 month

Condom use outcomes

Outcome	Intervention, Baseline, N = 21	Intervention, 3 month, N = 19	Intervention, 6 month, N = 21	Control, Baseline, N = 20	Control, 3 month, N = 17	Control, 6 month, N = 19
Number of condomless anal sex acts with partner who was HIV serodiscordant or status unknown Prior 3 months Mean (SD)	5 (7.7)	3.2 (1.74)	1.1 (0.92)	9 (11.2)	4.5 (2.06)	2.8 (1.74)
Number of condomless anal sex acts with partner who was HIV serodiscordant or status unknown, while using meth Prior 3 months Mean (SD)	4.5 (7.3)	2.7 (1.74)	1 (0.92)	8 (11)	3.6 (2.06)	2.5 (1.74)

Number of condomless anal sex acts with partner who was HIV serodiscordant or status unknown - Polarity - Lower values are better

Number of condomless anal sex acts with partner who was HIV serodiscordant or status unknown, while using meth - Polarity - Lower values are better

Paper reports mean and SD at baseline but mean and SE for 3- and 6-month follow-up. SEs converted to SD by analyst.

TIDier Checklist

Study details

Brief name	IMPACT (Intervention with MSM to Prevent Acquisition of HIV through Crystal methamphetamine Treatment) (p. 1084).
Rationale/theory/Goal	Crystal methamphetamine (crystal meth) use is endemic to urban MSM. The prevalence of crystal meth use among MSM has been shown to be 20 times that of the general population, with an estimated 10–25% of MSM reporting use of crystal meth in the context of sexual behaviour in the past six months. Multiple studies have documented that, among MSM, crystal meth use is associated with a higher number of sexual partners, greater engagement in condomless anal sex (CAS) acts, and HIV acquisition. Given research reporting that HIV infection is the primary medical correlate of crystal meth use, HIV-uninfected MSM who use crystal meth at a severity high enough to warrant a threshold-level DSM-IV diagnosis are at exceptionally high risk for HIV acquisition – largely due to concomitant drug-associated sexual risk behaviors. Interventions to address problematic crystal meth use and associated sexual risk behaviours are warranted. (p. 1083-1084).
Materials used	
Procedures used	- Participants were recruited using a variety of purposive sampling strategies including active (i.e. in person) and passive (i.e. flyers) outreach at community-based health clinics, bars, nightclubs, internet, and other drug treatment centres. - Potential participants were assessed for eligibility, written informed consent was obtained, and enrolled participants were randomly assigned to condition. - All assessments were conducted using the same procedures and assessments at baseline, 3- and 6- months. Each assessment lasted approximately 2 hours and were conducted by assessors blind to participants' condition.

	- Participants were also tested for HIV at each assessment using rapid HIV screening tests (FDA approved OraQuick® ADVANCETM HIV-1/2 Antibody Test). All reactive and indeterminate HIV test results were lab confirmed. (p. 1084-1085)
Setting/location of intervention	All study activities took place at The Fenway Institute (p. 1085). This is a large health centre for sexual and gender minority populations (from Safren 2013 p. 2)
Other details	Incentives were $50 for each assessment visit (p. 1085)

Study arms

Intervention (N = 21) Behavioural Activation and Sexual Risk Reduction counselling (BA-SRR)

Brief name	Behavioural Activation and Sexual Risk Reduction counselling (BA-SRR) (p. 1085).
Rationale/theory/Goal	Problematic crystal meth use can impact MSM's ability to benefit from HIV risk reduction counselling, so it is important to integrate sexual risk reduction counselling with behavioural activation (BA). In formative work, MSM crystal meth users reported a decreased ability to enjoy other life activities that did not involve drug use. For many, this led to them seeing continued crystal meth use as the only way to experience pleasure. BA is an evidence-based cognitive behavioural therapy that involves helping the client learn how to re-engage in life by identifying and actively participating in pleasurable, goal-directed activities. It is hypothesised that via BA participants will learn to enjoy safe but pleasurable activities, will develop mood management skills, and will experience improvements in mood, all of which will reduce crystal meth use and facilitate their ability to engage in risk reduction counselling (p. 1084).
Materials used	No specific materials reported.
Procedures used	13 intervention sessions consisting of the following modules, all of which employ a therapeutic stance informed by Motivational Interviewing: <u>Baseline (1 session)</u>

	Designed to establish rapport, gather information on participants' mental health, patterns of substance use, and prior substance use treatment experiences. Provides outline of intervention and rationale for approaches. Sexual Risk Reduction Modules (2 sessions) Consistent with the IMB model, these modules 1) promote knowledge about risk reduction related to sexual behaviour and substance abuse via psychoeducation, 2) enhance motivation to engage in healthier behaviours through a non-judgemental exploration of the participants' sexual history and perceived benefits and risks of their current sexual behaviour, and 3) support participants to develop their skills and strategies to change behaviour, including developing an individualised motivational and behavioural skills plan to address potential areas for change (including disclosure of HIV status to sexual partners, condom use skills, strategies for negotiating sexual safety). A portion of the module is also used to identify triggers for crystal meth use and explore the impact of crystal meth use on the participant's life (e.g., changes in mood and decreased opportunities for enjoyment and mastery). CBT for substance abuse (3 sessions) CBT was used to help the participant identify triggers for stimulant use and to teach, strengthen and generalise skills to successfully manage those triggers. Included psychoeducation about urges and craving, and discussed various strategies to cope with high risk people, places or activities. Clients are taught to change their schedules, try new activities, limit unstructured time, manage money more successfully, and to "urge surf" to allow the craving to pass. Behavioural Activation integrated with risk reduction counselling (6 sessions) BA techniques are used to increase the amount of time the participant spends engaged in pleasurable activities without using crystal meth, which should, in turn, promote positive mood, reduce the desire to use substances, and bolster the participant's motivation to engage in sexual risk reduction. Components of problem solving training are used to help break maladaptive cycles, and a mood and activity monitoring sheet is used to track daily behaviour and note the context and impact of pleasurable, non-drug use activities. Review and plan for relapse prevention (1 session) Skills discussed in prior modules are reviewed and the participant in supported to engage in problem solving to address remaining obstacles blocking the client's attainment of their substance use and sexual risk behaviour goals. The

	interventionist provides information is about how to differentiate a “lapse” from a “relapse”, and to anticipate difficult or high-risk situations that may triggers drug use. (p. 1086-1087).
Provider	No detail provided
Method of delivery	Face to face one-to-one sessions (p. 1085)
Intensity/duration of the intervention	13 sessions; session duration not reported (p. 1085)
Tailoring/adaptation	Not reported
Unforeseen modifications	None reported
Planned treatment fidelity	Not reported
Actual treatment fidelity	Not reported
Other details	Intervention participants were also asked to rate their level of acceptability of the intervention on a 4-point scale (not acceptable, less acceptable, acceptable, and very acceptable) (p. 1088). All intervention participants rated it as 'acceptable' or 'highly acceptable' (p. 1089).

Control (N = 20)

2 sessions of sexual risk reduction counselling

Procedures used	Participants in the control condition received two sessions of the IMB skills change approach to sexual risk reduction. As described in the intervention section, these sessions aim to 1) promote knowledge about risk reduction related to sexual behaviour and substance abuse, 2) enhance the participants' motivation to engage in healthier behaviours, and 3) support participants to develop strategies to change their behaviour. These sessions address both sexual behaviour and crystal meth use (p. 1085 and p. 1087).
Provider	Not reported
Method of delivery	Not reported but assumed face to face one-to-one sessions.

Intensity/duration of the intervention	2 sessions; session duration not reported (p. 1087).
Tailoring/adaptation	Not reported
Unforeseen modifications	None reported
Planned treatment fidelity	Not reported
Actual treatment fidelity	Not reported

Risk of Bias Assessment

Section	Risk of Bias	Reason
Domain 1: Bias arising from the randomisation process	Some concerns	Limited information provided on randomisation procedure or allocation concealment but no baseline differences between groups
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Low	No information on participant blinding but deviations from intended interventions unlikely
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	Some concerns	Intervention adherence not assessed but failures in delivering the intervention unlikely and sessions were 1-to-1 so likely that interventionists ensures participants adhered to session content
Domain 3. Bias due to missing outcome data	Low	Outcome data available for almost all participants, 98% completion rate
Domain 4. Bias in measurement of the outcome	Low	Outcome assessment the same for both groups, outcome assessors blind to study condition
Domain 5. Bias in selection of the reported result	Some concerns	Trial not registered
Overall bias and Directness	Low	Limited information on randomisation method or allocation concealment; intervention adherence not assessed (but 1-to-1 sessions so adherence likely); trial not registered

Section	Risk of Bias	Reason
	Overall Directness	Partially applicable (US study)

Nostlinger, 2016

Bibliographic Reference Nostlinger, Christiana; Platteau, Tom; Bogner, Johannes; Buyze, Jozefien; Dec-Pietrowska, Joanna; Dias, Sonia; Newbury-Helps, John; Kocsis, Agnes; Mueller, Matthias; Rojas, Daniela; Stanekova, Danica; van Lankveld, Jacques; Colebunders, Robert; Eurosupport Study, Group; Implementation and Operational Research: Computer-Assisted Intervention for Safer Sex in HIV-Positive Men Having Sex With Men: Findings of a European Randomized Multi-Center Trial.; Journal of acquired immune deficiency syndromes (1999); 2016; vol. 71 (no. 3); e63-72

Study details

Study design	Randomised controlled trial (RCT)
Trial registration number	Not reported
Study start date	Feb-2011
Study end date	Feb-2013
Aim	To evaluate a theory-guided computer-assisted safer sex intervention for PLHIV, delivered across 9 different European HIV-care settings.
Country/geographical location	Multicentre trial conducted in 9 European countries: Belgium, Italy, France, Germany, The Netherlands, Poland, Spain and England.
Setting	HIV care centres serving MSM populations in each of the included countries.
Inclusion criteria	- Age 18 or above

	- Diagnosed HIV positive for at least 6 months - Able to understand the study goals and procedures involved - Fluency in 1 of the study languages (Dutch, English, German, French, Italian, Polish, Portuguese, Slovak, Spanish) - Providing written informed consent - Self-identified as MSM (a man having regular or occasional sexual contacts with other men)
Exclusion criteria	None reported
Method of randomisation	Computerised randomisation procedure
Method of allocation concealment	Copmuterised procedure concealed from study investigators
Unit of allocation	Participant
Unit of analysis	Participant
Statistical method(s) used to analyse the data	- According to the sample size calculation, a sample of 182 participants was needed to detect a difference in intervention effect of 20% in the control group and 40% in the intervention group with a power of 80%. - Stata version 12.1 was used for statistical analyses. - Descriptive statistics for socio-demographic, health-related, mental health variables, and HIV disclosure, as well as for the additionally computed outcome variables (“transmission risk score,” “lower transmission risk”) were calculated using baseline data and subsequently compared between the intervention and control groups. - To compare the CISS intervention and control group, the change over time for the outcome variables was modelled by linear or logistic mixed effects model including a random intercept. - For the outcome variable condom use at last intercourse, 3 generalized linear regression models were used to test the effect of theoretically grounded mediator variables (ie, condom use self-efficacy; attitudes towards condom use; and depression). This allowed for splitting the total intervention effect into direct and directly observed changes.

Attrition	No information on uptake provided N = 122 participants completed the baseline assessment and were randomised to condition (n=55 intervention and n=57 control). Follow-up rates were n=75 (67%) at 3 months and n=76 (68%) at 6 months. 36 men (32%) were lost to follow up and were comparable with those retained on all baseline variables, suggesting nondifferential drop-out.
Study limitations (author)	- Study participation was voluntary and motivation was an inclusion criterion. - Self-reported outcome data may potentially be biased, eg, because of under-reporting sexual risk behaviour or false assumptions about partner's HIV status. - Randomisation was not blinded, which lies in the nature of the intervention. - The overall number of HIV-positive MSM screened was not registered, therefore, it is not possible to compare participants with nonparticipants nor assess the reasons for declining participation. - The study team were not able to recruit the desired number of participants, resulting in reduced power. Barriers to recruitment related to both the individual level (eg, motivation, fear to discuss problems with condom use in HIV-care settings) and structural issues (eg, legal barriers in countries where HIV transmission can be legally prosecuted, HIV-stigma).
Study limitations (reviewer)	Intervention delivery, fidelity or adherence was not assessed. Delivery may have varied across countries or study sites.
Source of funding	The Eurosupport study group received funding from the European Union's Public Health Programme 2008–2013, grant nr. 2008 1204. Additional funding was received through unconditional grants from Gilead, Abbott and Merck. M. Mueller received a grant from MSD Sharp & Dohme GmbH, Germany.

Study arms

Intervention (N = 55)

Computer-assisted intervention for safer sex (CISS): 3 semi-structured counselling sessions delivered by trained service providers using interactive computer-assisted tools

Control (N = 57)

The control group received sexual health advice delivered as part of regular HIV care.

Characteristics

Arm-level characteristics

Characteristic	Intervention (N = 55)	Control (N = 57)
Age Median (IQR)	40 (32 to 47)	42 (33 to 45)
Gender	n = 55 ; % = 100	n = 57 ; % = 100
Relationship status		
Single	n = 29 ; % = 52.7	n = 32 ; % = 56.1
With a male partner	n = 26 ; % = 47.3	n = 23 ; % = 40.4
With a female partner	n = 0 ; % = 0	n = 2 ; % = 3.5
On antiretroviral treatment	n = 46 ; % = 83.6	n = 49 ; % = 86
HIV disclosure to main partner	n = 24 ; % = 88.9	n = 20 ; % = 90.9

Characteristic	Intervention (N = 55)	Control (N = 57)
HIV disclosure to casual partners		
(Almost) all of them	n = 13 ; % = 26	n = 13 ; % = 25
Some of them	n = 5 ; % = 10	n = 16 ; % = 30.8
(Almost) none of them	n = 32 ; % = 64	n = 23 ; % = 44.2

Outcomes

Study timepoints

- Baseline
- 3 month
- 6 month

Condom use outcomes

Outcome	Intervention, 3 month vs Baseline, N = 37	Intervention, 6 month vs Baseline, N = 41	Control, 3 month vs Baseline, N = 38	Control, 6 month vs Baseline, N = 57
Condom use at last intercourse Odds ratio/95% CI	6.77 (2.48 to 18.52)	5.46 (2.16 to 13.79)	1.77 (0.72 to 4.32)	2.53 (0.98 to 6.52)

Condom use at last intercourse - Polarity - Higher values are better

HIV transmission risk

Outcome	Intervention, 3 month vs Baseline, N = 37	Intervention, 6 month vs Baseline, N = 41	Control, 3 month vs Baseline, N = 38	Control, 6 month vs Baseline, N = 57
HIV transmission risk score Standardised Mean (95% CI)	-1.19 (-1.8 to -0.57)	-0.67 (-1.25 to -0.09)	-0.68 (-1.27 to -0.09)	-0.51 (-1.14 to 0.12)

HIV transmission risk score - Polarity - Lower values are better

MEAN DIFFERENCE NOT STANDARDISED MEAN (no option on EPPI to report mean difference so SM selected) To calculate a HIV transmission risk score, several variables were combined to generate a composite score reflecting a nuanced individual HIV transmission risk profile. This was generated using number of unprotected sexual contacts (with man and casual sex partners with HIV-negative or unknown status), participants viral load, and self-reported STI diagnosis in the previous 3 months. Scores from participants who reported no condomless encounters were automatically set to '0' because there was no transmission risk, regardless of current viral load or STI diagnoses. For further analyses, this variable was dichotomised into 'high transmission risk' vs 'low transmission risk' (score > 1 vs score less than or equal to 1).

Condom use outcomes

Outcome	Intervention, Baseline, N = 55	Intervention, 3 month, N = 37	Intervention, 6 month, N = 41	Control, Baseline, N = 57	Control, 3 month, N = 38	Control, 6 month, N = 35
Condom use at last sex No of events	n = 19 ; % = 35	n = 25 ; % = 68	n = 27 ; % = 66	n = 17 ; % = 30	n = 17 ; % = 45	n = 17 ; % = 49

Condom use at last sex - Polarity - Higher values are better

TIDier Checklist

Study details

Rationale/theory/Goal	Approximately 42% of new HIV diagnoses are reported among MSM, accounting for the majority of new HIV cases and with unprotected sex between men being the predominant transmission mode. Unprotected sex has many determinants, which may include depressive symptoms, substance abuse, negative attitudes towards condom use, and low self-efficacy to adopt protective behaviour. Treatment optimism (a decreased concern about HIV transmission because of the availability of effective combination antiretroviral treatment), treatment fatigue eventually leading to declined adherence over time, and improved quality of life of HIV-infected MSM may also contribute to increased sexual risk behaviour. For behavioural interventions to be effective, delivery channels must be appealing to the target groups needs and preferred lifestyles. Internet-based tools and computer assisted technologies may support this. (p. 63-64).
Materials used	
Procedures used	- All consecutive patients were invited to participate in the screening procedure if they met the eligibility criteria. - An online screening instrument assessed eligibility; eligible participants were automatically directed to the baseline questionnaire, a computer-administered self-interview. - Upon completing the baseline questionnaire, participants were randomly assigned to the intervention (CISS) or control condition. - Each participant received an information leaflet providing information on local sexual health services. - Controls were also offered to receive the intervention after completion of the study. - All study participants completed computer-administered self-interview questionnaires at three and six months follow-up (p. 65)
Other details	Participants did not receive any incentives for their study participation (p. 65)

Study arms

Intervention (N = 55) Computer-assisted intervention for safer sex (CISS): 3 semi-structured counselling sessions delivered by trained service providers using interactive computer-assisted tools

Brief name	Computer-assisted Intervention for Safer Sex (CISS) (p. 65)
Rationale/theory/Goal	Intervention development was guided by the IMB model (addressing motivations and behavioural skills including self-efficacy) and Social Cognitive Theory (addressing relevant influencing factors from the participant's personal and social environment such as attitudes and social norms, and inducing behaviour change through role modelling and guided practice). Theories emerging from cognitive neuroscience also provided insight into how behaviors are emotionally driven. “System 1–System 2 Thinking” differentiates between intuitive decision making in affect-laden situations (automated brain processing or 'fast thinking'), and rational, analytical decision-making ('slow thinking') and can contribute to explaining the gap between safer sex knowledge and practice. This particular theory base led to developing computer-assisted tools depicting personal stories about safer sex acted by role models using sexualized images rather than traditional methods of cognitive “education.” (p. 64-65)
Materials used	Video materials and interactive slide shows available on a DVD (p. 65)
Procedures used	The intervention consisted of 3 semi-structed counselling sessions delivered by service providers, who worked with the participants through a series of video materials and interactive slide shows. <u>Session 1: 'Who am I?'</u> Focused on exploring participants’ emotional response to individual problems with safer sex, using the filmed role models. Participants could choose the personally most relevant clips addressing barriers to safer sex including relationship issues, emotions and mood, sexuality and pleasure, drugs/alcohol and sex, HIV, health and sex (including sexual problems and infectiousness).

	Session 2: 'Working Through' Focused on developing personal solutions for the identified problems that would fit participants' context and lifestyles using video clips and interactive or educational slides. Session 3: 'Making your plan' Identified the necessary steps to achieve the behavioural goal through the counselling interaction and resulted in a personalised risk reduction plan. The counselling style adopted a motivational interviewing (MI) approach, with problem solving and cognitive behavioural goal setting strategies to identify personally tailored solutions with safer sexual behaviors. (p. 65)
Provider	Service providers who received 2 days training facilitated by intervention developers (p. 65)
Method of delivery	Not reported but presumed face to face
Intensity/duration of the intervention	Three 50 minute sessions delivered every 3 weeks (p. 65)
Tailoring/adaptation	Not reported
Unforeseen modifications	Not reported
Planned treatment fidelity	Not reported
Actual treatment fidelity	Not reported

Control (N = 57)

The control group received sexual health advice delivered as part of regular HIV care.

Brief name	Standard care (p. 63)
Procedures used	Participants in the control group received sexual health counselling as part of the regular care offered at their local clinic. They also received a leaflet providing information on local sexual health services. Control participants were offered to receive the intervention after completion of the study (p. 65)

Risk of Bias Assessment

Section	Risk of Bias	Reason
Domain 1: Bias arising from the randomisation process	Low	Appropriate randomisation procedures and no baseline differences
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Low	Deviations from intended interventions unlikely
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	Some concerns	Intervention adherence not assessed but sessions were 1-to-1 and led by trained facilitators, suggesting they guided participants through all intervention components
Domain 3. Bias due to missing outcome data	Some concerns	32% loss to follow-up at 6 months. Paper does not give accurate rates of follow-up by condition, only overall, so not possible to determine if differential drop-out by condition
Domain 4. Bias in measurement of the outcome	Low	Assessments conducted by ACASI, same measures for both conditions. Use of composite measure of HIV transmission risk may cause concern as not validated
Domain 5. Bias in selection of the reported result	Some concerns	Trial not registered
Overall bias and Directness	Some concerns	32% loss to follow-up; attrition by group not reported only overall attrition. Intervention adherence not assessed. Trial not registered
	Overall Directness	Partially applicable (Multi-site study across 8 European countries)

O’Donnell, 2014

Bibliographic Reference	O'Donnell, Lydia; Stueve, Ann; Joseph, Heather A; Flores, Stephen; Adapting the VOICES HIV behavioral intervention for Latino men who have sex with men.; AIDS and behavior; 2014; vol. 18 (no. 4); 767-75

Study details

Study design	Randomised controlled trial (RCT)
Trial registration number	Not reported
Study start date	Aug-2008
Study end date	Aug-2009
Aim	To adapt a widely disseminated intervention 'Voices/Voces (V/V)' for use with culturally diverse English- and Spanish-speaking gay and bisexual Latino men, and to test its efficacy in reducing risk behaviours and promoting HIV testing.
Country/geographical location	New York City, USA
Setting	Community health centre study sites; men were able to choose one of several study locations to suit them.
Inclusion criteria	- Self-identification as Latino - Sex with 2 or more partners in the last 3 months - HIV status negative or unknown - No exposure to HIV prevention education (research or non-research) in the last 6 months - Age 18-49 years
Exclusion criteria	None reported

Method of randomisation	Not reported
Method of allocation concealment	Not reported
Unit of allocation	Participant
Unit of analysis	Participant
Statistical method(s) used to analyse the data	- Preliminary analyses were conducted to assess whether there were significant differences by socio-demographic and risk behaviours between the two conditions at baseline using Chi square (percentages) and one-way ANOVA (means). - Outcome analyses were conducted within an intent-to-treat model. - Repeated-measures ANOVA was performed for the outcome 'number of unprotected sex acts' and logistic regression was used to examine the relationship of the intervention to the dichotomised follow-up outcome 'condom use at last sex', adjusting for the effects of covariates. Covariates considered include language preference (Spanish vs. not), sexual orientation, age (40 and under vs. over 40), education (less than high school; high school; some college; college graduate); and HIV status (negative vs. unknown). - Analyses also considered whether effects differed by age by adding a cross-product term (age by intervention) to equations. When this interaction was significant at $p<0.05$, analyses were repeated within age subgroups. - All analyses were conducted using PASW Statistics 18
Attrition	Of 370 men enrolled, 346 completed follow-up surveys, for a retention rate of 93.5% (93.2% and 93.9% for intervention and control groups, respectively). There were no significant baseline differences in covariates or outcome measures between those retained and those lost to follow up. Gay identity was the only significant baseline difference across study arms; men in the intervention group were more likely to identify themselves as gay (70%) or bisexual (26.8%) than those in the control condition (57.5% gay and 34.1% bisexual). There were no significant differences in baseline reports of sexual behaviours by treatment condition.
Study limitations (author)	- In both conditions, there was a marked decrease in all risk behaviours from baseline to follow-up. These overall decreases may have limited power to detect treatment differences. While the sample of Latino MSM was relatively large

	for an initial efficacy trial and included a broad age range of participants, there was limited power to conduct subgroup analyses. - It was relatively difficult to recruit men for the study. Research requirements added substantially to participant burden, more than doubling the time for an intervention session alone, and requiring a return visit to take a follow up survey. - Although the protocol did not require participants to provide social security numbers or other verification, it is possible that undocumented Latinos would be wary about participating in a research study that required personal contact information for scheduling return visits.
Study limitations (reviewer)	None to add
Source of funding	This study was part of a multi-site initiative funded by the Centers for Disease Control and Prevention's Division of HIV/AIDS Prevention (No Excuse/Sin Buscar Excusas Intervention to Reduce Latino Men's HIV Risks, Grant # 5UR6PS0004250).

Study arms

Intervention (N = 190)

No excuses / Sin buscar excusas: a brief, single session group intervention for Latino MSM focusing on sexual safety, condom use and partner negotiation. Participants could choose whether it was delivered in Spanish or English.

Control (N = 180)

Non-attention control condition. Participants were offered an HIV test.

Characteristics

Arm-level characteristics

Characteristic	**Intervention (N = 190)**	**Control (N = 180)**
Age Mean (SD)	37.2 (9.3)	36 (9.8)
18-40 years	n = 103 ; % = 54.5	n = 105 ; % = 58.7
41 years and over	n = 86 ; % = 45.5	n = 74 ; % = 41.3
Born in US	n = 98 ; % = 51.6	n = 107 ; % = 59.8
Sexual identification		
Homosexual, gay, same gender loving	n = 133 ; % = 70	n = 102 ; % = 57.5
Bisexual	n = 51 ; % = 26.8	n = 61 ; % = 34.1
Other (e.g. questioning, straight)	n = 6 ; % = 3.2	n = 17 ; % = 8.4
H**IV testing and status**		
Ever tested	n = 122 ; % = 64.2	n = 120 ; % = 66.7
Self-report HIV+	n = 5 ; % = 2.6	n = 2 ; % = 1.1

Outcomes

Study timepoints

- Baseline
- 3 month

Condom use outcomes

Outcome	Intervention, Baseline, N = 190	Intervention, 3 month, N = 177	Control, Baseline, N = 180	Control, 3 month, N = 169
Number of UAI acts with last 2 male partners During the last 3 months Mean (SD)	8.4 (*empty data*)	3.8 (*empty data*)	6.2 (*empty data*)	3.8 (*empty data*)

Number of UAI acts with last 2 male partners - Polarity - Lower values are better

From paper: From baseline to follow-up, there is a sharper drop in mean number of UAI acts in the intervention group, with a decrease of 59 % over the two time points (from an average of 8.4 unprotected acts to 3.8), compared with a 39 % change among controls (6.2–3.8). Repeated measures ANOVA for number of UAI acts was significant: $F(1, 320) = 4.10$, $p < .05$. For condom use at last sex, men exposed to the intervention were more likely to report this protective behaviour: (AOR = 1.69; 95 % CI 1.02–2.81, $p<.05$).

Study details

Rationale/theory/Goal	Evidence-based HIV behavioural interventions typically have been developed and disseminated to meet the prevention needs of specific target populations, defined by their cultural, gender, sexual orientation and risk factors. Adaptation of existing interventions is an expeditious and pragmatic strategy that builds on lessons learned, avoids the need for reinvention of proven risk-reduction strategies, and has the potential to fill gaps in prevention approaches to reached underserved populations. There is a pressing need to identify evidence-based programs for high priority populations

	including minority gay and bisexual men. This study addresses this by adapting the Voices/Voces (V/V) intervention, originally designed for African American and Latino heterosexual adults, for use with Latino MSM (p. 767-768).
Procedures used	- The intervention adaptation was accomplished through the collaborative efforts of the original V/V development team: a film company experienced producing videos for V/V; about 70 community participants who attended a series of focus groups; and an advisory board with expertise working with Latino MSM. The intervention content and activities were adapted to assure cultural and linguistic relevancy, while maintaining the core elements, or critical design features, of the original intervention. - To test the efficacy of the adaptation using an RCT, men were recruited through multiple channels, including street outreach, listservs, and marketing through the Hispanic AIDS Forum and Callen-Lorde Community Health Center, the study sites. - Screening was conducted either face-to-face or over the phone by trained research staff. - Eligible participants were invited to a study site to complete baseline audio-computer assisted surveys (A-CASI) and other study activities (depending upon their random assignment). Men were able to choose one of several dates, times, and locations, as well as whether they preferred to participate in English or Spanish. After completing surveys, men were assigned at random to participate in the intervention or non-attention control condition. - Men were re-contacted 2 weeks prior to their 3-month follow up date to schedule a time for completing the final survey.

Study arms

Intervention (N = 190) No excuses / Sin buscar excusas: a brief, single session group intervention for Latino MSM focusing on sexual safety, condom use and partner negotiation. Participants could chose whether it was delivered in Spanish or English.

Brief name	*No Excuses / Sin buscar excusas* (p. 768)
Rationale/theory/Goal	Grounded in a social-cognitive theoretical model, the intervention focuses on sexual safety, condom use and partner negotiation and aims to address the prevention needs of Latino MSM participants through gender, cultural and orientation relevancy (p. 768-769).

Materials used	The session includes a soap-opera style video that models common risks, relationships and prevention messages in culturally relevant contexts (p. 768). The video was available in English or Spanish (p. 769). In these videos, attention was paid to character selection (e.g., age, orientation, cultural diversity); relationships (i.e., new, casual, and steady), contexts (e.g., online hook ups), key prevention messages (i.e., condom use, safety negotiation, and HIV testing), and modelling of realistic, desired behaviours as well as peer and community support (p. 769).
Procedures used	- The intervention began with the soap-opera style video addressing common risks, relationships and prevention messages in culturally relevant contexts. - The videos then served as a tool for initiating a 15-20 minute non-judgemental discussion about sexual safety geared towards participants experiences. - This was followed by 10 minutes of condom education, addressing common problems and barriers to use. Each participant then chose a selection of condoms to take home. - The session ends with the facilitator reinforcing the importance of consistent condom use for oneself, one's partners, family and community (p. 768-769). - Intervention participants were also offered an HIV test at the conclusion of the intervention session (p. 770).
Provider	Not reported
Method of delivery	Face to face group sessions
Setting/location of intervention	Participating study sites and community health centres (p. 770)
Intensity/duration of the intervention	Brief, single session, approximately 45 minutes duration (p. 770)
Tailoring/adaptation	None reported
Unforeseen modifications	None reported
Planned treatment fidelity	Not reported

Actual treatment fidelity	Not reported
Other details	Limited information on group format provided - no detail on number of participants in each group, how many English or Spanish language groups there were, or details relating to group facilitators.

Control (N = 180)

Non-attention control condition. Participants were offered an HIV test.

Procedures used	Participants in the control condition were offered a HIV test after they completed their baseline assessment (p. 770).
Provider	Not reported
Method of delivery	N/A
Setting/location of intervention	Participating study sites and community health centres (p. 770)
Intensity/duration of the intervention	N/A
Tailoring/adaptation	N/A
Unforeseen modifications	N/A
Actual treatment fidelity	N/A

Risk of Bias Assessment

Section	Risk of Bias	Reason
Domain 1: Bias arising from the randomisation process	Some concerns	Limited information on randomisation procedures provided; baseline differences in gay identity but no differences in any other demographics or baseline reports of sexual behaviours

Section	Risk of Bias	Reason
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Low	Deviations from intended interventions unlikely
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	Low	Brief single session led by facilitator so adherence likely to be high
Domain 3. Bias due to missing outcome data	Low	
Domain 4. Bias in measurement of the outcome	Low	Assessments conducted by ACASI, same measures for both conditions
Domain 5. Bias in selection of the reported result	Some concerns	Trial not registered
Overall bias and Directness	Some concerns	Limited information on randomisation procedures and trial not registered
	Overall Directness	Partially applicable (US study with Latino males)

Rhodes, 2017

Bibliographic Reference	Rhodes, Scott D; Alonzo, Jorge; Mann, Lilli; Song, Eunyoung Y; Tanner, Amanda E; Arellano, Jorge Elias; Rodriguez-Celedon, Rodrigo; Garcia, Manuel; Freeman, Arin; Reboussin, Beth A; Painter, Thomas M; Small-Group Randomized Controlled Trial to Increase Condom Use and HIV Testing Among Hispanic/Latino Gay, Bisexual, and Other Men Who Have Sex With Men.; American journal of public health; 2017; vol. 107 (no. 6); 969-976

Study details

Study design	Randomised controlled trial (RCT)

Trial registration number	The clinical trials protocol number for this study is NCT01626898
Study start date	Dec-2012
Study end date	Feb-2015
Aim	To evaluate the *HOLA en Grupos* intervention, a Spanish-language small group behavioral HIV prevention intervention designed to increase condom use and HIV testing among Hispanic/Latino gay, bisexual, and other men who have sex with men.
Country/geographical location	Charlotte and Greensboro, North Carolina, USA
Setting	Community-based settings (e.g. community organisations and business meeting spaces)
Inclusion criteria	- Those who self-identified as a Hispanic/Latino male or transgender person - Aged 18 years or older - Spoke fluent Spanish - Reported male-to-male sexual contact since age 18 - Provided written informed consent
Exclusion criteria	- Persons who had participated in any other HIV prevention intervention in the past 12 months
Method of randomisation	Block randomisation scheme (block size = 4) generated with SAS version 9.3
Method of allocation concealment	Computer generated
Unit of allocation	Participant
Unit of analysis	Participant

Statistical method(s) used to analyse the data	- Intent-to-treat protocol used to analyse participants' outcomes relative to their assigned intervention group, irrespective of the number of sessions they attended. - Differences between groups at baseline assessed using the Student t test for continuous variables and chi square for categorical variables. - Primary data analyses to evaluate HOLA en Grupos efficacy compared rates of past 3-month consistent condom use reported by intervention and comparison participants at 6-month follow-up while adjusting for baseline rates. - Statistical analysis used multivariable random effects logistic regression modelling that adjusted for potential clustering within intervention groups. This adjustment accounted for the possibility that participants in the same study wave and intervention group may exhibit more similar patterns of condom use at 6-month follow-up as participants in other study waves. - Models were adjusted for the corresponding baseline measures and age, education level, and country of origin to obtain adjusted odds ratios (AORs) and computed the 95% confidence interval (CI) and corresponding P values. Models were fit using PROC GLIMMIX in SAS. - For secondary analyses, the t test was used to assess changes in psychosocial factors - For each psychosocial scale, missing scale items were replaced with the person-mean imputed value for each specific scale if 20% or less of scale item responses were missing. If more than 20% was missing, that scale was considered missing and was not used in analyses. - For each model, adjusted means and SEs were calculated and differences of adjusted means and the corresponding P value. All models were estimated in the context of multivariable random effects linear regression modelling using PROC MIXED in SAS. - All analyses were performed using SAS/STAT.
Attrition	**Uptake**

	N=401 participants were screened. N=97 were ineligible, of which n=22 were not interested in participating and n=20 were not able to participate due to work conflicts. **Attrition** Participant retention at 6 month follow up was 100% for both intervention and control groups.
Study limitations (author)	- The study relied on self-reported data - HOLA en Grupos was developed using a Community-Based Participatory Research (CBPR) approach, with participants from urban and rural communities; it should be tested with Hispanic/Latino MSM elsewhere in the United States to assess the generalisability of findings. - This intervention is 16 hours long, limiting its ability to be easily implemented. Future studies should determine whether an abbreviated version of HOLA en Grupos has the same impact.
Study limitations (reviewer)	The paper reports that 'dinner was served' at each intervention session but it is not clear whether the control group also received a meal after each session.
Source of funding	Funding for this evaluation study was provided by the Centers for Disease Control and Prevention to Wake Forest School of Medicine (cooperative agreement PS09-007, award U01PS001570). The authors also acknowledge the Program in Community Engagement of the Wake Forest Clinical and Translational Science Institute, which is supported by the National Center for Advancing Translational Sciences, National Institutes of Health (grant UL1TR001420).

Study arms

Intervention (N = 152)

HOLA en Grupos; a Spanish-language small group behavioural HIV prevention intervention designed to increase condom use and HIV testing among Hispanic/Latino gay, bisexual and other men who have sex with men.

Control (N = 152)

General health education comparison intervention

Characteristics

Arm-level characteristics

Characteristic	Intervention (N = 152)	Control (N = 152)
Age Mean (SD)	30.4 (9)	30.5 (8.8)
Country of origin		
El Salvador	n = 6 ; % = 4.1	n = 10 ; % = 6.6
Guatemala	n = 7 ; % = 4.7	n = 6 ; % = 3.9
Honduras	n = 9 ; % = 6.1	n = 10 ; % = 6.6
Mexico	n = 93 ; % = 62.8	n = 93 ; % = 61.2
US	n = 14 ; % = 9.5	n = 14 ; % = 9.2
Other	n = 19 ; % = 12.8	n = 19 ; % = 12.5
Orientation / identity		
Heterosexual	n = 7 ; % = 4.8	n = 8 ; % = 5.4
Gay	n = 100 ; % = 68	n = 94 ; % = 63.5

Characteristic	Intervention (N = 152)	Control (N = 152)
Bisexual	n = 31 ; % = 21.1	n = 38 ; % = 25.7
Transgender identity	n = 9 ; % = 6.1	n = 8 ; % = 5.4

Outcomes

Study timepoints

- 6 month

Condom use outcomes - MSM who report sex with men or women

Outcome	Intervention, 6 month, N = 109	Control, 6 month, N = 108
Consistent condom use during past 3 months Number reporting yes to using condoms during every instance of insertive or receptive anal sex No of events	n = 69 ; % = 63.3	n = 37 ; % = 34.3

Consistent condom use during past 3 months - Polarity - Higher values are better

Condom use outcomes - MSM who report sex with men only

Outcome	Intervention, 6 month, N = 95	Control, 6 month, N = 94
Consistent condom use during past 3 months Number reporting yes to using condoms during every instance of insertive or receptive anal sex No of events	n = 61 ; % = 64.2	n = 34 ; % = 36.2

Consistent condom use during past 3 months - Polarity - Higher values are better

Condom use outcomes - all participants

Outcome	Intervention, 6 month, N = 152	Control, 6 month, N = 152
Condom use skills Adapted version of Condom-Use Skills Checklist to assess knowledge about correct condom use Mean (95% CI)	17.1 (16.7 to 17.5)	14.6 (14.3 to 15)
Condom use self-efficacy Condom Use Self-Efficacy Scale to assess confidence about being able to successfully use condoms with a sexual partner Mean (95% CI)	86.3 (84.1 to 88.6)	76.9 (74.7 to 79.2)

Condom use skills - Polarity - Higher values are better

Condom use self-efficacy - Polarity - Higher values are better

Values reported are adjusted means. Adjusted means were determined by multivariable ransom-effect linear mixed models with covariates of age, education attainment, and country of origin with corresponding baseline measure.

HIV/STI Knowledge outcomes

Outcome	Intervention, 6 month, N = 152	Control, 6 month, N = 152
HIV Knowledge Assessed using true/false items relating to modes of transmission, signs, symptoms and prevention strategies Mean (95% CI)	16.3 (16 to 16.6)	13.8 (13.5 to 14.1)
STI knowledge Assessed using true/false items relating to types, modes of transmission, signs, symptoms and prevention strategies Mean (95% CI)	12.1 (11.7 to 12.5)	9.5 (9.1 to 9.9)

HIV Knowledge - Polarity - Higher values are better

STI knowledge - Polarity - Higher values are better

Values reported are adjusted means. Adjusted means were determined by multivariable ransom-effect linear mixed models with covariates of age, education attainment, and country of origin with corresponding baseline measure.

Sexual communication

Outcome	Intervention, 6 month, N = 152	Control, 6 month, N = 152
Sexual communication 9-item adapted version of the Health-Protective Sexual Communication measure, capturing sexual communication and safer sex negotiation skills Mean (95% CI)	4.7 (4 to 5.3)	3.6 (2.9 to 4.2)

Sexual communication - Polarity - Higher values are better

Values reported are adjusted means. Adjusted means were determined by multivariable ransom-effect linear mixed models with covariates of age, education attainment, and country of origin with corresponding baseline measure.

TIDier checklist

Study details

Rationale/theory/Goal	Although MSM represent approximately 4% of the adult male population in the United States, in 2014, they accounted for 82.7% of new HIV infections among men. Among Hispanics/Latinos, men accounted for 85% of new HIV diagnoses in 2013, 81% of which were attributed to male-to-male sex. Despite the impact of HIV on Hispanic/Latino MSM, few evidence based behavioural HIV prevention interventions exist for this group. Community-based participatory research (CBPR) has been identified as an effective approach to developing interventions by blending the perspectives of lay community members, organisation representatives, and academic partners. In this study, CBPR was used to adapt a previous HIV prevention intervention for predominantly heterosexual Hispanic/Latino male soccer team members, into one tailored to the needs and priorities of Hispanic/Latino MSM. (p. 969-970).
Materials used	
Procedures used	Participants were recruited by distributing information about the study (e.g., posters, flyers, and brochures) at gay bars and clubs, community colleges, Hispanic/Latino-owned businesses, and at community events (e.g., gay pride and Hispanic/Latino cultural events); through the use of mass media (i.e., newspaper and radio) and social media; and by word of mouth when study participants invited friends to participate. Eligible participants completed informed consent and a baseline assessment then were randomised to groups. Follow up assessments were conducted at 6 months (p. 970).
Other details	Participants were given cash as a token of appreciation for completing the baseline assessment ($40), the 4 intervention sessions ($40 per session), and the 6-month follow-up assessment ($50). Dinner was served at each session. Participants also received a T-shirt in session 2 and a cap in session 3, each with the project logo. A graduation ceremony was provided for participants after completing all intervention and comparison sessions, and participants received a framed signed certificate of completion (p. 970-971).

Study arms

Intervention (N = 152) HOLA en Grupos; a Spanish-language small group behavioural HIV prevention intervention designed to increase condom use and HIV testing among Hispanic/Latino gay, bisexual and other men who have sex with men.

Brief name	*HOLA en Grupos* (p. 969)
Rationale/theory/Goal	HOLA en Grupos is grounded in Social Cognitive Theory, empowerment education, and traditional Hispanic/Latino cultural values. It is also based on previous interventions and effective approaches for increasing condom use among Hispanic/Latino MSM (p. 970).
Materials used	- Various brands and types of condom were given to participants to try and determine their preferences - A DVD showing a testimonial from a Hispanic/Latino MSM with HIV - Dinner was served at each session - Participants received a T-shirt and a cap with the project logo (p. 970-971)
Procedures used	<u>Module 1</u> - Introduces the intervention purpose - Describes the impacts of HIV and STIs on Hispanic/Latino MSM - Summarises HIV and STI facts including transmission, prevention strategies, testing, and health care access <u>Module 2</u> - Includes activities designed to provide guidance on how to protect oneself and one's partners from HIV and STIs through learning and practicing new skills, including negotiating condom use and correct condom use.

	- Participants are given a range of condom brands and types to take away and try <u>Module 3</u> - Explores how Hispanic/Latino cultural values and the local context can affect sexual health. - Reciprocal determinism is used to illustrate how Hispanic/Latino cultural values, such as machismo (proving one's manhood by being perceived by others as powerful and dominant and taking risks) and fatalism (the belief that all events are predetermined and therefore inevitable), can affect sexual risks. - Provides information about locally available HIV- and STI-related services for which they are eligible, including HIV testing - Teaches participants how to overcome challenges they may face when accessing services; and provides modelling to overcome barriers faced when accessing testing services. <u>Module 4</u> - Reviews all previously covered concepts. - Includes a DVD featuring a testimonial from a Hispanic/Latino MSM with HIV as a trigger to discuss what it is like to live with HIV. (p. 970)
Provider	Three Hispanic/Latino gay men (originally from Mexico or Peru) were trained to deliver the intervention (p. 971).
Method of delivery	Face to face small group sessions (p. 971)
Setting/location of intervention	Conveniently located community settings (community organisations or business meeting spaces) (p. 971).
Intensity/duration of the intervention	Four sessions lasting 4 hours each, delivered on consecutive Sunday evenings (p. 971)
Tailoring/adaptation	Not reported

Unforeseen modifications	Not reported
Planned treatment fidelity	Interventionists received training, observed demonstrations of activities, participated in group discussions and role plays, and practiced implementation. Raters provided quality assurance by attending each session and recording whether activities were implemented with fidelity (p. 971)
Actual treatment fidelity	The interventions were delivered with a high degree of fidelity (p. 973)

Control (N = 152)

General health education comparison intervention

Brief name	General health education intervention (p. 970)
Materials used	No specific materials reported
Procedures used	The comparison sessions focused on prostate, lung, and colorectal cancers; diabetes; high cholesterol; cardiovascular disease; and alcohol misuse. The sessions included didactic learning, DVDs and facilitated group discussions (p. 970)
Provider	A trained gay Hispanic/Latino interventionist (originally from Cuba) delivered the comparison intervention (p. 971)
Method of delivery	Face to face small group sessions (p. 971)
Setting/location of intervention	At a nearby location to the intervention sessions (p. 971)
Intensity/duration of the intervention	Four sessions lasting 4 hours each delivered on consecutive Sunday evenings and ran concurrently with the intervention sessions (p. 971)
Tailoring/adaptation	None reported
Unforeseen modifications	None reported
Planned treatment fidelity	Not reported

Actual treatment fidelity	Not reported

Risk of Bias Assessment

Section	Risk of Bias	Reason
Domain 1: Bias arising from the randomisation process	Low	Appropriate randomisation procedures; no baseline differences between groups
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Low	Deviations from intended interventions unlikely
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	Low	Intervention delivered by trained facilitators who are likely to have encouraged adherence. Most participants attended all sessions
Domain 3. Bias due to missing outcome data	Low	No missing data; 100% retention
Domain 4. Bias in measurement of the outcome	Low	Project staff other than interventionists collected follow-up data
Domain 5. Bias in selection of the reported result	Low	Trial registered and analyses conducted in line with prespecified plan
Overall bias and Directness	Low	
	Overall Directness	Partially applicable (US study)

Safren, 2013

Bibliographic Reference	Safren, Steven A; O'Cleirigh, Conall M; Skeer, Margie; Elsesser, Steven A; Mayer, Kenneth H; Project enhance: a randomized controlled trial of an individualized HIV prevention intervention for HIV-infected men who have sex with men conducted in a

primary care setting.; Health psychology : official journal of the Division of Health Psychology, American Psychological Association; 2013; vol. 32 (no. 2); 171-9

Study details

Study design	Randomised controlled trial (RCT)
Trial registration number	Not reported
Study start date	Apr-2004
Study end date	Jul-2008
Aim	To test a brief, culturally relevant, proactive case management prevention intervention for HIV infected MSM, which could be integrated in HIV care.
Country/geographical location	Boston, USA
Setting	HIV primary care clinics (Fenway Health in Boston, MA; the largest centre in New England caring for sexual and gender minority populations)
Inclusion criteria	- Self-identified HIV-infected MSM 18 years of age or older - Receive primary care at Fenway Health for at least 3 months - Engaged in at least one instance of HIV transmission risk behaviour (TRB; self-reported unprotected sex with either HIV-negative and/or HIV-unknown status partners) in the 6 months prior to baseline - Willing to be followed by a study case manager
Exclusion criteria	None reported
Method of randomisation	Computer-generated sequences.

Method of allocation concealment	The computer-generated, randomisation-allocation number list was prepared by a staff member with no participant contact in the trial, and details of the allocation group were contained onsite in sequentially numbered sealed envelopes. At enrolment, the responsible interventionist would assign randomisation by opening the next sequentially numbered envelope.
Unit of allocation	Participant
Unit of analysis	Participant
Statistical method(s) used to analyse the data	- All participants included in analyses and analysed according to the condition they were originally assigned (i.e., intent to treat). - Baseline differences in demographic, HIV-disease stage, mental health, and sexual risk variables between conditions were examined with Chi-square tests of independence and Fisher's exact tests for categorical variables and t tests for continuous variables. - Changes in TRB were assessed using a generalised linear model. Because the measure of TRB was a count variable with positive skew, a negative binomial distribution and logit-link function was used to determine the risk of engaging in TRB. For the dichotomous outcome, a longitudinal logistic regression analysis was conducted to determine if there were significant changes in the odds of engaging in TRB. Longitudinal differences in TRB between the intervention and control conditions were assessed by including interaction terms between intervention status and time in the corresponding models. - Power analysis indicated a sample size of 100 per condition for .80 power. This was based on the standard deviation of the outcome variable approximating that found in previous studies conducted at Fenway Community Health (M = .50; SD = .43), $\alpha = .05$; $\beta = .20$, and a medium effect size ($\eta = .20$; Cohen et al., 2002). - All longitudinal regression analyses used direct likelihood-estimation procedures with PROC GLIMMIX in SAS version 9.2.
Attrition	**Uptake** N=503 potential participants completed a screening assessment via ACASI. N=205 were enrolled into a different parallel trial with peer interventionists. N=73 did not meet eligibility criteria. N=24 declined to participate in the intervention / longitudinal aspects of the study.

	Attrition *Intervention* Baseline: n=100 3 months: n=74 (74%) 6 months: n=81 (81%) 9 months: n=72 (72%) 12 months: n=86 (86%) *Control* Baseline: n=101 3 months: n=74 (73.3%) 6 months: n=72 (71.3%) 9 months: n=69 (68.3%) 12 months: n=86 (85.1%)
Study limitations (author)	- Data are limited by self-report on an anonymous computerised survey. - Because the intervention occurred in the HIV-care setting, those who engaged in risk may have felt it necessary to report that they had changed their behaviour for the better. Hence, demand characteristics may be an issue in terms of interpreting the results.

	- Selecting for individuals who reported recent risk may have increased the chances of regression to the mean. - Although 93% of the sample returned for at least one follow-up and 85.6% for the 12-month follow-up, overall retention could have been better than it was. Baseline data revealed high rates of mental-health and substance-abuse comorbidities in the sample, and hence retention may be due to the complexity of psychosocial issues involved with living with HIV as an MSM. - Failure to detect differences between intervention and control groups in TRB reduction may be attributed to the possibility that many people who choose to enter a study and have a recent history of risk are individuals already motivated to make changes, hence even minimal intervention (assessment only) might be helpful.
Study limitations (reviewer)	None to add
Source of funding	This study was supported by NIMH grant 5R01MH068746-05

Study arms

Intervention (N = 100)

Case management provided by a medical social worker plus tailored counselling addressing psychosocial concerns and HIV risk reduction for MSM with HIV.

Control (N = 101)

Standard care - counselling and case management as per routine clinic care

Characteristics

Arm-level characteristics

Characteristic	**Intervention (N = 100)**	**Control (N = 101)**
Age Mean (SD)	40.3 (8.1)	41.1 (7.5)
Gender Male	n = 100 ; % = 100	n = 101 ; % = 100
Ethnicity		
White	% = 70	% = 79.2
Black/African American	% = 13	% = 10.9
Latino/Hispanic	% = 13	% = 4
Other	% = 4	% = 5.9
Met PHQ-9 screening criteria for depression	% = 14	% = 11.9
CD4 count (cells/mm3) Mean (SD)	520.2 (296.9)	556.6 (276.3)
Viral load Mean plasma HIV RNA: copies/ml Mean (SD)	19073 (48842)	17569 (56644)
Undetectable viral load	% = 55	% = 45
Currently taking HIV medication	% = 61	% = 52.5
Ever taken HIV medication	% = 70	% = 62.4

Outcomes

Study timepoints

- Baseline
- 3 month
- 6 month
- 9 month
- 12 month

HIV transmission risk behaviour

Outcome	Intervention, Baseline, N = 100	Intervention, 3 month, N = 74	Intervention, 6 month, N = 81	Intervention, 9 month, N = 72	Intervention, 12 month, N = 86	Control, Baseline, N = 101	Control, 3 month, N = 74	Control, 6 month, N = 72	Control, 9 month, N = 69	Control, 12 month, N = 86
HIV TRB number of insertive or receptive anal intercourse acts with HIV-uninfected partners or partners of unknown status within the past 3 months. Mean (SD)	5.12 (8.46)	2.82 (5.35)	2.56 (6.03)	5.03 (23.81)	2.72 (7.89)	3.67 (6.25)	3.04 (8.56)	2.04 (7.12)	1.2 (2.58)	2.22 (4.27)

HIV TRB - Polarity - Lower values are better

Transmission risk behaviour (TRB) was operationalised as number of insertive or receptive anal intercourse acts with HIV-uninfected partners or partners of unknown status within the past 3 months.

TIDier Checklist

Study details

Brief name	Project Enhance (p. 1)
Rationale/theory/Goal	Individuals with HIV who have entered routine care can still transmit HIV to others. Although many MSM may be entering and benefitting from treatment, this has not yet been associated with a general decrease in new transmissions among MSM. Accordingly, one important strategy to prevent the transmission of HIV is to promote sexual risk reduction for people living with HIV. It is also important to address psychosocial concerns for MSM living with HIV, since wider contextual factors such as mental health, substance abuse, distress associated with stigma and disclosure, anxiety about living with chronic illness, and adhering to treatment can impact transmission risk behaviour (p. 2-3)
Materials used	
Procedures used	HIV-infected MSM receiving primary care at Fenway Health centre were screened for eligibility and completed an ACASI. Eligible participants were randomised to intervention or control groups. Both groups completed the same follow-up assessments at 3, 6, 9 and 12 months (p. 3)
Other details	Participants were compensated $25 for their first assessment and $50 for each completed 3-month assessment thereafter for a total of $225 over the course of the study. Participants did not receive a financial incentive for the intervention visits (p. 3).

Study arms

Intervention (N = 100)

Case management provided by a medical social worker plus tailored counselling addressing psychosocial concerns and HIV risk reduction for MSM with HIV.

Rationale/theory/Goal	The intervention was based in the IMB model and used motivational interviewing during each session. The modules were also influenced by Project EXPLORE but adapted to meet the needs of HIV infected MSM (p. 4).
Materials used	No specific materials reported
Procedures used	The intervention comprised five visits with a medical social worker, covering an intake session followed by four intervention sessions. These were followed by four follow-up 'booster visits'. The modules and booster sessions were focused on issues relating to HIV but delivered in a flexible and individualised manner. All sessions followed the same format: information on the topic, motivational interviewing techniques to discuss barriers to change, and behaviour change via the use of new skills. Session content was as follows: Intake - each participant completed an intake session where they met their new medical social worker and involved rapport building and an overall assessment of case-management needs 'Having Sex' (mandatory module) - this core module involved education about HIV transmission (e.g. HIV risk, viral load, HIV medications, HIV superinfection) and identification of the participants sexual risk limits. During this session participants also selected 3 (out of 6) topics most relevant to their needs and the remaining sessions covered those topics. Party drugs - this module reviewed various substances that MSM commonly use and their effects on physical functioning and HIV medications. Participants discussed the factors that lead to their use of drugs and/or combining unsafe sex with substance use, and developed ways to reduce this. This module included role-play and skills-building exercises. Managing stress - This module involved learning stress reduction techniques, and discussing a potential relationship between stress and sex, and how negative coping may lead to increased sexual risk taking. Mindfulness and relaxation training techniques were introduced. Triggers - This module focused on situations or other factors related to temptation to go outside of one's prespecified sexual risk limits. As a skill-building exercise, each participant completed a trigger worksheet that examined goals, choices, and action plans to reduce the influence of triggers on engaging in sexual HIV TRB. Cultures, Communities and You - This module addressed cultural concerns and issues relating to racial or ethnic identity and how they might relate to sexual decision making. Counselors would try to help participants increase their

	connectedness to their own communities, build social support, and improve self-efficacy and resiliency in order to make informed choices about sexual experiences. Disclosure - This module focused on HIV status disclosure to partners and others in one's life. Participants would discuss the pros and cons of disclosure in sexual situations, and, accordingly, identify barriers to disclosure. Skill-building and role-play techniques were also employed. Getting the relationships you want - This module focused on differentiating sexual and/or romantic longer term relationships and articulating what kinds of relationships the participants may desire. Barriers and facilitators to longer term versus shorter term sexual partnerships were also discussed. (p. 4-5)
Provider	Medical social workers trained via didactic instruction, listening to audio-recordings of sessions of senior interventionists during a pilot phase, and through standardised role plays. They used a modular workbook to facilitate the counselling sessions (p. 4).
Method of delivery	Face to face 1-to-1 sessions (p. 4)
Setting/location of intervention	Fenway Health primary care centre, the largest centre in New England caring for sexual and gender minority populations (p. 2-3).
Intensity/duration of the intervention	Five 50-90 minute visits over the course of approximately 3 months, followed by four follow-up 'booster' visits at 3, 6, 9 and 12 months which occurred during study assessment visits. Follow-up visits and assessments were quarterly to complement the standard of care for HIV clinic visits (p. 4)
Tailoring/adaptation	Participants were able to select three of six modules most relevant to them which allowed the intervention to be tailored to their specific risk reduction needs (p. 4).
Unforeseen modifications	None reported
Planned treatment fidelity	Not reported
Actual treatment fidelity	Not reported

Control (N = 101)

Standard care - counselling and case management as per routine clinic care

Brief name	Standard clinic care (p. 2)
Materials used	No specific materials reported
Procedures used	The comparison condition received standard HIV care as it would normally occur at Fenway Health. This involved having a medical social worker as part of one's treatment team for as-needed case management services. There was an expectation of at least quarterly HIV care visits with appropriate blood monitoring. The comparison condition completed all baseline and follow-up assessments (3, 6 9 and 12 months) (p. 5).
Provider	Clinic staff (p. 5)
Method of delivery	Face to face (p. 5)
Setting/location of intervention	Fenway Health primary care centre, the largest centre in New England caring for sexual and gender minority populations (p. 2-3).
Intensity/duration of the intervention	Not reported
Tailoring/adaptation	Not reported
Unforeseen modifications	Not reported
Planned treatment fidelity	Not reported
Actual treatment fidelity	Not reported

Risk of Bias Assessment

Section	Risk of Bias	Reason
Domain 1: Bias arising from the randomisation process	Low	Appropriate randomisation procedures; no baseline differences between groups
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Low	Post-randomisation, study condition was not concealed. Intention to treat analyses used
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	Low	Interventions delivered 1-to-1 by trained specialists so deviations unlikely
Domain 3. Bias due to missing outcome data	Low	Relatively low attrition (85-86% retention)
Domain 4. Bias in measurement of the outcome	Low	Outcome assessments the same for both groups and conducted using ACASI
Domain 5. Bias in selection of the reported result	Low	Trial not registered but reported results unlikely to have been generated by multiple analyses of the data
Overall bias and Directness	Low	
	Overall Directness	Partially applicable (US study)

Schwarcz, 2013

Bibliographic Reference Schwarcz, Sandra K; Chen, Yea-Hung; Murphy, Jessie L; Paul, Jay P; Skinta, Matthew D; Scheer, Susan; Vittinghoff, Eric; Dilley, James W; A randomized control trial of personalized cognitive counseling to reduce sexual risk among HIV-infected men who have sex with men.; AIDS care; 2013; vol. 25 (no. 1); 1-10

Study details

Study design	Randomised controlled trial (RCT)
Trial registration number	Not reported
Study start date	17-Nov-2006
Study end date	07-Apr-2010
Aim	To test the efficacy of Personalised Cognitive Counselling (PCC) for HIV-positive MSM compared to standard risk reduction counselling in reducing future episodes of UAI.
Country/geographical location	San Francisco, USA
Setting	Unclear but paper states the intervention tested in this study is designed to be administered in care settings.
Inclusion criteria	- HIV infected men who were diagnosed with HIV at least 6 months prior to screening - 18 years or older - Reported UAI (either as the insertive or receptive partner) with 2 or more men of negative or unknown HIV serostatus within the previous 6 months - Men who reported UAI with one casual partner (e.g. 'one night stand,' 'prostitute,' or a man who had been a partner for < 3 months and was not a primary partner) were also eligible. - Participants were required to be receiving HIV-related medical or mental health care
Exclusion criteria	- Men who had UAI with only a primary partner - Men who did not speak English - Men who were not competent to provide informed consent - People who identified as transgender

	- Men who were currently enrolled in any other potentially confounding behavioural or clinical trial
Method of randomisation	Randomly permuted blocks of six.
Method of allocation concealment	Cards with study ID number and group assignment were placed inside sealed opaque envelopes which had the study ID number on the outside. Study ID numbers were assigned in sequential order to each participant deemed eligible at screening. The corresponding envelope was then opened and the participants was scheduled for sessions according to group assignment.
Unit of allocation	Participant
Unit of analysis	Participant
Statistical method(s) used to analyse the data	- Differences between baseline characteristics of participants in the two arms were assessed using chi square. - The treatment effect was assessed by intention-to-treat, using generalized estimating equation (GEE) Poisson models with robust standard errors to account for both over-dispersion and clustering within participants of the baseline, 6 month, and 12 month outcomes. The treatment effect was captured in the Poisson model by the time-by-treatment interaction. -Statistical analyses were done using STATA 9.2.
Attrition	**<u>Uptake</u>** Of 1002 persons screened, n=505 were ineligible and n=86 were eligible but declined. **<u>Attrition</u>** N=411 were enrolled into the study. N=37 were excluded from analyses due to duplicate enrolment (n=22) or because their baseline data was lost due to a technical error with the ACASI (n=15). For the intervention group, n=178 completed baseline assessments and n=151 (84.8%) completed all follow-up assessments. For the control group, n=196 completed baseline assessments and n=165 (84.2%) completed all follow-up assessments.

Study limitations (author)	- Because the degree of risk was lower at baseline than had been anticipated, and numbers of UAI episodes were much more variable, power was considerably lower than planned. - The baseline characteristics of participants may have contributed to a smaller than expected response to the intervention. In particular, 42% of men indicated that they had no desire to change and 62% reported that they were moderately to extremely comfortable with their degree of sexual risk-taking. - This study was conducted among residents of the San Francisco Bay Area. San Francisco is a city with a long history of HIV infection where the epidemic has been limited almost entirely to MSM; community norms may have a powerful impact on risk behaviors. - The study was brief; effecting change among HIV infected persons may take more time than was permitted in this trial.
Study limitations (reviewer)	- A higher proportion of men in the intervention arm reported that they experienced 'some' or 'moderate' mental stress after the first counselling session than men in the control arm. The authors note that this was expected, because the PCC intervention required participants to confront the possibility that they may have exposed an uninfected man to HIV. This impact of this mental stress on intervention efficacy was not examined. - Lifetime substance use was common in this study sample
Source of funding	This research was supported by the National Institute of Mental Health (R01-MH73425-04).

Study arms

Intervention (N = 178)

Personalised Cognitive Counselling (PCC) focusing on self-justifications for engaging in risk behaviour

Control (N = 196)

Standard risk reduction counselling

Characteristics

Arm-level characteristics

Characteristic	Intervention (N = 178)	Control (N = 196)
Age		
18-30 years	n = 7 ; % = 4	n = 13 ; % = 6.7
31-40 years	n = 47 ; % = 26.9	n = 64 ; % = 33.2
41-50 years	n = 89 ; % = 50.9	n = 84 ; % = 43.5
> 50 years	n = 32 ; % = 18.3	n = 32 ; % = 16.6
Gender Male	n = 178 ; % = 100	n = 196 ; % = 100
Ethnicity		
White	n = 71 ; % = 40.3	n = 81 ; % = 42
African American	n = 48 ; % = 27.3	n = 55 ; % = 28.5
Latino	n = 32 ; % = 18.2	n = 29 ; % = 15
Asian/Pacific islander	n = 5 ; % = 2.8	n = 2 ; % = 1
More than one race/ethnicity	n = 8 ; % = 4.5	n = 8 ; % = 4.1
Other	n = 12 ; % = 6.8	n = 18 ; % = 9.3
Duration known to be HIV infected		

Characteristic	Intervention (N = 178)	Control (N = 196)
6 years or less	n = 48 ; % = 27.4	n = 69 ; % = 35.4
7-12 years	n = 44 ; % = 25.1	n = 36 ; % = 18.5
13-18 years	n = 44 ; % = 25.1	n = 45 ; % = 23.1
19 years or more	n = 39 ; % = 22.3	n = 45 ; % = 23.1
STI diagnosed in past 12 months, by self-report	n = 51 ; % = 28.8	n = 51 ; % = 26.3
Reported mental health counselling in the past 6 months	n = 88 ; % = 54.3	n = 90 ; % = 51.1
Degree od desire to change sexual behaviour		
Extreme	n = 27 ; % = 15.3	n = 28 ; % = 14.7
Considerable	n = 29 ; % = 16.5	n = 28 ; % = 14.7
Moderate	n = 26 ; % = 14.8	n = 45 ; % = 23.7
Slight	n = 15 ; % = 8.5	n = 11 ; % = 5.8
None	n = 79 ; % = 44.9	n = 78 ; % = 41.1

Outcomes

Study timepoints

- Baseline

- 6 month
- 12 month

Condom use outcomes

Outcome	Intervention, Baseline, N = 178	Intervention, 6 month, N = 151	Intervention, 12 month, N = 151	Control, Baseline, N = 196	Control, 6 month, N = 165	Control, 12 month, N = 165
Number of episodes of UAI with a non-primary partner of different or unknown HIV status In prior 90 days Mean (SD)	2.97 (*empty data*)	1.78 (*empty data*)	1.6 (*empty data*)	3.14 (*empty data*)	2.33 (*empty data*)	3.36 (*empty data*)

Number of episodes of UAI with a non-primary partner of different or unknown HIV status - Polarity - Lower values are better

STI incidence outcomes

Outcome	Intervention, Baseline, N = 175	Intervention, 6 month, N = 141	Intervention, 12 month, N = 146	Control, Baseline, N = 196	Control, 6 month, N = 163	Control, 12 month, N = 156
N. gonorrhoeae Number of diagnoses No of events	n = 1 ; % = 0.6	n = 0 ; % = 0	n = 3 ; % = 2.1	n = 9 ; % = 4.6	n = 1 ; % = 0.6	n = 5 ; % = 3.2
C. trachomatis Number of diagnoses No of events	n = 6 ; % = 3.4	n = 7 ; % = 5	n = 3 ; % = 2.1	n = 11 ; % = 5.6	n = 7 ; % = 4.3	n = 9 ; % = 5.8

N. gonorrhoeae - Polarity - Lower values are better

C. trachomatis - Polarity - Lower values are better

Condom use outcomes

Outcome	Intervention, Baseline, N = 178	Intervention, 6 month, N = 151	Intervention, 12 month, N = 151	Control, Baseline, N = 196	Control, 6 month, N = 165	Control, 12 month, N = 165
Number of men reporting any episodes of UAI with a non-concordant partner No of events	n = 86 ; % = 48.3	n = 46 ; % = 30.8	n = 42 ; % = 27.8	n = 92 ; % = 46.9	n = 47 ; % = 28.4	n = 37 ; % = 22.3

Number of men reporting any episodes of UAI with a non-concordant partner - Polarity - Lower values are better

Paper reports percentages only; n's calculated by analyst

TIDier checklist

Study details

Rationale/theory/Goal	Previous work has demonstrated that a brief, cognitive behavioural counselling intervention provided at the time of HIV testing was effective at reducing future episodes of HIV serodiscordant unprotected anal sex among HIV-uninfected MSM (Dilley et al., 2002, 2007), but has not yet been tested among HIV infected MSM. Given the success of PCC among HIV-uninfected men, the study aimed to adapt the intervention for use with HIV-infected MSM and test its efficacy at reducing UAI (p. 1).
Materials used	All study participants were given a 'Living with HIV/AIDS' pamphlet developed by the CDC (p. 2).

Procedures used	- Potential participants were identified through referrals from their health care providers (HIV care clinicians from private, public, and university clinics and hospitals throughout San Francisco), recruitment fliers and posters in HIV health care settings and MSM-focused community-based organizations, retail outlets, entertainment sites, and advertisements for study volunteers on websites (e.g., craigslist.com). - Recruitment materials provided the study coordinator's telephone number for interested men to contact. Men were screened further for eligibility by telephone and, if eligible, scheduled for a baseline study visit. - At baseline visit, participants provided written informed consent and completed the baseline questionnaire via ACASI. - At baseline, 6- and 12-months, participants were given instructions and materials for the collection of rectal and urine samples which were transported to an external lab for STI testing using the Aptima Combo-2 nucleic acid amplification assay. (p. 2).
Setting/location of intervention	Not specifically stated but assumed HIV care clinics.
Other details	- Participants found to have Chlamydia or gonorrhoea infections were contacted by phone and offered the option of receiving treatment in-person at the study clinic or by mail. Treatment for partners was also offered (p. 2). - Participants were reimbursed for their time using an escalating schedule consistent with community norms (p. 2).

Study arms

Intervention (N = 178)

Personalised Cognitive Counselling (PCC) focusing on self-justifications for engaging in risk behaviour

Brief name	Personalised Cognitive Counselling (PCC) (p. 1)

Rationale/theory/Goal	PCC is based on the hypothesis that MSM who are knowledgeable about the risks of HIV from high risk sex such as unprotected anal intercourse and yet still engage in this activity employ one or more self-justifications (i.e. the thoughts, attitudes and beliefs that relate to that behaviour and risk) that rationalise their decision at the moment of arousal. These rationalisations serve to minimise the risk in 'the heat of the moment' and allow the desired, admittedly risky, behaviour to occur. PCC is hypothesised to be effective at behaviour change by presenting a framework for men to identify and examine their self-justifications in the presence of an empathetic counsellor who assists the client in reframing these cognitions and developing a plan to reduce future sexual risk behaviour (p. 1).
Materials used	No intervention-specific materials reported
Procedures used	- A participant randomised to PCC met with the therapist and was asked to recall a recent, memorable sexual encounter during which he engaged in UAI with a partner of negative or unknown HIV status. - They were instructed to remember the episode in as much detail as possible then complete a self-justification questionnaire, which presented 67 possible self-justifications (e.g. "I've seen him in places where other positive men go, like an HIV services organisation, so I figure he must be positive"). Participants rated how true they found the statements or how strongly they experienced the thoughts or beliefs. - After completing the questionnaire, the therapist asked the participant to describe the specific episode in as much detail as possible. He was then asked to reflect on his self-justifications and how they contributed to his behaviour. - With the help of the therapist, the participant identified the flaws in these rationalisations and developed potential plans to reduce future risk behaviour. - Participants received a booster session at 6 months that followed the same format. (p. 2-3)
Provider	A licensed mental health professional trained to deliver PCC (p. 2)
Method of delivery	Individual counselling sessions (p. 2)
Setting/location of intervention	
Intensity/duration of the intervention	Two sessions (session duration not reported); one main intervention session at baseline plus a booster session 6 months after baseline (p. 1 and 3).

Tailoring/adaptation	Not reported
Unforeseen modifications	None reported
Planned treatment fidelity	Unless the participant refused, all counselling sessions were audio-recorded and reviewed by the investigators to ensure adherence to the protocol (p. 2).
Actual treatment fidelity	Not reported

Control (N = 196)

Standard risk reduction counselling

Brief name	Standard risk reduction counselling (p. 3).
Materials used	No specific control group materials reported
Procedures used	- Control group counselling sessions followed the CDC guidelines for HIV prevention counselling. - Consisted of a psychosocial assessment which included relationship history, mental health, substance use, and experiences with HIV. - Participants also had opportunity to ask questions about HIV - In contrast to PCC, it did not include identifying a high-risk episode, identifying self-justifications for risk behaviour, or reframing these thoughts and developing a plan to reduce risk behaviour (p. 3).
Provider	A licensed mental health professional trained in general risk-reduction counselling (p. 2)
Method of delivery	Individual counselling sessions (p. 2)
Intensity/duration of the intervention	Two sessions (session duration not reported) spaced 6 months apart (p. 1)
Tailoring/adaptation	Not reported

Unforeseen modifications	None reported
Planned treatment fidelity	Unless the participant refused, all counselling sessions were audio-recorded and reviewed by the investigators to ensure adherence to the protocol (p. 2).
Actual treatment fidelity	Not reported

Risk of Bias Assessment

Section	Risk of Bias	Reason
Domain 1: Bias arising from the randomisation process	Low	Appropriate randomisation procedures; no baseline differences between groups
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Low	No information on participant blinding. ITT analyses used
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	Some concerns	Intervention adherence not assessed but sessions delivered 1-to-1 by trained counsellors so deviations from intervention content unlikely
Domain 3. Bias due to missing outcome data	Low	84% completion rate and no difference in missing outcome data between groups
Domain 4. Bias in measurement of the outcome	Low	Standardised outcome measures the same across groups and assessed using ACASI
Domain 5. Bias in selection of the reported result	Some concerns	Trial not registered
Overall bias and Directness	Some concerns	
	Overall Directness	Partially applicable (US study)

Sikkema, 2011

Bibliographic Reference	Sikkema, K.J.; Hansen, N.B.; Kochman, A.; Santos, J.; Watt, M.H.; Wilson, P.A.; Delorenzo, A.; Laudato, J.; Mayer, G.; The development and feasibility of a brief risk reduction intervention for newly HIV-diagnosed men who have sex with men; Journal of Community Psychology; 2011; vol. 39 (no. 6); 717-732

Study details

Study design	Randomised controlled trial (RCT) Pilot RCT
Trial registration number	Not reported
Study start date	Nov-2006
Study end date	Sep-2007
Aim	To develop, pilot test and assess the potential effectiveness of a theoretically-based brief risk reduction intervention to reduce HIV transmission risk among newly diagnosed MSM.
Country/geographical location	New York City, USA
Setting	HIV primary medical care settings
Inclusion criteria	- Diagnosis of HIV positive serostatus within the past 3 months, identified through testing at or referral to the Federally Qualified Health Centre's (FQHC) HIV Primary Care Clinic, and receipt of HIV care at the community health centre - Male to-male sexual behavior or self-identification as gay or bisexual male - Unprotected anal intercourse (UAI) in the 6 months prior to diagnosis

	- Age 18 or older - English speaking - Provision of written informed consent for study participation.
Exclusion criteria	- Impaired mental status detected at screening by the Mini Mental Status Exam.
Method of randomisation	Not reported
Method of allocation concealment	Not reported
Unit of allocation	Participant
Unit of analysis	Participant
Statistical method(s) used to analyse the data	- Because this was an intervention development and feasibility study, it was not powered for statistical comparisons between conditions. - To examine the potential effectiveness, effect sizes were computed for each study outcome variable in each of the study conditions and the difference in the effect sizes between the two intervention conditions was compared. The effect size was computed by dividing the difference between the mean at time 1 (baseline) and the mean at time 2 (3-month follow-up) by the pooled standard deviations; and doing the same for time 1 (baseline) and time 3 (6-month follow-up).
Attrition	**Uptake** Over the 10-month referral period, 204 men who tested HIV positive were informed of the study. Ninety men (44.1%) expressed interest in study participation and 84 were screened for study eligibility; 69 men were eligible and 65 men (77% of those screened) enrolled in the study. **Attrition** Of the 65 men enrolled in the study, n=53 completed the 3 month follow up (82%) and n=50 completed the 6 month follow up (77%). Retention by study group not reported.

Study limitations (author)	- As a feasibility study, the sample size is small and findings are preliminary. - Because of the limited sample size, UAI was summed across relationship status and partner serostatus. Future studies with larger sample sizes should examine sexual risk behaviour by partner serostatus (HIV positive, HIV negative or unknown serostatus). - While the retrospective period for sexual behaviour was 3 months, not all participants completed the baseline assessment 3 months postdiagnosis. Thus, it is possible that subportions of the behavioural risk assessed at baseline occurred before the participant had confirmed knowledge of his HIV diagnosis. - The intervention was initiated at approximately 3 months after receiving an HIV diagnosis, for methodological reasons (sufficient period of time to assess behavioural risk) and to provide an initial adjustment period. It is possible that the intervention would be more appropriate sooner after diagnosis for some, including before any transmission risk behaviour occurs, and beyond 3 months for others who may be experiencing other stressful events related either to the HIV diagnosis or life chaos that necessitates stabilization. - Effect sizes for reducing sexual risk were relatively small. - Although PC intervention participants reported greater reductions in risk behaviour, since there were differences between conditions at baseline, actual frequency of risk behaviors were not necessarily different at follow-up. - The study was conducted in a large community-based health center serving a diverse patient population in a major city so the results may not generalize to other HIV primary care settings. Further tailoring to community norms and social context may be needed in future research.
Study limitations (reviewer)	None to add
Source of funding	This research was supported by a supplement to P30-MH66294, the Duke CFAR (P30-AI064518), R01-MH078731, and the Gilead Foundation.

Study arms

Intervention (N = 35)

The Positive Choices intervention (PC): a brief risk reduction intervention for MSM newly diagnosed with HIV.

Control (N = 30)

Comprehensive standard of care (C-SoC)

Characteristics

Study-level characteristics

Characteristic	**Study (N = 65)**
Age Mean (SD)	32.4 (7.8)
Gender Male	n = 65 ; % = 100
Ethnicity	
White (including Eastern European immigrants)	% = 51
African American	% = 20
Hispanic or Latino ethnicity	% = 12
Mixed Race	% = 11
Asian	% = 5
Pacific Islander	% = 1
Viral load (copies per mL) Mean (SD)	117945 (194130)
CD4 counts Range	18 to 1112

Characteristic	Study (N = 65)
CD4 counts Mean (SD)	515 (243)
Substance use in the 6 months prior to HIV diagnosis	% = 99
Use of substances co-occurring with sexual behaviour in the 6 months prior to HIV diagnosis	% = 90
Unprotected anal intercourse in 3 months prior to HIV diagnosis	% = 90
Number of episodes of UAI in 3 months prior to HIV diagnosis Mean (SD)	13.1 (43.4)

Outcomes

Study timepoints

- Baseline
- 3 month (After completion of the intervention; 3 months after baseline)
- 6 month

Condom use outcomes

Outcome	Intervention, Baseline, N = 29	Intervention, 3 month, N = 29	Intervention, 6 month, N = 29	Control, Baseline, N = 21	Control, 3 month, N = 21	Control, 6 month, N = 21
Unprotected anal intercourse with any partner (primary and non-primary) Number of episodes Mean (SD)	3.6 (5.4)	3.3 (5.7)	2.8 (4.6)	1 (1.6)	2.1 (3.7)	1.7 (3.4)

Unprotected anal intercourse with any partner (primary and non-primary) - Polarity - Lower values are better

STI incidence outcomes

Outcome	Intervention, Baseline, N = 29	Intervention, 3 month, N = 29	Intervention, 6 month, N = 29	Control, Baseline, N = 21	Control, 3 month, N = 21	Control, 6 month, N = 21
Self-report of having been diagnosed with or experiencing physical symptoms associated with STIs No of events	n = 8 ; % = 27.6	n = 9 ; % = 31	n = 7 ; % = 24.1	n = 3 ; % = 14.3	n = 5 ; % = 25	n = 6 ; % = 28.6

Self-report of having been diagnosed with or experiencing physical symptoms associated with STIs - Polarity - Lower values are better

Paper only reports percentages; n's calculated by analyst

TIDier Checklist

Study details

Brief name	
Rationale/theory/Goal	While the majority of people newly diagnosed with HIV respond to their HIV diagnosis by adopting lower risk sexual behaviours, a substantial proportion continue to engage in high risk behaviours. For MSM, studies indicate that over 50% of recently diagnosed MSM report sexual risk behaviour within 3-12 months of diagnosis, suggesting that secondary prevention efforts should target people soon after HIV diagnosis. From a behavioural perspective, the first year after diagnosis appears to be a critical period for risk reduction, particularly for men. Health behaviour theory suggests heightened emotions of a diagnosis and the reevaluation of one's identity can help to make an individual more ready to introduce risk reduction behaviours, making this a critical opportunity for intervening. The HIV medical care setting has been seen as an important venue for delivering prevention messages to newly diagnosed MSM receiving HIV primary care (p. 2-3).
Procedures used	- Potential participants were informed of the study by HIV test counsellors after receipt of diagnosis or during their first postdiagnosis visit with a clinic nurse and/or case manager.

	- Men who were interested in participating were referred to the study coordinator and screened for study eligibility. - If eligible, the baseline assessment was administered, and participants were then randomly assigned to the intervention or control condition. - After completion of the three-session intervention, and 3 months after the baseline, a post-assessment was administered. A follow-up assessment was administered 3 months later, at month six of study participation. - All assessments were administered using a computer assisted survey instrument (CASI) (p. 4-5)

Study arms

Intervention (N = 35)

The Positive Choices intervention (PC): a brief risk reduction intervention for MSM newly diagnosed with HIV.

Brief name	Positive Choices (PC)
Rationale/theory/Goal	The intervention centred on principles from the IMB model (p. 6) and was developed using a collaborative, community-based approach and formulated by research partners, Federally Qualified Health Centre (FQHC) providers and HIV counsellors. The aim was to develop a brief risk reduction intervention for newly diagnosed HIV positive MSM that could be delivered by HIV counsellors in primary care and provided a supportive context for 'positive sexuality'. Focus groups with HIV counsellors highlighted that the current posttest counselling protocol, delivered in a single session immediately after diagnosis, was not sufficient to address sexual risk, substance abuse, or the emotional needs of the men who tested HIV positive, and suggested that providing sessions after completion of the patient's initial physician appointment to discuss treatment options and tailor risk reduction strategies within their medical care plan (e.g., viral load, sexually transmitted infection treatment, adherence counselling) was desirable. Feedback from newly HIV-diagnosed MSM on the intervention framework confirmed that intervening approximately 4 weeks after diagnosis would allow some of the shock of receiving the diagnosis to subside, the diagnosis may be more 'real', and individuals may be more ready to do something about it (p. 3-4).
Materials used	No specific materials reported

Procedures used	- All participants in the intervention condition received Comprehensive Standard of Care plus the brief risk reduction intervention Positive Choices. - 3 sessions; first 2 delivered within 2 weeks of the initial physician appointment and third was a 'booster' session delivered 1 month later - Sessions 1 and 2 focused on developing a personalized risk reduction plan through: (a) delivering information relevant to sexual health in newly diagnosed MSM, such as increased transmission risk with high viral load (e.g., acute infection, STI symptoms), increased risk in relation to substance abuse, the importance of HIV disclosure, and strategies to maintain healthy sexual relationships while living with HIV; (b) increasing motivation for transmission risk reduction by instilling a sense of personal vulnerability to the consequences of risk behaviors and a sense of personal responsibility for protecting the health of others; and (c) developing behavioural skills for health protection such as disclosure decision-making and communication skills, and self management skills around substance abuse. - Session three was a booster session to review the personalised risk reduction plan over the previous month and address integration of risk reduction into the overall treatment plan, address barriers to implementation, and practice communication skills that can aid the participant in the HIV primary care setting.
Provider	Sessions were delivered by FQHC HIV counsellors or social workers who had received intervention training (p. 4)
Method of delivery	Individual face-to-face sessions (p. 6)
Setting/location of intervention	HIV primary care clinics (p. 5)
Intensity/duration of the intervention	Three 60 minute sessions; first two sessions delivered within 2 weeks of initial physician visit and third session 1 month later (p. 6)
Tailoring/adaptation	Not reported
Unforeseen modifications	None reported

Planned treatment fidelity	Throughout the intervention process, counsellors met regularly with the project director to monitor intervention fidelity (p. 4). Each counsellor completed a quality assurance worksheet detailing the extent to which content, skills and exercises to be covered within each intervention session were addressed (p. 6).
Actual treatment fidelity	Adherence to the PC protocol was high, with 91% of the protocol covered specific to each session, and all of the intervention components covered over the course of the 3 sessions (p. 6).
Other details	After completing the intervention and all follow up assessments, intervention participants were asked to complete a 4-item evaluation of the intervention. Results showed PC participants provided a very favourable assessment of the intervention: 75% strongly agreed and 25% agreed that their experience with the program was positive and they felt supported as a newly diagnosed person; 60% strongly agreed and 40% agreed that each session was appropriate to his needs; and 80% strongly agreed and 20% agreed that they would recommend this program to a newly HIV-positive person (p. 8).

Control (N = 30)

Comprehensive Standard of Care (C-SoC)

Brief name	Comprehensive Standard of Care (C-SoC) (p. 5).
Materials used	No specific materials reported
Procedures used	- Regular meetings with nurses, cases managers, and physicians - Referrals for mental health and substance abuse providers - Optional participation in a newly diagnosed support group - Health promotion behaviors, related primarily to medication adherence, were addressed during clinic visits with all patients, but a standard prevention intervention was not offered in routine medical care (p. 5).
Provider	Clinic staff
Method of delivery	Face to face

Setting/location of intervention	HIV primary care clinics (p. 5)
Intensity/duration of the intervention	Not reported
Tailoring/adaptation	Not reported
Unforeseen modifications	None reported
Planned treatment fidelity	Not reported
Actual treatment fidelity	Not reported

Risk of Bias Assessment

Section	Risk of Bias	Reason
Domain 1: Bias arising from the randomisation process	High	No information provided on randomisation and there were significant baseline differences between groups on key variables: the intervention group reported significantly higher UAI frequency (mean 3.6, SD 5.4) than the control group (mean 1.0, SD 1.6); and significantly higher STI incidence (27.6% vs 14.3%)
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Low	No information on participant blinding; deviations from intended intervention unlikely
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	Some concerns	Intervention adherence not assessed but sessions delivered 1-to-1 by trained counsellors so deviations from intervention content unlikely
Domain 3. Bias due to missing outcome data	Some concerns	77% retention at 6 month follow-up. No attrition analyses or comparisons of completers vs non-completers on any study variables
Domain 4. Bias in measurement of the outcome	Some concerns	Outcome assessments conducted using CASI and the same for both groups. STI outcome was self-report of having been diagnosed with or experiencing physical symptoms of STI; not a reliable measure because

Section	Risk of Bias	Reason
		not possible to distinguish those with clinically confirmed STI and those self-reporting symptoms
Domain 5. Bias in selection of the reported result	Some concerns	Trial not registered
Overall bias and Directness	High	Limited information on randomisation and significant baseline differences on key study variables. No information on blinding. 77% retention and no comparison of completers and non-completers. Unreliable assessment of STI incidence. Trial not registered.
	Overall Directness	Partially applicable (US study)

Sikkema, 2014

Bibliographic Reference Sikkema, Kathleen J; Abler, Laurie; Hansen, Nathan B; Wilson, Patrick A; Drabkin, Anya S; Kochman, Arlene; MacFarlane, Jessica C; DeLorenzo, Allyson; Mayer, Gal; Watt, Melissa H; Nazareth, William; Positive choices: outcomes of a brief risk reduction intervention for newly HIV-diagnosed men who have sex with men.; AIDS and behavior; 2014; vol. 18 (no. 9); 1808-19

Study details

Study design	Randomised controlled trial (RCT)
Trial registration number	Not reported
Study start date	Jun-2009
Study end date	May-2011
Aim	To evaluate whether Positive Choices (PC), a brief risk reduction intervention for newly diagnosed MSM in HIV care, reduced sexual risk behaviour in the year following HIV diagnosis.

Country/geographical location	New York City, USA
Setting	A Federally Qualified Health Centre (FQHC) specialising in care for lesbian, gay, bisexual and transgender communities.
Inclusion criteria	1) HIV diagnosis within the past three months 2) English fluency 3) UAI with a male partner in the three months prior to HIV diagnosis 4) 18 years or older 5) identified as male sex at birth (regardless of current gender identity) 6) accessing health care services at the study health center.
Exclusion criteria	None reported
Method of randomisation	Not reported
Method of allocation concealment	Not reported
Unit of allocation	Participant
Unit of analysis	Participant
Statistical method(s) used to analyse the data	- Descriptive analyses were conducted to examine the baseline characteristics of the total sample and by study condition. T-tests were used to compare continuous variables; chi-square tests and Fisher's exact tests were used to compare categorical variables. - A two-sample test of equal proportions was calculated to determine if the drop-out rate differed by condition or by baseline risk behaviour, and no differences were found.

	- To assess the changes in the frequency of the UAI and UAI-SD outcomes by condition, generalized linear mixed modelling (GLMM) using the PROC GLIMMIX procedure in SAS was used. Because the outcomes were measured repeatedly, GLMM was used to examine the longitudinal random and fixed effects by testing the difference in the rate of occurrence of the outcome between the two conditions over time. - Two longitudinal models were conducted separately for the UAI and UAI-SD outcomes and fitted to a negative binomial distribution to account for the overdispersion in the count outcomes. Each model contained three independent variables: 1) time of the assessment, with baseline as the reference; 2) the intervention condition; and 3) a time by condition interaction term. - The adjusted mean counts for the UAI and UAI-SD outcomes by condition were calculated from the longitudinal models to characterize the patterns of change over the study period. A post-hoc analysis was conducted to explore the UAI and UAI-SD outcomes by partner type. - Effect sizes were calculated for the 3-, 6-, and 9-months follow-up assessments using Cohen's d to examine the relative impact of the PC condition on the outcomes compared to the C-SoC condition.
Attrition	**Uptake** Of the 150 patients who completed the screening, 119 (79.3%) met eligibility criteria for the study. Of the eligible patients, 102 (85.7%) enrolled, completed the baseline assessment, and were randomly assigned to either the intervention or control condition. **Attrition** For participants allocated to the intervention condition (n=51), n=38 (75%) completed the 3 month follow-up assessment, n=33 (65%) completed the 6 month follow-up assessment, and n=32 (63%) completed the 9 month follow-up assessment. For participants allocated to the comparison condition (n=51), n=41 (80%) completed the 3 month follow-up assessment, n=36 (71%) completed the 6 month follow-up assessment, and n=27 (53%) completed the 9 month follow-up assessment.

	There was no significant difference by condition in the percentage of participants lost to follow-up and no difference on any study baseline measures between those retained and those lost to follow-up.
Study limitations (author)	- Because of the high levels of risk behaviour reported by the population of MSM recruited and enrolled from one health center, the findings may not be generalisable to MSM with different risk profiles in different settings. - There was substantial participant drop-out over time, albeit equally by study condition and by the sexual risk behaviors reported at the time of diagnosis. Attrition levels were due, in part, to a study protocol decision to include only participants who received care at the community health center. Of those who did not complete all assessments, 35% were lost to follow-up because they left care at the community health center. - This study used self-reported outcome data. Participants may have incorrectly assumed the serostatus of their sexual partners and a large number of unknown serostatus partners may have in fact been HIV positive. However, since partner serostatus was unknown, it suggests the occurrence of risk behaviour. - A potential threat to internal validity is that the study did not use blinded treatment assignment, which may have resulted in differential responses to the outcome assessments by condition.
Study limitations (reviewer)	None to add
Source of funding	This research was funded by the NIH grant R01-MH078731.

Study arms

Intervention (N = 51)

Positive Choices (PC), a brief sexual risk reduction intervention for newly HIV-diagnosed MSM.

Control (N = 51)

Comprehensive Standard of Care (C-SoC)

Characteristics

Arm-level characteristics

Characteristic	**Intervention (N = 51)**	**Control (N = 51)**
Age Mean (SD)	30.2 (7.7)	34.3 (9.4)
Male	n = 47 ; % = 92.2	n = 51 ; % = 100
Transgender	n = 4 ; % = 7.8	n = 0 ; % = 0
Race/ Ethnicity		
White	n = 21 ; % = 41.2	n = 17 ; % = 33.3
African American / Black	n = 8 ; % = 15.7	n = 7 ; % = 13.7
Hispanic / Latino	n = 13 ; % = 25.5	n = 17 ; % = 33.3
Other	n = 9 ; % = 17.6	n = 10 ; % = 19.7
Sexual orientation		
Gay/homosexual	n = 47 ; % = 92.2	n = 50 ; % = 98
Bisexual	n = 1 ; % = 2	n = 1 ; % = 2
Straight / heterosexual	n = 3 ; % = 5.9	n = 0 ; % = 0
Has a primary partner	n = 20 ; % = 39.2	n = 21 ; % = 41.2
Number of partners Mean (SD)	4 (4.7)	4.5 (6.3)

Characteristic	Intervention (N = 51)	Control (N = 51)
CD4 count Mean (SD)	503 (255)	476 (218)
Viral load Mean (SD)	63040 (140670)	40150 (76000)
Currently on ART	n = 15 ; % = 29.4	n = 13 ; % = 25.5

Outcomes

Study timepoints

- Baseline
- 3 month
- 6 month
- 9 month

Condom use outcomes

Outcome	Intervention, Baseline, N = 51	Intervention, 3 month, N = 38	Intervention, 6 month, N = 33	Intervention, 9 month, N = 32	Control, Baseline, N = 51	Control, 3 month, N = 41	Control, 6 month, N = 36	Control, 9 month, N = 27
Total number of insertive or receptive anal intercourse acts with any partner In prior 3 months Mean (SD)	10.27 (18.28)	5.01 (11.5)	7.44 (20.5)	11.39 (36.3)	8.9 (15.85)	10.53 (23)	6.24 (16.64)	6.32 (21.5)

Total number of insertive or receptive anal intercourse acts with any partner - Polarity - Lower values are better

Paper reports mean and SE; SDs calculated by analyst

Condom use outcomes

Outcome	Intervention, Baseline, N = 38	Intervention, 3 month, N = 38	Intervention, 6 month, N = 38	Intervention, 9 month, N = 38	Control, Baseline, N = 42	Control, 3 month, N = 42	Control, 6 month, N = 42	Control, 9 month, N = 42
Total number of insertive or receptive anal intercourse acts with HIV-negative or unknown status partners In prior 3 months Mean (SD)	4.03 (9.99)	2.91 (8.2)	1.14 (4.81)	0.45 (2.71)	1.76 (4.47)	2.69 (7.65)	0.76 (3.37)	2.92 (18.53)

Total number of insertive or receptive anal intercourse acts with HIV-negative or unknown status partners - Polarity - Lower values are better

Paper reports mean and SE; SDs calculated by analyst Only includes the subsample of participants who reported sexual activity with an HIV-negative or unknown status partner during the study

TIDier Checklist

Study details

Rationale/theory/Goal	The period following HIV diagnosis provides a unique window of opportunity for intervening on sexual transmission risk behaviours. For many newly-diagnosed MSM, counselling and testing, and the impact of diagnosis, lead to reductions in UAI, but after a short period, risk behaviour often rebounds to levels demonstrated prior to diagnosis, and more than half of HIV positive MSM report UAI within one year of diagnosis. To maintain reductions in risk behaviour in the period following diagnosis, the standard of care post-test counselling should be coupled with strategies that continue to address sexual risk behaviors in the months following an HIV diagnosis. Brief interventions that incorporate relevant behaviour

	change skills can influence sexual risk behaviors after HIV diagnosis, when MSM are redefining themselves as living with HIV and motivating themselves to develop patterns of safer sex behaviors (p. 2-3).
Procedures used	- Recruitment brochures were distributed at the health centre, and care providers informed HIV positive patients about the study either upon receipt of diagnosis or during the first clinic visit post-diagnosis. - Patients who were within three months of learning their HIV diagnosis provided written informed consent and were screened to determine study eligibility. Patients who met eligibility criteria were scheduled to complete a baseline assessment three months following HIV diagnosis, then were randomly assigned to intervention or control conditions. - Participants completed additional assessments at 3-(post intervention), 6-, and 9-months after baseline to comprise a one year study period. - During all assessments, demographic and psychosocial constructs were measured using a computer assisted self-interview (CASI) and detailed sexual behaviour was assessed using an interviewer-administered time-line follow-back (TLFB) instrument. - Electronic medical records were reviewed to extract data on clinical factors related to HIV care and treatment outcomes. (p. 4) - All participants (intervention and control) were offered C-SoC services.
Other details	Participants were remunerated $35 for each assessment visit (p. 4)

Study arms

Intervention (N = 51)

Positive Choices (PC): a brief sexual risk reduction intervention for newly HIV-diagnosed MSM.

Brief name	Positive Choices (PC) Intervention (p. 4)

Rationale/theory/Goal	The 3-session intervention was developed through community-based collaboration and incorporated components of the IMB model and the Transtheoretical model. The primary goal of the intervention was to reduce HIV transmission risk behaviour through enhancing risk reduction decision making and disclosure skills, assisting participants in the transition to HIV care, and promoting positive attitudes toward risk reduction (p. 4).
Materials used	No specific materials reported
Procedures used	*Session 1: Risk Reduction Plan* Addressed the sexual health of newly-diagnosed MSM using discussion tailored to address the participant's health status, care and treatment plan, and health priorities established after the first medical visit (e.g. STIs, high viral load). It also included development of a sexual risk reduction plan specific to the participant's current stage of coping with his diagnosis. *Session 2: Disclosure of Serostatus* Focused on disclosure decision making, enhancing communication skills, and setting achievable disclosure goals. *Session 3: Protecting Sexual Health* Reviewed the materials from sessions 1 and 2, and functioned as a booster to improve risk reduction strategies regarding health overall, treatment-related concerns, and maintenance of risk reduction strategies. All intervention sessions included interactive tasks such as self-assessment handouts to guide session content and progress; exercises to tailor goals to the stage of readiness for behaviour change and to increase motivation; self regulation skills for sexual and substance use risk reduction plans; and role plays for enhancing decision-making and communication skills. (p. 4-5)
Provider	Health centre HIV counsellors, who had substantial experience and/or received counselling and testing certification from the Department of Health. They were trained by the study coordinator to facilitate the intervention using a detailed manual, counsellor workbook and role plays (p. 4)
Method of delivery	Face to face one-to-one sessions (p. 4)

Setting/location of intervention	A Federally Qualified Health Centre specialising in care for lesbian, gay, bisexual and transgender communities (p. 3).
Intensity/duration of the intervention	Three 60 minute sessions. The first two sessions occurred in consecutive weeks following the baseline assessment, and the third session occurred one month later (p. 5).
Tailoring/adaptation	Not reported
Unforeseen modifications	None reported
Planned treatment fidelity	The HIV counsellors delivering the intervention received ongoing supervision to enhance fidelity to the intervention. After each session, counsellors completed a detailed quality assurance worksheet to document fidelity to the intervention content, skills and activities. The assurance worksheets were reviewed by the study coordinator (p. 4-5)
Actual treatment fidelity	The counsellors' adherence to the PC protocol was high, with all of the intervention components covered in the course of the three sessions (p. 5).
Other details	Most participants (76%) attended all 3 sessions. 8% attended only 1 or 2 sessions, and 16% attended no intervention sessions. Participants were retained in the study regardless of intervention exposure (p. 5) All intervention participants also received C-SoC services (p. 5)

Control (N = 51) Comprehensive Standard of Care (C-SoC)

Brief name	Comprehensive Standard of Care (C-SoC) (p. 5)
Materials used	No specific materials reported
Procedures used	- C-SoC participants were offered a variety of HIV-related support services provided through the health centre's comprehensive standard of care for newly-diagnosed individuals.

	- All participants had regularly scheduled appointments with clinic providers (nurses, case managers, physicians, adherence nurse); referrals to mental health, psychiatric, and substance use providers (available at the health center as well as outside referrals); and the option to participate in support groups for newly HIV-diagnosed individuals. (p. 5)
Provider	Health centre clinic providers (p. 5)
Method of delivery	Face to face individual care (p. 5)
Setting/location of intervention	A Federally Qualified Health Centre specialising in care for lesbian, gay, bisexual and transgender communities (p. 3).
Intensity/duration of the intervention	Not reported
Tailoring/adaptation	Not reported
Unforeseen modifications	None reported
Planned treatment fidelity	Not reported
Actual treatment fidelity	Not reported

Risk of Bias Assessment

Section	Risk of Bias	Reason
Domain 1: Bias arising from the randomisation process	Some concerns	No information on randomisation or allocation concealment procedures. No baseline differences between groups
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Low	No deviations from intended intervention
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	Some concerns	8% attended only 1 or 2 sessions and 16% did not attend any intervention sessions. Impact of session attendance on outcomes not analysed

Section	Risk of Bias	Reason
Domain 3. Bias due to missing outcome data	Some concerns	High attrition: 63% follow up in intervention group; 53% follow up in control group, but no significant difference in attrition by group
Domain 4. Bias in measurement of the outcome	Some concerns	Psychosocial constructs assessed using CASI; sexual behaviour assessed by interviewer-administered timeline follow-back instrument. No information on whether interviewers were blind to condition
Domain 5. Bias in selection of the reported result	Some concerns	Trial not registered
Overall bias and Directness	High	Limited information on randomisation and blinding of participants or outcome assessors; impact of intervention adherence not assessed; high attrition; trial not registered
	Overall Directness	Partially applicable (US study)

D.8 Effectiveness evidence for Young MSM

Hidalgo, 2015

Bibliographic Reference Hidalgo, Marco A; Kuhns, Lisa M; Hotton, Anna L; Johnson, Amy K; Mustanski, Brian; Garofalo, Robert; The MyPEEPS randomized controlled trial: a pilot of preliminary efficacy, feasibility, and acceptability of a group-level, HIV risk reduction intervention for young men who have sex with men.; Archives of sexual behavior; 2015; vol. 44 (no. 2); 475-85

Study details

Study design	Randomised controlled trial (RCT) Pilot
Trial registration number	ClinicalTrials.gov number: NCT01771237
Study start date	Jul-2009
Study end date	Dec-2010

Aim	To determine the initial efficacy, feasibility and acceptability of a group-based primary prevention intervention designed to reduce HIV risk behaviour in ethnically diverse groups of young MSM aged 16-20.
Country/geographical location	Large Midwestern city in the US.
Setting	A LGBT community health centre.
Inclusion criteria	- MSM aged 16-20 years - Reported having anal intercourse with another male in the past 12 months - HIV negative (self report) - Resided in large Midwestern city
Exclusion criteria	Not reported
Method of randomisation	Most participants (85%) were randomised using a 1:1 allocation to intervention vs. time-matched active control. However, at three randomisation time-points (equating to 15% of the sample), the cohort sizes were too small to allocate a sufficient amount of participants into both group conditions. Therefore, participants were allocated at the group-level (i.e., group condition was randomly selected into which all members of the cohort were then allocated), resulting in slightly imbalanced overall allocation between conditions: 57% to the intervention (n=58) and 43% to the control (n=43) condition.
Method of allocation concealment	Not reported
Unit of allocation	Participant
Unit of analysis	Participant
Statistical method(s) used to analyse the data	- Descriptive analysis included an examination of frequencies, variable distributions, and measures of central tendency for sociodemographic characteristics, and cognitive and behavioural variables. Cronbach's alpha was used to assess internal consistency of multi-item scales. - Comparisons between baseline characteristics of intervention and control groups were conducted using Chi-square tests for categorical variables and t-tests and Wilcoxon tests for parametric and non-parametric continuous variables, respectively.

	- Multivariable analyses were used to control variables for which differences of $p<0.15$ at baseline existed, or that were considered potential confounders based on empirical evidence and prior literature. To control for baseline differences between groups, the baseline value of the outcome was controlled for in all analyses. - Generalised linear models (GLM) were used to assess intervention effects on primary and intermediate outcomes at follow-up, with link functions as appropriate based on the distribution of the outcome variable (e.g., logit link for binary outcomes, negative binomial for count outcomes, and identity for continuous outcomes). - The Generalised estimating equation (GEE) extension of GLM was used to assess average differences between MyPEEPS and the control group over the entire 12-week follow-up period. Controlled for in GEE models were baseline values of the outcome variable as a covariate and adjusted for age, race/ethnicity, time, and number of sessions attended. - All analyses were conducted using SAS version 9.2
Attrition	**Uptake** Of 280 individuals approached by study recruitment staff, approximately two thirds (n=187) agreed to be screened. Of those 187 people assessed for eligibility, 47 were ineligible and 31 participants were eligible but declined to participate. A further 98 completed the baseline assessment but were lost to follow-up prior to randomisation. **Attrition** Of the 58 participants randomised to the intervention group, 72.4% completed the 6-week follow-up and 72.4% completed the 12-week follow-up. Of the 43 participants randomised to the control group, 62.8% completed the 6-week follow-up and 60.5% completed the 12-week follow-up. There were no significant differences in follow-up completion rates between the two groups.

	Overall, 62 participants (61.4%) were assessed at both 6- and 12-weeks, and 75 participants (74.3%) had any follow up. With respect to session attendance, 62% of intervention participants attended 3 or more sessions; 42% of control participants attended 3 or more sessions.
Study limitations (author)	- The validity of these findings is contingent upon the accuracy of participant retrospective self-report - The questionnaire did not include items that examined specific high risk sexual behaviors (e.g., insertive versus receptive anal intercourse) or the specific substances used during sex (e.g., marijuana versus cocaine use) so was limited in detecting intervention effects on specific risk behaviours linked to HIV. - The non-probabilistic method of sampling in LGBT community venues limits this pilot's results from generalising to all 16 to 20 year-old, young MSM, especially those whom may not partake in activities organized by LGBT community venues. - The relatively short period between two follow-up assessments (i.e., 6 weeks) prevented the measurement of long-term intervention effects. - One in four enrollees did not complete both of the follow-up assessments. Significant differences were not observed among those with complete vs. incomplete follow-up data on factors related to treatment group assignment, participant demographics, or baseline risk behaviors; however, the significant attrition observed across assessment points may limit the study's generalisability.
Study limitations (reviewer)	Session attendance was relatively low: only 62% of intervention and 42% of control participants attended at least 3 of the 6 sessions. This study also assessed intervention acceptability using an 8-item scale (possible range 8-48; higher scores are better) and participants rated MyPEEPS as moderately acceptable (mean=24.7; SD=13.6). Only 55% reported finding the program helpful and 50% agreed that the program positively influenced their safe sex behaviour. The authors conclude the intervention is acceptable but the moderate acceptability ratings, relatively low session attendance and relatively high attrition indicate that for some participants this may not have suited them.
Source of funding	The project described was supported by Award Number R34 MH079707 from the National Institute of Mental Health

Study arms

Intervention (N = 58)

MyPEEPS (Male Youth Pursuing Empowerment, Education and Prevention around Sexuality): a group-level intervention to reduce sexual risk behaviours among young MSM.

Control (N = 43)

Time-matched group level intervention focusing on HIV risk reduction but relying on lecture format and didactic delivery (not interactive, content not tailored to male-male sex).

Characteristics

Arm-level characteristics

Characteristic	Intervention (N = 58)	Control (N = 43)
Age Mean (SD)	18.6 (1.3)	19 (1.1)
Age Median (IQR)	19 (17 to 20)	19 (18 to 20)
Gender	n = 58 ; % = 100	n = 43 ; % = 100
Ethnicity		
White	n = 16 ; % = 27.6	n = 7 ; % = 16.3
Black / African American	n = 20 ; % = 34.5	n = 19 ; % = 44.2

Characteristic	Intervention (N = 58)	Control (N = 43)
Hispanic / Latino	n = 17 ; % = 29.3	n = 10 ; % = 23.3
Other race (including multiracial)	n = 5 ; % = 8.6	n = 7 ; % = 16.3
Ever incarcerated	n = 5 ; % = 8.6	n = 6 ; % = 13.9

Outcomes

Study timepoints

- Baseline
- 6 week
- 12 week

Condom use outcomes

Outcome	Intervention, Baseline, N = 58	Intervention, 6 week, N = 42	Intervention, 12 week, N = 43	Control, Baseline, N = 43	Control, 6 week, N = 33	Control, 12 week, N = 31
Unprotected anal sex In the last 6 weeks No of events	n = 19 ; % = 33.3	n = 9 ; % = 21.4	n = 11 ; % = 25.6	n = 16 ; % = 37.2	n = 7 ; % = 21.2	n = 8 ; % = 25.8
Unprotected sex under the influence of alcohol or drugs In the past 6 weeks No of events	n = 7 ; % = 12.3	n = 2 ; % = 4.8	n = 2 ; % = 4.7	n = 7 ; % = 16.3	n = 4 ; % = 12.1	n = 6 ; % = 19.4

Outcome	Intervention, Baseline, N = 58	Intervention, 6 week, N = 42	Intervention, 12 week, N = 43	Control, Baseline, N = 43	Control, 6 week, N = 33	Control, 12 week, N = 31
Number of unprotected anal sex acts with male partners In past 6 weeks Mean (SD)	0.96 (2.4)	0.52 (1.5)	1.12 (2.9)	1.5 (3.6)	0.91 (2.9)	1.2 (2.3)
Condom errors Assessed using 12-item Condom Use Errors and Problems Questionnaire (Crosby et al., 2002). Higher score indicates increased HIV transmission potential through condom errors (e.g. condom breakage, slippage). Mean (SD)	0.72 (0.46)	0.55 (0.5)	0.56 (0.52)	0.66 (0.41)	0.58 (0.43)	80.74 (0.48)

Unprotected anal sex - Polarity - Lower values are better

Unprotected sex under the influence of alcohol or drugs - Polarity - Lower values are better

Number of unprotected anal sex acts with male partners - Polarity - Lower values are better

Condom errors - Polarity - Lower values are better

Note that for 'Number of unprotected anal sex acts with male partners' the data is restricted to those reporting any anal sex at baseline (n=34 in intervention group and n=33 in control group)

Secondary Outcomes

Outcome	Intervention, Baseline, N = 58	Intervention, 6 week, N = 42	Intervention, 12 week, N = 43	Control, Baseline, N = 43	Control, 6 week, N = 33	Control, 12 week, N = 31
Self-efficacy for safer sex Assessed using 10-item Self-Efficacy for Safer Sex scale (Parsons et al., 2000), which measures self-efficacy in practicing condom use and safer sex communication with a partner Mean (SD)	45 (3.7)	46.6 (3.5)	NA (NA)	45.3 (4.3)	45.5 (4.7)	NA (NA)
Health Protective Communication Assessed using the 9-item Health Protective Communication Scale (Catania, 1998) which captures the quality of safer sex verbal communication between partners. Mean (SD)	18.8 (4.6)	19.4 (5)	17.3 (5.9)	14.1 (4.5)	17.3 (4.3)	18.8 (4.7)

Self-efficacy for safer sex - Polarity - Higher values are better

Health Protective Communication - Polarity - Higher values are better

Note Self-efficacy for safer sex only assessed at baseline and 6-weeks.

TIDier Checklist

Study details

Brief name	

Rationale/theory/Goal	In the US, annual rates of HIV infection in young MSM continue to rise, indicating a need for primary prevention with increasingly younger groups of MSM. In young MSM, HIV risk behaviour has been linked to social cognitive and skills-based factors, namely low knowledge and self-efficacy regarding safe sex, ineffective condom use skills, and ineffective sexual health-related communication with sexual partners. No existing evidence based interventions have yet to address HIV risk in MSM under age 18, and there is evidence of documented increases in HIV incidence in this population (p. 2-3).
Procedures used	- Study recruitment staff approached all adolescent and young adult males at public events frequented by LGBT youth (e.g. dances, LGBT community festivals), in LGBT youth-serving community-based organisations, at high school gay-straight alliances, and college student groups throughout the greater metropolitan area. - During these interactions, recruitment staff introduced themselves, shared information about the study aim and procedures, conducted a 10-item eligibility screener, and scheduled an initial baseline visit for people who screened as eligible. - Study promotional materials, which provided study telephone and email contact, were distributed in recruitment settings, restaurants and businesses frequented by youth, and on social networking websites (e.g, Twitter, Facebook). Individuals who contacted the study were then scheduled to undergo eligibility screening either in person or by phone. To confirm eligibility status, individuals deemed eligible via phone screening were re-screened in person at the start of their initial baseline visit. - After obtaining informed consent/assent, the baseline assessment was administered using CASI then participants were randomised to group. - On completion of all intervention/control sessions, participants completed 6- and 12-week follow up assessments using CASI. (p. 3; 5).
Other details	Participants were reimbursed for their time following each study visit: $20 at baseline, $10 at each group session, an additional $10 for perfect 6-session attendance, $30 at 6-week follow-up, and $30 at 12-week follow-up; a total of up to $150 (p. 8).

Study arms

Intervention (N = 58)

MyPEEPS (Male Youth Pursuing Empowerment, Education and Prevention around Sexuality): a group-level intervention to reduce sexual risk behaviours among young MSM.

Brief name	MyPEEPS (Male Youth Pursuing Empowerment, Education and Prevention around Sexuality) (p. 4).
Rationale/theory/Goal	Informed by social cognitive theory (Bandura, 1994), MyPEEPS aims to educate participants about modes of HIV transmission, increase self-efficacy for condom use, increase assertive safer sex-related communication, generate situation-specific risk reduction strategies, and increase awareness about the influence of substance use on sexual risk. It was developed based on semi-structured interviews with a multiethnic sample of 21 young MSM whom had acquired HIV through male-male sexual activity between ages 16-20. These qualitative findings indicated the importance of addressing homophobia and racism in primary prevention efforts, therefore theories of sexual minority stress, racial identity development and stigma management were also integrated into the intervention (p. 4).
Materials used	Cartoon vignettes were used in each session, in which a fictitious young MSM managed his sexual health against a backdrop of personal, family-based and relational challenges (p. 4).
Procedures used	The intervention is a manualised curriculum consisting of 6 modular, interactive group sessions which consisted of brief lectures, demonstrations, group exercises, small and large group discussions, and role plays. As adolescent behaviour is highly peer influenced, the small group sessions enhanced opportunities for prosocial peer feedback regarding sexual health behaviour. Session content was as follows: 1. Introduction and communication: intervention overview, HIV/STI epidemiology in YMSM, discuss effective interpersonal communication 2. HIV/AIDS and STIs: discuss safe sex specific to YMSM, effective condom use, distinction between viral, bacterial and parasitic STIs. 3. Managing minority stress: discuss minority stress, its influence on motivation to practice safer sex, and role-play safer sex strategies in situations involving minority stress.

	4. Affect and emotion regulation: discuss the influence of emotion regulation on motivation to practice safer sex, and role-play safer sex strategies related to session content. 5. Interpersonal and substance-related risk factors: discuss the influence of partner communication and substance use on motivation to practice safer sex, and role-play safer sex strategies related to session content. 6. Goal-making and wrap up: review intervention content, develop personal risk reduction plans, and identify strategies to overcome barriers to success. (p. 4; 16)
Provider	Two gay/bisexual male facilitators, both of whom had extensive experience leading group-based interventions among LGBT youth (p. 4)
Method of delivery	Face to face small group sessions (5-10 participants per group) (p. 4).
Setting/location of intervention	An LGBT community health centre (p. 4)
Intensity/duration of the intervention	Six 2-hour sessions delivered twice weekly for 3 weeks (p. 4).
Tailoring/adaptation	None reported
Unforeseen modifications	None reported
Planned treatment fidelity	Not reported
Actual treatment fidelity	Not reported

Control (N = 43)

Time-matched group level intervention focusing on HIV risk reduction but relying on lecture format and didactic delivery (not interactive, content not tailored to male-male sex).

Brief name	Time-matched control (p. 5)
Materials used	No specific materials reported
Procedures used	The control condition consisted of a group-level intervention that also focused on HIV risk reduction but relied entirely on lecture format using slideshows and led by one facilitator so was largely didactic. Session content was as follows: 1. STIS: present distinctions between viral, bacterial, and parasitic STIs, and information regarding the course and symptomology of STIs. 2. HIV myths and facts: distinguish factual information from common misconceptions and beliefs about HIV transmission and treatment. 3. What are HIV and AIDS? define HIV and AIDS, and describe the biological and behavioural modes of HIV transmission. 4. Who's most at risk for HIV infection? Highlight populations most vulnerable to HIV infection, including YMSM. Present HIV/AIDS epidemiology in YMSM. 5. HIV prevention: Describe abstinence and methods of safer sex behaviour, including condom use, and the effectiveness of each method at preventing HIV transmission. 6. HIV treatment options: Describe treatment options for HIV and notable side effects of medications to treat HIV. (p. 5; 16).
Provider	One facilitator; no details provided on facilitator characteristics (p. 5).
Method of delivery	Face to face small group sessions with 5-10 participants (p. 5).
Setting/location of intervention	An LGBT community health centre (the same building as intervention sessions) (p. 5).
Intensity/duration of the intervention	Six 2-hour sessions delivered twice weekly for 3 weeks (p. 4).
Tailoring/adaptation	Not reported

Unforeseen modifications	None reported
Planned treatment fidelity	Not reported
Actual treatment fidelity	Not reported

Risk of Bias Assessment

Section	Risk of Bias	Reason
Domain 1: Bias arising from the randomisation process	Low	Appropriate randomisation procedures and no baseline differences between groups
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Some concerns	No information on participant blinding and ITT not used, but deviations from intended intervention unlikely
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	Some concerns	Intervention adherence was fairly low (only ~60% completed at least 3 of the 6 sessions) but number of sessions attended was used as a covariate in the analyses to control for differences in levels of intervention exposure)
Domain 3. Bias due to missing outcome data	Some concerns	High attrition (only 61% completed both 6- and 12-week follow ups; 74% completed any follow-up) and while attrition did not differ by group, no analyses of completers vs non completers were reported
Domain 4. Bias in measurement of the outcome	Low	Outcomes assessed using CASI for both groups
Domain 5. Bias in selection of the reported result	Low	Trial registered and data analysed in accordance with pre-specified plan
Overall bias and Directness	Some concerns	No information on participant blinding; ITT analyses not used; low intervention adherence; relatively high attrition
	Overall Directness	Partially applicable (US study)

Parsons, 2014

Bibliographic Reference	Parsons, Jeffrey T; Lelutiu-Weinberger, Corina; Botsko, Michael; Golub, Sarit A; A randomized controlled trial utilizing motivational interviewing to reduce HIV risk and drug use in young gay and bisexual men.; Journal of consulting and clinical psychology; 2014; vol. 82 (no. 1); 9-18

Study details

Study design	Randomised controlled trial (RCT)
Trial registration number	Not reported
Study start date	Sep-2007
Study end date	Aug-2010
Aim	To test a brief Motivational Interviewing (MI) intervention to reduce both risky sex and drug use among HIV negative young gay and bisexual men (YGBM).
Country/geographical location	New York City, USA
Setting	Research centre
Inclusion criteria	- Male - Resided in the New York City metropolitan area - Age 18-29 years - Reported negative or unknown HIV status - Reported at least 5 days of drug use (specifically cocaine, methamphetamine, gamma hydroxybutyrate, ecstasy, ketamine or poppers) in the last 90 days

	- Reported at least one incident of UAI with a high risk male partner (HIV+ or unknown serostatus main partner, or a casual partner of any HIV status) in the last 90 days
Exclusion criteria	None reported
Method of randomisation	Participants were randomised using urn randomisation procedures, which are systematically biased in favour of balancing groups.
Method of allocation concealment	Urn randomisation
Unit of allocation	Participant
Unit of analysis	Participant
Statistical method(s) used to analyse the data	- The analytic sample was limited to YGBM who reported at least one incident of anal sex with a casual male partner in the last 30 days prior to the baseline assessment. - All participants who had a main partner that was HIV-positive at baseline (n=5) were excluded from these analyses because there was an insufficient number of serodiscordant couples in the sample to include for moderation effects in the models. - Participants who reported only having sex with their main partner 30 days prior to baseline (n = 9) were also excluded from analyses because the focus of the intervention was on reduction of UAI with casual sex partners. - Comparability of demographics, drug use, and UAI risk after baseline intervention assignment were assessed using Chi-square and Fisher exact tests for categorical variables and student t-tests for continuous variables. - Generalised Estimating Equation (GEE) Modeling techniques were used to assess change in aggregated days of drug use and acts of UAI within each quarterly reporting period across conditions and time. - All analyses were conducted using SPSS version 19.0.
Attrition	**<u>Uptake</u>** Of 1282 eligibility phone screenings, 266 men provided informed consent and completed the baseline assessment. Of those, 143 were randomised. Of the 123 not randomised, 66 were found to be ineligible and 57 declined randomisation.

	There were no significant differences in demographics or primary outcome variables between those who agreed to randomisation and those who declined. **Attrition** In the intervention condition (n=73), follow-up rates were 83.6% (n=61) at 3 months, 74% (n=54) at 6 months, 75.3% (n=55) at 9 months, and 80.8% (n=59) at 12 months. In the control condition (n=70), follow-up rates were 88.6% (n=62) at 3 months, 78.6% (n=55) at 6 months, 81.4% (n=57) at 9 months, and 77.1% (n=54) at 12 months. Between-condition sample retention rates did not differ significantly at any assessment point. The number of sessions completed did not differ significantly between the intervention and control conditions (M=3.6, SD=0.8 and M=3.5, SD=1.0, respectively).
Study limitations (author)	- The inclusion criteria required that self-reported UAI occurred in the past 90 days, whereas the analyses focused on the 30-day timeline follow-back (TLFB) data, given that only this time period was assessed at a day level. The 60 days prior to these 30 days were reviewed with each participant in a summary manner; therefore, day-level sexual behaviour and substance use data were not available for a longer period of assessment. - Additionally, because the time period for eligibility was the past 90 days, and day-level analyses examined the past 30 days, 14% of control participants and 18% of intervention participants did not report UAI in the past 30 days. Similarly, 20% of control participants and 18% of intervention participants did not report drug use in the past 30 days at baseline. Consequently, reductions in risk behaviour may have been underestimated in the analyses, given that it was not possible to account for the entire sample's risk behaviour. - Study outcomes were based on self-report, which could generate unreliable data. In order to increase accuracy of self-report of sensitive data, participants were allowed to report on various behaviors via ACASI, which can increase participants' level of comfort and minimise socially desirable answers. Further, all staff underwent extensive training on participant interaction issues, especially around eliciting accurate data in a sensitive and non-judgmental manner.
Study limitations (reviewer)	The paper did not report mean or SDs for participant's age; only the range (18-29).

Source of funding	The Young Men's Health Project was supported by a grant from the National Institute on Drug Abuse (NIDA) (R01-DA020366, Jeffrey T. Parsons, Principal Investigator).

Study arms

Intervention (N = 73)

Four sessions of Motivational Interviewing focusing on club drugs and the risks of UAI with casual male partners.

Control (N = 70)

Four sessions of content-matched education about club drug use and HIV sexual risk reduction.

Characteristics

Study-level characteristics

Characteristic	**Study (N = 143)**
Age Range	18 to 29
Gender Male Sample size	n = 143 ; % = 100

Arm-level characteristics

Characteristic	Intervention (N = 73)	Control (N = 70)
Ethnicity		
White	n = 30 ; % = 41.1	n = 23 ; % = 32.9
Latino	n = 18 ; % = 24.7	n = 23 ; % = 32.9
Black	n = 17 ; % = 23.3	n = 13 ; % = 18.6
Other/Mixed	n = 8 ; % = 10.1	n = 11 ; % = 15.7
Sexual orientation		
Gay	n = 67 ; % = 91.8	n = 64 ; % = 91.4
Bisexual	n = 6 ; % = 8.2	n = 6 ; % = 8.6
Substance use in prior 30 days		
Any cocaine	n = 48 ; % = 65.8	n = 49 ; % = 70
Any ecstasy	n = 22 ; % = 30.1	n = 22 ; % = 31.4
Any methamphetamine	n = 13 ; % = 17.8	n = 11 ; % = 15.7
Any GHB	n = 8 ; % = 11	n = 7 ; % = 10
Any ketamine	n = 7 ; % = 9.6	n = 6 ; % = 8.7

Outcomes

Study timepoints

- Baseline
- 3 month
- 6 month
- 9 month
- 12 month

Condom use outcomes

Outcome	Intervention, Baseline, N = 73	Intervention, 3 month, N = 61	Intervention, 6 month, N = 54	Intervention, 9 month, N = 55	Intervention, 12 month, N = 59	Control, Baseline, N = 70	Control, 3 month, N = 62	Control, 6 month, N = 55	Control, 9 month, N = 57	Control, 12 month, N = 54
Any UAI With a casual partner; during prior 30 days No of events	n = 60 ; % = 82.2	n = 33 ; % = 54.1	n = 25 ; % = 46.3	n = 25 ; % = 45.5	n = 18 ; % = 30.5	n = 60 ; % = 85.7	n = 35 ; % = 56.5	n = 29 ; % = 52.7	n = 35 ; % = 61.4	n = 22 ; % = 48.1
Any UAI while under the influence of drugs or alcohol with a casual partner;	n = 62 ; % = 84.9	n = 35 ; % = 57.4	n = 31 ; % = 57.4	n = 33 ; % = 60	n = 28 ; % = 47.5	n = 61 ; % = 87.1	n = 42 ; % = 67.7	n = 36 ; % = 65.5	n = 43 ; % = 75.4	n = 32 ; % = 59.3

Outcome	Intervention, Baseline, N = 73	Intervention, 3 month, N = 61	Intervention, 6 month, N = 54	Intervention, 9 month, N = 55	Intervention, 12 month, N = 59	Control, Baseline, N = 70	Control, 3 month, N = 62	Control, 6 month, N = 55	Control, 9 month, N = 57	Control, 12 month, N = 54
during prior 30 days No of events										

Any UAI - Polarity - Lower values are better

Any UAI while under the influence of drugs or alcohol - Polarity - Lower values are better

Study details

Brief name	The Young Men's Health Project (YMHP) (p. 3)
Rationale/theory/Goal	Young gay and bisexual men (YGBM) are at disproportionate risk of HIV infection, with 73% of new infections among 13-24 year old males in the US being attributed to male-to-male sexual transmission. YGBM who use recreational drugs are particularly susceptible to HIV infection. YGBM who use drugs and engage in UAI are in critical need of behavioural interventions, although engaging this population in interventions has been proven to be difficult due to several factors (including generational shifts in perception of HIV threat, YGBM who engage in episodic drug use and sexual risk may be unresponsive to studies that they believe target those with 'serious' problems, and socio-cultural changes that may differentially impact risk for GBM of different generations). Non-treatment seeking YGBM need to be targeted in a way that is not threatening and reaches those who are ambivalent about changing their risk behaviour (p. 2).
Materials used	
Procedures used	- YGBM were recruited through a multi-method approach using both active and passive recruitment strategies. For active recruitment, recruiters screened potential participants for eligibility using Palm Pilots in a variety of venues catering to YGBM - including bars, clubs, sex venues, streets in predominately gay neighborhoods, and at LGBT community events. For passive recruitment, tear-off flyers and project recruitment cards were distributed to potential participants or left on

	premises, and advertisements were placed in gay and non-gay publications. These approaches were supplemented with internet-based efforts (recruitment via chat rooms and banner advertisements) and friendship referrals. - Contact information from potential participants was used to conduct a more thorough second eligibility screening over the phone. Those eligible and interested were scheduled for a baseline appointment. - After obtaining informed consent, baseline assessments were conducted using ACASI for psychosocial characteristics and an interviewer-administered timeline followback (TLFB) calendar for substance use and sexual behaviours. - Different staff members were used for TLFB assessments and delivery of intervention and control sessions. Assessors were blind to condition as randomisation occurred after the baseline assessment. - The first intervention or control sessions occurred immediately after the baseline assessment. - Participants returned for follow-up assessments at 3, 6, 9 and 12 months post-baseline. (p. 3-4).
Other details	Participants were compensated $40 for the 2 hour baseline assessment, and this amount increased by $5 for each subsequent follow-up (p. 4).

Study arms

Intervention (N = 73)

Four sessions of Motivational Interviewing focusing on club drugs and the risks of UAI with casual male partners.

Brief name	The Motivational Interviewing Intervention (MI) (p. 4)
Rationale/theory/Goal	MI is an intervention approach ideally suited to non-treatment seeking YGBM because it is a collaborative, participant-centred therapeutic approach to strengthening motivation to change. It has been validated empirically across several problem behaviours but research is inconclusive regarding the effects of MI for HIV negative GBM, and further investigation is needed to determine its efficacy among HIV negative substance-using YGBM (p. 2-3).

	The MI intervention was designed to provide information about club drugs and the risk of UAI with casual male partners; to enhance motivation and personal responsibility; and establish goals for reducing both target behaviours (p. 4).
Materials used	No specific materials reported
Procedures used	Session 1 - Therapist provided an overview of the MI approach; emphasis on understanding participants' readiness for change rather than pressurising change. - Participants asked to choose which target behaviour to focus on first (substance use or UAI) and therapist elicited participants' view of the behaviour using MI techniques. - Focus on contemplation of, or commitment to, change; completion of a plan for change including goals and potential barriers. Session 2 - Similar format to session 1 but focusing on the other target behaviour not yet addressed. - Therapist provides structured personalised feedback on both behaviours and how they may interact - Participants complete staging ruler and decisional balance exercises relating to their perceptions of risks and benefits for both behaviours Session 3 - Therapist reviewed progress in ambivalence or readiness for change; addressed motivation; affirmed gains and commitment. - Re-examine goals and decisional balance for both behaviours Session 4

	- Final review and revisions of participant's goals and change plan; discussion around relapse prevention. - Emphasis on self-efficacy for attaining goals - Continued discussion of connection between substance use and UAI - Review of community resources and support services available. Individualised referral list. (p. 5)
Provider	MI sessions were delivered by Masters- and PhD-level therapists who participated in a three-day MI training delivered by the Principal Investigator, engaged in 2-3 pilot cases, and received weekly individual and group supervision throughout the project. There were 12 different therapists and post hoc analyses showed no differences in primary outcomes by therapist assignment (p. 4).
Method of delivery	Face to face, one-to-one sessions (p. 4)
Setting/location of intervention	Research centre (p. 3)
Intensity/duration of the intervention	Four 1-hour sessions. Participants had a window of 12 weeks to complete all 4 sessions (p. 4).
Tailoring/adaptation	Not reported
Unforeseen modifications	None reported
Planned treatment fidelity	- All MI sessions were video recorded and therapists met bi-weekly in supervision to view videotapes and discuss implementation issues. Eighty percent of all MI sessions were reviewed by a licensed clinical psychologist with expertise in MI. - Fidelity was addressed throughout the trial through the use of the Motivational Interviewing Treatment Integrity (MITI) coding system (Moyers, Martin, Manuel, Miller, & Ernst, 2007).

	- Ten members of the MITI Coding Team coded sessions. To ensure reliability, each rater coded the same 20-minute portion of a taped session. The intraclass correlation for this coded segment was shown to be highly reliable (Cronbach =.97; intraclass correlation average = 0.97). The MITI codes were also used to provide feedback to the supervisor and therapists on the quality of delivery of MI throughout the trial, in order to reduce therapist drift and sustain fidelity. (p. 4-5)
Actual treatment fidelity	Not reported

Control (N = 70)

Four sessions of content-matched education about club drug use and HIV sexual risk reduction.

Brief name	Education control (p. 5)
Materials used	Educational videos focusing on HIV sexual risk reduction (p. 5)
Procedures used	- This intervention provided factual information about club drug use and HIV sexual risk reduction. - Each session followed a detailed schedule including educational video segments that incorporated standard HIV sexual risk reduction messages and factual information about the physical and cognitive effects of club drugs, and the link between club drug use and high risk sex. - Structured discussion was also used to deliver material. - All session content focused on objective, factual information. (p. 5)
Provider	Educators rigorously trained in the content and delivery procedures for each session, completed mock sessions, and received feedback prior to delivering sessions to participants (p. 5)

Method of delivery	Face to face one-to-one sessions (p. 5)
Setting/location of intervention	Research centre (p. 3)
Intensity/duration of the intervention	Four 1-hour sessions. Participants had a window of 12 weeks to complete all 4 sessions (p. 4).
Tailoring/adaptation	None reported
Unforeseen modifications	None reported
Planned treatment fidelity	Educators attended regular supervision meetings to ensure fidelity to protocol. Approx 80% of all education sessions were viewed and individual feedback was provided to each educator on their delivery style and material coverage (p. 5).
Actual treatment fidelity	Not reported

Risk of Bias Assessment

Section	Risk of Bias	Reason
Domain 1: Bias arising from the randomisation process	Low	Appropriate randomisation procedures and no baseline differences between groups
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Some concerns	No information on participant blinding and ITT not used, but deviations from intended intervention unlikely
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	Low	Good adherence (participants attended mean 3.5 and 3.6 out of 4 sessions) and individual sessions led by trained facilitator so deviations from manual unlikely
Domain 3. Bias due to missing outcome data	Low	Moderately low attrition (80.8% and 77.1% retention at 12 months follow-up) and no differential attrition by group
Domain 4. Bias in measurement of the outcome	Low	Appropriate outcome measures assessed using timeline followback (TLFB) methods; assessors blind to condition.)
Domain 5. Bias in selection of the reported result	Some concerns	Trial not registered

Section	Risk of Bias	Reason
Overall bias and Directness	Some concerns	No information on participant blinding and ITT not used, but deviations from intended intervention unlikely and intervention adherence good. Trial not registered
	Overall Directness	Partially applicable (US study)

D.9 Effectiveness evidence for men from a Black African or Caribbean family background who have sex with men

Arnold, 2019

Bibliographic Reference	Arnold, Emily A; Kegeles, Susan M; Pollack, Lance M; Neilands, Torsten B; Cornwell, Stephanie M; Stewart, William R; Benjamin, Michael; Weeks, John; Lockett, Gloria; Smith, Carla Dillard; Operario, Don; A Randomized Controlled Trial to Reduce HIV-Related Risk in African American Men Who Have Sex with Men and Women: the Bruthas Project.; Prevention science : the official journal of the Society for Prevention Research; 2019; vol. 20 (no. 1); 115-125

Study details

Study design	Randomised controlled trial (RCT)
Trial registration number	The trial was registered at Clinicaltrials.gov (NCT01270230)
Study start date	Feb-2011
Study end date	May-2014
Aim	To evaluate the effects of the *Bruthas Project* on HIV risk behaviour among African American men who have sex with men and women (MSMW) who do not identify as gay/homosexual or bisexual.
Country/geographical location	San Francisco Bay Area, USA

Setting	Private mobile clinics or the project office.
Inclusion criteria	- At least 18 years old - Identifying as cis-gender male - Living in the San Francisco Bay Area - Had sex (anal, vaginal or oral) with at least one male and one female in the past 12 months - Not currently enrolled in another HIV prevention intervention program - Individuals who identified as HIV-negative, status unknown, and HIV-positive were all eligible
Exclusion criteria	None reported
Method of randomisation	Participants were randomised to condition by a research assistant using a pre-determined randomisation pattern produced by a computer algorithm. To ensure the intervention and control groups were balanced, a separate randomisation pattern was executed for each of 4 groups defined through simultaneous stratification of potential participants by HIV status (HIV-negative/HIV-unknown vs. HIV-positive) and baseline sexual risk behaviour (condomless anal intercourse with a male partner in the past 3 months vs. no condomless anal intercourse in the past 3 months).
Method of allocation concealment	Randomisation pattern was generated by computer algorithm
Unit of allocation	Participant
Unit of analysis	Participant
Statistical method(s) used to analyse the data	- Prior to data collection, it was estimated that a minimum of n=170 individuals per group would be needed for analysis under the assumptions of power (1-β)=0.80, α=0.05, three observational assessments per individual, and a Cohen h statistic effect size range from 0.2 to 0.3. - All statistical analyses were performed using algorithms in Stata Version 14 which employ maximum likelihood estimation of parameters in mixed effects models.
Attrition	N=396 men were enrolled into the study and randomised to the intervention (n=199) or control (n=197) conditions.

	In the intervention group, n=160 (80%) completed the 6-month follow up and n=166 (83%) completed the 9-month follow up In the control group n=150 (76%) completed the 6-month follow up and n=153 (78%) completed the 9-month follow up There were no significant differences in attrition between intervention and control condition.
Study limitations (author)	- Because the study design involved a highly active control group, it was not possible to compare behaviour changes in the single-session counselling and testing control condition or supplemental 4-session Bruthas intervention condition compared with a non-active control (e.g., no-treatment or delayed control). - Biological assessments of HIV or STI at 6- or 9-month follow-up we not used, so findings rely on self-report. - Assessments did not include measures that might have better captured secondary outcomes related to intervention content such as relationship dynamics and communication, as well as awareness of situational triggers of condomless sex.
Study limitations (reviewer)	The study is described as an RCT involving African American MSMW but the stated eligibility criteria do not refer to African American race/ethnicity. The race/ethnicity of the sample is also not described with all other sample characteristics.
Source of funding	Funding was received from the National Institutes of Health to conduct this study, NIH/NIMH R01 MH090899 (PI: Arnold); NIH/NCRR CTSI UTLITR00004.

Study arms

Intervention (N = 199)

The Bruthas Intervention: a behavioural HIV prevention program for African American MSMW who do not identify as gay/homosexual or bisexual.

Control (N = 197)

Single session, culturally appropriate HIV testing and counselling.

Characteristics

Arm-level characteristics

Characteristic	Intervention (N = 199)	Control (N = 197)
Age Mean (SD)	46.41 (9.33)	45.39 (9.93)
Homeless in past year	n = 107 ; % = 54	n = 96 ; % = 48.7
Incarceration history		
Never	n = 18 ; % = 9.1	n = 12 ; % = 6.1
> 3 months ago	n = 156 ; % = 78.3	n = 150 ; % = 76
In past 3 months	n = 25 ; % = 12.6	n = 35 ; % = 17.9
Serostatus		
HIV-negative	n = 164 ; % = 82.4	n = 166 ; % = 84.3
HIV-positive	n = 35 ; % = 17.6	n = 31 ; % = 15.7

Outcomes

Study timepoints

- Baseline
- 6 month
- 9 month

Condom use outcomes

Outcome	Intervention, Baseline, N = 199	Intervention, 6 month, N = 199	Intervention, 9 month, N = 199	Control, Baseline, N = 197	Control, 6 month, N = 197	Control, 9 month, N = 197
Mean number of condomless intercourse events with any partner In prior 3 months. Includes men, women and transwomen Mean (SD)	17.02 (*empty data*)	11.54 (*empty data*)	8.77 (*empty data*)	14.73 (*empty data*)	8.58 (*empty data*)	8.66 (*empty data*)
Mean number of condomless intercourse events with any main partner In prior 3 months. Includes men, women and transwomen Mean (SD)	7.81 (*empty data*)	7 (*empty data*)	6.87 (*empty data*)	4.78 (*empty data*)	5.48 (*empty data*)	5.93 (*empty data*)
Mean number of condomless intercourse events with any casual partner In prior 3 months. Includes men, women and transwomen Mean (SD)	9.22 (*empty data*)	4.78 (*empty data*)	1.92 (*empty data*)	9.77 (*empty data*)	3.16 (*empty data*)	2.7 (*empty data*)

Mean number of condomless intercourse events with any partner - Polarity - Lower values are better

Mean number of condomless intercourse events with any main partner - Polarity - Lower values are better

Mean number of condomless intercourse events with any casual partner - Polarity - Lower values are better

TIDier Checklist

Study details

Brief name	
Rationale/theory/Goal	A growing body of research brings attention to African American MSM who also have sex with women but do not identify as gay/homosexual or bisexual. Evidence indicates high levels of condomless sex with both male and female partners. Given the complexity of the sexual lives of this population, their dense social and sexual networks, and continued risk for HIV, culturally sensitive prevention programs that meet the unique needs of this population continue to be needed, particularly as existing HIV prevention approaches for MSM may focus explicitly on sexual orientation categories and identities. In particular, African American MSMW who do not identify as gay or bisexual are unlikely to participate in programs that prioritise gay identity. A behavioural HIV prevention intervention for African American MSMW who do not identify as gay/homosexual or bisexual is therefore warranted (p. 2-3)
Procedures used	- With input from a community advisory board, community and commercial venues (e.g., parks, nightclubs, bars), street locations, and non-profit and health service agencies where members of the target population gather were identified. Using mobile units, participants were recruited from outside nightclubs, parks, and street locations. Informational fliers about the research study were also disseminated and contained contact information for the project office. - Potential participants were informally screened on the street and then invited inside private mobile clinics or to the project office for formal computer-based screening and study intake. Everyone who screened as eligible was enrolled. - After providing informed consent, participants completed a baseline survey using audio computer-assisted self-interviewing (ACASI) and provided personal contact information. Participants were then randomised to the intervention or control condition by a research assistant. - Participants who self-reported being HIV-negative or status-unknown in the baseline survey then completed rapid HIV testing and counselling with trained project staff, who were African American men themselves. One participant tested positive for HIV during this process and was immediately referred to confirmatory testing and care, but remained enrolled in the study.

	- Participants randomly assigned to the intervention group received schedules for subsequent counselling sessions, and all participants received schedules for 6- and 9- month follow-up assessments. Phone calls were made to all participants after 3-months to update their contact information and to remind them of the time and location of follow-up assessments (p. 5).
Other details	Participants received $35 for each survey assessment and counselling session completed.

Study arms

Intervention (N = 199)

The Bruthas Intervention: a behavioural HIV prevention program for African American MSMW who do not identify as gay/homosexual or bisexual.

Brief name	The Bruthas Project (p. 1)
Rationale/theory/Goal	The development of he Bruthas Project was guided by principles of community-based participatory research, and is based on the IMB model of health behaviour change. As research has indicated that MSMW who do not identify as gay or bisexual prioritise secrecy about their same sex behaviours and prefer not to disclose their sexuality in group settings, intervention format was via individual counselling sessions. It was designed to be delivered in conjunction with culturally sensitive HIV testing and counselling services in community based settings, providing space for men to discuss their HIV related risk behaviours with a trained peer educator. Sessions addressed principles of HIV and STI transmission risk, HIV testing behaviours, contextual and relationship factors related to sex with both male and female partners, and motivational or situational triggers of condomless sex such as loneliness, anxiety or drug use (p. 3-4).
Materials used	No specific materials reported
Procedures used	**Intake session:** included rapid HIV testing and counselling, which featured discussion of general HIV and STI risk factors, condom use, and recognising personal risk. This content was tailored from standardized testing and counselling to be specific to MSMW. Emphasis on non-judgemental approach to complex sexual partnerships and interactions. **Session 1:** covered information about the local epidemic; a personal risk assessment including discussion of relationships and sexual communication; a condom demonstration; and the importance of regular testing.

	Session 2: addressed sexual risk behaviours and routes for HIV transmission with female partners, as well as relationship dynamics with main female sex partners and casual female sex partners. **Session 3:** addressed sexual risk behaviour and routes for HIV transmission with male partners, as well as relationship dynamics with main male sex partners and casual male sex partners. **Session 4:** addressed situational contexts and motivational "triggers" for condomless sex with female and male partners (both main and casual), and concluded with a specific individualised plan for reducing HIV-related risk behaviour according to gender and type of partner. Counsellors were trained in principles of motivational counselling (e.g., using affirming and non-judgmental language and reinforcement) and were instructed to not make assumptions about participants' sexual identity or orientation in all sessions. Sessions 2-4 included interactive role play scenarios in which participants described their responses to realistic sexual episodes with female and male partners. Counsellors provided supportive feedback and reinforcement about engaging in lower risk behaviours. As "homework" assignments between sessions 2-4, participants were asked to practice behavioural risk reduction skills with their partners. (p. 5-6)
Provider	Trained African American male counsellors (p. 5)
Method of delivery	Face to face individual sessions (p. 5)
Setting/location of intervention	Private mobile clinics or the project office (p. 4)
Intensity/duration of the intervention	Four sessions (duration not reported), delivered once every two weeks over approximately 3 months (p. 5)
Tailoring/adaptation	The content was tailored to MSMW (p. 5)
Unforeseen modifications	None reported
Planned treatment fidelity	Not reported
Actual treatment fidelity	Not reported

Control (N = 197)

Single session, culturally appropriate HIV testing and counselling.

Procedures used	Control participants completed only the culturally tailored HIV testing and counselling, which featured a general discussion of HIV and STI risk factors, condom use, the importance of knowing one's HIV status, and recognising personal risk. This was based on standardised HIV testing and counselling, but tailored to African American MSMW in that it included non-judgemental and open discussion of sexual activities with both men and women (p. 6).
Provider	Not reported
Method of delivery	Face to face individual session (p. 6)
Setting/location of intervention	Private mobile clinics (p. 5)
Intensity/duration of the intervention	N/A
Tailoring/adaptation	HIV testing and counselling was tailored to African American MSMW (p. 6)
Unforeseen modifications	None reported
Planned treatment fidelity	N/A
Actual treatment fidelity	N/A

Risk of Bias Assessment

Section	Risk of Bias	Reason
Domain 1: Bias arising from the randomisation process	Low	Appropriate randomisation procedures and no baseline differences between groups
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Low	

Section	Risk of Bias	Reason
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	Low	
Domain 3. Bias due to missing outcome data	Some concerns	Moderate attrition at 9 months (83% retained in intervention group; 78% retained in the control group); no comparison of those retained and those lost to follow up, but attrition did not significantly differ by group
Domain 4. Bias in measurement of the outcome	Low	
Domain 5. Bias in selection of the reported result	Low	Trial registered and analyses completed in line with those specified in the protocol
Overall bias and Directness	Some concerns	Moderate attrition at 9 months (83% retained in intervention group; 78% retained in the control group); no comparison of those retained and those lost to follow up, but attrition did not significantly differ by group
	Overall Directness	Partially applicable (US study)

Eaton, 2018

Bibliographic Reference	Eaton, Lisa A; Kalichman, Seth C; Kalichman, Moira O; Driffin, Daniel D; Baldwin, Robert; Zohren, Larissa; Conway-Washington, Christopher; Randomised controlled trial of a sexual risk reduction intervention for STI prevention among men who have sex with men in the USA.; Sexually transmitted infections; 2018; vol. 94 (no. 1); 40-45

Study details

Study design	Randomised controlled trial (RCT)
Trial registration number	Clinicaltrials.gov (NCT02128594)

Study start date	Dec-2012
Study end date	Nov-2014
Aim	To test the impact of a single session intervention focusing on sexual risk decision making and the limitations of serosorting, on sexual risk behaviours and STIs in MSM.
Country/geographical location	Atlanta, USA
Setting	A community based research site.
Inclusion criteria	- 18 years old or older - assigned male gender at birth and identify as male or transgender female - report HIV negative or unknown serostatus - report 2 or more male sex partners in the past year - report condomless anal sex in the past year
Exclusion criteria	None reported
Method of randomisation	Randomisation software
Method of allocation concealment	Not reported
Unit of allocation	Participant
Unit of analysis	Participant
Statistical method(s) used to analyse the data	- Descriptive data provided for all study variables: means and SDs, or numbers and percentages. - For all analyses, generalised estimating equations (GEE) were conducted using a negative binomial distribution for count data, a binary logistic distribution for dichotomous data and a linear distribution for normal data.

	- Intent-to-treat data-analytic approach employed. - Baseline behavioural data entered as covariates, and condition, time and condition×time were modelled. - IBM SPSS Statistics V.21.0 was used for all analyses
Attrition	**<u>Uptake</u>** Of n=1719 people eligible for the study, n=719 declined or did not show for the baseline assessment. **<u>Attrition</u>** N=600 consented to participate. 1 withdrew, 1 was removed and 1 had missing data, so n=300 were randomised to the intervention group and n=297 were randomised to the control group. *Intervention:* 3 month follow-up 89% 6 month follow-up 85% 12 month follow-up 82% *Control* 3 month follow-up 85% 6 month follow-up 87%

	12 month follow-up 85%
Study limitations (author)	- Findings are limited to a sample of MSM reporting sexual risk taking and residing in and around the Atlanta, Georgia, USA area and may not be generalisable to all MSM. - The effect of the experimental intervention may have been muted by using a control arm focused on sexual risk reduction. - Lab-based STI testing focused on chlamydia and gonorrhoea only, therefore intervention effects on other biologically assessed STIs were not included.
Study limitations (reviewer)	None to add
Source of funding	This study was funded by the National Institutes of Health grants R01MH094230, R01NR013865 and P30AI050409 (Emory University Center for AIDS Research).

Study arms

Intervention (N = 300)

A single-session, Conflict Theory of Decision Making (CTDM)-based intervention focused on sexual risk decision making including the limitations of serosorting

Control (N = 297)

A single-session, Centers for Disease Control and Prevention (CDC)-based, sexual risk reduction intervention

Characteristics

Arm-level characteristics

Characteristic	Intervention (N = 300)	Control (N = 297)
Age Mean (SD)	35.36 (11.95)	33.77 (12.06)
Male	n = 274 ; % = 91.3	n = 280 ; % = 94.3
Transgender female	n = 26 ; % = 8.7	n = 17 ; % = 5.7
Race / Ethnicity		
Black	n = 263 ; % = 87.7	n = 267 ; % = 89.9
White	n = 20 ; % = 6.7	n = 17 ; % = 5.8
Asian	n = 1 ; % = 0.3	n = 0 ; % = 0
Other	n = 16 ; % = 5.3	n = 13 ; % = 4.4
Hispanic	n = 5 ; % = 1.7	n = 8 ; % = 2.7
Gender identity		
Same gender loving / gay	n = 129 ; % = 43.6	n = 131 ; % = 44.4
Bisexual	n = 126 ; % = 42.6	n = 117 ; % = 39.7
Heterosexual	n = 41 ; % = 13.9	n = 47 ; % = 15.9
Relationship status		

Characteristic	Intervention (N = 300)	Control (N = 297)
Single	n = 230 ; % = 71	n = 215 ; % = 72.4
In a relationship with no outside partners	n = 31 ; % = 10.3	n = 33 ; % = 11.1
In a relationship with outside partners	n = 56 ; % = 18.7	n = 49 ; % = 16.5
PrEP use	n = 4 ; % = 1.3	n = 4 ; % = 1.3

Outcomes

Study timepoints

- 3 month
- 6 month
- 12 month

Condom use outcomes

Outcome	Intervention, 3 month, N = 267	Intervention, 6 month, N = 255	Intervention, 12 month, N = 246	Control, 3 month, N = 252	Control, 6 month, N = 258	Control, 12 month, N = 252
Proportion of anal sex acts with condom use In prior 3 months Mean (95% CI)	69.57 (69.3 to 69.9)	70.93 (70.7 to 71.2)	70.36 (70.1 to 70.7)	66.65 (66.4 to 66.9)	63.99 (63.7 to 64.3)	66.11 (65.8 to 66.4)

Outcome	Intervention, 3 month, N = 267	Intervention, 6 month, N = 255	Intervention, 12 month, N = 246	Control, 3 month, N = 252	Control, 6 month, N = 258	Control, 12 month, N = 252
Proportion of anal sex acts with condom use In prior 3 months Mean (SD)	69.57 (2.5)	70.93 (2.04)	70.36 (2.4)	65.65 (2.02)	63.99 (2.46)	66.11 (2.43)
Number of condomless sex acts In prior 3 months Mean (95% CI)	2.41 (2.33 to 2.49)	1.95 (1.88 to 2.01)	1.92 (1.85 to 1.99)	2.34 (2.26 to 2.42)	2.9 (2.8 to 3)	3.13 (3.02 to 3.24)
Number of condomless sex acts In prior 3 months Mean (SD)	2.41 (0.67)	1.95 (0.53)	1.92 (0.56)	2.34 (0.65)	2.9 (0.82)	3.13 (0.89)
Number of condomless anal insertive sex acts In prior 3 months Mean (95% CI)	1.27 (1.22 to 1.32)	0.98 (0.95 to 1.01)	0.92 (0.89 to 0.95)	1.14 (1.09 to 1.19)	1.94 (1.86 to 2.02)	2.12 (2.04 to 2.2)
Number of condomless anal insertive sex acts In prior 3 months Mean (SD)	1.27 (0.42)	0.98 (0.24)	0.92 (0.24)	1.14 (0.4)	1.94 (0.66)	2.12 (0.65)

Outcome	Intervention, 3 month, N = 267	Intervention, 6 month, N = 255	Intervention, 12 month, N = 246	Control, 3 month, N = 252	Control, 6 month, N = 258	Control, 12 month, N = 252
Number of condomless anal receptive sex partners In prior 3 months Mean (95% CI)	1.19 (1.15 to 1.23)	1.08 (1.03 to 1.13)	1 (0.96 to 1.04)	0.99 (0.95 to 1.03)	1 (0.96 to 1.04)	1.01 (0.97 to 1.05)
Number of condomless anal receptive sex partners In prior 3 months Mean (SD)	1.19 (0.33)	1.08 (0.41)	1 (0.32)	0.99 (0.32)	1 (0.33)	1.01 (0.32)

Proportion of anal sex acts with condom use - Polarity - Higher values are better

Number of condomless sex acts - Polarity - Lower values are better

Number of condomless anal insertive sex acts - Polarity - Lower values are better

Number of condomless anal receptive sex partners - Polarity - Lower values are better

Paper reports mean and 95%CIs; converted to mean and SD by analyst

STI incidence outcomes

Outcome	Intervention, 3 month, N = 267	Intervention, 6 month, N = 255	Intervention, 12 month, N = 246	Control, 3 month, N = 252	Control, 6 month, N = 258	Control, 12 month, N = 252
Self-reported STI diagnosis Self report of whether they had been diagnosed with chlamydia, gonorrhoea,	n = 42 ; % = 15.7	n = 45 ; % = 17.6	n = 32 ; % = 13.1	n = 55 ; % = 21.7	n = 50 ; % = 19.5	n = 43 ; % = 17

Outcome	Intervention, 3 month, N = 267	Intervention, 6 month, N = 255	Intervention, 12 month, N = 246	Control, 3 month, N = 252	Control, 6 month, N = 258	Control, 12 month, N = 252
syphilis, herpes or genital warts in the past 3 months No of events						
Lab diagnosed gonorrhoea or chlamydia Urine sample No of events	n = 4 ; % = 1.5	n = 5 ; % = 2.1	n = 6 ; % = 2.6	n = 12 ; % = 4.9	n = 6 ; % = 2.5	n = 9 ; % = 3.9
Lab diagnosed gonorrhoea or chlamydia Rectal swab No of events	n = 26 ; % = 10	n = 16 ; % = 6.7	n = 19 ; % = 8.2	n = 15 ; % = 6.1	n = 12 ; % = 4.9	n = 17 ; % = 7.3

Self-reported STI diagnosis - Polarity - Lower values are better

Lab diagnosed gonorrhoea or chlamydia - Polarity - Lower values are better

Lab diagnosed gonorrhoea or chlamydia - Polarity - Lower values are better

Participants self-collected urine samples and rectal swabs for gonorrhoea and chlamydia testing. Nucleic acid amplification tests (NAAT) were conducted for all STI tests.

TIDier Checklist

Study details

Rationale/theory/Goal	Serosorting, or limiting condomless sex acts to partners of the same HIV status, is commonly practiced among MSM yet can lead to STIs. Serosorting relies on having accurate information about HIV status which can be difficult to ascertain. Research on the overall effectiveness of serosorting for preventing HIV transmission is mixed, yet there is considerable evidence that reliance on serosorting can lead to HIV/STI transmission due to difficulties (e.g. infrequent HIV testing, acute HIV infection, misrepresentation of HIV status) in being certain of one's own and one's partner's HIV statuses and lack of explicit conversations around HIV status disclosure. Furthermore, serosorting does not explicitly address STIs, which can also exacerbate HIV transmission risks. This area of sexual risk taking could be addressed using a single-session intervention (p. 40).
Procedures used	Participants were recruited at LGBT identified venues (e.g. bars, clubs, parties), online sites (e.g. dating sites and apps), and over the phone through fliers and word of mouth. Prior to enrolment, all participants were tested for HIV using a rapid antibody test; all participants testing negative were offered enrolment into the trial, and all testing positive were linked to care. Participants completed baseline and 3-, 6-, and 12-month follow up appointments which included computerised assessments and STI testing (p. 41).
Provider	Intervention and control session counsellors were trained in client-centred counselling and motivational interviewing (p. 41)
Method of delivery	Face to face 1-to-1 session (p. 41)
Setting/location of intervention	Community-based research site (p. 41)
Other details	All participants were compensated US$45 for each assessment (p. 41)

Study arms

Intervention (N = 300)

A single-session, Conflict Theory of Decision Making (CTDM)-based intervention focused on sexual risk decision making including the limitations of serosorting

Rationale/theory/Goal	The intervention is based on the Conflict Theory of Decision Making (CTDM), which guides decision making under conditions of uncertainty by highlighting the importance of gathering all relevant information, weighing the costs and benefits of each possible decision, and choosing the decision that best represents an individuals needs. It is based on the perspective that individuals will benefit from greater risk awareness and understanding of behavioural risks posed to them, which will guide them to more effective behavioural decisions (p. 41).
Materials used	No specific materials reported
Procedures used	- The main focus of the intervention was to highlight misbeliefs about selecting sexual partners; to shape accurate beliefs and perceptions of risk about the use of serosorting for HIV/STI prevention; and to determine a practical, risk reduction strategy tailored for each participant. - A graphic novel was created to convey messages about serosorting. The novel depicted a fictitious (but evidence-based) story of a man who tests HIV negative, uses serosorting as an HIV prevention strategy and then tests HIV positive at the end of the story. This activity led to a discussion about how the main character could have become HIV positive (eg, acute HIV infection, non-explicit disclosure of HIV status, misrepresentation of HIV status, infrequent HIV testing) or transmitted HIV to his partners. - Guided by CTDM, the counsellor and participant worked together to identify and discuss these varying scenarios with a focus on what the main character could have done to reduce his risk for HIV. - Next, participants were asked to create a sexual network diagram providing information on their recent sex partners and sex acts. Participant diagrams were compared with the character's diagram, thereby allowing participants to observe how their behaviours related to those of an evidence-based character who tests HIV positive, and to reflect on instances in which they potentially exposed themselves to HIV/STI. - Participants used their sexual network diagram as a guide to forming a plan they could carry out to reduce their risks. Plans included increases in condom use, reductions in sex partners and acts, alternatives to condomless anal intercourse and greater inquiry into a sexual partner's HIV status and testing history. Thus, the participant along with the counsellor generated a menu of harm reduction options by weighing the relative costs and benefits of each and deciding on the optimal choice for the participant (p. 41).
Intensity/duration of the intervention	Single session lasting on average 45 minutes (p. 41)

Tailoring/adaptation	The intervention session was not specifically tailored but the risk reduction plan developed during the session was tailored to each participants (p. 41).
Unforeseen modifications	None reported
Planned treatment fidelity	Intervention sessions were audio-recorded and evaluated using a checklist rubric for fidelity (p. 41)
Actual treatment fidelity	Not reported

Control (N = 297)

A single-session CDC-based sexual risk reduction intervention (standard care)

Materials used	No specific materials reported
Procedures used	Participants in the control condition received a contact-matched, standard-of-care, HIV/STI risk-reduction counselling session consistent with CDC post-HIV test guidelines. The session was tailored to address sexual risk taking, safer sex practices, and inhibitors and triggers to sexual risk taking. Substance use in the context of sexual decision making was a primary focus. Counselling regarding serosorting-related practices was not included in order to avoid contamination with the experimental arm (p. 41).
Intensity/duration of the intervention	Attention-matched (45 minutes) (p. 41)
Tailoring/adaptation	Not reported
Unforeseen modifications	Not reported
Planned treatment fidelity	Not reported
Actual treatment fidelity	Not reported

Risk of Bias Assessment

Section	Risk of Bias	Reason
Domain 1: Bias arising from the randomisation process	Low	Randomisation software used; no baseline differences between groups
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Low	No information on blinding but control group received active control (CDC intervention). ITT used
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	Low	Intervention was 1 to 1 session with trained counsellors so deviation from intervention unlikely
Domain 3. Bias due to missing outcome data	Low	Low attrition
Domain 4. Bias in measurement of the outcome	Low	Outcomes assessed using computerised surveys or STI test results
Domain 5. Bias in selection of the reported result	Low	Trial registered and analyses completed in line with those specified in the protocol
Overall bias and Directness	Low	Appropriate randomisation procedures; no baseline differences; no concerns relating to intervention adherence; limited missing data; appropriate analyses
	Overall Directness	Partially applicable (US study)

Fernandez, 2016

Bibliographic Reference	A Randomized Controlled Trial of POWER: an Internet-Based HIV Prevention Intervention for Black Bisexual Men; AIDS and behavior; 2016; vol. 20 (no. 9); 1951-1960

Study details

Study design	Randomised controlled trial (RCT)
Trial registration number	Not reported
Study start date	Jun-2011
Study end date	Nov-2012
Aim	To test the efficacy of the POWER intervention in reducing sexual risk behaviours for Black MSMW.
Country/geographical location	Chicago, USA
Setting	Online delivery
Inclusion criteria	- Identified as a Black male (defined as being of African descent including African-American, Black Latino, Caribbean, African immigrant, and bi/multi-racial) - At least 18 years of age - Lived in the greater Chicago metropolitan area - Had both a male and a female sex partner in the past 12 months - Had two or more sex partners in the past 3 months - Had at least one episode of condomless sex with either a man or woman in the past 3 months
Exclusion criteria	- People who had injected drugs in the past 12 months - People who identified as transgender
Method of randomisation	Computer generated block randomisation; block size 10.
Method of allocation concealment	Computer generated randomisation.

Unit of allocation	Participant
Unit of analysis	Participant
Statistical method(s) used to analyse the data	- The main outcome variable was originally conceptualised as number of episodes of condomless vaginal or anal intercourse (CVAI) overall and stratified by partner gender and partner serostatus. However, because the distributions of these count variables were highly skewed, binary outcomes were created for use in these analyses (any CVAI vs. none). - An intent-to-treat approach was used and included the 6% of participants who completed the baseline assessment but did not attend any session. One participant assigned to the control group mistakenly received the POWER intervention; this participant was retained in the treatment condition to which he was originally assigned. - Participant characteristics at baseline were compared using generalized estimating equation models (GEEs) to account for correlations between members of the same recruitment chain, with an exchangeable correlation structure and link functions based on the distribution of the dependent variable (logit link for binary outcomes). Univariable and multivariable GEEs were also used to assess the effect of the intervention on sexual risk behaviors at follow-up. In addition to intervention group assignment, HIV status was also included in all models to help account for potential differences by HIV status in sociodemographic variables and risk behaviors. - SAS version 9.3 was used for all analyses.
Attrition	**Uptake** 398 potential participants were pre-screened via telephone, of which 288 were eligible and were invited to attend the research office for a formal eligibility screen. 237 were screened at the office; 227 were eligible and 224 enrolled in the study. **Attrition** For intervention participants, 108 completed the baseline assessment, n=81 (75%) completed the immediate post-test, and n=84 (77.8%) completed the 3-month follow-up. Session attendance: completed 0 sessions n=26 (24.1%), completed 1 session n=11 (10.2%), completed 2 sessions n=4 (3.7%), and completed all 3 sessions n=66 (61.1%).

	For control participant, 103 completed the baseline assessment, n=82 (79.6%) completed the immediate post-test, and n=82 (79.6%) completed the 3-month follow-up. Session attendance: completed 0 sessions n=26 (25.2%), completed 1 session n=76 (73.8), and completed 3 sessions n=1 (1%)*. * one participant assigned to the control group mistakenly received the POWER intervention so attended 3 sessions.
Study limitations (author)	- The non-random chain referral recruitment method employed with data from only one site yielded a sample that may not be generalisable. - Contamination between the conditions could have occurred if participants recruited a sex partner. Since there were no between group differences in the proportion of participants referred to the study by a current or former sex partner, the threat of cross contamination is minimised. - Although the comparison intervention was comparable to POWER in terms of structure and delivery modality, it consisted of only one longer session, so number of sessions was not controlled for. - Although the sample size was moderate, there may not have been sufficient power to conduct some analyses, particularly those stratified by serostatus. - Even though data were collected using ACASI, a modality previously shown to reduce reporting bias, findings relied on self-report of sexual practices and did not use biological markers to support findings. - The conceptualisation of serodiscordant sex and high risk behaviors did not include information regarding viral load, use of PreP, or other biomedical prevention modalities. - Scale-up of this type of on-line intervention delivered by a facilitator in real time may be challenging in light of reduced prevention resources for individual level behavioural interventions. However, it may be possible to modify certain features to reduce costs while retaining essential elements, particularly with a hybrid administration structure in which some sessions are facilitated in real time and others are not.
Study limitations (reviewer)	Almost 1 in 4 participants did not attend any sessions (intervention or control).
Source of funding	Not reported

Study arms

Intervention (N = 108)

POWER: an IMB theory-based online HIV prevention intervention for Black MSMW delivered by facilitators using real-time live chat

Control (N = 103)

HEALTH: a control condition focusing on health issues impacting Black men, including sexual health and condom use.

Characteristics

Study-level characteristics

Characteristic	**Study (N = 211)**
Gender Male	n = 211 ; % = 100
Race / ethnicity	
African-American	% = 93
Black-Latino	% = 2
Other	% = 3
Multiple Black identities	% = 2
Sexual orientation	
Bisexual	% = 83.8
Heterosexual or straight	% = 2.9
Homosexual or gay	% = 7.1
Unsure, questioning or other	% = 6.2

Arm-level characteristics

Characteristic	Intervention (N = 108)	Control (N = 103)
Age Mean (SD)	45.1 (7.7)	44.2 (9.7)
HIV positive	n = 70 ; % = 65.4	n = 62 ; % = 60.2
In care (Among HIV positive participants; n=131)	n = 66 ; % = 95.7	n = 58 ; % = 93.6
Undetectable viral load Among HIV positive participants, n=103	n = 44 ; % = 78.6	n = 37 ; % = 78.7
Homeless in the past 12 months	n = 38 ; % = 35.2	n = 31 ; % = 30.1
Drug use in last 3 months	n = 58 ; % = 54.7	n = 57 ; % = 55.3
Ever incarcerated	n = 71 ; % = 67	n = 64 ; % = 62.8
STI in last 12 months	n = 15 ; % = 14.2	n = 22 ; % = 21.4
Male partners Median (IQR)	3 (2 to 5)	3 (1 to 5)
Female partners Median (IQR)	2 (1 to 4)	2 (1 to 4)

Outcomes

Study timepoints

- Baseline
- 3 month

Condom use outcomes

Outcome	Intervention, Baseline, N = 108	Intervention, 3 month, N = 84	Control, Baseline, N = 103	Control, 3 month, N = 82
Any condomless vaginal or anal intercourse (CVAI) In the last 3 months No of events	n = 108 ; % = 100	n = 52 ; % = 62.7	n = 103 ; % = 100	n = 63 ; % = 76.8
CAI with males In past 3 months No of events	n = 96 ; % = 88.9	n = 42 ; % = 50.6	n = 89 ; % = 86.4	n = 52 ; % = 63.4
CVAI with females In past 3 months No of events	n = 86 ; % = 80.4	n = 30 ; % = 36.6	n = 82 ; % = 80.4	n = 33 ; % = 40.2
Any Serodiscordant anal or vaginal intercourse (SDAI or SDVI) In past 3 months No of events	n = 74 ; % = 69.2	n = 34 ; % = 41.5	n = 59 ; % = 57.8	n = 40 ; % = 48.8
Any SDAI with males In past 3 months No of events	n = 48 ; % = 44.4	n = 17 ; % = 20.5	n = 44 ; % = 42.7	n = 28 ; % = 34.2
Any SDVI or SDAI with females In past 3 months No of events	n = 53 ; % = 49.5	n = 21 ; % = 25.6	n = 45 ; % = 44.1	n = 27 ; % = 32.9

Any condomless vaginal or anal intercourse (CVAI) - Polarity - Lower values are better

CAI with males - Polarity - Lower values are better

CVAI with females - Polarity - Lower values are better

Any Serodiscordant anal or vaginal intercourse (SDAI or SDVI) - Polarity - Lower values are better

Any SDAI with males - Polarity - Lower values are better

Any SDVI or SDAI with females - Polarity - Lower values are better

TIDier Checklist

Study details

Rationale/theory/Goal	Black and Hispanic MSMW have significantly higher HIV prevalence than their white counterparts and may be diagnosed later in the disease course than MSM. Many MSM and MSMW also suffer serious mental health disparities compared to heterosexuals, and these are likely to be compounded for BMSMW who have dual stigmatised identities, Black and MSM. Despite conflicting evidence, MSMW have been characterised as a ‘‘bridge population’’ in the HIV transmission cycle contributing to the spread of the virus from the high prevalence group of MSM to the general heterosexual population. There is a pressing need to develop HIV prevention interventions for BMSMW that are culturally tailored to reflect their lived experiences and sufficiently flexible to address issues relevant to HIV positive as well as negative men (p. 1952). Given the widespread use of the Internet among gay and bisexual men, there is a new opportunity to deliver interventions on-line, which may be particularly useful for men who may be unwilling to attend face-to-face sessions because of stigma related to being identified as bisexual. Interventions offered in real time via live chat can offer an engaging and individualised approach, and can overcome barriers such as transportation and concerns about privacy and disclosure of sexual orientation (p. 1952).
Procedures used	- Active and passive recruitment methods were employed. For passive recruitment, posters and palm cards were displayed at community-based agencies and on the project website. - Active recruitment consisted of a chain referral strategy whereby 10 individuals were identified to be the initial 'seeds' and these seeds recruited up to 5 potentially eligible peers, who in turn recruited up to 5 eligible peers. The chain referral continued until the required sample size was reached. Each participant was given up to 5 individually numbered coupons

	and instructed to recruit only men that they knew personally (such as a sexual partner, friend, relative, co-worker) and who met the age and place of residence eligibility criteria. Participants were given $15 for each man they recruited who enrolled in the study. - When potential participants contacted the office, their referral source was verified via their coupon number and they were then screened them for eligibility. - After providing informed consent, participants completed the baseline assessment and were then randomised to intervention or control group. The first session was scheduled within 2 weeks of the baseline assessment. - Each participant received a card with a unique username and password to access their sessions. - Participants reporting limited internet access or no private and safe space completed their sessions on a dedicated laptop in a private room in the research office. - Participants completed an immediate post-test (which only assessed acceptability; no assessment of sexual behaviours) and a 3-month follow-up assessment. (p. 1953).
Method of delivery	Both the POWER and HEALTH interventions were administered online in real-time via live chat (p. 1953).
Setting/location of intervention	Online (p. 1953)
Other details	All study participants had access to condoms and lubricants for the duration of the study (p. 1953). Participants received $40 in cash for the baseline, $50 for the immediate-post and $60 for the 3 months assessment. For each intervention session completed, they received a $25 electronic gift card (p. 1953).

Study arms

Intervention (N = 108)

POWER: an IMB theory-based online HIV prevention intervention for Black MSMW delivered by facilitators using real-time live chat

Brief name	POWER (p. 1951)
Rationale/theory/Goal	- Grounded in the IMB model, POWER consisted of 3 individual sessions focused on providing culturally relevant information on HIV risk and protection, and increasing motivation and behavioural skills to promote adoption of safe practices. - Sessions followed the same format of reviewing goals, introducing new materials and concepts, skills-building with coaching, feedback and reinforcement, and setting goals. - Publicly available media clips (e.g. YouTube) were used to introduce concepts, promote interactions and dispel myths. (p. 1954)
Materials used	Video clips; a commerically available inexpensive secure internet platform that could be readily modifiable (p. 1954)
Procedures used	- Participants accessed the POWER website via a secure portal using a unique ID and password at their set appointment time and were met by their facilitator in virtual form. - Via live chat, the facilitator interacted with them, motivating, reinforcing and challenging him as needed. The facilitator also helped the participant to navigate the website, access relevant videos and complete the skill building exercises and role plays. Session 1: *Understanding the influence of culture and society on behaviour* 3 culturally appropriate video clips were used to prompt discussion of how media messages and stereotypes of Black men can influence behaviour. Facilitator provided information; enhanced motivation for change; taught key problem solving skills Completed an exercise to recognise significant people if their life and their role in promoting safe or unsafe behaviours Session 2: *Information and choices for improving sexual health and owning one's power*

	Focused on clarifying facts and myths about HIV and HIV risk; learning HIV prevention strategies; acquiring behavioural skills to help the participant develop strategies for improving his sexual health. Session ended with setting goals and identifying barriers to achieving those goals. Session 3: *Communication, resources and support* Participant learned about verbal and nonverbal communication, practiced communication skills and sexual negotiation skills. Applied problem solving skills and role played options for improving his sexual health. Participant identified resources for social support and completed a plan for staying healthy. (p. 1954).
Provider	Trained, experienced facilitators who were not ethnically matched with participants but were experienced in working with ethnic minority MSM and some had worked with BMSMW. To control for facilitator effects, facilitators administered both POWER and HEALTH (p. 1953).
Intensity/duration of the intervention	Three sessions lasting approximately 60-90 minutes each; administered weekly during a 3 week period (p. 1954).
Tailoring/adaptation	Facilitators were trained to tailor the words, scenarios or examples used in each session to reflect the participant's unique life situation and HIV status using the participant's words, concerns and issues (p. 1954).
Unforeseen modifications	None reported
Planned treatment fidelity	The chat transcripts of each session were reviewed to ensure session facilitators were delivering the core conceptual components with fidelity. Facilitators also completed checklists after each session that were reviewed during weekly supervision meetings (p. 1954).
Actual treatment fidelity	Not reported
Other details	Participants completed an acceptability measure consisting of 20 items rated on a 5 point scale in which 5 was the most positive option. Acceptability of the POWER intervention was very high: 96% of participants who completed the

	acceptability assessment found the sessions easy to understand and 97% agreed or strongly agreed that they would recommend the program to a friend. 90% felt the information in the session could easily be applied in real life (p. 1955; 1957).

Control (N = 103)

HEALTH: a control condition focusing on health issues impacting Black men, including sexual health and condom use.

Brief name	HEALTH (p. 1953)
Materials used	No specific materials reported
Procedures used	- The HEALTH comparison intervention consisted of one session administered online in real-time via live chat by trained facilitators. - Session content focused on health issues disproportionately impacting Black men. - Participants learned strategies to improve their physical and sexual health including preventing STIs, correct condom use and where to access STI/HIV testing. - Participants identified barriers to achieving better physical and sexual health and discussed ways to live a healthier life. (p. 1954)
Provider	Trained, experienced facilitators who were not ethnically matched with participants but were experienced in working with ethnic minority MSM and some had worked with BMSMW. To control for facilitator effects, facilitators administered both POWER and HEALTH (p. 1953).
Intensity/duration of the intervention	One 3-4 hour session (p. 1954).
Tailoring/adaptation	None reported
Unforeseen modifications	None reported
Planned treatment fidelity	Not reported

Actual treatment fidelity	Not reported

Risk of Bias Assessment

Section	Risk of bias	Reason
Domain 1: Bias arising from the randomisation process	Low	Appropriate randomisation procedures and no baseline differences between groups
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Some concerns	No information on participant blinding. One participant assigned to the control group mistakenly received the POWER intervention but was kept in the treatment condition to which he was originally assigned. Findings from intent-to-treat and as-treated analyses were the same
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	Some concerns	24% of intervention participants did not attend any sessions and 25% of control participants did not attend the control session. Impact of session attendance not assessed
Domain 3. Bias due to missing outcome data	Some concerns	Participant retention was 78% in the intervention group and 80% in the control group. No comparisons of retained participants and those lost to follow-up reported
Domain 4. Bias in measurement of the outcome	Low	Method of measuring outcome appropriate and did not differ between groups. Outcomes assessed using ACASI for both groups.
Domain 5. Bias in selection of the reported result	Some concerns	Trial not registered
Overall bias and Directness	Some concerns	No information on participant blinding. Approx 25% of participants did not attend any intervention or control sessions; impact of adherence not assessed. Approx 80% retention; comparisons of completers vs non-completers not reported. Trial not registered
	Overall Directness	Partially applicable (US study)

Harawa, 2013

Bibliographic Reference	Harawa, Nina T; Williams, John K; McCuller, W J; Ramamurthi, Hema C; Lee, Martin; Shapiro, Martin F; Norris, Keith C; Cunningham, William E; Efficacy of a culturally congruent HIV risk-reduction intervention for behaviorally bisexual black men: results of a randomized trial.; AIDS (London, England); 2013; vol. 27 (no. 12); 1979-88

Study details

Study design	Randomised controlled trial (RCT)
Trial registration number	Clinical Trials Registration Number: NCT 01492530
Study start date	Aug-2007
Study end date	May-2011
Aim	To test the efficacy of the Men of African American Legacy Empowering Self (MAALES) intervention for reducing sexual risk behaviours in Black MSMW.
Country/geographical location	Los Angeles, USA
Setting	Baseline and follow-up assessments were conducted at University study offices (n=299), community-based agencies (n=96), or in the field (n=42). Intervention sessions were held at community-based agencies that provided a range of services to at-risk and HIV-infected clients.
Inclusion criteria	- Self-identify as a Black/African American man - Labeled male at birth - At least 18 years of age

	- Reported at least one sexual activity (mutual masturbation, oral, vaginal, anal intercourse) with a biological female and a male (or male-to-female transgender) in the past 24 months - Could not have participated in an HIV-prevention program in the prior 6 months
Exclusion criteria	None reported
Method of randomisation	The Data Manager used a balanced-block randomisation procedure. Individuals were randomised into cohorts which formed the intervention groups.
Method of allocation concealment	Sealed envelopes
Unit of allocation	Participant
Unit of analysis	Participant
Statistical method(s) used to analyse the data	- In order to detect moderate effect sizes (at least 0.36 standard deviations) with 80% power and a one-sided significance level of 0.05, and assuming loss-to-follow-up of 20% and clustering effects (using an intraclass correlation of 0.05, to account for clustering inherent to a group training setting, and an average cluster size of 6 subjects), the required sample was at least 300 participants. - All analyses were conducted using SAS (version 9.2). - Descriptive statistics were used to examine differences between intervention and control conditions on key baseline variables. - To compare intervention-associated changes at the 6 month follow-up between conditions, multiple regression models were employed. The models controlled for baseline values of the key outcome variables and independent variables that differed between those assigned to each condition at baseline ($p < 0.1$). - A zero-inflated Poisson regression model was used to estimate the relative reduction in frequency of unprotected intercourse and numbers of partners. This model accounts for both true zeros (individuals who did not experience the event) and structural zeros (individuals who did not have the opportunity to experience the event). Risk ratios were determined from the Poisson model by exponentiating its regression coefficients. For dichotomous outcomes, logistic regression was used to estimate the relative odds of reporting any engagement in the risk behaviors.

Attrition	Of the 862 individuals screened, 491 (57%) were found eligible. Of these, 437 enrolled and 386 were randomized into the intervention (n=198) and control (n=188) conditions. 5 of those randomised were later excluded leaving 381 participants. In the intervention condition, 81% completed at least one session; n=114 (58%) completed the 3-month follow-up and n=143 (73%) completed the 6-month follow-up. In the control condition, 83% completed the control session; n=118 (63.8%) completed the 3-month follow-up and n=131 (70.8%) completed the 6-month follow-up. Reasons for loss to follow up in both conditions included incarceration, substance use, medical reasons, could not be contacted, and moving out of state.
Study limitations (author)	- Limitations related to sample composition and retention may lessen generalisability of study findings. Participants tended to be over 35 years of age and to report low socioeconomic status. - Despite efforts to engage men of diverse sexual identities, heterosexually identified men may have been less willing than other MSMW to engage in a group intervention. - Even with intensive retention efforts, loss to follow-up was significant. A potential contributor to this is the high incarceration rate of Black men. At least 16% of participants who were not retained were incarcerated at their 6-month follow-up interview.
Study limitations (reviewer)	24.2% of intervention participants and 35.9% of control participants were currently in treatment for substance abuse. This may have impacted the efficacy of the sexual risk reduction intervention in ways that could not be determined.
Source of funding	This study was supported by the Drew/UCLA Project EXPORT, 2P20MD000182 from NIMHD. Additional funding for formative and pilot work was provided by the Universitywide AIDS Research Program (now the California HIV/AIDS Program), grant numbers AL04-DREW-840, AL04-UCLA-841, AL04-AMASS-842, AL04-PRCF-843, AL04-JWCH-844.

Study arms

Intervention (N = 196)

Men of African American Legacy Empowering Self (MAALES): a multi-session small group, holistically-framed intervention designed to build skills, address sociocultural issues and reduce risk behaviours in Black men who have sex with men and women (MSMW)

Control (N = 185)

Brief HIV education and risk reduction session based on a standard HIV test counselling approach

Characteristics

Arm-level characteristics

Characteristic	Intervention (N = 196)	Control (N = 185)
Age group		
Less than 30 years	% = 14.3	% = 13.5
30 to 39 years	% = 19.4	% = 17.8
40 to 49 years	% = 42.3	% = 42.2
50+	% = 24	% = 26.5
Gender Male	n = 196 ; % = 100	n = 185 ; % = 100
Ethnicity Black / African American	n = 196 ; % = 100	n = 185 ; % = 100
Housing instability (past 12 months)	% = 33.2	% = 44.3
Substance abuse treatment (current)	% = 24.2	% = 35.9
Ever incarcerated	% = 74.2	% = 77.8
HIV status		

Characteristic	Intervention (N = 196)	Control (N = 185)
HIV positive	% = 49	% = 47.8
HIV negative	% = 40.6	% = 44.6
HIV other (indeterminate, inconclusive)	% = 2.1	% = 1.6
Never tested	% = 8.3	% = 6
Sexual orientation		
Heterosexual	% = 10.7	% = 17.3
Gay/homosexual	% = 14.3	% = 9.2
Bisexual	% = 60.2	% = 60.5
Same gender loving / SGL	% = 2	% = 1.2
Down low or DL	% = 6.1	% = 8.1
Other / none of the above	% = 6.6	% = 3.8

Outcomes

Study timepoints

- Baseline
- 6 month

Condom use outcomes

Outcome	Intervention, Baseline, N = 149	Intervention, 6 month, N = 149	Control, Baseline, N = 142	Control, 6 month, N = 142
Unprotected anal intercourse with males Prior 90 days Mean (SD)	3.43 (10.52)	1.43 (7.62)	1.83 (6.21)	1.69 (9.28)
Unprotected vaginal or anal intercourse with females In prior 90 days Mean (SD)	5.09 (16.41)	1.5 (4.48)	2.72 (6.62)	3.21 (16.46)
Unprotected intercourse with males or females In prior 90 days Mean (SD)	8.65 (22.27)	2.95 (8.76)	4.66 (9.61)	5.96 (24.79)

Unprotected anal intercourse with males - Polarity - Lower values are better

Unprotected vaginal or anal intercourse with females - Polarity - Lower values are better

Unprotected intercourse with males or females - Polarity - Lower values are better

So-called chemsex outcomes

Outcome	Intervention, Baseline, N = 149	Intervention, 6 month, N = 149	Control, Baseline, N = 142	Control, 6 month, N = 142
Any risky drug use with sex Heroin, powder or crack cocaine, poppers, club drugs, or methampetamines. In prior 90 days	n = 34 ; % = 24	n = 22 ; % = 15	n = 22 ; % = 16	n = 16 ; % = 12

Outcome	Intervention, Baseline, N = 149	Intervention, 6 month, N = 149	Control, Baseline, N = 142	Control, 6 month, N = 142
No of events				

Any risky drug use with sex - Polarity - Lower values are better

TIDier Checklist

Study details

Brief name	
Rationale/theory/Goal	Black MSM are more likely than White MSM to be bisexually active or identified (men who have sex with men and women; MSMW) and less likely to disclose their same sex activities to others. Because of their frequent lack of identification with gay communities or labels, experiences of racism, concerns with fulfilling traditional gender expectations, discreteness regarding same-sex behaviour, and relationships with both men and women, many Black MSMW may not respond to interventions targeting gay-identified men. Hence, intervention experts and community leaders have called for prevention approaches for this subgroup that address these intersecting concerns and identities. To address the needs of Black bisexual men, paradigm shifts must occur in how sexuality is conceptualised. An alternative approach considers a variety of activities, such as sex with women, with men, with transgender people, or a combination at different times or in different circumstances, as potentially normative expressions of sexual fluidity. Interventions adopting these alternative conceptualisations are required (p. 2-3).
Procedures used	- Recruitment strategies included outreach in public venues, provider referrals, and incentivised referrals from participants. In addition, the study team posted flyers and ran advertisements on buses, on bus benches, in local community publications and on Internet sites. The majority of recruitment efforts occurred in venues that attracted African American men as a group, with fewer efforts in gay-oriented venues. - Trained staff screened interested individuals either in the field or by phone. - Eligible individuals provided informed consent and completed the baseline interview using ACASI.

	- Follow-up ACASI interviews were scheduled within 2 weeks following the final intervention session and at 3- and 6-months - Participants in both study arms were offered condoms at each follow-up survey - Control participants were waitlisted and invited to attend MAALES sessions after their 6-month follow-up assessment (p. 4-5)
Other details	Sample characteristics showed that monthly incomes were low; unemployment rates were high; over 35% had experienced housing instability in the prior 12 months and over 75% had been incarcerated in their lifetimes (p. 7).

Study arms

Intervention (N = 196)

Men of African American Legacy Empowering Self (MAALES): a multi-session small group, holistically-framed intervention designed to build skills, address sociocultural issues and reduce risk behaviours in Black men who have sex with men and women (MSMW)

Brief name	Men of African American Legacy Empowering Self (MAALES) (p. 3)
Rationale/theory/Goal	- The intervention was developed with collaborating agencies and informed by extensive formative research and community advisory board members. - Guided by Theory of Reasoned Action and Planned Behaviour; Empowerment Theory; and the Critical Thinking and Cultural Affirmation Model (an Afrocentric model based on Social Cognitive Theory). - Took a holistic approach and addressed social influences and cultural norms to encourage health-promoting behaviours that also benefitted participants' sexual partners, families and communities. - Gender and ethnicity also emphasised, with participants' shared legacies as African American men providing a starting place for many discussions. (p. 3-4).

Materials used	No specific materials reported
Procedures used	- MAALES primary risk reduction goals were to decrease the frequency of unprotected intercourse and reduce sex while under the influence of drugs. - Used small group intervention sessions - Sessions 1 and 2: focused on past experiences and social expectations of African American men, historical discrimination and disenfranchisement, risky behaviors, HIV testing, and societal impacts on individual health and sexual-decision making. - Sessions 3 and 4 focused on current health behaviors, with specific attention on developing sexual risk-reduction goals, communication and empowerment skills and identifying personal motivators for preserving health. - Sessions 5 and 6 focused on overcoming challenges to risk-reduction and developing strategies for sustaining and committing to these efforts. - Group booster sessions reviewed concepts and skills learned in the core curriculum and encouraged participants to share successes and challenges in applying them. - Participants were also encouraged to identify and address other health-related risks such as diet, smoking or lack of exercise, using many of the specific intervention tools in other areas of their life. (p. 3-4)
Provider	Intervention sessions were facilitated by two African American men who were knowledgeable about HIV, familiar with the population and experienced with group facilitation. The received training on intervention implementation (p. 4).
Method of delivery	Small group sessions (p. 4)
Setting/location of intervention	Intervention sessions were held at partner agencies (community-based organisations providing a range of services to at-risk and HIV-infected clients (p. 3).
Intensity/duration of the intervention	Six 2-hour sessions conducted over 3 weeks, with 2 booster sessions at 6 and 18 weeks post-intervention (p. 4).

Tailoring/adaptation	None reported
Unforeseen modifications	None reported
Planned treatment fidelity	Not reported
Actual treatment fidelity	Not reported

Control (N = 185)

Brief HIV education and risk reduction session based on a standard HIV test counselling approach

Brief name	HIV education and risk reduction (p. 4)
Materials used	No specific materials reported
Procedures used	- The control condition involved a client-centered HIV education and risk-reduction session based on a standard HIV test counselling approach. - The single session occurred at or soon after randomisation and explored the individual's HIV/STI risks, their priorities for risk reduction and discussed the importance of regular HIV testing. - Participants identified 3 risk-reduction action items that they would commit to over the next month. - Control participants were also waitlisted and invited to attend MAALES sessions after their 6-month assessment (p. 4)
Provider	Not reported; assumed clinic staff
Method of delivery	Face to face session; assumed individual
Setting/location of intervention	Not reported; assumed partner agencies

Intensity/duration of the intervention	15-25 minutes (p. 4)
Tailoring/adaptation	Not reported
Unforeseen modifications	Not reported
Planned treatment fidelity	Not reported
Actual treatment fidelity	Not reported

Risk of Bias Assessment

Section	Risk of Bias	Reason
Domain 1: Bias arising from the randomisation process	Some concerns	Appropriate randomisation procedures but some evidence of baseline differences: controls were significantly more likely to report recent housing instability and current treatment for substance abuse than intervention participants. Also baseline differences in key outcome variables (unprotected anal intercourse with males; unprotected intercourse with females; and unprotected intercourse with males or females)
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Low	Deviations from intended intervention unlikely
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	Some concerns	Impact of intervention adherence not assessed but non-adherence unlikely.
Domain 3. Bias due to missing outcome data	Some concerns	Relatively high attrition (~70% retention at 6 months) and no analysis of baseline characteristics of completers vs non-completers, but rates of attrition comparable for intervention and control groups
Domain 4. Bias in measurement of the outcome	Low	Outcomes assessed using ACASI and same measures used for both groups

Section	Risk of Bias	Reason
Domain 5. Bias in selection of the reported result	Low	Trial registered and analyses completed in line with those specified in the protocol
Overall bias and Directness	Some concerns	Baseline differences between groups on key variables; impact of adherence not assessed; high attrition and no comparison of completers vs non completers
	Overall Directness	Partially applicable (US study; sample had unique characteristics (high incarceration history; relatively high number currently in substance abuse treatment))

Jemmott, 2015

Bibliographic Reference Jemmott, John B 3rd; Jemmott, Loretta Sweet; O'Leary, Ann; Icard, Larry D; Rutledge, Scott E; Stevens, Robin; Hsu, Janet; Stephens, Alisa J; On the Efficacy and Mediation of a One-on-One HIV Risk-Reduction Intervention for African American Men Who Have Sex with Men: A Randomized Controlled Trial.; AIDS and behavior; 2015; vol. 19 (no. 7); 1247-62

Study details

Study design	Randomised controlled trial (RCT)
Trial registration number	Not reported
Study start date	Apr-2008
Study end date	May-2012
Aim	To examine the efficacy of the Being Responsible for Ourselves (BRO) HIV/STI risk reduction intervention, designed to increase consistent condom use, in African American MSM
Country/geographical location	Philadelphia, USA
Setting	A university research centre

Inclusion criteria	- At least 18 years of age - Self-identified as Black or African American - Were born a male - Reported having anal intercourse with a man in the previous 90 days
Exclusion criteria	- Reported having anal intercourse with only one main male partner in the past 90 days - Had participated in an HIV/STI risk-reduction intervention in the past 12 months
Method of randomisation	Computer-generated random number sequences
Method of allocation concealment	A biostatistician generated the random assignments; the project director implemented the assignments.
Unit of allocation	Participant
Unit of analysis	Participant
Statistical method(s) used to analyse the data	- In a pilot survey, 42% of African American MSM reported consistent condom use in the past 90 days. An absolute increase of 14 % points in consistent condom use was selected as a clinically and substantively important effect size. Assuming a two-tailed test, $\propto = 0.05$, 20% attrition, and a 14 % increase in consistent condom use from 42% in the control group to 56% in the intervention group, with N=594 men enrolled in the trial, the estimated statistical power was 84%. - Descriptive statistics were used to summarise baseline socio-demographic variables and chi squared test and logistic regression was used to analyse attrition. - The efficacy of the intervention averaged over the 6- and 12-month follow-ups compared with the health promotion control was tested using logistic generalised- estimating-equations (GEE), adjusting for the longitudinal repeated measurements and controlling for baseline measure of the outcome.

	- Models were fit and contrast statements specified to obtain estimated odds ratios and their corresponding 95% confidence intervals (CI). - Analyses were performed using an intent-to-treat model with participants analysed based on their intervention assignment, regardless of the number of intervention or data-collection sessions they attended. - Analyses were completed using SAS V9.
Attrition	No information on uptake. N=595 men were randomised: N=295 to the intervention and N=300 to the control. For the intervention condition, n=272 (92%) attended all 3 intervention sessions. At 6 months n=255 (86.4%) and at 12 months n=255 (86.4%). For the control condition, n=280 (93.3%) attended all 3 intervention sessions. At 6 months n=250 (83.3%) and at 12 months n=248 (82.7%). There were no significant group differences in the percentage attending at least one follow-up.
Study limitations (author)	- Behavior was measured with self-reports, which may be subject to social desirability bias. Although the use of ACASI may have mitigated potential problems with self reports, objective indicators of sexual-risk behaviour such as biologically confirmed STIs would have improved the study. - The findings may not generalise to all African-American MSM because participants were not randomly selected.
Study limitations (reviewer)	None to add
Source of funding	This study was funded by research Grant 1 R01 MH079736 from the National Institute of Mental Health.

Study arms

Intervention (N = 295)

Being Responsible for Ourselves (BRO): a one-to-one HIV/STI risk reduction intervention designed to increase consistent condom use

Control (N = 298)

Attention-matched health promotion intervention

Characteristics

Arm-level characteristics

Characteristic	Intervention (N = 295)	Control (N = 298)
Age Mean (SE)	41.44 (0.63)	41.85 (0.61)
Gender Male	n = 295 ; % = 100	n = 298 ; % = 100
Ethnicity Black / African American	n = 295 ; % = 100	n = 298 ; % = 100
Sexual self-identity		
Gay	n = 128 ; % = 43.4	n = 113 ; % = 37.9
Straight	n = 20 ; % = 6.8	n = 25 ; % = 8.4
Bisexual	n = 124 ; % = 42	n = 121 ; % = 40.6
On the down low	n = 23 ; % = 7.8	n = 39 ; % = 13.1

Characteristic	Intervention (N = 295)	Control (N = 298)
Intercourse with a woman in the past 90 days	n = 129 ; % = 43.7	n = 130 ; % = 43.6
HIV positive	n = 83 ; % = 29.2	n = 85 ; % = 29.8
Sexually abused as a child	n = 143 ; % = 48.5	n = 147 ; % = 49.3
Intimate partner violence victim	n = 104 ; % = 35.2	n = 116 ; % = 38.9
Alcohol dependent Based on a score of 2 or greater on the CAGE questionnaire	n = 143 ; % = 48.5	n = 121 ; % = 40.6
Drug dependent Based on a score of 3 or greater on the TCUDS questionnaire	n = 52 ; % = 17.6	n = 47 ; % = 15.8
Ever incarcerated	n = 148 ; % = 50.2	n = 159 ; % = 53.4

Outcomes

Study timepoints

- Baseline
- 6 month
- 12 month

Condom use outcomes

Outcome	Intervention, Baseline, N = 275	Intervention, 6 month, N = 203	Intervention, 12 month, N = 194	Control, Baseline, N = 273	Control, 6 month, N = 190	Control, 12 month, N = 190
Consistent condom use Whether participant reported using a condom every time he had anal or vaginal sex in the prior 90 days No of events	n = 147 ; % = 53.4	n = 128 ; % = 63	n = 124 ; % = 63.9	n = 142 ; % = 52	n = 124 ; % = 65.3	n = 112 ; % = 59
Proportion of condom-protected intercourse In prior 90 days Mean (SD)	0.75 (0.35)	0.77 (0.37)	0.77 (0.38)	0.72 (0.38)	0.77 (0.37)	0.72 (0.4)

Consistent condom use - Polarity - Higher values are better

Proportion of condom-protected intercourse - Polarity - Higher values are better

Paper reports mean and SE; SDs calculated by analyst

Condom use outcomes

Outcome	Intervention, Baseline, N = 275	Intervention, 6 month, N = 202	Intervention, 12 month, N = 193	Control, Baseline, N = 273	Control, 6 month, N = 187	Control, 12 month, N = 188
Unprotected intercourse Whether participants reported any unprotected vaginal or anal intercourse in the past 90 days No of events	n = 122 ; % = 44.4	n = 74 ; % = 36.6	n = 69 ; % = 35.8	n = 125 ; % = 45.8	n = 66 ; % = 35.3	n = 76 ; % = 40.4

Unprotected intercourse - Polarity - Lower values are better

Second table required as n's are different for this outcome

Sexual Health Knowledge Outcomes

Outcome	Intervention, Baseline, N = 295	Intervention, 6 month, N = 254	Intervention, 12 month, N = 254	Control, Baseline, N = 298	Control, 6 month, N = 251	Control, 12 month, N = 241
HIV risk reduction knowledge Assessed using 16 true/false items regarding transmission of HIV, risk of different behaviours and correct use of condoms Mean (SD)	12.23 (2.4)	13.04 (2.55)	12.93 (2.87)	12.13 (2.76)	12.65 (2.69)	12.5 (2.95)
Condom-use knowledge 5 true/false items on the correct use of condoms Mean (SD)	4.33 (0.86)	4.56 (0.8)	4.5 (0.96)	4.31 (1.04)	4.48 (0.95)	4.41 (1.09)

HIV risk reduction knowledge - Polarity - Higher values are better

Condom-use knowledge - Polarity - Higher values are better

Paper reports mean and SE; SDs calculated by analyst

TIDier Checklist

Study details

Rationale/theory/Goal	Despite the high rate of HIV diagnosis among African American MSM, limited progress has been made in developing efficacious interventions for this population. The goal of this study was to develop and test a theoretically grounded HIV risk reduction intervention for this population (p. 1248)
Procedures used	- Participants were recruited in the Philadelphia area (a) through advertising in local newspapers read by African American MSM, (b) through community-based organisations (CBOs) serving African American MSM, (c) through recruitment flyers posted at colleges, universities, parks, bars, and adult bookstores, (d) through face-to-face recruitment at social events, activities, and parties where a large turnout of African American MSM was expected, and (e) through the referrals of participants (i.e., snowballing). - Potential participants were screened for eligiblity. Those eligible were invited to participate and informed consent was obtained. - Participants completed confidential questionnaires via ACASI at baseline and at 6- and 12-months follow up. (p. 1248-9; 1251)
Provider	- Session facilitators were employed irrespective of gender or sexual orientation. The facilitators were 23 adults (17 women and 6 men) 28–64 years of age (mean age = 44.2). Twenty were African American, two were Latino, and one was white. About 56.5 % had a Master's degree; 79.1 % had previously facilitated HIV/STI risk-reduction interventions, 50.0 % had previously facilitated health-promotion interventions, and 65.2 % had previously worked with African American MSM. - Facilitators were stratified by gender and age then randomly assigned to be trained to implement one of the two interventions. (p. 1250-1)
Method of delivery	One-to-one individual sessions (p. 1249)
Setting/location of intervention	University research centre (p. 1249)

Other details	Participants were compensated with $25 for the pre-intervention assessment, $25 for each of the three intervention sessions, $25 for the immediate postintervention assessment, and $50 for each of the two follow-up assessments (p. 1249).

Study arms

Intervention (N = 295)

Being Responsible for Ourselves (BRO): a one-to-one HIV/STI risk reduction intervention designed to increase consistent condom use

Brief name	Being Responsible for Ourselves, BRO (p. 1249)
Rationale/theory/Goal	- Based on Social Cognitive Theory and the Reasoned Action approach, as well as extensive formative research (focus groups, pilot testing). - Most relevant to this intervention are the social-cognitive-theory constructs of ‘‘outcome expectancy,’’ beliefs about the consequences of a specific behaviour, and ‘‘self-efficacy,’’ people’s confidence that they can execute a specific behaviour; its emphasis on behavioural skills; and its methods for increasing skills, particularly practice with performance feedback (e.g., role-playing). - Use of qualitative formative research to identify population-specific beliefs and employ intervention activities designed to influence those. - Use of 1-to-1 intervention to allay concerns some African American MSM may have about revealing their sexual behaviour with other men within a group-based intervention. - The delivery the intervention sessions was tailored to information that participants provided during the sessions about relevant behaviours, contexts and motivations. - Intervention was designed to address aspects of self-efficacy including technical skills to use condoms correctly without interfering with sexual enjoyment, impulse control to exercise the necessary control to use condoms even when sexually excited, under the influence of alcohol or drugs, and skills to negotiate condom use.

	- It was also designed to increase knowledge regarding STI/HIV acquisition and transmission (p. 1249)
Materials used	No specific materials reported
Procedures used	Session 1 - Introduction session - provide overview, build trust, create enthusiasm. Facilitator learned about participants goals, reasons for participating, sexual risk behaviour, types of sex they had, and condom use. This information was all used to tailor the sessions and activities. - Participants completed a sexual risk-assessment activity designed to help them recognise their personal risk and understand triggers to sexual risk behaviour. - This session also included a mini-lecture covering HIV/STI symptoms, transmission and prevention. - Homework assignment: to identify a behavioural goal based on his own sexual risk, and to develop a personal HIV sexual risk-reduction plan that could be employed to attain that goal. Session 2 - Addressed outcome expectancies around condom use, the correct and consistent use of condoms, and vulnerability to STIs/HIV. - Facilitator used an anatomical model to demonstrate correct condom use then participants practiced the correct steps. - Participants were encouraged to think about ways they could make condom use fun and pleasurable, and how alcohol/drug use may affect condom use. - Participants were asked to list excuses that he and/or his partners give for not using condoms then think of responses to neutralise them.

	- Homework assignment: to imagine they were faced with triggers for unsafe sex and identify ways to avoid such triggers, and discreet ways of always having condoms available. <u>Session 3</u> - Focus on building knowledge, self-efficacy and skills for negotiating condom use, including reenacting role plays about African American men negotiating condom use in intertive or receptive roles; and with steady, casual, female or paying partners. - Participants learned and practiced the "Say no, Explain why, Provide alternatives, and Talk it out (SWAT) four step strategy for effectively communicating their decision to use condoms and abstain from unprotected sex. - Interactive videos allowed participants to practice these skills in a variety of personally relevant risk situations. - Participants reviewed their personal risk reduction plan created in session 1 and explored ways to overcome obstacles and sustain change. - Participants wrote a safer-sex promise letter to themselves which was mailed to them 6 weeks after the intervention to remind them of their commitment to be safe sexually. (p. 1249-50)
Provider	Facilitators who had received three 8-hour days of training in intervention procedures. Training included project overview, theoretical framework, effective facilitation techniques, presentation style, verbal and nonverbal communication, and issues of specific relevance (e.g. transgender issues, sexual identity development). (p. 1251)
Intensity/duration of the intervention	Three 90-minute sessions implemented during 3 consecutive weeks (p. 1249)
Tailoring/adaptation	Facilitators used information provided by the participant about their sexual risk behaviours to tailor some of the intervention activities (e.g. role plays) (p. 1250).
Unforeseen modifications	None reported

Planned treatment fidelity	During facilitator training, the importance of implementation fidelity was stressed. Facilitators kept session logs after each session which were reviewed by the project supervisor and used to indicate the extent to which the facilitator had completed all session activities. The supervisor also reviewed digital recordings of the sessions and provided performance feedback, and retraining where necessary (p. 1251).
Actual treatment fidelity	Not reported

Control (N = 298)

Attention matched health promotion control

Brief name	Health promotion intervention (p. 1250)
Materials used	No specific materials reported
Procedures used	The control group's activities, while similar to those in the HIV/STI risk-reduction intervention in terms of time and dose, focused on increasing physical activity and fruit-and-vegetable consumption and decreasing fat consumption to reduce the risk of chronic diseases including heart disease, hypertension, stroke, diabetes, and certain cancers—leading causes of morbidity and mortality among African Americans (p. 1250).
Provider	Trained facilitators (p. 1250)
Intensity/duration of the intervention	Three 90-minute sessions implemented during 3 consecutive weeks (p. 1249)
Tailoring/adaptation	None reported
Unforeseen modifications	None reported
Planned treatment fidelity	Not reported
Actual treatment fidelity	Not reported

Risk of Bias Assessment

Section	Risk of Bias	Reason
Domain 1: Bias arising from the randomisation process	Low	Appropriate randomisation procedures and no baseline differences between groups
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Low	Deviations from intended intervention unlikely and ITT used
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	Low	Intervention adherence high - high session attendance across groups and 1-to-1 sessions led by trained facilitators who could encourage adherence to session protocol
Domain 3. Bias due to missing outcome data	Low	Relatively low attrition and rates the same across groups
Domain 4. Bias in measurement of the outcome	Low	Outcomes assessed using ACASI and same measures used for both groups
Domain 5. Bias in selection of the reported result	Some concerns	Trial not registered
Overall bias and Directness	Some concerns	Trial not registered
	Overall Directness	Partially applicable (US study)

Koblin, 2012

Bibliographic Reference Koblin, Beryl A; Bonner, Sebastian; Powell, Borris; Metralexis, Peter; Egan, James E; Patterson, Jocelyn; Xu, Guozhen; Hoover, Donald R; Goodman, Krista; Chin, John; Tieu, Hong V; Spikes, Pilgrim; A randomized trial of a behavioral intervention for black MSM: the DiSH study.; AIDS (London, England); 2012; vol. 26 (no. 4); 483-8

Study details

Study design	Randomised controlled trial (RCT)

Trial registration number	Not reported
Study start date	May-2008
Study end date	Jun-2009
Aim	To test a new behavioural intervention for Black MSM in reducing sexual risk and increasing social support and intentions to use condoms.
Country/geographical location	New York City, USA
Setting	No information
Inclusion criteria	- 18 years of age or older - New York City area residents - Understood and read English - Self-identified as male and as African–American, Black, Caribbean Black, or multiethnic Black - Had two or more sexual partners (male or female) and reported unprotected anal intercourse (UAI) with a man in the past 3 months - Were available for the study duration
Exclusion criteria	- Men who self-identified as a transgender woman - Refused HIV testing - Newly diagnosed with HIV infection within the prior 6 months.
Method of randomisation	No information
Method of allocation concealment	No information

Statistical method(s) used to analyse the data	- Intent-to-treat comparisons were used. - Binary behavioral outcomes at baseline were compared by study arm using contingency tables and exact tests. - For continuous variables, baseline mean values were compared by study arm using Wilcoxon rank sum test. - Changes in outcomes between baseline and 3 months were compared using McNemar discordant pair analysis (binary variables) or Wilcoxon signed-rank sum test (continuous variables). - Differences between baseline and 3-month visit by study arm of binary outcomes were calculated and compared using Cochran-Armitage trend test. For continuous variables, Wilcoxon rank sum test was used.
Attrition	Among 828 men screened, 474 met the eligibility criteria, 328 completed the baseline visit and 283 were randomised. 85.9% of participants completed at least 4 intervention sessions. 3 month follow-up assessments were completed by 128 (90.1%) of intervention participants and 130 (92.2%) of control participants. There was no significant difference between the groups. Men retained were more likely to report unknown/serodiscordant unprotected insertive anal intercourse and had lower sexual self-efficacy.
Study limitations (author)	- Improvements were observed in both groups; men who agreed to take part in this trial may have been ready for change, so the baseline assessment and risk reduction counselling could have provided a sufficient boost for behaviour change. - There is the possibility of cross-contamination among participants as it is possible that the men from the study arms knew each other. - Although computer interviewing can reduce socially desirable responding, the data reported by participants may not accurately reflect actual risk behaviour. - The sample was too small for assessing whether subgroups of men benefitted more from the intervention - The sample may not be representative of Black MSM in New York City

Study limitations (reviewer)	None to add
Source of funding	This study was supported by a cooperative agreement between the New York Blood Center and the Centers for Disease Control and Prevention (3UR6PS000437-03W1).

Study arms

Intervention (N = 142)

Standard HIV testing and counselling PLUS intervention sessions focused on creating a group environment with sexual risk reduction information and exercises woven into joint meal preparation and sharing activities.

Control (N = 141)

Standard HIV testing and counselling

Characteristics

Arm-level characteristics

Characteristic	Intervention (N = 142)	Control (N = 141)
Age		
18-30 years	n = 40 ; % = 28.2	n = 24 ; % = 17
31-40 years	n = 30 ; % = 21.1	n = 34 ; % = 24.1
41-45 years	n = 47 ; % = 33.1	n = 42 ; % = 29.8

Characteristic	Intervention (N = 142)	Control (N = 141)
46 years and above	n = 25 ; % = 17.6	n = 41 ; % = 29.1
Gender Male	n = 142 ; % = 100	n = 141 ; % = 100
Sexual identity		
Gay	n = 95 ; % = 66.9	n = 96 ; % = 68.1
Bisexual	n = 40 ; % = 28.2	n = 36 ; % = 25.5
Other	n = 7 ; % = 4.9	n = 9 ; % = 6.4
HIV negative	n = 57 ; % = 40.1	n = 49 ; % = 34.8
HIV positive	n = 85 ; % = 59.9	n = 92 ; % = 65.3

Outcomes

Study timepoints

- Baseline
- 3 month

Condom use outcomes - with most recent partner

Outcome	Intervention, Baseline, N = 128	Intervention, 3 month, N = 128	Control, Baseline, N = 130	Control, 3 month, N = 130
Unprotected insertive anal intercourse UIA No of events	n = 60 ; % = 46.9	n = 33 ; % = 25.8	n = 59 ; % = 45.7	n = 34 ; % = 26.2
Unprotected receptive anal intercourse URA No of events	n = 50 ; % = 39.1	n = 31 ; % = 24.2	n = 51 ; % = 39.5	n = 30 ; % = 23.1
Unknown / serodiscordant unprotected insertive anal intercourse USDUIA No of events	n = 26 ; % = 20.6	n = 10 ; % = 7.8	n = 29 ; % = 22.7	n = 8 ; % = 6.3
Unknown / serodiscordant unprotected receptive anal intercourse USDURA No of events	n = 22 ; % = 17.5	n = 10 ; % = 7.8	n = 30 ; % = 23.4	n = 13 ; % = 10.2
Unprotected anal sex with drug or alcohol use by partner or participant No of events	n = 60 ; % = 47.2	n = 29 ; % = 22.7	n = 69 ; % = 53.5	n = 34 ; % = 26.4

Unprotected insertive anal intercourse - Polarity - Lower values are better

Unprotected receptive anal intercourse - Polarity - Lower values are better

Unknown / serodiscordant unprotected insertive anal intercourse - Polarity - Lower values are better

Unknown / serodiscordant unprotected receptive anal intercourse - Polarity - Lower values are better

Unprotected anal sex with drug or alcohol use by partner or participant - Polarity - Lower values are better

Condom use outcomes - with any partner

Outcome	Intervention, Baseline, N = 128	Intervention, 3 month, N = 128	Control, Baseline, N = 130	Control, 3 month, N = 130
Unprotected insertive anal intercourse UIA No of events	n = 89 ; % = 69.5	n = 56 ; % = 39.4	n = 90 ; % = 69.8	n = 51 ; % = 36.2
Unprotected receptive anal intercourse URA No of events	n = 76 ; % = 59.4	n = 50 ; % = 35.2	n = 70 ; % = 54.3	n = 42 ; % = 29.8
Unknown / serodiscordant unprotected insertive anal intercourse USDUIA No of events	n = 60 ; % = 47.6	n = 23 ; % = 18.3	n = 53 ; % = 41.4	n = 22 ; % = 17.3
Unknown / serodiscordant unprotected receptive anal intercourse USDURI No of events	n = 46 ; % = 36.5	n = 21 ; % = 17.1	n = 38 ; % = 29.7	n = 20 ; % = 15.8

Unprotected insertive anal intercourse - Polarity - Lower values are better

Unprotected receptive anal intercourse - Polarity - Lower values are better

Unknown / serodiscordant unprotected insertive anal intercourse - Polarity - Lower values are better

Unknown / serodiscordant unprotected receptive anal intercourse - Polarity - Lower values are better

Secondary outcomes

Outcome	Intervention, Baseline, N = 128	Intervention, 3 month, N = 128	Control, Baseline, N = 130	Control, 3 month, N = 130
Sexual self-efficacy Assessed using 7 items rated on 5 point scale. Example items: "I can choose safer sex with a man I have sex with regularly" Mean (SD)	3.31 (1.06)	3.58 (0.93)	3.34 (0.97)	3.64 (0.94)

Sexual self-efficacy - Polarity - Higher values are better

TIDier Checklist

Study details

Brief name	The DiSH study (p. 483)
Rationale/theory/Goal	Black MSM are diagnosed with HIV at greatly disproportionately higher rates compared to other groups of MSM and few interventions have been developed for reducing sexual risk among Black MSM (p. 483).
Procedures used	- Black MSM were recruited through outreach in New York City, referrals from organisations and study participants, recruitment flyers and advertisements. - Participants gave written informed consent then completed a computer-administered behavioural assessment. - All participants then received HIV risk reduction counselling - A follow-up questionnaire was completed 3-months after completion of the intervention sessions, or 3 months after the baseline visit for the control arm.

	(p. 484)

Study arms

Intervention (N = 142)

Standard HIV testing and counselling PLUS intervention sessions focused on creating a group environment with sexual risk reduction information and exercises woven into joint meal preparation and sharing activities.

Rationale/theory/Goal	Based on Bandura's Social Cognitive Theory. Aims to create a group environment through joint meal preparation and sharing, where sexual risk reduction information and exercises are completed (p. 483-484).
Materials used	Sessions involved preparing meals so required ingredients and simple cooking appliances (p. 484)
Procedures used	- In each session, participants jointly prepared healthy, low-cost meals - In session 1, participants chose from ingredients to make pizzas and fruits to make smoothies. The emphasis on food choice was extended to participants choosing condoms and lubricant types and preferences. - Participants explored some of the factors that can influence both eating and sexual behaviours (e.g cultural history, racism, homophobia), and were encouraged to draw parallels between planning ahead for healthy eating and healthy sex - In subsequent sessions, participants continued to cook and eat meals together, engaging over a range of nutrition and HIV-related health topics and considering the overlap between healthy diet and healthy sex. - Themes included obstacles to change, self-worth, remorse/shame, what leads to overeating or unsafe sex, environmental determinants of health behaviours such as support networks and impact of drug/alcohol use on decision making. - The final session focused on promoting commitment to change, including proximal goal setting, self-evaluation of progress towards goals, and self-rewards. (p. 484)

Provider	Trained facilitators (p. 484)
Method of delivery	Face to face group sessions (p. 484)
Setting/location of intervention	Unclear
Intensity/duration of the intervention	Five 2 hour sessions over 2 weeks (p. 484)
Tailoring/adaptation	Not reported
Unforeseen modifications	None reported
Planned treatment fidelity	Sessions were audio recorded and scored for content and fidelity by two of the study team (p. 484)
Actual treatment fidelity	Adherence to the intervention manual was high. Mean adherence score for all sessions was 4.4 out of 5 and 81.4% of sessions had a score of at least 4 (p. 485)
Other details	Paper does not report the number of participants in each intervention session.

Control (N = 141)

Standard HIV testing and counselling

Procedures used	- Control participants received standard HIV risk reduction counselling (p. 484)
Provider	Not reported
Method of delivery	Not reported; assumed face to face
Setting/location of intervention	Not reported
Intensity/duration of the intervention	Not reported; assumed single session
Tailoring/adaptation	Not reported

Unforeseen modifications	Not reported
Planned treatment fidelity	Not reported
Actual treatment fidelity	Not reported
Other details	Very limited information provided about control condition.

Risk of Bias Assessment

Section	Risk of Bias	Reason
Domain 1: Bias arising from the randomisation process	Some concerns	Limited information on randomisation procedure; men in the intervention condition were younger than controls but there were no other significant differences between groups at baseline
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Low	Deviations from intended intervention unlikely and ITT used
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	Low	Intervention adherence high
Domain 3. Bias due to missing outcome data	Some concerns	Low attrition (~91% retention) but men retained were more likely to report USDUIA and have lower sexual self-efficacy
Domain 4. Bias in measurement of the outcome	Low	Outcome assessment the same for both groups and used follow-up questionnaires
Domain 5. Bias in selection of the reported result	Some concerns	Trial not registered
Overall bias and Directness	Some concerns	Limited information on randomisation procedures; low attrition (~91% retention) but men retained differed from non-completers on key variables; trial not registered
	Overall Directness	Partially applicable (US study)

Lauby, 2018

Bibliographic Reference	Lauby J; Milnamow M; Joseph HA; Hitchcock S; Carson L; Pan Y; Mendoza M; Millett G; Evaluation of Project RISE, an HIV Prevention Intervention for Black Bisexual Men Using an Ecosystems Approach.; AIDS and behavior; 2018; vol. 22 (no. 1)

Study details

Study design	Randomised controlled trial (RCT)
Trial registration number	Not reported
Study start date	2010
Study end date	2012
Aim	To test the effect of the RISE intervention on sexual risk outcomes in Black MSMW.
Country/geographical location	Philadelphia, USA
Setting	Community healthcare settings providing services to LGBT people of colour.
Inclusion criteria	- Men that reported having anal, vaginal or oral sex with both male and female partners in the past 12 months. - At least two sexual partners, regardless of gender, in the past 3 months - At least one instance of anal or vaginal sex without condoms in the past 3 months - Self-identified as Black (including African American, African, West Indian, Caribbean). Men reporting multiple racial groups were included as long as their primary identification was Black. - 18 years or older

	- Lived in Philadelphia or in one of the other eight counties in the Philadelphia Metropolitan Region. - Men were eligible to participate regardless of their HIV status.
Exclusion criteria	- Those reporting any injection drug use in the past 12 months were not eligible.
Method of randomisation	Participants were randomised by cluster: modified chain referral sampling was used to recruit participants so everyone in the same recruitment chain was treated as a cluster and randomised to the same treatment condition to minimise contamination. Actual method of randomisation not reported
Method of allocation concealment	Not reported
Unit of allocation	Cluster (participants in the same recruitment chain)
Unit of analysis	Participant
Statistical method(s) used to analyse the data	- Data analysis was conducted using the Stata version 13. - Analytic sample included only participants with complete data on outcome measures at baseline and 5 month follow-up. No data imputation was used, as over 95% of participants who completed the follow-up survey had complete data for the variables used in outcome analysis. - Group differences in demographic characteristics, HIV rates and testing, and risk factors at baseline were assessed using Chi square for categorical variables and t-tests for interval-level variables. - Because of the lack of precision and inaccurate or unreliable reporting that can occur when participants have to recall condom use for sexual episodes over a 3 month period, this outcome was converted into a categorical variable. This strategy also reduced the influence of extreme values. Based on the distribution of responses and the clinical significance of the behaviour change, three categories were defined: (1) a large decrease in number of episodes without condoms (a decrease of 10 or more episodes), (2) a small to moderate decrease in episodes without condoms (a decrease of 2–9 episodes) and (3) no change (including a decrease of 1 episode) or an increase in episodes without condoms. - Impact of the intervention on number of unprotected episodes was assessed using these three categories. Chi square statistics were used for bivariate group comparisons and multinomial logistic regression (Stata mlogit procedure) was

	used to assess the impact of treatment condition on this variable, controlling for HIV status, age and baseline number of sexual episodes without condoms. - The cluster variable was not included in the final outcome models due to lack of statistical power. Given that the intervention was delivered on an individual basis, clustering in the group assignment may not have much of an impact on intervention outcome.
Attrition	**Uptake** Of 404 men screened, 182 were not eligible. Of the 222 potentially eligible participants, 39 were re-screened as ineligible and 18 did not attend the baseline interview, leaving a final sample of 165 eligible participants who completed the baseline assessment and were randomised. **Attrition** In the intervention group, 72.2% attended all 6 sessions; 9.7% attended 2-5 sessions; 11.1% attended only one session; and 6.9% did not attend any sessions. 63 out of 72 (87.5%) completed the 8 week post-baseline survey (1 week post intervention) and 62 out of 72 (86.1%) completed the 5 month post-baseline survey (3 months post intervention). In the control group, 90.3% attended the session. 87 out of 93 (93.5%) completed the 8 week post-baseline survey, and 81 out of 93 (87.1%) completed the 5 month post-baseline survey. Retention rates did not significantly differ by group, and attrition analyses found no significant differences between participants retained and lost to follow-up within the intervention group. Participants retained in the control group were significantly older and were more likely to have completed high school than those lost to follow-up.
Study limitations (author)	- The control condition consisted of only one session, unlike the 6-session RISE intervention; some of the increased impact of RISE may have been due to the additional intervention time. - The relatively small sample size did not allow for sub-group comparisons that would have been helpful, such as examining differential intervention effects by HIV status.

	- The sample may not have been truly representative of Black MSMW in Philadelphia, given the large number of low-income men. In addition, MSMW who were not known to others in the LGBT community, or who were not comfortable volunteering for the project, were not likely to be reached by recruitment efforts, resulting in a sample of MSMW who may have been more comfortable revealing their sexual orientation. - Because a modified cluster sampling technique was used, sample participants cannot be considered as independent units and the cluster effect was not controlled for in all analysis models. - All outcome measures relied on self-report and did not assess whether or not partners were seroconcordant.
Study limitations (reviewer)	Although overall men in the intervention and control conditions had similar demographic and risk characteristics at baseline, the groups differed significantly on HIV status. Participants in the intervention condition were more likely to report being HIV-positive: 31.0% compared to 7.7% of control participants (p<0.0001).
Source of funding	This work was funded by the Centers for Disease Control and Prevention cooperative agreement #1UR6PS0001099

Study arms

Intervention (N = 72)

Project RISE: a 6-session individual-level intervention developed for Black MSMW using an ecosystems approach.

Control (N = 93)

Single session individual-level HIV risk reduction intervention.

Characteristics

Arm-level characteristics

Characteristic	Intervention (N = 72)	Control (N = 93)
Age Mean (SD)	45.02 (8.26)	44.88 (9.45)
Gender Male	% = 100	% = 100
Ethnicity Self-identified as Black	% = 100	% = 100
Sexual orientation		
Bisexual	% = 64.5	% = 78.8
Straight	% = 11.3	% = 10
Gay	% = 8.1	% = 3.8
Unsure/questionning/other	% = 16.1	% = 7.5
Homeless in the last 12 months	% = 51.6	% = 51.9
Ever incarcerated	% = 63.9	% = 63
Drug use in the last 3 months	% = 61.3	% = 60.5
HIV positive status	% = 31.2	% = 7.5
Receiving HIV care Including only HIV positive men, n=25	% = 100	% = 100

Note study characteristics are reported for the study sample retained at follow-up (intervention n=62; control n=81)

Outcomes

Study timepoints

- 3 month (Paper reports this as 5 month follow-up as it is 5 months from the baseline assessment; recoded as 3-months as it is 3 months from intervention completion.)

Condom use outcomes

Outcome	Intervention, 3 month, N = 62	Control, 3 month, N = 81
No change or increase in number of episodes of condomless sex with male partners No of events	n = 19 ; % = 30.6	n = 43 ; % = 53.1
Small or moderate decrease in number of episodes of condomless sex with male partners No of events	n = 30 ; % = 48.4	n = 29 ; % = 35.8
Large decrease in number of episodes of condomless sex with male partners No of events	n = 13 ; % = 21	n = 9 ; % = 11.1
No change or increase in number of episodes of condomless sex with female partners No of events	n = 26 ; % = 41.9	n = 36 ; % = 44.4
Small or moderate decrease in number of episodes of condomless sex with female partners No of events	n = 23 ; % = 37.1	n = 25 ; % = 30.9

Outcome	Intervention, 3 month, N = 62	Control, 3 month, N = 81
Large decrease in number of episodes of condomless sex with female partners No of events	n = 13 ; % = 21	n = 20 ; % = 24.7

No change or increase in number of episodes of condomless sex with male partners - Polarity - Lower values are better

Small or moderate decrease in number of episodes of condomless sex with male partners - Polarity - Higher values are better

Large decrease in number of episodes of condomless sex with male partners - Polarity - Higher values are better

No change or increase in number of episodes of condomless sex with female partners - Polarity - Lower values are better

Small or moderate decrease in number of episodes of condomless sex with female partners - Polarity - Higher values are better

Large decrease in number of episodes of condomless sex with female partners - Polarity - Higher values are better

Condom use was assessed by asking participants to report the total number of vaginal or anal sexual episodes they had with each type of partner in the previous 3 months and the number of these episodes when no condom was used. This outcome was then converted into a categorial variable based on the change in number of condomless episodes: 1) a large decrease in the number of episodes (decrease of 10 or more); 2) a small to moderate decrease in number of episodes (decrease of 2-9), or 3) no change (including a decrease of 1 episode) or an increase in episodes.

TIDier Checklist

Study details

Rationale/theory/Goal	Previous research indicates that 20–40% of Black MSM have both male and female sex partners. The health of men who have sex with men and women (MSMW) is often overlooked and frequently conflated with that of MSM, however MSMW experience unique risk factors separate from the risk factors of MSM. Interventions developed for gay men may not be relevant or appropriate for MSMW, many of whom do not self-identify as gay and may require different prevention strategies for their male and female partners (p. 164).

Procedures used	- The sample was recruited using chain referral techniques. - Initial participants ('seeds') were recruited in several ways: 21% were referred by staff of LGBT serving organisations, 14% were recruited by Community Advisory Board members and 65% volunteered in response to flyers and newspaper ads. - Each seed was asked to recruit up to five eligible participants from his social network and was given a small cash payment ($15) for each eligible recruit who joined the study. Once new recruits completed the baseline survey, they were asked to recruit up to five participants each. - All potential participants were given the project phone number and callers were asked to complete a short telephone screening interview. Eligible participants were given an interview appointment where they were screened again. - After giving informed consent, eligible participants completed a baseline survey comprising questions relating to demographic characteristics and sexual risk behaviours assessed using ACAS, followed by a computer assisted personal interview conducted by an interviewer to measure coping behaviour and questions relating to access to HIV prevention programs and services. - Intervention and control sessions were scheduled for the week after baseline assessment, and follow-up assessments were conducted at 8 weeks post-baseline (1 week after intervention completion) and 5 months post-baseline (3 months after intervention completion) using the same assessments as the baseline. (p. 166-167).
Other details	- Participants in both the intervention and control conditions were offered HIV and STI testing (p. 166). - Participants were compensated for their time and received $50, $50 and $75 for completing the baseline, 8-week and 5-month assessments, respectively. Intervention participants received $20 for each session they attended. Participants also received $15 for each eligible participant they recruited (up to 5) (p. 167).

Study arms

Intervention (N = 72)

Project RISE: a 6-session individual-level intervention developed for Black MSMW using an ecosystems approach.

Brief name	Project RISE (p. 164)
Rationale/theory/Goal	- The intervention was developed with the assistance of a community advisory board (CAB) of 15 bisexually-active Black men. - Based on Social Cognitive Theory; Stress and Coping Theory; and using an ecosystems perspective, the intervention uses counselling sessions focusing on the relationship between the person and their social environment. - Sessions were designed to address issues of stress and coping; experiences of discrimination and other life concerns; and sexual risk behaviours. - The focus on life issues was intended to make the intervention more comprehensive, appealing and relevant to participants rather than focusing exclusively on HIV risk behaviours. By helping men deal with their daily concerns, they may become more open to making changes in their sexual behaviour. (p. 166).
Materials used	No specific materials reported
Procedures used	- In the first session, eco-mapping was used to develop a graphic depiction providing an aerial view of the relationship between the person and their social environment. The map was used throughout all sessions to address strengths and stressors in various relationships, including those with partners, families, children and other systems. - Topics covered across the six sessions were (1) Black Male Identity and Life Context, (2) Assessing Coping Abilities and Coping Strategies, (3) Sexual Partners and Sexual Relationships, (4) Perception of Risk and HIV/STD Knowledge, (5) Factors Related to Sexual Behavior and Exploration of Condom Use, (6) Optional Content Module and Closure. - Discussion of sexual relationships and HIV risk was introduced in session 3 after rapport had been established and the counsellor had a good understanding of the participant's life circumstances and relationships. - Session 4 included a discussion of the need for HIV testing. Participants were offered HIV and STI testing through a community partner agency.

	- For the optional content module, participants could choose modules addressing specific issues most relevant to them such as spirituality, recovery from sexual abuse, disclosure of sexual identity, or particular needs of HIV positive participants. - Topics of particular concern to Black MSMW were addressed throughout the intervention, including stigma and discrimination due to race and sexual orientation. - Life coaching principles were used throughout to tailor the content to the needs of individual participants and to help men work through problem areas and generate an action plan. - The promotion of a positive self-identity and development of coping strategies were essential components. (p. 165-166)
Provider	Four trained counsellors with backgrounds in psychology or social work delivered the intervention. They received two 4-hour training sessions covering the intervention's theoretical framework and content of each session, and completed practice sessions (p. 166).
Method of delivery	One-to-one face to face sessions (p. 166)
Setting/location of intervention	Offices of the project's community partner agency, which provides services to LGBT people of colour (p. 166)
Intensity/duration of the intervention	Six 90-120 minute sessions, delivered once per week for 6 weeks. Some participants received 2 sessions per week if that was there preference (p. 166).
Tailoring/adaptation	The intervention content could be tailored to the needs of individual participants (p. 166)
Unforeseen modifications	None reported
Planned treatment fidelity	A detailed intervention manual was developed to ensure fidelity to the theoretical model and consistency in implementation. Counsellors completed a self-assessment form after each session to document activities completed, engagement of participants and challenges encountered. Monthly supervision sessions were completed with the intervention director (p. 166).
Actual treatment fidelity	Not reported.

Control (N = 93)

Single session individual-level HIV risk reduction intervention.

Materials used	No specific materials reported
Procedures used	- Control participants received a standard single-session individual-level HIV risk reduction intervention. - Session content included an assessment of HIV risk and a discussion of ways to reduce or eliminate risk. The content was not tailored to MSMW. - Control participants were also offered HIV and STI testing (p. 166).
Provider	The control session was delivered by staff of the community partner agency. The two counsellors providing the control session were not involved in the intervention sessions (p. 166).
Method of delivery	One to one face to face session (p. 166).
Setting/location of intervention	Offices of the project's community partner agency which provides services to LGBT people of colour (p. 166).
Intensity/duration of the intervention	One 60 minute session (p. 166).
Tailoring/adaptation	Not reported
Unforeseen modifications	None reported
Planned treatment fidelity	Not reported
Actual treatment fidelity	Not reported

Risk of Bias Assessment

Section	Risk of Bias	Reason
Domain 1: Bias arising from the randomisation process	Some concerns	No information on allocation concealment and baseline differences between groups: intervention participants were more likely to report being HIV positive (31% intervention vs 7.7% control)
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Low	Deviations from intended intervention unlikely
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	Some concerns	Trained counsellors delivered the interventions and implementation failures were unlikely, but session adherence was moderate: 72.2% attended all six sessions, 9.7% attended 2–5 sessions, 11.1% attended only one session and 6.9% did not attend any sessions; and impact of adherence not assessed
Domain 3. Bias due to missing outcome data	Low	86.7% retention rate and no difference in retention rate between conditions and no differences between those retained and those lost to follow up in the intervention group (participants retained in the control group were older and more likely to have completed high school than those lost to follow-up
Domain 4. Bias in measurement of the outcome	Some concerns	Appropriate outcome assessment methods used but some concerns about the conversion of condom use outcome measure into categorical variable and the theoretical / clinic rationale for the chosen categories
Domain 5. Bias in selection of the reported result	Some concerns	Trial not registered
Overall bias and Directness	Some concerns	Baseline differences between groups of HIV status; session adherence was moderate and impact of adherence not assessed; some concerns over conversion of condom use outcome into categorial variable; trial not registered
	Overall Directness	Partially applicable (US study)

Tobin, 2013

Bibliographic Reference	Tobin, K; Kuramoto, SJ; German, D; Fields, E; Spikes, PS; Patterson, J; Latkin, C; Unity in diversity: results of a randomized clinical culturally tailored pilot HIV prevention intervention trial in Baltimore, Maryland, for African American men who have sex with men; Health education & behavior; 2013; vol. 40 (no. 3); 286-295

Study details

Study design	Randomised controlled trial (RCT)
Trial registration number	Not reported
Study start date	Aug-2007
Study end date	Aug-2008
Aim	To evaluate the efficacy of Unity iN Diversity (UND) on participant sexual risk in African American MSM.
Country/geographical location	Baltimore, Maryland, USA.
Setting	Data collection and intervention sessions were held in the research clinic.
Inclusion criteria	- Aged 18 years old or older - Identifying as African American or Black race/ethnicity - Having at least two sex partners in the prior 90 days (at least one of whom must be a male partner) - Having unprotected anal sex with a male partner in the prior 90 days - Willing to take an HIV test. *Note the paper does not report being male as an inclusion criteria but assumed this is an error; all participants were male.

Exclusion criteria	None reported
Method of randomisation	After approximately 12 participants completed the baseline visit, a randomisation session was scheduled during which a computerised program was used by the Data Manager to assigned individuals to a condition using a two-block design. The first session of the intervention condition and the only session of the control condition were conducted immediately after randomisation. Condition sessions ended at different times to minimise contamination between conditions.
Method of allocation concealment	Computerised random allocation
Unit of allocation	Participant
Unit of analysis	Participant
Statistical method(s) used to analyse the data	- Chi-square tests for categorical and t-tests for continuous variables were used to compare baseline demographics. Fisher's exact test was used in lieu of chisquare tests when variables had sparse cells (less than five participants in a category). - Logistic regressions were conducted to examine the association between intervention status and dichotomised outcomes of sexual risk behaviour and sex under the influence at follow-up. - For condom use with HIV-positive partners and HIV-negative/unknown partners, these analyses were only conducted among those with HIV-positive partners and HIV-negative/unknown partners at baseline, respectively. - Each model further adjusted for respective outcome at baseline to account for potential regression to the mean, as well as HIV status and insurance status, which were statistically different ($p<0.05$) between conditions at baseline. - All analyses were based on the intent-to-treat assumption regardless of number of sessions attended. - Analyses were conducted using Stata 10 (StataCorp, 2007).
Attrition	N=971 potential participants completed the first screen; n=509 were excluded (ineligible; not AAMSM). A further n=274 were excluded during the second screen due to ineligibility (90% did not report unprotected anal sex). N=188 completed the baseline assessment but 41 of those participants did not attend for the randomisation session leaving n=147 (78%). Of the 75 participants in the intervention condition, 73 (96%) completed the 3 month follow up.

	Of the 72 participants in the control condition, 71 (96%) completed the 3 month follow up. Intervention session attendance ranged from 76% to 100%. There were no differences between intervention and control participants on most baseline characteristics but control participants were more likely to be HIV positive (60% vs 41%) and less likely to have health insurance (65% vs 80%).
Study limitations (author)	- Used a convenience sample that were predominately older men who were not currently working full-time, which limits generalisability to younger men and those who were unable to commit to attending two sessions a week in the afternoon. - The outcomes were based only on self-reports and the measures included in this analysis did not differentiate by partner type or insertive versus receptive anal sex. - Though the control condition received high quality risk reduction counselling during the baseline visit, this condition was not equal attention - The experimental condition received more remuneration for their session attendance (up to $140) as compared to $20 for one session. - Potential contamination between conditions was not assessed, but may explain the limited effects of the intervention. - The 3-month follow-up period to assess behaviour change limits the ability to determine sustainability of effects.
Study limitations (reviewer)	None to add
Source of funding	Not reported

Study arms

Intervention (N = 75)

Unity in Diversity (UND): a group-based culturally tailored HIV prevention intervention for African American MSM.

Control (N = 72)

Single small group-based HIV prevention and care session.

Characteristics

Arm-level characteristics

Characteristic	Intervention (N = 75)	Control (N = 72)
Age Mean (SD)	38.4 (10.8)	39.5 (9.6)
Ethnicity African American / Black	n = 75 ; % = 100	n = 72 ; % = 100
History of incarceration		
Never in lifetime	n = 21 ; % = 28	n = 22 ; % = 31
Lifetime; not in past 3 months	n = 41 ; % = 55	n = 44 ; % = 61
In past 3 months	n = 13 ; % = 17	n = 6 ; % = 8
Homeless in past 3 months	n = 11 ; % = 15	n = 7 ; % = 10
HIV status		
Positive	n = 31 ; % = 41	n = 43 ; % = 60
Negative/unknown	n = 44 ; % = 59	n = 29 ; % = 40
Injected drugs in past 3 months	n = 11 ; % = 15	n = 6 ; % = 8

Characteristic	Intervention (N = 75)	Control (N = 72)
Used heroin in past 3 months	n = 18 ; % = 24	n = 12 ; % = 17
Used crack in past 3 months	n = 30 ; % = 40	n = 29 ; % = 40
Used cocaine in past 3 months	n = 18 ; % = 24	n = 20 ; % = 28
Used amphetamine in past 3 months	n = 4 ; % = 5	n = 2 ; % = 3
Used club drugs in the past 3 months	n = 4 ; % = 5	n = 8 ; % = 11
Sexual identity		
Gay, same gender loving, homosexual	n = 44 ; % = 60	n = 43 ; % = 61
Bisexual	n = 20 ; % = 28	n = 25 ; % = 36
Straight, heterosexual	n = 9 ; % = 12	n = 2 ; % = 3
Other, unsure	n = 2 ; % = 3	n = 2 ; % = 3

Outcomes

Study timepoints

- Baseline
- 3 month

Condom use outcomes

Outcome	Intervention, Baseline, N = 73	Intervention, 3 month, N = 45	Control, Baseline, N = 71	Control, 3 month, N = 52
100% condom use with all partners During past 3 months No of events	n = 5 ; % = 7	n = 14 ; % = 31	n = 5 ; % = 7	n = 12 ; % = 23
[Reverse score 100% condom use] Unprotected intercourse with all partners During past 3 months No of events	n = 68 ; % = 93	n = 31 ; % = 69	n = 66 ; % = 93	n = 40 ; % = 77

100% condom use with all partners - Polarity - Higher values are better

[Reverse score 100% condom use] Unprotected intercourse with all partners - Polarity - Lower values are better

Individual outcome tables for each outcome because n's are different. Follow-up data restricted to subsample of participants who reported having partners at baseline and follow-up Reverse scored items calculated by analyst

Condom use outcomes

Outcome	Intervention, Baseline, N = 73	Intervention, 3 month, N = 44	Control, Baseline, N = 71	Control, 3 month, N = 52
100% condom use with male partners During past 3 months No of events	n = 9 ; % = 13	n = 17 ; % = 39	n = 5 ; % = 8	n = 13 ; % = 25
[Reverse score 100% condom use] Unprotected intercourse with male partners during past 3 months	n = 64 ; % = 87	n = 27 ; % = 61	n = 66 ; % = 92	n = 39 ; % = 75

Outcome	Intervention, Baseline, N = 73	Intervention, 3 month, N = 44	Control, Baseline, N = 71	Control, 3 month, N = 52
No of events				

100% condom use with male partners - Polarity - Higher values are better

[Reverse score 100% condom use] Unprotected intercourse with male partners - Polarity - Lower values are better

Individual outcome tables for each outcome because n's are different. Follow-up data restricted to subsample of participants who reported having male partners at baseline and follow-up

Condom use outcomes

Outcome	Intervention, Baseline, N = 73	Intervention, 3 month, N = 48	Control, Baseline, N = 71	Control, 3 month, N = 53
100% condom use with HIV+ partner During past 3 months No of events	n = 50 ; % = 71	n = 40 ; % = 83	n = 45 ; % = 65	n = 37 ; % = 70
[Reverse score 100% condom use with HIV+ partners] Unprotected intercourse with HIV+ partners during past 3 months No of events	n = 23 ; % = 29%	n = 8 ; % = 17	n = 26 ; % = 35	n = 16 ; % = 30

100% condom use with HIV+ partner - Polarity - Higher values are better

Individual outcome tables for each outcome because n's are different. Follow-up data restricted to subsample of participants who reported having HIV+ partners at baseline and follow-up

Condom use outcomes

Outcome	Intervention, Baseline, N = 73	Intervention, 3 month, N = 44	Control, Baseline, N = 71	Control, 3 month, N = 54
100% condom use with HIV-/unknown status partners During past 3 months No of events	n = 18 ; % = 25	n = 23 ; % = 52	n = 19 ; % = 31	n = 23 ; % = 43

100% condom use with HIV-/unknown status partners - Polarity - Higher values are better

Individual outcome tables for each outcome because n's are different. Follow-up data restricted to subsample of participants who reported having HIV-/unknown status partners at baseline and follow-up

Drug use during sex

Outcome	Intervention, Baseline, N = 73	Intervention, 3 month, N = 73	Control, Baseline, N = 71	Control, 3 month, N = 71
Drug use during last sex No of events	n = 31 ; % = 43	n = 12 ; % = 25	n = 33 ; % = 47	n = 23 ; % = 41

Drug use during last sex - Polarity - Lower values are better

TIDier Checklist

Study details

Rationale/theory/Goal	African American MSM experience 2.5 to 4 times the rate of HIV compared to white MSM. Research has identified high levels of stigmatisation and reluctance to identify as gay or bisexual, as well as varying patterns of heterosexual activity and HIV risk disclosure to female partners among African American MSM. Diversity within the African American MSM population warrants tailored intervention approaches. Addressing social influence processes, social norms and support is also important in promoting and maintaining behaviour change (p. 1-2).

Procedures used	- Participants were recruited from several different venues including bars, clubs, cafes, restaurants and college campuses. Print advertisements in city and University-based newspapers, and internet-based recruitment using websites that catered for African American MSM, were also used. Referrals to the study were also obtained from local agencies providing services to African American MSM. - Potential participants were screened using a 2-step process: a telephone-based survey followed by an in-person screening visit using ACASI. - Eligible participants provided written informed consent then completed a baseline assessment using ACASI. A trained research assistant then completed a social network inventory survey to collect information about the participant's support network and drug or sex network. - At the end of the baseline visit, participants reporting negative or unknown HIV status were tested for HIV antibodies using Oraquick testing kits and provided with HIV pre- and post-test counselling. - After approximately 12 participants had completed a baseline visit, a randomisation session was scheduled during which participants were randomly assigned to intervention or control group. the first intervention session and only control session were conducted immediately after this randomisation session. (p. 2-3).
Other details	All participants, regardless of eligibility, received $20 for completing the in-person screening visit. Participants received $40 for the baseline assessment; $25 for each intervention session attended; $25 for attending the control session; and $45 for the follow-up session (p. 2-4).

Study arms

Intervention (N = 75)

Unity in Diversity (UND): a group-based culturally tailored HIV prevention intervention for African American MSM.

Brief name	Unity in Diversity (UND) (p. 1)

Rationale/theory/Goal	The intervention was informed by a number of behaviour change theories: The IMB model was used to increase knowledge about HIV risk and testing and increase motivation to engage in preventive behaviours; Social Network Theory informed the decision to use small group sessions and facilitate learning from peers experiences, as well as establishing and promoting social norms about condom use and testing; and Social Cognitive Theory was used to inform components relating to self-efficacy. The intervention sought to 1) teach information and skills about HIV risk, 2) establish pro-social norms about HIV testing and condom use, 3) increase proper and consistent condom use 4) improve communication skills for negotiating HIV risk reduction with partners and 5) encourage diffusion of information and skills to individuals' social network members. (p. 2; 3).
Materials used	Videos; alcohol-vision goggles to simulate challenges to correct condom use whilst under the influence of drugs or alcohol (p. 3)
Procedures used	6 group sessions plus one individual session: 1. Introduction: introduce program goals; increase awareness of HIV; group discussion about stereotypes and assumptions about HIV and MSM. 2. Taking Care of Self: review HIV and STI knowledge; emphasise importance of knowing your HIV status; increase motivation and self-efficacy for HIV testing. 3. Taking Care of Self: review condom use skills and increase efficacy for condom use; condom skills practice activity; group discussion of personal responsibility to use condoms and to ask partners about their HIV status. 4. Taking Care of Relationships: review effective communication skills with social networks; communication role plays; practice skills for talking to partners about testing and disclosure of HIV status. 5. Taking Care of Community: discuss mentoring of social network members; decreasing HIV and MSM stigma 6. Individual session: conducted in private setting; conduct personal risk assessment and set goals for risk reduction; increase motivation to engage in preventive behaviours.

	7. Graduation and Sustainability of Skills: discuss risk behaviour relapse prevention strategies; group discussion about relapse triggers; reminders to complete 3 month follow up. Throughout the sessions, videos, group discussions, problem solving activities and role plays were used. In each session participants were also given an assignment to have a conversation with someone in their social network about the topics discussed in the group session. (p. 3; 12)
Provider	Two African American male co-facilitators (p. 3)
Method of delivery	Face to face small group sessions (mean of 6 participants; range 4-8) (p. 3)
Setting/location of intervention	Research clinic (p. 3)
Intensity/duration of the intervention	Six 2-hour groups sessions plus one individual session, held twice a week, typically in the afternoon (1-3pm) (p. 3).
Tailoring/adaptation	Not reported
Unforeseen modifications	None reported
Planned treatment fidelity	All sessions were audio-recorded. Sessions were randomly selected and reviewed by a trained research assistant for fidelity to content and procedures (p. 3).
Actual treatment fidelity	Fidelity was high: over 90% of sessions were rated as adequate (p. 3).

Control (N = 72)

Single small group-based HIV prevention and care session.

Materials used	No specific materials reported
Procedures used	The control group received one small-group HIV prevention and care session in which a facilitator reviewed the different health resources available in the city to African American MSM (p. 4)

Provider	A trained facilitator (p. 4).
Method of delivery	Face to face small group session (p. 4)
Setting/location of intervention	Research clinic (p. 4)
Intensity/duration of the intervention	10-15 minutes (p. 4)
Tailoring/adaptation	None reported
Unforeseen modifications	None reported
Planned treatment fidelity	Not reported
Actual treatment fidelity	Not reported

Risk of Bias Assessment

Section	Risk of Bias	Reason
Domain 1: Bias arising from the randomisation process	Some concerns	Appropriate randomisation procedures but baseline differences: control participants were more likely to be HIV positive (60% vs 41%) and less likely to have health insurance (65% vs 80%)
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Some concerns	No information on participant blinding. Deviations from intended intervention unlikely. ITT used
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	Some concerns	Trained counsellors delivered the interventions and implementation failures were unlikely, but session adherence was moderate: 72.2% attended all six sessions, 9.7% attended 2–5 sessions, 11.1% attended only one session and 6.9% did not attend any sessions; and impact of adherence not assessed

Section	Risk of Bias	Reason
Domain 3. Bias due to missing outcome data	Low	Impact of intervention adherence not assessed but fidelity was high and the intervention was small group sessions led by trained facilitators so adherence likely
Domain 4. Bias in measurement of the outcome	Low	Outcomes assessed using ACASI for behavioural variables and using interviewer administered survey for other measures; interviewers were blinded to condition
Domain 5. Bias in selection of the reported result	Some concerns	Trial not registered
Overall bias and Directness	Some concerns	Appropriate randomisation procedures but no information on participant blinding and baseline differences between groups on HIV status and health insurance. Trial not registered
	Overall Directness	Partially applicable (US study)

Williams, 2013

Bibliographic Reference Williams, John K; Glover, Dorie A; Wyatt, Gail E; Kisler, Kimberly; Liu, Honghu; Zhang, Muyu; A sexual risk and stress reduction intervention designed for HIV-positive bisexual African American men with childhood sexual abuse histories.; American journal of public health; 2013; vol. 103 (no. 8); 1476-84

Study details

Study design	Randomised controlled trial (RCT)
Trial registration number	Not reported
Study start date	2007
Study end date	2011

Aim	To develop and test the Enhanced Sexual Health Intervention for Men (ES-HIM) for HIV-positive African American MSMW who did not self-identify as gay and who had histories of CSA, to explore the intervention's effects on sexual risk behaviours.
Country/geographical location	Los Angeles, USA
Setting	Unclear
Inclusion criteria	- African American male - At least 18 years of age - English speaking, - HIV positive - Did not self-identify as gay - Had engaged in unprotected anal or vaginal sex (or both) with a male as well as a female partner in the preceding 90 days - Had a history of CSA (had experienced any unwanted or forced sexual contact (ranging from touching and fondling to intercourse) or had had sexual experiences with someone at least 5 years older when they were less than 18 years of age were defined as having a CSA history).
Exclusion criteria	None reported
Method of randomisation	Not reported
Method of allocation concealment	Not reported
Unit of allocation	Participant
Unit of analysis	Participant

Statistical method(s) used to analyse the data	- Repeated measures analyses of variance were conducted to examine group and time effects for all outcome measures. - Planned contrasts were used to examine changes from baseline to the 3-month follow-up and from the 3-month to 6-month follow-ups. - Log transformations were necessary for all sexual risk outcomes. - SAS statistical software, version 9.2 was used for the analyses, and the macro procedure %GLIMMIX was used to fit the generalised linear repeated measures models.
Attrition	Of 295 men screened, 117 met the eligibility criteria and were randomised. Of 64 men assigned to the intervention, n=44 attended at least session 1; n=43 completed the 3-month assessment and n=43 completed the 6 month assessment. The 20 participants that did not receive any intervention were excluded from analyses. Of 53 men assigned to the control, n=44 attended at least session 1; n=42 completed the 3-month assessment and n=41 completed the 6 month assessment. The 9 participants that did not receive any control intervention were excluded from analyses. There were no differences between the 29 eligible participants that were not retained and the 88 that were on any demographic characteristics.
Study limitations (author)	- Despite standard randomisation procedures, ES-HIM participants exhibited a greater prevalence of high-severity CSA at baseline. The failure of randomisation to control baseline group differences undermines clear interpretation of the findings. - The study included a population of men with limited education, extremely modest incomes, and histories of being incarcerated.
Study limitations (reviewer)	None to add
Source of funding	Support for this research was provided by the National Institute of Mental Health (grants 1 R34 MH077550 and 5P50MH073453).

Study arms

Intervention (N = 44)

Enhanced Sexual Health Intervention for Men (ES-HIM): a stress-focused sexual risk reduction intervention for African American MSMW with a history of childhood sexual abuse (CSA)

Control (N = 44)

Attention-matched health promotion intervention (HP).

Characteristics

Study-level characteristics

Characteristic	**Study (N = 88)**
Age Mean (SD)	46.6 (8.3)
Gender Male	n = 88 ; % = 100
Ethnicity African American	n = 88 ; % = 100
Unemployed or unable to work	n = 73 ; % = 83.9
Spent more than 1 day in jail or prison	n = 60 ; % = 68.6
Mean number of times incarcerated Mean (SD)	5.5 (4.5)

Outcomes

Study timepoints

- Baseline
- 3 month
- 6 month

Condom use outcomes

Outcome	Intervention, Baseline, N = 44	Intervention, 3 month, N = 44	Intervention, 6 month, N = 44	Control, Baseline, N = 44	Control, 3 month, N = 44	Control, 6 month, N = 44
Unprotected anal sex (insertive) In prior 3 months Mean (SD)	1.79 (19.83)	0.67 (10.54)	0.46 (13.33)	1.02 (10.94)	0.41 (7.1)	0.9 (19.63)
Unprotected anal sex (receptive) In prior 3 months Mean (SD)	1.62 (15.19)	0.2 (5.97)	0.29 (6.1)	1.3 (18.44)	0.34 (6.89)	0.49 (12.6)
Unprotected vaginal sex In prior 3 months Mean (SD)	1.7 (13.2)	0.21 (4.78)	0.05 (2.08)	2.84 (19.83)	0.12 (2.98)	0.02 (1.06)

Unprotected anal sex (insertive) - Polarity - Lower values are better

Unprotected anal sex (receptive) - Polarity - Lower values are better

Unprotected vaginal sex - Polarity - Lower values are better

Paper reports SEs; SDs calculated by analyst

TIDier Checklist

Study details

Rationale/theory/Goal	African American MSMW may be less likely to respond to interventions that are developed for gay men, or to those not contextualised for African American experiences. Individual behaviour change is complicated by personal, environmental, historical, and institutional factors. Trauma exposure, and in particular childhood sexual abuse (CSA), may be contributing to the HIV epidemic; associations between CSA and increased HIV sexual risk behaviours have been shown, and mental health symptoms such as PTSD and depression may also play a role in the relationship between CSA and sexual risk. Experiencing CSA may have an impact on interpersonal relationships in adulthood (e.g., how they select and interact with their intimate sexual partners), and societal and environmental factors such as the stigma associated with sexual abuse may also contribute to negative psychosocial health outcomes. Comprehensive interventions designed to reduce sexual risk behaviours and psychological difficulties in HIV-positive men with a history of CSA are lacking (p. 1476-1477).
Procedures used	- Fliers, print advertisements, and face-to-face strategies were used to recruit a community sample of HIV-positive African American MSMW from HIV and other service agencies - Prospective participants were screened and eligible participants then provided informed consent then completed a 90-minute questionnaire via laptop and ACASI. - After completing the baseline assessment, participants were randomised to condition. After completing all sessions, participants were post-tested at 3- and 6-months. (p. 1477)
Other details	This study also assessed intervention impacts on psychological symptoms of PTSD and depression, and primary neurohormonal mediators (cortisol and catecholamines) and neopterin (used as an indicator of HIV disease progression). These biomarkers required collection of 12-hour overnight urine samples and urine collection diaries. Data for these outcomes were not included in this review so information relating to these aspects of the procedure have not been extracted.

	Participants were compensated up to $220 for full study attendance and collection of biomarkers (p. 1478).

Study arms

Intervention (N = 44)

Enhanced Sexual Health Intervention for Men (ES-HIM): a stress-focused sexual risk reduction intervention for African American MSMW with a history of childhood sexual abuse (CSA)

Brief name	Enhanced Sexual Health Intervention for Men (ES-HIM) (p. 1477)
Rationale/theory/Goal	- ES-HIM was adapted from the evidence-based Sexual Health Intervention for Men, a 6-session intervention targeting HIV-positive African American and Latino men with histories of CSA - Guided by cognitive-behavioural approaches and an ecological framework that addresses individual, interpersonal, social, and cultural factors, it recognises that previous experiences, both individually and cumulatively, can affect sexual decision making. - It focuses on both changes in sexual behaviour and improvements in psychological health. (p. 1478).
Materials used	No specific materials reported
Procedures used	- The intervention comprised 6 small group sessions where issues relating to sexual behaviour and psychological health were discussed; all discussions were framed within a culturally congruent social context. - Sexual risk reduction was framed from the perspective of each participant being a member of a triple minority group (i.e., being HIV positive and being a member of an ethnic and a sexual minority group). Issues associated with stigma and social isolation were discussed.

	- Sexual ownership (i.e., being able to make independent choices about sex and being responsible for one's own sexual and physical health) was prioritised along with caring for one's sexual partners, family, and community. - Cultural and religious messages that could contradict HIV prevention efforts were acknowledged. - Discussion topics included the influence of gender and ethnicity; early socialisation; adult experiences (e.g., being a bisexual vs a heterosexual individual within the African American community); HIV stigma; recognition of stressors (including trauma histories); learned coping strategies and affect regulation. - Issues relating to trauma and their history of CSA were also addressed, including cognitive distortions, negative thoughts and emotions, the impact of CSA on personal decision making, behavioural patterns surrounding sexual behaviours, and how triggers can lead to unhealthy decisions and high risk behaviours. - Participants learned communication skills with an emphasis on negotiation, assertiveness training and establishing safer sex boundaries. (p. 1478).
Provider	A trained, ethnically matched male facilitator (p. 1477)
Method of delivery	Small group sessions (p. 1477)
Setting/location of intervention	No information
Intensity/duration of the intervention	Six 2-hour sessions administered over 3 weeks (p. 1477).
Tailoring/adaptation	Not reported
Unforeseen modifications	None reported
Planned treatment fidelity	Not reported
Actual treatment fidelity	Not reported

Control (N = 44)

Attention-matched health promotion intervention (HP)

Materials used	No specific materials reported
Procedures used	- The Health Promotion (HP) control sessions addressed health issues such as certain cancers, hypertension, diabetes, and heart disease, all of which are common among African American men, but did not focus on sexual behaviours. - Participants were taught about changing personal behaviours and their impact on these diseases (e.g. increasing physical exercise, changing their diet, early detection and screening). (p. 1478).
Provider	A trained, ethnically matched male facilitator (p. 1477).
Method of delivery	Small group sessions (p. 1477)
Setting/location of intervention	Not reported
Intensity/duration of the intervention	Six 2-hour sessions administered over 3 weeks (p. 1477)
Tailoring/adaptation	None reported
Unforeseen modifications	None reported
Planned treatment fidelity	Not reported
Actual treatment fidelity	Not reported

Risk of Bias Assessment

Section	Risk of Bias	Reason
Domain 1: Bias arising from the randomisation process	Some concerns	Limited information provided on the randomisation process. There were significant baseline differences in biomarker composite scores (stress-related neurohormones; not extracted for this review)
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Some concerns	No information on participant blinding. Deviations from intended intervention unlikely
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	Some concerns	Intervention adherence not assessed but small sessions led by trained facilitators so non-adherence unlikely
Domain 3. Bias due to missing outcome data	Some concerns	Moderate attrition (75% retained) but no differences between completers and non-completers.
Domain 4. Bias in measurement of the outcome	Low	Outcomes assessed using ACASI and the same for both groups
Domain 5. Bias in selection of the reported result	Some concerns	Trial not registered
Overall bias and Directness	Some concerns	No information on randomisation procedures or blinding; intervention adherence not assessed; moderate attrition but no differential attrition; trial not registered
	Overall Directness	Partially applicable (US study)

D.10 Effectiveness evidence for young men from a Black African or Caribbean family background who have sex with men

Crosby, 2018

Bibliographic Reference	Crosby, Richard A; Mena, Leandro; Salazar, Laura F; Hardin, James W; Brown, Tim; Vickers Smith, Rachel; Efficacy of a Clinic-Based Safer Sex Program for Human Immunodeficiency Virus-Uninfected and Human Immunodeficiency Virus-Infected

Young Black Men Who Have Sex With Men: A Randomized Controlled Trial.; Sexually transmitted diseases; 2018; vol. 45 (no. 3); 169-176

Study details

Study design	Randomised controlled trial (RCT)
Trial registration number	The study was registered with Clinical Trials.gov (ID: NCT00849823)
Study start date	Sep-2012
Study end date	Dec-2015
Aim	To test the efficacy of a single-session, clinic-based intervention designed to promote condom use among young Black men who have sex with men (YBMSM).
Country/geographical location	Jackson, Mississippi, USA.
Setting	2 sexual health clinics receiving state/federal support for screening and treatment of STIs/HIV.
Inclusion criteria	- Assigned male at birth - Self-identification as Black/African American - 15 to 29 years of age - Attending the clinic to be tested for HIV or other STIs - Engaged in anal sex with a male in the past 6 months - Able to speak/comprehend English
Exclusion criteria	None reported
Method of randomisation	Computer generated algorithm

Method of allocation concealment	Computer generated algorithm
Unit of allocation	Participant
Unit of analysis	Participant
Statistical method(s) used to analyse the data	From Crosby (2018b) - Incidence of rectal, pharyngeal, and urethral infections was calculated by 2 methods: (1) case counts and (2) by person. For case incidence, the number of infections at each study visit was counted. For person incidence, the number of individuals who had at least 1 infection was counted. - Generalised Estimation Equation (GEE) binomial models were estimated to assess group differences regarding the likelihood of 6 outcomes: (1) a positive CT/NG test during the study period, (2) a positive urethral and/or rectal Chlamydia trachomatis/Nisseria gonorrhoeae (CT/NG) test during the study period, (3) proportion of condom use during insertive anal sex, (4) proportion of condom use during receptive anal sex, (5) consistent condom use during insertive anal sex, and (6) consistent condom use during receptive anal sex. - All models controlled for the previously enumerated covariates. - Analyses were conducted using Stata version 14 and SPSS version 24.0. From Crosby et al. (2018a): - Difference scores between baseline and 12-month assessment were calculated and an independent groups t-test was used to compare means by condition, stratified by HIV status. - Logistic regression was also used to determine intervention efficacy. Models were tested separately for HIV positive and HIV negative men.
Attrition	**Uptake** 871 potential participants were assessed for eligibility: 250 were not eligible and 21 declined to participate due to lack of interest, yielding an overall participation rate of 96.6%.

	Attrition 600 men were randomised to the intervention (n=299) and control (n=301) groups. In the intervention group, n=200 (68%) completed the 3-month follow-up and n=200 (70%) completed the 12-month follow-up. In the control group, n=184 (62%) completed the 3-month follow-up and n=194 (66%) completed the 12-month follow-up. Overall, n=394 (68%) were retained to study completion. There were no significant differences between those retained and those not retained.
Study limitations (author)	- The retention rate of 68% is less than desirable; however, differential attrition was not observed. - The design decision to provide high-end condoms and lubricants to the control group may have obscured intervention effects that would otherwise occur in a true standard-of-care control condition. - The study design did not account for potential misclassification bias caused by the incorrect use of condoms. - The intervention and the analyses did not account for seroadaptive behaviors or the use of antiretroviral that may have displaced condoms.
Study limitations (reviewer)	Although randomisation procedures were appropriate, there were baseline differences between conditions on age, education beyond high school, a measure of income ('having to borrow money to get by'), and condomless anal insertive sex, which may have influenced intervention efficacy in ways that could not be determined.
Source of funding	This study was funded by a grant from the National Institute of Mental Health to the first author, R01MH092226.

Study arms

Intervention (N = 299)

Focus on the Future (FoF): a single session, clinic-based, sex positive, one-to-one intervention focusing on condom use.

Control (N = 301)

Standard of care control (STI and HIV testing plus access to a large range of high quality condoms and lubricants)

Characteristics

Arm-level characteristics

Characteristic	Intervention (N = 299)	Control (N = 301)
Age Mean (SD)	22.91 (*empty data*)	22.36 (*empty data*)
Gender Male	n = 299 ; % = 100	n = 301 ; % = 100
Ethnicity Self-identified as Black / African American	n = 299 ; % = 100	n = 301 ; % = 100
Frequency of incarceration in past 12 months Mean (SD)	6.37 (*empty data*)	6.59 (*empty data*)
HIV infected at study enrolment Includes those who were unaware of their infection until baseline HIV testing	% = 29.7	% = 27.5
Rectal infections At study enrolment	% = 30.1	% = 23.5
Urethral infections At study enrolment	% = 10.9	% = 9.6

Characteristic	Intervention (N = 299)	Control (N = 301)
Pharyngeal infections At study enrolment	% = 14.7	% = 12.2

Outcomes

Study timepoints

- 12 month

STI incidence outcomes

Outcome	Intervention vs Control, 12 month, N1 = 194, N2 = 200
Likelihood of positive CT/NG test Odds ratio/95% CI	1.18 (0.95 to 1.47)
Likelihood of positive CT/NG test Excluding oral test results (rectal or urethral infections only) Odds ratio/95% CI	1.17 (0.89 to 1.52)

Taken from Crosby (2018a) Paper also reports outcomes for condom use but these are stratified by HIV status so not extracted

Condom use outcomes

Outcome	Intervention, 12 month, N = 200	Control, 12 month, N = 194
Always using condoms for anal sex In prior 3 months	n = 103 ; % = 51.5	n = 92 ; % = 47.5

Outcome	Intervention, 12 month, N = 200	Control, 12 month, N = 194
No of events		

Always using condoms for anal sex - Polarity - Higher values are better

Taken from Crosby (2018b) Paper only reports %; n's calculated by analyst Outcome data using the scale assessing whether condom use added to sexual pleasure could not be extracted because means and SDs were not reported by group.

Condom use outcomes

Outcome	Intervention, 12 month, N = 51	Control, 12 month, N = 45
Always using condoms for anal sex In prior 3 months Sample size	n = 24 ; % = 47.1	n = 16 ; % = 35.6

Always using condoms for anal sex - Polarity - Higher values are better

Taken from Crosby (2018b). Analyses restricted to participants reporting recent sex with 'side' (non-main) partners (n=96). Paper only reports %; n's calculated by analyst

TIDier Checklist

Study details

Rationale/theory/Goal	Young Black men who have sex with men (YBMSM) have a 1 in 4 chance of becoming infected with HIV before age 25 years and a 1 in 2 chance of becoming infected in their lifetime. A compelling case exists to promote consistent condom use as a primary intervention strategy for YBMSM that could be used in conjunction with biomedical approaches. An ideal is an efficacious condom use promotion program that can be delivered in a single session format to both HIV infected and HIV uninfected YBMSM as part of clinical care. This type of intervention would be especially useful if it could become part of standard care counselling for those newly diagnosed with STIs, HIV, or patients taking anti-retroviral medications (p. 169-170).

Procedures used	- All age-eligible Black males attending the sexual health clinic for STI/HIV testing were approached in the clinic waiting area and asked if they were interested in volunteering. - The study was also promoted through social media and print material (posted in and near the clinics); and recruiters attended bars/nightclubs to encourage YBMSM to get tested for STIs/HIV at either clinic and made them aware of the study. - Men expressing an interest were screened for eligibility. - Before study procedures were applied, clinical standard-of-care services were provided and included assessment for chlamydia and gonorrhoea in 3 anatomic locations via urine samples and rectal and bucosal swabs, and HIV testing via blood samples. All men were interviewed about their sexual risk and protective behaviours by the attending clinician. - Study procedures began after testing. Participants provided written informed consent then completed an online baseline questionnaire using Qualtrics in a private office. The questionnaire had an optional audio component for men reporting literacy issues. - Outcome assessments were completed at 3, 6, 9 and 12 months using the same online method as at baseline and repeat STI/HIV testing procedures. Medical records were also accessed to abstract any diagnosed cases of HIV or STIs occurring between study visits. - Retention procedures for both groups included frequent (as often as once per week) text messaging with study staff; phone calls/texts in the week before the next quarterly assessment; and other reminders via email or social media depending on the participant's stated preference. - 3 times per year, food and entertainment events were held to thank participants for their efforts. (p. 170-171).
Setting/location of intervention	Two sexual health clinics receiving state/federal support for screening and treatment of STIs/HIV (p. 170)
Other details	Men were compensated US $50 for the baseline assessment and US $55, US $60, US $65, and US $70, respectively, for each quarterly follow-up assessment (p. 170).

Study arms

Intervention (N = 299)

Focus on the Future (FoF): a single session, clinic-based, sex positive, one-to-one intervention focusing on condom use.

Brief name	Focus on the Future (p. 170)
Rationale/theory/Goal	Focus on the Future is a sex positive intervention that has previously been established as an evidence-based intervention for young Black men having sex with women. Using the ADAPT-ITT model, FoF was redesigned for YBMSM (p. 170). It is a tailored program and allows the educator to select content options that will best meet the client's prevention needs (from Crosby 2018a, p. 199).
Materials used	High quality condoms and single use lubricants; small canvas bags for participants to fill with condoms and keep (p. 170-171)
Procedures used	- In addition to all standard of care procedures (STI/HIV testing and discussion of sexual risk and protective behaviours), intervention participants received the FoF program. - The basis of the program is to build trust and rapport with the client over their future goals and aspirations. That trust is then used to help personalise the education session as a means of achieving freedom to pursue life goals in the absence of HIV acquisition risk (or transmission of HIV for HIV positive individuals). There is an emphasis on correct and consistent condom use as part of satisfying and pleasurable sex with other men (from Crosby 2018a, p. 199). - The adapted FoF program comprised 9 basic objectives: (1) establish rapport and show how the HIV epidemic disproportionately impacts young Black men, especially MSM; (2) explain how condom use can enhance sexual experience/pleasure; (3) determine past negative and positive experiences the client has had using condoms; rectify misconceptions and provide new information as needed; (4) learn about the importance, and acquire the needed skills, of finding the optimal “fit and feel” of condoms; (5) learn about the importance, and acquire the needed skills, of adding lubricants to condoms; (6) become highly proficient in quick and effortless condom application; (7) acquire skills needed to use condoms correctly; (8) learn how to introduce condom use into

	existing relationships; and (9) learn to “plan ahead” for condom-protected sex and when to discuss/apply condoms during arousal. - During the entire session, the educator reinforced the value of “better sex with latex” as a means of providing strength, power, and protection of life goals. - The session also included a 'tour' of a large display of an extensive array of high quality expensive condoms including different types, brands and sizes, and single-use lubricants. The educator used this as a teaching opportunity and encouraged participants to explore the range of products available. They were encouraged to take away a variety of condoms and lubricants to practice and find the optimal fit and feel for themselves and their partners. (p. 170-171)
Provider	Project health educator (p. 170)
Method of delivery	Face to face one-to-one session (p. 170)
Intensity/duration of the intervention	Single session; duration not reported (p. 170)
Tailoring/adaptation	The intervention was tailored to the needs of YBMSM but each session could also be tailored to meet the client's specific needs (e.g. whether they were HIV infected or uninfected) (Crosby 2018a, p. 199).
Unforeseen modifications	None reported
Planned treatment fidelity	Not reported
Actual treatment fidelity	Not reported

Control (N = 301)

Standard of care control (STI and HIV testing plus access to a large range of high quality condoms and lubricants)

Brief name	Standard of care control (p. 170).

Materials used	High quality condoms and single use lubricants; small canvas bags for participants to fill with condoms and keep (p. 170-171)
Procedures used	In addition to all standard of care procedures (STI/HIV testing and discussion of sexual risk and protective behaviours), control participants also received access to the same condom and lubricant display that was offered to intervention participants. However, their access was not used as a teaching opportunity and was not interactive; they were simply encouraged to take away as many condoms and lubricants as they wanted to (p. 171).
Provider	Not reported; assumed clinic staff
Method of delivery	Face to face
Intensity/duration of the intervention	Single session; duration not reported
Tailoring/adaptation	Not reported
Unforeseen modifications	None reported
Planned treatment fidelity	Not reported
Actual treatment fidelity	Not reported

Risk of Bias Assessment

Section	Risk of Bias	Reason
Domain 1: Bias arising from the randomisation process	Some concerns	Appropriate randomisation procedures but baseline differences between groups on age, education, income and condomless anal insertive sex
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Some concerns	No information on participant blinding; deviations from intended interventions unlikely; ITT not used
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	Low	Intervention adherence not assessed but single one-to-one session so non-adherence unlikely

Section	Risk of Bias	Reason
Domain 3. Bias due to missing outcome data	Some concerns	High attrition (only 68% of the sample were retained to study completion) but attrition analyses showed no differences between those retained and those not retained
Domain 4. Bias in measurement of the outcome	Low	Appropriate outcome assessment using online self-administered questionnaire for both groups
Domain 5. Bias in selection of the reported result	Some concerns	Many of the analyses were stratified by HIV status but this was not specified in the trial registry. The same trial was reported across 3 papers with different analyses and outcomes for each
Overall bias and Directness	Some concerns	Baseline differences between groups; no information on participant blinding; high attrition (68% retention) but no differences between those retained and those not retained; unplanned analyses using stratification of groups by HIV status and multiple publications of the same trial
	Overall Directness	Partially applicable (US study)

Crosby, 2019

Bibliographic Reference Crosby, R.A.; Mena, L.; Vickers Smith, R.; Randomised controlled trial of a brief, clinic-based intervention to promote safer sex among young Black men who have sex with men: Implications for pre-exposure prophylaxis-related counselling; Sexual Health; 2019; vol. 16 (no. 2); 187-191

Study details

Study design	Randomised controlled trial (RCT)
Aim	This paper is a secondary publication of Crosby (2018a) and reports on an analysis of the data restricted to HIV uninfected participants and at 3-month follow-up only.

Statistical method(s) used to analyse the data	- Contingency table analyses were used to determine the effect size and significance of the intervention program relative to condomless anal and oral sex. McNemar tests were used to determine whether the change in proportion over the 3-month period was significant within and between groups. - To control for effects of age and number of anal sex partners, logistic regression models were constructed to calculate adjusted odds ratios, 95% CIs and two-sided P values.
Attrition	Of the 600 participants enrolled in the trial, 179 were HIV positive at baseline, leaving 421 participants for the present substudy. Of these 421, 277 (66%) completed the 3-month follow-up assessment and thus formed the analytical sample (n=142 intervention group and n=135 control group).

Study arms

Intervention (N = 142)

Focus on the Future (FoF): a single session, clinic-based, sex positive intervention promoting condom use for YBMSM

Control (N = 135)

Standard of care control: STI/HIV testing and risk reduction discussion plus access to high quality condoms and lubricants

Characteristics

Arm-level characteristics

Characteristic	Intervention (N = 142)	Control (N = 135)
Age Mean	22.91	22.36

Characteristic	Intervention (N = 142)	Control (N = 135)
Gender Male	n = 142 ; % = 100	n = 135 ; % = 100
Ethnicity Self-identified as Black / African American	n = 142 ; % = 100	n = 135 ; % = 100
Frequency of incarceration In prior 12 months Mean (SD)	6.37 (*empty data*)	6.59 (*empty data*)

Outcomes

Study timepoints

- Baseline
- 3 month

Condom use outcomes

Outcome	Intervention, Baseline, N = 129	Intervention, 3 month, N = 134	Control, Baseline, N = 124	Control, 3 month, N = 131
Condomless anal insertive sex In prior 3 months No of events	n = 26 ; % = 20.2	n = 15 ; % = 11.2	n = 38 ; % = 30.6	n = 27 ; % = 20.6

Condomless anal insertive sex - Polarity - Lower values are better

Reported in separate tables because ns for each outcome are different

Condom use outcomes

Outcome	Intervention, Baseline, N = 97	Intervention, 3 month, N = 142	Control, Baseline, N = 89	Control, 3 month, N = 134
Condomless anal receptive sex In prior 3 months No of events	n = 31 ; % = 32	n = 17 ; % = 12	n = 33 ; % = 37.1	n = 29 ; % = 21.6

Condomless anal receptive sex - Polarity - Lower values are better

Reported in separate tables because ns for each outcome are different

Condom use outcomes

Outcome	Intervention, Baseline, N = 136	Intervention, 3 month, N = 142	Control, Baseline, N = 132	Control, 3 month, N = 135
Any condomless anal sex In prior 3 months No of events	n = 51 ; % = 37.5	n = 26 ; % = 18.3	n = 53 ; % = 40.2	n = 42 ; % = 31.8

Any condomless anal sex - Polarity - Lower values are better

Reported in separate tables because ns for each outcome are different

Condom use outcomes

Outcome	Intervention, Baseline, N = 121	Intervention, 3 month, N = 72	Control, Baseline, N = 120	Control, 3 month, N = 76
Any condomless oral sex In prior 3 months No of events	n = 101 ; % = 83.5	n = 33 ; % = 45.8	n = 96 ; % = 80	n = 48 ; % = 63.2

Any condomless oral sex - Polarity - Lower values are better

Reported in separate tables because ns for each outcome are different

D.11 Effectiveness evidence for MSM and transwomen of mixed immigrant status

Rhodes 2020

Bibliographic Reference	Rhodes, Scott D; Alonzo, Jorge; Mann-Jackson, Lilli; Song, Eunyoung Y; Tanner, Amanda E; Garcia, Manuel; Smart, Benjamin D; Baker, Logan S; Eng, Eugenia; Reboussin, Beth A; A peer navigation intervention to prevent HIV among mixed immigrant status Latinx GBMSM and transgender women in the United States: outcomes, perspectives and implications for PrEP uptake.; Health education research; 2020; vol. 35 (no. 3); 165-178

Study details

Study design	Randomised controlled trial (RCT)
Trial registration number	Not reported

Aim	To develop, implement and evaluate a Spanish-language peer navigation intervention designed to increase HIV testing and condom use among social networks of immigrant Latinx GBMSM and trans women.
Country/geographical location	North Carolina, USA
Setting	Community settings
Inclusion criteria	21 Latinx GBMSM and TW were recruited to serve as Navegantes; selection of these individuals focused on primary characteristics that were identified as essential to Navegante success by the CBPR partnership: - Personal characteristics included attributes such as being a natural leader, dedicated and respectful, having a sense of humour, and be comfortable talking and offering sound advice about sensitive issues (e.g. sexual health) - Performance characteristics included the ability to read low-literacy study materials, complete low-literacy process evaluation data collection forms (i.e. Activity Logs), communicate orally, participate in meetings and work with members of their social networks. - Situational characteristics included time availability and access to transportation. Additionally, each Navegante was required to recruit eight non-overlapping members of their social networks who were GBMSM or TW and reported sex with men to participate in the study.
Exclusion criteria	None reported
Method of randomisation	Twenty-one naturally existing social networks of Latinx GBMSM and TW were identified; each network had eight members plus one Navegante. Social networks were randomised into groups using a standard numbers table.
Method of allocation concealment	Not reported
Unit of allocation	Social network group
Unit of analysis	Individual
Statistical method(s) used to analyse the data	- An intent-to-treat protocol was used to analyse participants' outcomes relative to their assigned group (i.e. intervention or waitlist control).

	- At baseline, descriptive statistics were used to summarise the characteristics of intervention and waitlist participants. - Differences between the groups at baseline were assessed using the Student's t-test for continuous variables and chi squared for categorical variables. - Primary data analyses to evaluate the efficacy of the intervention compared rates of past 3- month condom use and past 12-month HIV testing reported by intervention and waitlist participants at post-intervention follow-up while adjusting for baseline rates. - Statistical analysis used multivariable random effects logistic regression modelling that adjusted for potential clustering within social networks. This adjustment accounted for the possibility that participants in the same network may exhibit more similar patterns of condom use and HIV testing at 12-month follow-up as participants in other social networks. - Models were adjusted by baseline age, educational attainment and country of origin to obtain adjusted odds ratios (AORs) and the 95% CI and corresponding P values were computed. - Models were fit using PROC GLIMMIX in SAS
Attrition	176 social network members were screened for possible participation. n = 10 were ineligible (n = 1 did not meet inclusion criteria; n = 5 moved before the program started; and n = 4 were unreachable). In the intervention group there were n = 11 social networks which resulted in n = 86 participants. At 12 month follow-up, 95% (n = 82) were retained. In the control group there were n = 10 social networks which resulted in n = 80 participants. At 12 month follow-up, 94% (n = 75) were retained.
Study limitations (author)	- The study relied on self-reported data; however, self-reported data can be reliable if collected carefully, including acknowledgments that some questions may cause discomfort and explanations concerning the importance of providing honest responses to ensure the usefulness of the research. - The increase in condom use in both the intervention and waitlist control groups suggest contamination between these groups, which may be related to the community capacity built by the intervention and participants' dissemination of knowledge and skills through natural helping activities with others. A study design that ensures that social networks are

	not geographically close in order to reduce contamination might be more successful in testing peer navigation within social networks.
Study limitations (reviewer)	The study does not capture or report the amount of interaction each participant had with their Navegante, so it is not possible to determine whether some participants received substantially more input (support; help; information) than others.
Source of funding	The National Institute of Health (grant R01MH087339) and the Program in Community Engagement of the Wake Forest Clinical and Translational Science Institute, which is supported by the National Center for Advancing Translational Sciences, National Institutes of Health (grant UL1TR001420).

Study arms

Intervention (N = 86)

HOLA; a community-level, Spanish-language, peer navigation intervention for Latinx GBMSM and trans women.

Control (N = 80)

Waitlist control

Characteristics

Arm-level characteristics

Characteristic	Intervention (N = 86)	Control (N = 80)
Age Mean (SD)	28.7 (6.5)	30.6 (6.7)
Country of origin		

Characteristic	Intervention (N = 86)	Control (N = 80)
Mexico	n = 64 ; % = 75.3	n = 63 ; % = 79.7
Other	n = 21 ; % = 24.7	n = 16 ; % = 20.3
Sexual orientation		
Heterosexual	n = 3 ; % = 3.5	n = 0 ; % = 0
Gay	n = 68 ; % = 80	n = 64 ; % = 84.2
Bisexual	n = 14 ; % = 16.5	n = 12 ; % = 15.8
Transgender identity	n = 6 ; % = 7.1	n = 12 ; % = 15.8
Time in the United States (years) Mean (SD)	10.5 (5.9)	9.7 (4.8)

Outcomes

Study timepoints

- Baseline
- 12 month

Condom use outcomes

Outcome	Intervention, Baseline, N = 86	Intervention, 12 month, N = 82	Control, Baseline, N = 80	Control, 12 month, N = 75
Past 3-month condom use (%) Values reflect mean condom use rates Mean (SD)	34.9 (*empty data*)	63.4 (*empty data*)	25 (*empty data*)	50.7 (*empty data*)
Condom use knowledge and skills Assessed using 18 correct/incorrect items Mean (SD)	14.3 (*empty data*)	17.2 (*empty data*)	14.5 (*empty data*)	15 (*empty data*)
HIV Knowledge Assessed using 12 true/false items relating to modes of transmission and prevention strategies Mean (SD)	8.5 (*empty data*)	11.1 (*empty data*)	8.2 (*empty data*)	8.8 (*empty data*)
STI knowledge Assessed using 12 true/false items relating to modes of transmission and prevention strategies Mean (SD)	4.9 (*empty data*)	9.4 (*empty data*)	5.6 (*empty data*)	6.2 (*empty data*)
Condom use self efficacy Mean (SD)	4.4 (*empty data*)	4.7 (*empty data*)	4.3 (*empty data*)	4.4 (*empty data*)

Past 3-month condom use - Polarity - Higher values are better

Condom use knowledge and skills - Polarity - Higher values are better

HIV Knowledge - Polarity - Higher values are better

STI knowledge - Polarity - Higher values are better

Condom use self efficacy - Polarity - Higher values are better

TIDier Checklist

Study details

Rationale/theory/Goal	The Latinx population (Latinx is a gender-neutral term used in lieu of Latina and Latino) is disproportionately affected by HIV and HIV incidence among Latinx GBMSM increased by 30% from 2010 to 2017. Despite this disproportionate burden, few strategies have been found to reduce that burden. The current study developed HOLA to address that gap (p. 166).
Procedures used	Naturally existing social networks of Latinx GBMSM and transwomen were identified via Navegantes, who were required to recruit eight non-overlapping members of their social networks who were GBMSM or TW and reported sex with men. Baseline data were collected from each social network member then social networks were randomised into intervention or control groups. Follow-up data were collected 12 months post-intervention (24 months from baseline). (p. 167)

Study arms

Intervention (N = 86)

HOLA; a community-level, Spanish-language, peer navigation intervention for Latinx GBMSM and trans women.

Brief name	HOLA (p. 165)
Rationale/theory/Goal	The HOLA intervention was developed via a CBPR partnership and was guided by collaboration with local Latinx community members, representatives from AIDS service organisations, public health departments, academic researchers, and other community organisations. HOLA is based on social cognitive theory, empowerment education, and social support. The intervention uses community peer navigators, known as Navegantes, who are lay community leaders and share similar backgrounds and demographic characteristics of the target community. Navegantes work within

	their existing social networks of Latinx GBMSM and TW to increase awareness and provide information, promote behaviour change, bolster positive and reframe negative perceptions and attitudes and advocate on behalf of communities (p. 166-167).
Materials used	- Each Navegante received a satchel that contained supplies and materials for distribution including all presentations used during the training, pocket-sized cards outlining the locations of HIV and STI testing sites and depicting how to correctly use a condom, condoms, individually packaged water-based lubricants, a penis model, brochures about HIV and other STIs, and a DVD with five different CBPR partnership-developed video segments that summarized key points related to HIV prevention that Navegantes could screen with their social network members individually or in groups. - Navegantes also received a t-shirt, a baseball cap, a nametag identifying them as Navegantes, and satchel, all with the project logo on it - Each social network member also received a t-shirt, a baseball cap, a drawstring bag, and a rubber bracelet with the project name and telephone number printed on it to facilitate connectedness and retention (p. 167 & 169)
Procedures used	- Because the reputation of each Navegante as a leader within existing social networks is critical to the success of interventions implemented within social networks, Navegantes were recruited primarily through word of mouth. - Navegantes were trained by two Latinx gay men during four 4 hour sessions in private rooms of Mexican restaurants. Training sessions were interactive and included opportunities to develop and practice role play scenarios and formal and informal helping. - The training included the impact of HIV and sexually transmitted infections (STIs) on Latinx populations and sexual and gender minorities; HIV and STI prevention strategies; the process for accessing health services and testing for HIV and STIs; the correct use of condoms (including internal condoms); factors that influence health, including cultural expectations, values and reciprocal determinism; what it is like to live with HIV; the roles and responsibilities of Navegantes; and effective communication and social support strategies. Navegantes were also taught how to explain study details and recruit their friends.

	- Once their training was completed, they met monthly for 12 months as a group with the HOLA project coordinator to obtain additional project and peer support, restock their satchels with supplies, and submit their activity logs to document their helping activites. - During the intervention period, Navegantes promoted sexual health, particularly HIV and STI testing and condom use, among their social network members by carrying out formal and informal helping. (p. 167).
Provider	Two Latinx gay men provided training for the Navegantes; the trained Navegantes then delivered the intervention (p. 167)
Method of delivery	Face to face informal and formal sessions (p. 167)
Setting/location of intervention	Community and social settings (p. 167)
Intensity/duration of the intervention	The intervention period was 12 months. The study does not report how much contact or interaction each participant had with their Navegante (p. 167).
Tailoring/adaptation	Not reported
Unforeseen modifications	Not reported
Planned treatment fidelity	Not reported
Actual treatment fidelity	Not reported
Other details	Navegantes were compensated $50 for each training session and each month for submitting their Activity Log. Dinner was served at each training session. Social network participants were compensated $30 for completing the baseline assessment and $50 for completing the follow-up assessment (p. 167-169).

Control (N = 80)

Procedures used	Waitlist control

Risk of Bias Assessment

Section	Risk of Bias	Reason
Domain 1: Bias arising from the randomisation process	Some concerns	Limited information on randomisation and no information on allocation concealment
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Some concerns	No information on blinding. ITT used.
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	High	No information on intervention adherence or participant contact time with Navegante; not possible to establish intervention 'dose' for participants. No assessment of intervention fidelity or adherence by Navegantes.
Domain 3. Bias due to missing outcome data	Low	
Domain 4. Bias in measurement of the outcome	Some concerns	Unclear whether outcome assessors were blinded
Domain 5. Bias in selection of the reported result	Some concerns	Trial not registered
Overall bias and Directness	High	Limited information on randomisation; no information on allocation concealment or on blinding. No assessment of intervention adherence or degree of contact with Navegante, and no fidelity assessments for Navegantes. Trial not registered
	Overall Directness	Indirectly applicable *(US study with Latinx immigrants.)*

Appendix E: Forest plots

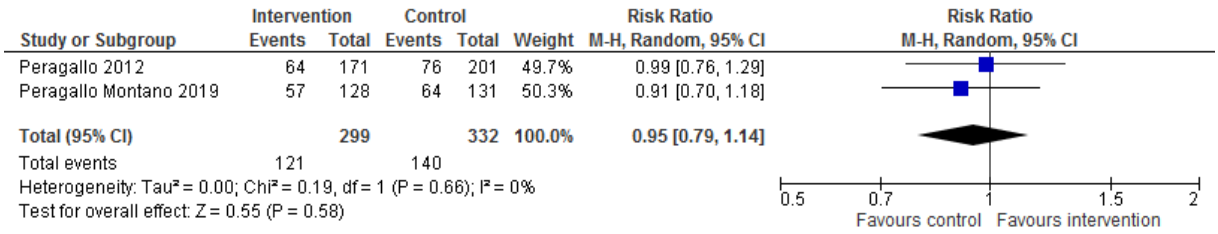
Forest plots were only produced when there was more than one study for the outcome; single study forest plots are not presented. Data for single study analyses are presented in GRADE.

E.1 Migrants

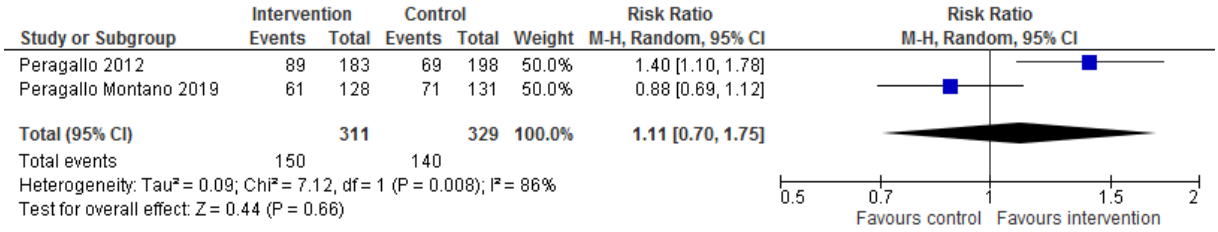
E.1.1 Culturally specific community-based group risk reduction intervention for Hispanic women vs. control

E.1.1.1 E.1.1.1 Condom use outcomes

Any condom use in prior 3 months, at 6 months (higher is better)

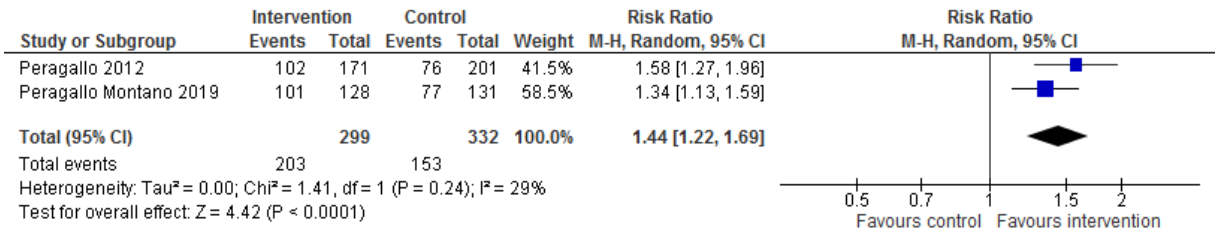


Any condom use in prior 3 months, at 12 months (higher is better)

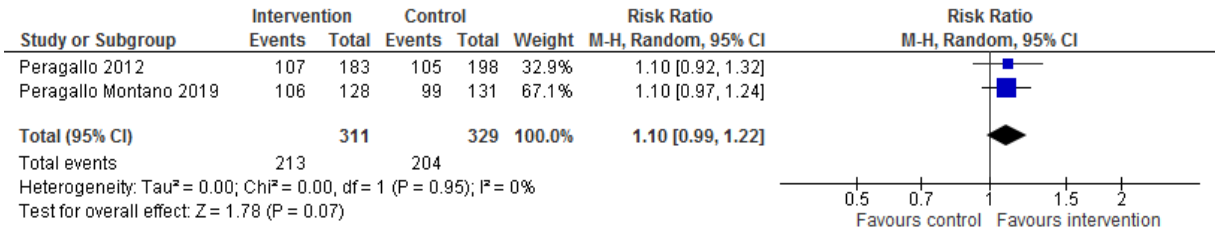


E.1.1.2 E.1.1.2 STI/HIV knowledge outcomes

HIV knowledge, at 6 months (higher is better)



HIV knowledge, at 12 months (higher is better)

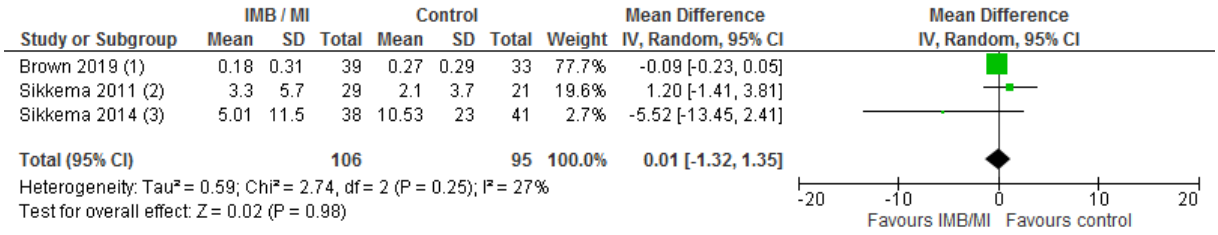


E.2 MSM

E.2.1 IMB / Motivational Interviewing-based approaches

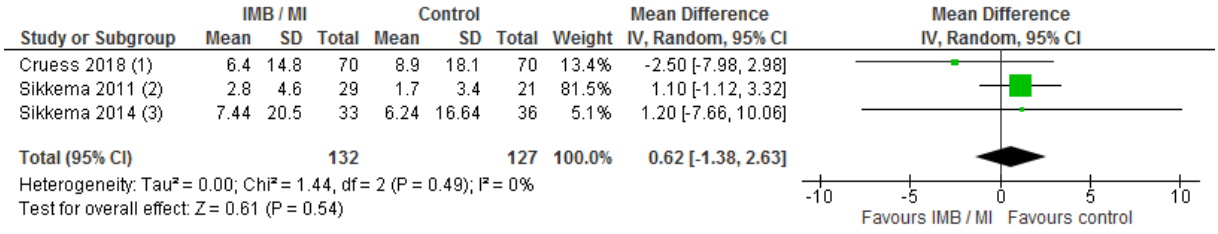
E.2.1.1 Condom use outcomes

Frequency of UAI in prior 3 months, at 3 months (mean number of episodes; lower is better)



Footnotes
(1) Group based sexual health and stress management intervention
(2) Brief 1:1 risk reduction intervention for newly diagnosed HIV+ MSM; pilot trial
(3) Brief 1:1 risk reduction intervention for newly diagnosed HIV+ MSM; full trial

Frequency of UAI in prior 3 months, at 6 months (mean number of episodes; lower is better)

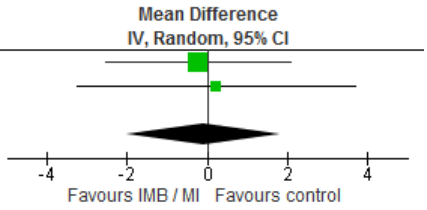


Footnotes
(1) Brief internet-based group intervention
(2) Brief 1:1 risk reduction intervention for newly diagnosed HIV+ MSM; pilot trial
(3) Brief 1:1 risk reduction intervention for newly diagnosed HIV+ MSM; full trial

Frequency of UAI with HIV- or unknown status partners in prior 3 months, at 3 months (mean number of episodes; lower is better)

Study or Subgroup	IMB / MI Mean	SD	Total	Control Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Safren 2013 (1)	2.82	5.35	74	3.04	8.56	74	69.7%	-0.22 [-2.52, 2.08]
Sikkema 2014 (2)	2.91	8.2	38	2.69	7.65	42	30.3%	0.22 [-3.27, 3.71]
Total (95% CI)			**112**			**116**	**100.0%**	**-0.09 [-2.01, 1.83]**

Heterogeneity: Tau² = 0.00; Chi² = 0.04, df = 1 (P = 0.84); I² = 0%
Test for overall effect: Z = 0.09 (P = 0.93)

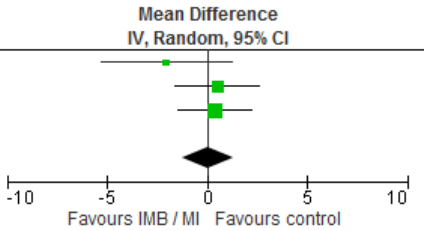


Footnotes
(1) Clinic based 1:1 HIV prevention MI and counselling delivered by medical social workers
(2) Brief 1:1 risk reduction intervention for newly diagnosed HIV+ MSM; full trial

Frequency of UAI with HIV- or unknown status partners in prior 3 months, at 6 months (mean number of episodes; lower is better)

Study or Subgroup	IMB / MI Mean	SD	Total	Control Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Cruess 2018 (1)	1.54	4.1	70	3.58	13.3	70	15.3%	-2.04 [-5.30, 1.22]
Safren 2013 (2)	2.56	6.03	81	2.04	7.12	72	36.7%	0.52 [-1.58, 2.62]
Sikkema 2014 (3)	1.14	4.81	38	0.76	3.37	42	48.1%	0.38 [-1.46, 2.22]
Total (95% CI)			**189**			**184**	**100.0%**	**0.06 [-1.21, 1.34]**

Heterogeneity: Tau² = 0.00; Chi² = 1.89, df = 2 (P = 0.39); I² = 0%
Test for overall effect: Z = 0.09 (P = 0.92)

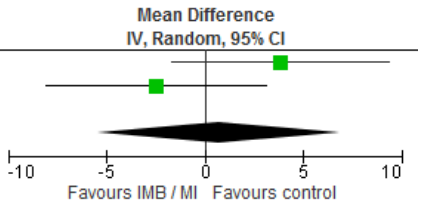


Footnotes
(1) Brief internet-based group intervention
(2) Clinic based 1:1 HIV prevention MI and counselling delivered by medical social workers
(3) Brief 1:1 risk reduction intervention for newly diagnosed HIV+ MSM; full trial

Frequency of UAI with HIV- or unknown status partners in prior 3 months, at 9 months (mean number of episodes; lower is better)

Study or Subgroup	IMB / MI Mean	SD	Total	Control Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Safren 2013 (1)	5.03	23.81	72	1.2	2.58	69	50.3%	3.83 [-1.70, 9.36]
Sikkema 2014 (2)	0.45	2.71	38	2.92	18.53	43	49.7%	-2.47 [-8.08, 3.14]
Total (95% CI)			**110**			**112**	**100.0%**	**0.70 [-5.48, 6.87]**

Heterogeneity: Tau² = 11.77; Chi² = 2.46, df = 1 (P = 0.12); I² = 59%
Test for overall effect: Z = 0.22 (P = 0.82)



Footnotes
(1) Clinic based 1:1 HIV prevention MI and counselling delivered by medical social workers
(2) Brief 1:1 risk reduction intervention for newly diagnosed HIV+ MSM; full trial

E.3 Men from a Black African or Caribbean family background who have sex with men

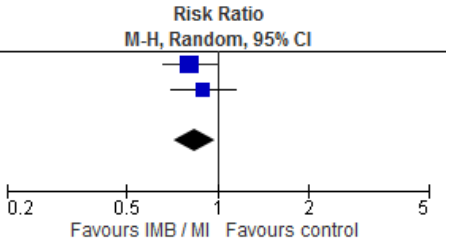
E.3.1 IMB / Motivational Interviewing-based interventions

E.3.1.1 Condom use outcomes

Any unprotected anal or vaginal intercourse in the past 3 months, at 3 months (lower is better)

Study or Subgroup	IMB / MI Events	IMB / MI Total	Control Events	Control Total	Weight	Risk Ratio M-H, Random, 95% CI
Fernandez 2016 (1)	52	84	63	82	59.0%	0.81 [0.66, 0.99]
Tobin 2013 (2)	31	45	40	52	41.0%	0.90 [0.70, 1.15]
Total (95% CI)		**129**		**134**	**100.0%**	**0.84 [0.72, 0.99]**
Total events	83		103			

Heterogeneity: Tau² = 0.00; Chi² = 0.42, df = 1 (P = 0.52); I² = 0%
Test for overall effect: Z = 2.14 (P = 0.03)

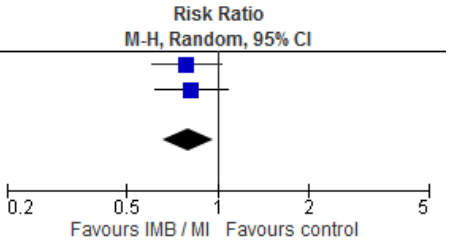


Footnotes
(1) 1:1 IMB-based HIV risk reduction delivered online via live chat
(2) Group-based culturally tailored HIV prevention intervention informed by IMB model

Any UAI with males in the past 3 months, at 3 months (lower is better)

Study or Subgroup	IMB / MI Events	IMB / MI Total	Control Events	Control Total	Weight	Risk Ratio M-H, Random, 95% CI
Fernandez 2016 (1)	42	84	52	82	52.2%	0.79 [0.60, 1.03]
Tobin 2013 (2)	27	44	39	52	47.8%	0.82 [0.62, 1.08]
Total (95% CI)		**128**		**134**	**100.0%**	**0.80 [0.66, 0.98]**
Total events	69		91			

Heterogeneity: Tau² = 0.00; Chi² = 0.04, df = 1 (P = 0.85); I² = 0%
Test for overall effect: Z = 2.21 (P = 0.03)



Footnotes
(1) 1:1 IMB-based HIV risk reduction delivered online via live chat
(2) Group-based culturally tailored HIV prevention intervention informed by IMB model

Appendix F: GRADE tables

F.1 Migrants

F.1.1 Culturally adapted Motivational Interviewing group intervention

Condom use outcomes for Culturally adapted Motivational Interviewing group intervention vs Health promotion control

Quality assessment							No of patients		Effect		Quality
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intervention	Control	Relative (95% CI)	Absolute	
Consistent condom use: past 90 days (follow-up 3 months)											
Sanchez 2013	randomised trial	serious[1]	N/A	serious[2]	no serious imprecision	none	63/140 (45%)	24/138 (17.4%)	RR 2.59 (1.72 to 3.89)	277 more per 1000 (from 125 more to 503 more)	⊕⊕OO LOW
Consistent condom use: past 90 days (follow-up 9 months)											
Sanchez 2013	randomised trial	serious[1]	N/A	serious[2]	no serious imprecision	none	54/140 (38.6%)	21/138 (15.2%)	RR 2.53 (1.62 to 3.96)	233 more per 1000 (from 94 more to 450 more)	⊕⊕OO LOW
Consistent condom use: past 30 days (follow-up 3 months)											
Sanchez 2013	randomised trial	serious[1]	N/A	serious[2]	no serious imprecision	none	72/140 (51.4%)	33/138 (23.9%)	RR 2.15 (1.53 to 3.02)	275 more per 1000 (from 127 more to 483 more)	⊕⊕OO LOW
Consistent condom use: past 30 days (follow-up 9 months)											
Sanchez 2013	randomised trial	serious[1]	N/A	serious[2]	no serious imprecision	none	62/140 (44.3%)	34/138 (24.6%)	RR 1.8 (1.27 to 2.54)	197 more per 1000 (from 67 more to 379 more)	⊕⊕OO LOW
Condom use at last sex (follow-up 3 months)											
Sanchez 2013	randomised trial	serious[1]	N/A	serious[2]	no serious imprecision	none	83/140 (59.3%)	44/138 (31.9%)	RR 1.86 (1.41 to 2.46)	274 more per 1000 (from 131 more to 466 more)	⊕⊕OO LOW
Condom use at last sex (follow-up 9 months)											
Sanchez 2013	randomised trials	serious[1]	N/A	serious[2]	serious[3]	none	70/140 (50%)	48/138 (34.8%)	RR 1.44 (1.08 to 1.91)	153 more per 1000 (from 28 more to 317 more)	⊕OOO VERY LOW

[1] Downgraded once for some concerns of bias due to insufficient information on randomisation and lack of allocation concealment
[2] Latino migrant workers in the USA
[3] Downgraded once as 95%CI crosses one MID

F.1.2 Culturally specific community-based group risk reduction intervention for Hispanic women

Condom use outcomes for Culturally specific community-based group risk reduction intervention for Hispanic women vs Control

Quality assessment							No of patients		Effect		Quality
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intervention	Control	Relative (95% CI)	Absolute	
Percent of sex events where condoms were used, at 6 months. MID = 22.4											
Peragallo Montano 2019	randomised trial	serious[1]	N/A	serious[2]	serious[3]	none	128	131	-	MD 8.42 lower (18.94 lower to 2.1 higher)	⊕OOO VERY LOW
Percent of sex events where condoms were used, at 12 months. MID = 22.2											
Peragallo Montano 2019	randomised trial	serious[1]	N/A	serious[2]	serious[3]	none	128	131	-	MD 4.38 lower (15.22 lower to 6.46 higher)	⊕OOO VERY LOW
Number of condomless sex events, at 6 months. MID = 4.2											
Peragallo Montano 2019	randomised trial	serious[1]	N/A	serious[2]	serious[3]	none	128	131	-	MD 1.42 higher (0.54 lower to 3.38 higher)	⊕OOO VERY LOW
Number of condomless sex events, at 12 months. MID = 4.5											
Peragallo Montano 2019	randomised trial	serious[1]	N/A	serious[2]	serious[3]	none	128	131	-	MD 0.37 lower (2.28 lower to 1.54 higher)	⊕OOO VERY LOW
Self-efficacy for condom use, at 6 months											
Peragallo Montano 2019	randomised trial	serious[1]	N/A	serious[2]	serious[4]	none	74/128 (57.8%)	58/131 (44.3%)	RR 1.31 (1.02 to 1.66)	137 more per 1000 (from 9 more to 292 more)	⊕OOO VERY LOW
Self-efficacy for condom use, at 12 months											
Peragallo Montano 2019	randomised trial	serious[1]	N/A	serious[2]	serious[4]	none	79/128 (61.7%)	64/131 (48.9%)	RR 1.26 (1.01 to 1.58)	127 more per 1000 (from 5 more to 283 more)	⊕OOO VERY LOW
Behavioural intention to use a condom, at 3 months											

Peragallo 2012	randomised trial	very serious[5]	N/A	serious[2]	serious[6]	none	102/143 (71.3%)	129/202 (63.9%)	RR 1.12 (0.96 to 1.29)	77 more per 1000 (from 26 fewer to 185 more)	⊕OOO VERY LOW
Behavioural intention to use a condom, at 6 months											
Peragallo 2021	randomised trial	very serious[5]	N/A	serious[2]	serious[3]	none	134/171 (78.4%)	153/201 (76.1%)	RR 1.03 (0.92 to 1.15)	23 more per 1000 (from 61 fewer to 114 more)	⊕OOO VERY LOW
Behavioural intention to use a condom, at 12 months											
Peragallo 2012	randomised trial	very serious[5]	N/A	serious[2]	serious[3]	none	144/183 (78.7%)	162/198 (81.8%)	RR 0.96 (0.87 to 1.06)	33 fewer per 1000 (from 106 fewer to 49 more)	⊕OOO VERY LOW
Any condom use, at 3 months											
Peragallo 2012	randomised trial	very serious[5]	N/A	serious[2]	serious[6]	none	55/143 (38.5%)	65/202 (32.2%)	RR 1.2 (0.9 to 1.59)	64 more per 1000 (from 32 fewer to 190 more)	⊕OOO VERY LOW
Any condom use, at 6 months											
2[a]	randomised trials	very serious[7]	no serious inconsistency	serious[2]	serious[6]	none	121/299 (40.5%)	140/332 (42.2%)	RR 0.95 (0.79 to 1.14)	21 fewer per 1000 (from 89 fewer to 59 more)	⊕OOO VERY LOW
Any condom use, at 12 months											
2[a]	randomised trials	very serious[7]	very serious[8]	serious[2]	very serious[9]	none	150/311 (48.2%)	140/329 (42.6%)	RR 1.11 (0.7 to 1.75)	47 more per 1000 (from 128 fewer to 319 more)	⊕OOO VERY LOW

[a] Peragallo 2012 and Peragallo Montano 2019

[1] Downgraded once for some concerns of bias due to no information on allocation concealment or blinding. Adherence issues: not all participants completed all sessions (only 71% completed all 3 and 16% did not complete any) and impact of adherence not analysed. Trial not registered.

[2] US study of Hispanic migrants

[3] Downgraded once as 95%CI crosses line of no effect

[4] Downgraded once as 95%CI crosses 1 MID

[5] Downgraded twice for high concerns of bias due to adherence to the intervention was poor (only 43% attended all sessions and 41% did not attend any session) and the impact of adherence was not assessed. Relatively high attrition (48% at 3-months and 33% at 12 months for intervention group) and no comparison of completers vs those lost to follow-up. Outcome assessors were not blind to condition. All outcomes were dichotomised due to skewed response patterns which did not allow for as rich of an analysis as if they had been retained as continuous variables, and may attenuate intervention effects. Trial not registered

[6] Downgraded once as 95%CI crosses line of no effect and 1 MID

[7] Serious risk of bias for Peragallo Montano 2019 (No information on allocation concealment or blinding. Adherence issues: not all participants completed all sessions (only 71% completed all 3 and 16% did not complete any) and impact of adherence not analysed. Trial not registered) and very serious risk of bias for Peragallo 2012 (Adherence to the intervention was poor (only 43% attended all sessions and 41% did not attend any session) and the impact of adherence was not assessed. Relatively high attrition (48% at 3-months and 33% at 12 months for intervention group) and no comparison of completers vs those lost to follow-up. Outcome assessors were not blind to condition. All outcomes were dichotomised due to skewed response patterns which did not allow for as rich of an analysis as if they had been retained as continuous variables, and may attenuate intervention effects. Trial not registered

[8] Downgraded twice as I2 = 86%. Random effects model used. Subgroup analyses not possible as only 2 studies.

[9] Downgraded twice as 95%CI crosses line of no effect and 2 MIDs

STI incidence outcomes for Culturally specific community-based group risk reduction intervention for Hispanic women vs Control

Quality assessment							No of patients		Effect		Quality
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intervention	Control	Relative (95% CI)	Absolute	
Chlamydia incidence, at 6 months											
Peragallo 2012	randomised trial	very serious[1]	N/A	serious[2]	very serious[3]	none	1/171 (0.58%)	0/201 (0%)	RR 3.52 (0.14 to 85.93)	-	⊕OOO VERY LOW
Chlamydia incidence, at 12 months											
Peragallo 2012	randomised trial	very serious[1]	N/A	serious[2]	very serious[3]	none	1/183 (0.55%)	3/198 (1.5%)	RR 0.36 (0.04 to 3.44)	10 fewer per 1000 (from 15 fewer to 37 more)	⊕OOO VERY LOW

[1] Downgraded twice for high risk of bias due to adherence to the intervention was poor (only 43% attended all sessions and 41% did not attend any session) and the impact of adherence was not assessed. Relatively high attrition (48% at 3-months and 33% at 12 months for intervention group) and no comparison of completers vs those lost to follow-up. Outcome assessors were not blind to condition. All outcomes were dichotomised due to skewed response patterns which did not allow for as rich of an analysis as if they had been retained as continuous variables, and may attenuate intervention effects. Trial not registered

[2] US study of Hispanic migrants

[3] Downgraded twice as 95%CI crosses line of no effect and 2 MIDs

STI/HIV knowledge outcomes for Culturally specific community-based group risk reduction intervention for Hispanic women vs Control

Quality assessment							No of patients		Effect		Quality
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intervention	Control	Relative (95% CI)	Absolute	
HIV knowledge, at 3 months											
Peragallo 2012	randomised trial	very serious[1]	N/A	serious[2]	serious[3]	none	88/143 (61.5%)	98/202 (48.5%)	RR 1.27 (1.05 to 1.54)	131 more per 1000 (from 24 more to 262 more)	⊕OOO VERY LOW
HIV knowledge, at 6 months											
2[a]	randomised trials	very serious[4]	no serious inconsistency	serious[2]	serious[3]	none	203/299 (67.9%)	153/332 (46.1%)	RR 1.44 (1.22 to 1.69)	203 more per 1000 (from 101 more to 318 more)	⊕OOO VERY LOW
HIV knowledge, at 12 months											
2[a]	randomised trials	very serious[4]	no serious inconsistency	serious[2]	serious[5]	none	213/311 (68.5%)	204/329 (62%)	RR 1.1 (0.99 to 1.22)	62 more per 1000 (from 6 fewer to 136 more)	⊕OOO VERY LOW

[a] Peragallo 2012 and Peragallo Montano 2019

[1] Downgraded twice for high risk of bias due to adherence to the intervention was poor (only 43% attended all sessions and 41% did not attend any session) and the impact of adherence was not assessed. Relatively high attrition (48% at 3-months and 33% at 12 months for intervention group) and no comparison of completers vs those lost to follow-up. Outcome assessors were not blind to condition. All outcomes were dichotomised due to skewed response patterns which did not allow for as rich of an analysis as if they had been retained as continuous variables, and may attenuate intervention effects. Trial not registered
[2] US study of Hispanic migrants
[3] Downgraded once as 95%CI crosses 1 MID
[4] Downgraded once for some concerns of bias for Peragallo Montano 2019 due to no information on allocation concealment or blinding; adherence issues: not all participants completed all sessions (only 71% completed all 3 and 16% did not complete any) and impact of adherence not analysed; trial not registered) and further downgraded for high risk of bias for Peragallo 2012 due to adherence to the intervention was poor (only 43% attended all sessions and 41% did not attend any session) and the impact of adherence was not assessed; relatively high attrition (48% at 3-months and 33% at 12 months for intervention group) and no comparison of completers vs those lost to follow-up; outcome assessors were not blind to condition; all outcomes were dichotomised due to skewed response patterns which did not allow for as rich of an analysis as if they had been retained as continuous variables, and may attenuate intervention effects; and trial not registered)
[5] Downgraded once as 95%CI crosses line of no effect

F.2 People who are homeless

F.2.1 Condom use outcomes

Quality assessment							No of patients		Effect		Quality
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intervention	Control	Relative (95% CI)	Absolute	
Proportion of unprotected sexual events, at 3 months (Better indicated by lower values). MID = 0.24											
Tucker 2017	randomised trial	very serious[1]	N/A	serious[2]	serious[3]	none	95	86	-	MD 0.01 higher (0.12 lower to 0.14 higher)	⊕OOO VERY LOW
Condom use self-efficacy, at 3 months (Better indicated by lower values). MID = 0.32											
Tucker 2017	randomised trial	very serious[1]	N/A	serious[2]	serious[3]	none	95	86	-	MD 0.13 higher (0.04 lower to 0.3 higher)	⊕OOO VERY LOW

[1] Downgraded twice for high risk of bias due to randomised cross-over trial with no information on blinding; intervention adherence was low and impact of intervention attendance on outcomes was not assessed; overall follow-up rates were high (91%) but follow-up was significantly higher in the intervention group (95%) than the control group (86%); trial not registered.
[2] US study
[3] Downgraded once as 95%CI crosses line of no effect

F.3 Young People

F.3.1 Consistent condom use

F.1.1.1 Peer facilitator intervention compared to expert facilitator intervention

Quality assessment							No of patients		Effect		Quality
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Peer led	Expert led	Relative (95% CI)	Absolute	
Consistent condom use for vaginal sex (follow-up: 1 month; assessed with: self-report of 'always' using condoms for vaginal sex)											
Giminez-Garcia 2018	randomised trial	very serious[1]	N/A	no serious indirectness	serious[2]	none	77/97 (79.4%)	79/93 (84.9%)	RR 0.93 (0.82 to 1.07)	59 fewer per 1000 (from 153 fewer to 59 more)	VERY LOW
Consistent condom use for vaginal sex (follow-up: 4 months; assessed with: self-report of 'always' using condoms for vaginal sex)											
Giminez-Garcia 2018	randomised trial	very serious[1]	N/A	no serious indirectness	serious[2]	none	72/82 (87.8%)	72/84 (85.7%)	RR 1.02 (0.91 to 1.15)	17 more per 1000 (from 77 fewer to 129 more)	VERY LOW
Consistent condom use for anal sex (follow-up: 1 month; assessed with: self-report of 'always' using condoms for anal sex)											
Giminez-Garcia 2018	randomised trial	very serious[1]	N/A	no serious indirectness	serious[2]	none	89/97 (91.8%)	89/93 (95.7%)	RR 0.96 (0.89 to 1.03)	38 fewer per 1000 (from 105 fewer to 29 more)	VERY LOW
Consistent condom use for anal sex (follow-up: 4 months; assessed with: self-report of 'always' using condoms for anal sex)											
Giminez-Garcia 2018	randomised trial	very serious[1]	N/A	no serious indirectness	serious[2]	none	75/82 (91.5%)	82/84 (97.6%)	RR 0.94 (0.87 to 1.10)	59 fewer per 1000 (from 127 fewer to 10 more)	VERY LOW

[1] Downgraded twice for high concerns of bias due to no information on participant blinding, adherence to intervention regimen or baseline differences between groups. Trial was not registered.
[2] Downgraded once as 95%CI crosses line of no effect

F.3.2 Unprotected sex in previous 3 months

F.1.2.1 STI risk reduction intervention with booster sessions compared to attention matched control

Quality assessment	No of patients	Effect	Quality

No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intervention	Control	Relative (95% CI)	Absolute	
Unprotected sex; any episodes (follow-up: 3 months; assessed with: self-report)											
Morrison-Beedy 2013	randomised trial	serious[1]	N/A	serious[2]	serious[3]	none	162/278 (58.3%)	162/259 (62.5%)	RR 0.93 (0.81 to 1.07)	44 fewer per 1000 (from 119 fewer to 44 more)	VERY LOW
Unprotected sex; any episodes (follow-up: 6 months; assessed with: self-report)											
Morrison-Beedy 2013	randomised trial	serious[1]	N/A	serious[2]	serious[4]	none	154/284 (54.2%)	176/262 (67.2%)	RR 0.81 (0.70 to 0.93)	128 fewer per 1000 (from 47 fewer to 202 fewer)	VERY LOW
Unprotected sex; any episodes (follow-up: 12 months; assessed with: self-report)											
Morrison-Beedy 2013	randomised trial	serious[1]	N/A	serious[2]	serious[3]	none	170/249 (68.3%)	171/235 (72.8%0	RR 0.94 (0.84 to 1.05)	44 fewer per 1000 (from 116 fewer to 36 more)	VERY LOW
Unprotected sex; number of episodes (follow-up: 3 months; assessed with: self-report). MID = 3.73											
Morrison-Beedy 2013	randomised trial	serious[1]	N/A	serious[2]	no serious imprecision	none	278	259		MD -0.70 (-1.93 to 0.53)	LOW
Unprotected sex; number of episodes (follow-up: 6 months; assessed with: self-report). MID = 4.42											
Morrison-Beedy 2013	randomised trial	serious[1]	N/A	serious[2]	no serious imprecision	none	284	262		MD -0.97 (-2.41 to 0.47)	LOW
Unprotected sex; number of episodes (follow-up: 12 months; assessed with: self-report). MID = 5.52											
Morrison-Beedy 2013	randomised trial	serious[1]	N/A	serious[2]	no serious imprecision	none	249	235		MD -1.06 (-3.04 to 0.92)	LOW

[1] Downgraded once for some concerns of bias due to no information on participant blinding or intervention adherence. 24% lost to follow-up and no attrition analyses.
[2] US study
[3] Downgraded once as 95%CI crosses line of no effect
[4] Downgraded once as 95%CI crosses 1 MID

F.3.3 Condom use outcomes

F.3.3.1 Brief MI intervention delivered in paediatric EDs vs. standard care

Quality assessment							No of patients		Effect		Quality

No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intervention	Control	Relative (95% CI)	Absolute	
Condom use at last sex (follow-up: 6 months)											
Miller 2021	randomised trial	serious[1]	N/A	serious[2]	very serious[3]	none	4/10 (40%)	8/14 (57.1%)	RR 0.70 (0.29 to 1.69)	171 fewer per 1000 (from 406 fewer to 394 more)	VERY LOW
Condom use intention (follow-up: 6 months). MID = 0.48											
Miller 2021	randomised trial	serious[1]	N/A	serious[2]	serious[4]	none	19	18	-	MD 0.54 lower (1.27 lower to 0.19 higher)	VERY LOW
Condom use confidence (follow-up: 6 months). MID = 0.62											
Miller 2021	randomised trial	serious[1]	N/A	serious[2]	serious[3]	none	19	18	-	MD 0.05 higher (0.82 lower to 0.92 higher)	VERY LOW

[1] Downgraded once for some concerns of bias due to high attrition (only 40.6% completion at 6 months) but no differential attrition by group; small final sample size (n = 37)
[2] US study delivered in paediatric ED setting
[3] Downgraded twice as 95%CI crosses line of no effect and 2 MIDs
[4] Downgraded once as 95%CI crosses line of no effect and 1MID

F.3.4 STI incidence

F.3.4.1 Group-based STI risk reduction workshops and counselling compared with waitlist control

Quality assessment	No of patients	Effect	Quality

No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intervention	Control	Relative (95% CI)	Absolute	
STI incidence (follow-up: up to 6 months; assessed with: clinic confirmed test)											
Champion 2012	randomised trial	no serious	N/A	serious[1]	serious[2]	none	0/155 (0%)	11/163 (6.7%)	RR 0.05 (0.00 to 0.77)	64 fewer per 1000 (from 16 fewer to 67 fewer)	LOW
STI incidence (follow-up: 12 months; assessed with: clinic confirmed test)											
Champion 2012	randomised trial	no serious	N/A	serious[1]	serious[3]	none	6/166 (3.6%)	13/167 (7.8%)	RR 0.46 (0.18 to 1.19)	42 fewer per 1000 (from 64 fewer to 15 more)	LOW

[1] US study of adolescent women with a history of sexual or physical abuse
[2] Downgraded once as 95%CI crosses line of no effect
[3] Downgraded once as 95%CI crosses line of no effect and 1 MID

F.3.5 STI knowledge

F.3.5.1 Peer facilitator intervention compared to expert facilitator intervention

Quality assessment							No of patients		Effect		Quality
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Peer led	Expert led	Relative (95% CI)	Absolute	
STI knowledge (follow-up: 1 month; assessed with: 13 true/false STI knowledge questions). MID = 0.73											
Giminez-Garcia 2018	randomised trial	very serious[1]	N/A	no serious indirectness	serious[2]	none	97	93		MD 0.10 (-0.32 to 0.52)	VERY LOW
STI knowledge (follow-up: 4 months; assessed with: 13 true/false STI knowledge questions). MID = 0.59											
Giminez-Garcia 2018	randomised trial	very serious[1]	N/A	no serious indirectness	no serious imprecision	none	82	84		0.07 (-0.32 to 0.46)	LOW

[1] Downgraded twice for high risk of bias due to limited information on randomisation and allocation concealment, no information on intervention adherence, missing data not reported, no attrition analyses by group, trial not registered.
[2] Downgraded once as 95%CI crosses line of no effect

F.4 Trans People

F.4.1 Condomless sex

F.2.1.1 Group-based HIV risk reduction and prevention intervention compared with standard care or attention-matched control

Quality assessment							No of patients		Effect		Quality
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intervention	Control	Relative (95% CI)	Absolute	
Number of condomless sex acts (follow-up: 4 months; assessed with: self-report). MID = 1.91											
Garofalo 2018	randomised trial	serious[1]	N/A	serious[2]	serious[3]	none	101	66	-	MD -0.88 (-1.90 to 0.14)	VERY LOW
Number of condomless sex acts (follow-up: 8 months; assessed with: self-report). MID = 1.03											
Garofalo 2018	randomised trial	serious[1]	N/A	serious[2]	serious[3]	none	100	67	-	MD -0.43 (-0.97 to 0.11)	VERY LOW
Number of condomless sex acts (follow-up: 12 months; assessed with: self-report). MID = 1.27											
Garofalo 2018	randomised trial	serious[1]	N/A	serious[2]	serious[4]	none	101	63	-	MD -0.69 (-1.37 to -0.01)	VERY LOW
Number of sex partners with whom participants had condomless sex (follow-up: 3 months; assessed with: self-report). MID = 0.38											
Sevelius 2019	randomsied trial	serious[5]	N/A	serious[2]	serious[4]	none	21	21	-	MD 0.29 (-0.20 to 0.78)	VERY LOW
Number of sex partners with whom participants had condomless sex (follow-up: 6 months; assessed with: self-report). MID = 0.41											
Sevelius 2019	randomised trial	serious[5]	N/A	serious[2]	serious[4]	none	21	21	-	MD -0.42 (-0.84 to 0.00)	VERY LOW

[1] Downgraded once for some concerns of bias due to an original third arm of the trial being dropped before study completion, and the trial was not registered

[2] US study

[3] Downgraded once as 95%CI crosses line of no effect

[4] Downgraded once as 95%CI crosses 1 MID

[5] Downgraded once for some concerns of bias due to lack of participant blinding and relatively high attrition

F.5 People from a Black African or Caribbean family background

F.5.1 Interactive HIV prevention workshops vs. information only comparison workshops

Quality assessment	No of patients	Effect	Quality

No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Intervention**	**Control**	**Relative (95% CI)**	**Absolute**	
Condom use at last vaginal, oral or anal sex with any partner (follow-up: 3 months; assessed with: self-report)											
Diallo (2010)[a]	randomised trial	no serious	N/A	serious[1]	serious[2]	none	42/59 (71%)	26/53 (49.5%)	RR 1.45 (1.06 to 2.00)	221 more per 1000 (from 29 more to 491 more)	Low
Condom use at last vaginal, oral or anal sex with any partner (follow-up: 6 months; assessed with: self-report)											
Diallo (2010)[a]	randomised trial	no serious	N/A	serious[1]	serious[2]	none	48/70 (67.8%)	33/67 (48.6%)	RR 1.39 (1.04 to 1.86)	192 more per 1000 (from 20 more to 424 more)	Low
Any unprotected sex in prior 3 months (follow-up: 3 months; assessed with: self-report)											
Diallo (2010)	randomised trial	no serious	N/A	serious[1]	very serious[3]	none	35/93 (37.6%)	34/94 (36.2%)	RR 1.04 (0.72 to 1.51)	14 more per 1000 (from 101 fewer to 184 more)	Very low
Any unprotected sex in prior 3 months (follow-up: 6 months; assessed with: self-report)											
Diallo (2010)	randomised trial	no serious	N/A	serious[1]	very serious[3]	none	37/120 (30.8%)	37/117 (31.6%)	RR 0.98 (0.67 to 1.42)	6 fewer per 1000 (from 104 fewer to 133 more)	Very low

[1] Downgraded once for indirectness as intervention is delivered to pre-existing groups of women (e.g. church groups, sororities) in locations of their choice (e.g. college campuses, their homes). This is not directly applicable to UK sexual health services context.
[2] Downgraded once as 95%CI crosses 1MID
[3] Downgraded twice as 95%CI crosses line of no effect and 2 MIDs
[a] Analyses restricted to sexually active participants only

F.5.2 Brief small-group peer-led HIV risk reduction intervention delivered in Barbershops vs. attention matched control

Quality assessment							**No of patients**		**Effect**		**Quality**
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Intervention**	**Control**	**Relative (95% CI)**	**Absolute**	

Any condomless sex (follow-up: 6 months; assessed with: self-report)											
Wilson (2019)	randomised trial	very serious[1]	N/A	serious[2]	serious[3]	none	124/351 (35.2%)	141/305 (46.2%)	RR 0.76 (0.63 to 0.92)	111 fewer per 1000 (from 37 fewer to 171 fewer)	Very low

[1] Downgraded twice for high risk of bias due to baseline differences between groups on key variables, differential attrition by group; an no participant blinding
[2] US study conducted in barbershops
[3] Downgraded once as 95%CI crosses 1 MID

F.5.3 Computer-based HIV prevention intervention with small group sessions vs. attention matched control

Quality assessment							No of patients		Effect		Quality
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Intervention**	**Control**	**Relative (95% CI)**	**Absolute**	
Proportion of condom-protected sex acts (follow-up: 3 months). MID = 0.05											
Wingood 2011	randomised trial	serious[1]	N/A	serious[2]	no serious	none	58	58		MD 0.32 higher (0.28 to 0,36 higher)	Low
Condom use self-efficacy (follow-up: 3 months). MID = 0.26											
Wingood 2011	randomised trial	serious[1]	N/A	serious[2]	no serious	none	58	58		MD 1.85 higher (1.66 to 2.04 higher)	Low
HIV/STI prevention knowledge (follow-up: 3 months). MID = 0.05											
Wingood 2011	randomised trial	serious[1]	N/A	serious[2]	no serious	none	58	58		MD 0.46 higher (0.43 to 0.49 higher)	Low

[1] Downgraded once for some concerns of bias due to impact of intervention adherence not assessed; 10.4% did not attend both intervention sessions; trial not registered
[2] US study

F.6 Young people from a Black African or Caribbean family background

F.6.1 Psychoeducational STI/HIV prevention intervention vs. attention matched control

Quality assessment	No of patients	Effect	Quality

No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intervention	Control	Relative (95% CI)	Absolute	
Proportion of condom protected vaginal sex; at 3 months. MID = 0.19											
Brawner 2021	randomised trial	serious[1]	N/A	serious[2]	serious[3]	none	21	20	-	MD 0.13 higher (0.1 lower to 0.36 higher)	VERY LOW
Proportion of condom protected vaginal sex; at 6 months. MID = 0.18											
Brawner 2021	randomised trial	serious[1]	N/A	serious[2]	very serious[4]	none	9	12	-	MD 0.14 lower (0.48 lower to 0.2 higher)	VERY LOW
Proportion of condom protected vaginal sex; at 12 months. MID = 0.1											
Brawner 2021	randomised trial	serious[1]	N/A	serious[2]	very serious[4]	none	5	9	-	MD 0.18 lower (0.59 lower to 0.23 higher)	VERY LOW
Condom use self-efficacy; at 3 months. MID = 0.29											
Brawner 2021	randomised trial	serious[1]	N/A	serious[2]	serious[5]	none	37	31	-	MD 0.31 higher (0.04 to 0.58 higher)	VERY LOW
Condom use self-efficacy; at 6 months. MID = 0.32											
Brawner 2021	randomised trial	serious[1]	N/A	serious[2]	serious[3]	none	17	18	-	MD 0.21 higher (0.17 lower to 0.59 higher)	VERY LOW
Condom use self-efficacy; at 12 months. MID = 0.31											
Brawner 2021	randomised trial	serious[1]	N/A	serious[2]	serious[3]	none	11	10	-	MD 0.25 higher (0.25 lower to 0.75 higher)	VERY LOW
Condom use knowledge; at 6 months. MID = 0.12											
Brawner 2021	randomised trial	serious[1]	N/A	serious[2]	serious[3]	none	17	18	-	MD 0.05 higher (0.09 lower to 0.19 higher)	VERY LOW
Condom use knowledge; at 12 months. MID = 0.16											
Brawner 2021	randomised trial	serious[1]	N/A	serious[2]	serious[3]	none	11	12	-	MD 0.09 higher (0.14 lower to 0.32 higher)	VERY LOW
HIV/STI knowledge; at 3 months. MID = 0.14											
Brawner 2021	randomised trial	serious[1]	N/A	serious[2]	serious[5]	none	36	30	-	MD 0.16 higher (0.04 to 0.28 higher)	VERY LOW
HIV/STI knowledge; at 6 months. MID = 0.09											
Brawner 2021	randomised trial	serious[1]	N/A	serious[2]	serious[3]	none	17	18	-	MD 0.04 higher (0.09 lower to 0.17 higher)	VERY LOW
HIV/STI knowledge; at 12 months. MID = 0.12											

Brawner 2021	randomised trial	serious[1]	N/A	serious[2]	serious[3]	none	11	12	-	MD 0.07 higher (0.11 lower to 0.25 higher)	VERY LOW

[1] Downgraded once for some concerns of bias due to baseline differences between groups, high attrition and trial not registered
[2] US study
[3] Downgraded once as 95%CI crosses line of no effect and 1 MID
[4] Downgraded twice as 95%CI crosses line of no effect and 2 MIDs
[5] Downgraded once as 95%CI crosses 1 MID

F.6.2 Group intervention addressing issues of gender, power and inequality vs. attention matched control

Quality assessment							No of patients		Effect		Quality
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Intervention**	**Control**	**Relative (95% CI)**	**Absolute**	
Any unprotected vaginal or anal sex in prior 3 months (follow-up: immediately post-test; assessed with: self-report)											
Brothers 2016	randomised trial	very serious[1]	N/A	serious[2]	very serious[3]	none	3/15 (20%)	5/15 (33.3%)	RR 0.6 (0.17 to 2.07)	133 fewer per 1000 (from 277 fewer to 357 more)	Very low
Any unprotected vaginal or anal sex in prior 3 months (follow-up: 3 months; assessed with: self-report)											
Brothers 2016	randomised trial	very serious[1]	N/A	serious[2]	very serious[3]	none	6/12 (50%)	6/13 (46.2%)	RR 1.08 (0.48 to 2.45)	37 more per 1000 (from 240 fewer to 669 more)	Very low
Condom use self-efficacy (follow-up: immediately post-test; assessed with: self-report). MID = 0.3											
Brothers 2016	randomised trial	very serious[1]	N/A	serious[2]	serious[4]	none	18	19	-	MD 0.11 higher (0.26 lower to 0.48 higher)	Very low
Condom use self-efficacy (follow-up: 3 months; assessed with: self-report). MID = 0.26											
Brothers 2016	randomised trial	very serious[1]	N/A	serious[2]	vserious[5]	none	18	18	-	MD 0.43 higher (0.11 to 0.75 higher)	Very low

[1] Downgraded twice for high risk of bias due to limited information on randomisation; baseline differences between groups; intervention adherence not assessed; trial not registered
[2] US study
[3] Downgraded twice as 95%CI crosses line of no effect and 2 MIDs
[4] Downgraded once as 95%CI crosses line of no effect and 1 MID
[5] Downgraded once as 95%CI crosses 1 MID

F.6.3 Small group IMB-based HIV prevention intervention vs. attention matched control

Quality assessment	No of patients	Effect	Quality

No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Intervention**	**Control**	**Relative (95% CI)**	**Absolute**	
Condom use self-efficacy (follow-up: 3 months). MID = 2.89											
Chandler 2019	randomised trial	serious[1]	N/A	serious[2]	serious[3]	none	24	21	-	MD 1.32 higher (2.06 lower to 4.7 higher)	Very low
HIV knowledge (follow-up: 3 months). MID = 1.01											
Chandler 2019	randomised trial	serious[1]	N/A	serious[2]	no serious	none	25	21	-	MD 3.07 higher (1.85 to 4.29 higher)	Low

[1] Downgraded once for some concerns of bias due to intervention adherence not assessed and trial not registered
[2] US study
[3] Downgraded once as 95%CI crosses line of no effect and 1 MID

F.6.4 Sex positive condom-focused intervention vs. attention matched control

Quality assessment							**No of patients**		**Effect**		**Quality**
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Intervention**	**Control**	**Relative (95% CI)**	**Absolute**	
Correct and consistent condom use (follow-up: 2 months)											

Crosby 2014	randomised trial	serious[1]	N/A	serious[2]	serious[3]	none	187/349 (53.6%)	175/353 (49.6%)	RR 1.08 (0.94 to 1.25)	40 more per 1000 (from 30 fewer to 124 more)	Very low
Correct and consistent condom use (follow-up: 6 months)											
Crosby 2014	randomised trial	serious[1]	N/A	serious[2]	serious[4]	none	180/349 (51.6%)	166/353 (47%)	RR 1.1 (0.94 to 1.27)	47 more per 1000 (from 28 fewer to 127 more)	Very low
STI incidence - CT or GC (follow-up: 6 months)											
Crosby 2014	randomised trial	serious[1]	N/A	serious[2]	very serious[5]	none	33/349 (9.5%)	26/353 (7.4%)	RR 1.28 (0.78 to 2.1)	21 more per 1000 (from 16 fewer to 81 more)	Very low

[1] Downgraded once for some concerns of bias due to baseline differences between groups on key variables (condom use and history of STIs); trial not registered.
[2] Downgraded twice for indirectness due to high rate of self-reported history of incarceration (42%) and because for participants younger than 18 years, only those who provided details of a parent or guardian who could provide in-person parental consent were eligible to participate. This group may not be representative of all sexually active males aged 15-18 years. US study
[3] Downgraded once as 95%CI crosses line of no effect
[4] Downgraded once as 95%CI crosses line of no effect and 1 MID
[5] Downgraded twice as 95%CI crosses line of no effect and 2 MIDs

F.6.5 Group intervention with supplementary brief telephone contacts vs. group intervention only

Quality assessment							No of patients		Effect		Quality
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Intervention**	**Control**	**Relative (95% CI)**	**Absolute**	
Proportion of condom-protected sex acts in prior 3 months (follow-up: 36 months). MID = 0.15											
DiClemente 2014	randomised trial	serious[1]	N/A	serious[2]	no serious	none	213	216	-	MD 0.09 higher (0.04 to 0.14 higher)	Low
Proportion of condom-protected sex acts in prior 6 months (follow-up: 36 months). MID = 0.15											

DiClemente 2014	randomised trial	serious[1]	N/A	serious[2]	no serious	none	213	216	-	MD 0.09 higher (0.04 to 0.14 higher)	Low
Chlamydia infection (follow-up: 36 months)											
DiClemente 2014	randomised trial	serious[1]	N/A	serious[2]	serious[3]	none	94/309 (30.4%)	104/318 (32.7%)	RR 0.93 (0.74 to 1.17)	23 fewer per 1000 (from 85 fewer to 56 more)	Very low
Gonococcal infection (follow-up: 36 months)											
DiClemente 2014	randomised trial	serious[1]	N/A	serious[2]	very serious[4]	none	48/309 (15.5%)	54/318 (17%)	RR 0.91 (0.64 to 1.31)	15 fewer per 1000 (from 61 fewer to 53 more)	Very low

[1] Downgraded once for some concerns of bias due to no information on blinding; intervention group received more phone sessions than control; high attrition.
[2] Downgraded for indirectness due to high rate of self-reported abuse history (56% emotional abuse; 39% physical abuse)
[3] Downgraded once as 95%CI crosses line of no effect and 1 MID
[4] Downgraded twice as 95%CI crosses line of no effect and 2 MIDs

F.6.6 Group intervention focusing on partner concurrency vs. attention matched control

Quality assessment							No of patients		Effect		Quality
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Intervention**	**Control**	**Relative (95% CI)**	**Absolute**	
Condom use self-efficacy (follow-up: 6 months). MID = 2.67											
Wingood 2013	randomised trial	serious[1]	N/A	serious[2]	no serious	none	441	194	-	MD 1.72 higher (0.86 to 2.58 higher)	Low
Condom use self-efficacy (follow-up: 12 months). MID = 1.85											
Wingood 2013	randomised trial	serious[1]	N/A	serious[2]	serious[3]	none	452	183	-	MD 0.45 lower (1.08 lower to 0.18 higher)	Very low

Non-viral STI incidence – CT, GC, TV (follow-up: 12 months)											
Wingood 2013	randomised trial	serious[1]	N/A	serious[2]	serious[4]	none	27/441 (6.1%)	19/194 (9.8%)	RR 0.63 (0.36 to 1.1)	36 fewer per 1000 (from 63 fewer to 10 more)	Very low
Non-viral STI incidence – CT, GC, TV (follow-up: 12 months)											
Wingood 2013	randomised trial	serious[1]	N/A	serious[2]	very serious[5]	none	42/452 (9.3%)	22/183 (12%)	RR 0.77 (0.48 to 1.26)	28 fewer per 1000 (from 63 fewer 31 more)	Very low
HPV incidence (follow-up: 12 months)											
Wingood 2013	randomised trial	serious[1]	N/A	serious[2]	serious[6]	none	36/153 (23.5%)	24/61 (39.3%)	RR 0.6 (0.39 to 0.91)	157 fewer 1000 (from 35 fewer to 240 fewer)	Very low

[1] Downgraded once for some concerns of bias due to trial not registered
[2] US study and participants limited to those with HMO health insurance
[3] Downgraded once as 95%CI crosses line of no effect
[4] Downgraded once as 95%CI crosses line of no effect and 1 MID
[5] Downgraded twice as 95%CI crosses line of no effect and 2 MIDs
[6] Downgraded once as 95%CI crosses 1 MID

F.7 MSM

F.7.1 IMB / Motivational Interviewing-based approaches

F.7.1.1 Condom use outcomes

Quality assessment							No of patients		Effect		Quality
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Intervention**	**Control**	**Relative (95% CI)**	**Absolute**	

Frequency of UAI in prior 3 months, at 3 months. MID = 1.85 (Better indicated by lower values)											
3[a]	randomised trials	very serious[1]	no serious inconsistency	serious[2]	serious[3]	none	106	95	-	MD 0.01 higher (1.32 lower to 1.35 higher)	⊕OOO VERY LOW
Frequency of UAI in prior 3 months, at 6 months. MID = 8.32 (Better indicated by lower values)											
3[b]	randomised trials	very serious[4]	no serious inconsistency	serious[2]	serious[3]	none	132	127	-	MD 0.62 higher (1.38 lower to 2.63 higher)	⊕OOO VERY LOW
Frequency of unprotected anal or oral sex in prior 3 months, at 3 months. MID = 0.04 (Better indicated by lower values)											
Brown 2019	randomised trial	serious[5]	N/A	serious[6]	no serious imprecision	none	39	33	-	MD 0.25 lower (0.43 to 0.07 lower)	⊕⊕OO LOW
Frequency of UAI in prior 3 months, at 9 months. MID = 10.75 (Better indicated by lower values)											
Sikkema 2014	randomised trial	serious[7]	N/A	serious[6]	serious[8]	none	32	27	-	MD 5.07 higher (9.89 lower to 20.03 higher)	⊕OOO VERY LOW
Frequency of UAI with HIV- or unknown status partners in prior 3 months, at 3 months. MID = 4.05 (Better indicated by lower values)											
2[c]	randomised trials	serious[7]	no serious inconsistency	serious[2]	serious[3]	none	112	116	-	MD 0.09 lower (2.01 lower to 1.83 higher)	⊕OOO VERY LOW
Frequency of UAI with HIV- or unknown status partners in prior 3 months, at 6 months. MID = 3.56 (Better indicated by lower values)											
3[d]	randomised trials	serious[7]	no serious inconsistency	serious[2]	serious[3]	none	189	184	-	MD 0.06 higher (1.21 lower to 1.34 higher)	⊕OOO VERY LOW
Frequency of UAI with HIV- or unknown status partners in prior 3 months, at 9 months. MID = 5.28 (Better indicated by lower values)											
2[c]	randomised trials	serious[7]	serious[10]	serious[2]	very serious[9]	none	110	112	-	MD 0.7 higher (5.48 lower to 6.87 higher)	⊕OOO VERY LOW
Frequency of UAI with HIV- or unknown status partners in prior 3 months, at 12 months. MID = 2.14 (Better indicated by lower values)											
Safren 2013	randomised trial	no serious risk of bias	N/A	serious[6]	serious[8]	none	86	86	-	MD 0.5 higher (1.4 lower to 2.4 higher)	⊕⊕OO LOW
Frequency of UAI with HIV+ partners in prior 6 months, at 6 months. MID = 6 (Better indicated by lower values)											
Cruess 2018	randomised trial	no serious risk of bias	N/A	serious[6]	serious[3]	none	70	70	-	MD 0.46 lower (4.67 lower to 3.75 higher)	⊕⊕OO LOW
Condom use at last sex, at 3 months											
Nostlinger 2016	randomised trial	serious[11]	N/A	serious[6]	serious[8]	none	25/37 (67.6%)	17/38 (44.7%)	RR 1.51 (0.99 to 2.29)	228 more per 1000 (from 4 fewer to 577 more)	⊕OOO VERY LOW
Condom use at last sex, at 6 months											
Nostlinger 2016	randomised trial	serious[11]	N/A	serious[6]	serious[8]	none	27/41 (65.9%)	17/35 (48.6%)	RR 1.36 (0.9 to 2.03)	175 more per 1000 (from 49 fewer to 500 more)	⊕OOO VERY LOW
Serodiscordant CAI with a male partner in prior 3 months, at 3 months											
Hart 2021	randomised trial[1]	serious[12]	N/A	serious[13]	serious[8]	none	45/89 (50.6%)	46/94 (48.9%)	RR 1.03 (0.77 to 1.38)	15 more per 1000 (from 113 fewer to 186 more)	⊕OOO VERY LOW
Serodiscordant CAI with a male partner in prior 3 months, at 6 months											

Hart 2021	randomised trial[1]	serious[12]	N/A	serious[13]	serious[8]	none	35/89 (39.3%)	45/94 (47.9%)	RR 0.82 (0.59 to 1.15)	86 fewer per 1000 (from 196 fewer to 72 more)	⊕OOO VERY LOW
Serodiscordant CAI with casual partner in prior 3 months, at 3 months											
Hart 2021	randomised trial[1]	serious[12]	N/A	serious[13]	serious[8]	none	41/89 (46.1%)	39/94 (41.5%)	RR 1.11 (0.8 to 1.54)	46 more per 1000 (from 83 fewer to 224 more)	⊕OOO VERY LOW
Serodiscordant CAI with casual partner in prior 3 months, at 6 months											
Hart 2021	randomised trial[1]	serious[12]	N/A	serious[13]	serious[8]	none	32/89 (36%)	40/94 (42.6%)	RR 0.84 (0.59 to 1.22)	68 fewer per 1000 (from 174 fewer to 94 more)	⊕OOO VERY LOW
Condom use self-efficacy, at 3 months. MID = 1.68											
Hart 2021	randomised trial[1]	serious[12]	N/A	serious[13]	serious[3]	none	89	94	-	MD 0.07 higher (0.86 lower to 1 higher)	⊕OOO VERY LOW
Condom use self-efficacy, at 6 months. MID = 1.50											
Hart 2021	randomised trial[1]	serious[12]	N/A	serious[13]	serious[3]	none	89	94	-	MD 0.03 higher (0.84 lower to 0.9 higher)	⊕OOO VERY LOW

[a] Brown 2019, Sikkema 2011, Sikkema 2014
[b] Cruess 2018, Sikkema 2011, Sikkema 2014
[c] Safren 2013, Sikkema 2014
[d] Cruess 2018, Safren 2013, Sikkema 2014
[1] Downgraded twice due to some concerns of bias for Brown 2019 due to no information on randomisation or allocation concealment; low intervention attendance (57%) and impact of adherence not included in analyses; trial not registered; and high risk of bias for Sikkema 2011 due to limited information on randomisation and significant baseline differences on key study variables; no information on blinding; 77% retention and no comparison of completers and non-completers; unreliable assessment of STI incidence; and trial not registered; and some concerns of bias for Sikkema 2014 due to limited information on randomisation and blinding of participants or outcome assessors; impact of intervention adherence not assessed; high attrition; trial not registered
[2] US studies
[3] Downgraded once as 95%CI crosses line of no effect
[4] Downgraded twice for Sikkema 2011: Limited information on randomisation and significant baseline differences on key study variables; no information on blinding; 77% retention and no comparison of completers and non-completers; unreliable assessment of STI incidence; and trial not registered; and Sikkema 2014: Limited information on randomisation and blinding of participants or outcome assessors; impact of intervention adherence not assessed; high attrition; trial not registered.
[5] Downgraded once for some concerns of bias due to no information on randomisation or allocation concealment; low intervention attendance (57%) and impact of adherence not included in analyses; trial not registered
[6] US study
[7] Downgraded once for some concerns of bias due to limited information on randomisation and blinding of participants or outcome assessors; impact of intervention adherence not assessed; high attrition; trial not registered
[8] Downgraded once as 95%CI crosses line of no effect and 1MID
[9] Downgraded twice as 95%CI crosses line of no effect and 2 MIDs
[10] Downgraded once for high I^2 = 59%. Random effects model used. Subgroup analyses not possible as only 2 studies.
[11] Downgraded once for some concerns of bias due to 32% loss to follow-up; attrition by group not reported only overall attrition; intervention adherence not assessed; and trial not registered
[12] Downgraded once for some concerns of bias due to limited information on randomisation method, no information on allocation concealment or participant blinding, and trial not registered
[13] Canadian study

F.7.1.2 STI incidence outcomes

Quality assessment							No of patients		Effect		Quality
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intervention	Control	Relative (95% CI)	Absolute	
Self-reported STI diagnosis or symptoms, at 3 months											
Sikkema 2011	randomised trial	very serious[1]	N/A	serious[2]	very serious[3]	none	9/29 (31%)	5/21 (23.8%)	RR 1.3 (0.51 to 3.33)	71 more per 1000 (from 117 fewer to 555 more)	⊕OOO VERY LOW
Self-reported STI diagnosis or symptoms, at 6 months											
Sikkema 2011	randomised trial	very serious[1]	N/A	serious[2]	very serious[3]	none	7/29 (24.1%)	6/21 (28.6%)	RR 0.84 (0.33 to 2.15)	46 fewer per 1000 (from 191 fewer to 329 more)	⊕OOO VERY LOW

[1] Downgraded twice for high risk of bias due to limited information on randomisation and significant baseline differences on key study variables; no information on blinding; 77% retention and no comparison of completers and non-completers; unreliable assessment of STI incidence; and trial not registered.
[2] US studies
[3] Downgraded twice as 95%CI crosses 2 MIDs

F.7.1.3 STI/HIV Knowledge-based outcomes

Quality assessment							No of patients		Effect		Quality
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intervention	Control	Relative (95% CI)	Absolute	
HIV transmission knowledge, at 3 months. MID = 0.89											

Brown 2019	randomised trial	serious[1]	N/A	serious[2]	no serious imprecision	none	39	33	-	MD 2.1 higher (1.17 to 3.03 higher)	⊕⊕OO LOW

[1] Downgraded once for some concerns of bias due to no information on randomisation or allocation concealment; low intervention attendance (57%) and impact of adherence not included in analyses; trial not registered.
[2] US study

F.7.2 Cognitive and CBT-based approaches

F.7.2.1 Condom use outcomes

Quality assessment							No of patients		Effect		Quality
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Intervention**	**Control**	**Relative (95% CI)**	**Absolute**	
UAI during last sex with non-primary partner, at 3 months											
Mansergh 2010	randomised trial	no serious risk of bias	N/A	serious[1]	serious[2]	none	225/524 (42.9%)	236/537 (43.9%)	RR 0.98 (0.85 to 1.12)	9 fewer per 1000 (from 66 fewer to 53 more)	⊕⊕OO LOW
UAI during last sex with non-primary partner, at 6 months											
Mansergh 2010	randomised trial	no serious risk of bias	N/A	serious[1]	serious[2]	none	224/520 (43.1%)	226/538 (42%)	RR 1.03 (0.89 to 1.18)	13 more per 1000 (from 46 fewer to 76 more)	⊕⊕OO LOW
UAI during last sex with a non-primary partner, at 12 months											
Mansergh 2010	randomised trial	no serious risk of bias	N/A	serious[1]	serious[2]	none	215/537 (40%)	206/542 (38%)	RR 1.05 (0.91 to 1.22)	19 more per 1000 (from 34 fewer to 84 more)	⊕⊕OO LOW
UAI during last sex with non-primary partner whose HIV status was unknown or serodiscordant, at 3 months											
Mansergh 2010	randomised trial	no serious risk of bias	N/A	serious[1]	serious[3]	none	100/524 (19.1%)	113/537 (21%)	RR 0.91 (0.71 to 1.15)	19 fewer per 1000 (from 61 fewer to 32 more)	⊕⊕OO LOW
UAI during last sex with non-primary partner whose HIV status was unknown or serodiscordant, at 6 months											
Mansergh 2010	randomised trial	no serious risk of bias	N/A	serious[1]	serious[3]	none	88/520 (16.9%)	97/538 (18%)	RR 0.94 (0.72 to 1.22)	11 fewer per 1000 (from 50 fewer to 40 more)	⊕⊕OO LOW
UAI during last sex with non-primary partner whose HIV status was unknown or serodiscordant, at 12 months											

Mansergh 2010	randomised trial	no serious risk of bias	N/A	serious[1]	serious[3]	none	97/537 (18.1%)	108/542 (19.9%)	RR 0.91 (0.71 to 1.16)	18 fewer per 1000 (from 58 fewer to 32 more)	⊕⊕OO LOW
Number of episodes of UAI with a HIV serodiscordant or status unknown partner in the past 3 months, at 3 months. MID = 1.03 (Better indicated by lower values)											
Mansergh 2010	randomised trial	no serious risk of bias	N/A	serious[1]	serious[4]	none	19	17	-	MD 1.3 lower (2.55 to 0.05 lower)	⊕⊕OO LOW
Number of episodes of UAI with a HIV serodiscordant or status unknown partner in the past 3 months, at 6 months. MID = 0.87 (Better indicated by lower values)											
Mansergh 2010	randomised trial	no serious risk of bias	N/A	serious[1]	serious[4]	none	21	19	-	MD 1.7 lower (2.58 to 0.82 lower)	⊕⊕OO LOW
Number of men reporting any episodes of UAI with a non-concordant partner, at 6 months											
Schwarcz 2013	randomised trial	serious[5]	N/A	serious[1]	serious[3]	none	46/151 (30.5%)	47/165 (28.5%)	RR 1.07 (0.76 to 1.5)	20 more per 1000 (from 68 fewer to 142 more)	⊕OOO VERY LOW
Number of men reporting any episodes of UAI with a non-concordant partner, at 12 months											
Schwarcz 2013	randomised trial	serious[5]	N/A	serious[1]	serious[3]	none	42/151 (27.8%)	37/165 (22.4%)	RR 1.24 (0.85 to 1.82)	54 more per 1000 (from 34 fewer to 184 more)	⊕OOO VERY LOW

[1] US study
[2] Downgraded once as 95%CI crosses line of no effect
[3] Downgraded once as 95%CI crosses line of no effect and 1MID
[4] Downgraded once as 95%CI crosses one MID
[5] Downgraded once for some concerns of bias due to intervention adherence not assessed and trial not registered

F.7.2.2 STI Incidence outcomes

Quality assessment							No of patients		Effect		Quality
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Intervention**	**Control**	**Relative (95% CI)**	**Absolute**	
Incidence of gonorrhoea, at 6 months											
Schwarcz 2013	randomised trial	serious[1]	N/A	serious[2]	serious[3]	none	0/141 (0%)	1/163 (0.61%)	OR 0.38 (0.02 to 9.47)	4 fewer per 1000 (from 6 fewer to 49 more)	⊕OOO VERY LOW
Incidence of gonorrhoea, at 12 months											

Schwarcz 2013	randomised trial	serious[1]	N/A	serious[2]	serious[3]	none	3/146 (2.1%)	5/156 (3.2%)	OR 0.63 (0.15 to 2.7)	12 fewer per 1000 (from 27 fewer to 50 more)	⊕OOO VERY LOW
Incidence of chlamydia, at 6 months											
Schwarcz 2013	randomised trial	serious[1]	N/A	serious[2]	serious[3]	none	7/141 (5%)	7/163 (4.3%)	RR 1.16 (0.42 to 3.22)	7 more per 1000 (from 25 fewer to 95 more)	⊕OOO VERY LOW
Incidence of chlamydia, at 12 months											
Schwarcz 2013	randomised trial	serious[1]	N/A	serious[2]	serious[3]	none	3/146 (2.1%)	9/156 (5.8%)	RR 0.36 (0.1 to 1.29)	37 fewer per 1000 (from 52 fewer to 17 more)	⊕OOO VERY LOW

[1] Downgraded once for some concerns of bias due to intervention adherence not assessed and trial not registered
[2] US study
[3] Downgraded once as 95%CI crosses line of no effect and 1 MID

F.7.2.3 Secondary outcomes – so-called chemsex

Quality assessment							No of patients		Effect		Quality
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Intervention**	**Control**	**Relative (95% CI)**	**Absolute**	
Drug use soon before or during UAI with a non-primary partner, at 3 months											
Mansergh 2010	randomised trial	no serious risk of bias	N/A	serious[1]	serious[2]	none	136/524 (26%)	129/537 (24%)	RR 1.08 (0.88 to 1.33)	19 more per 1000 (from 29 fewer to 79 more)	⊕⊕OO LOW
Drug use soon before or during UAI with a non-primary partner, at 6 months											
Mansergh 2010	randomised trial	no serious risk of bias	N/A	serious[1]	serious[2]	none	140/520 (26.9%)	124/538 (23%)	RR 1.17 (0.95 to 1.44)	39 more per 1000 (from 12 fewer to 101 more)	⊕⊕OO LOW
Drug use soon before or during UAI with a non-primary partner, at 12 months											
Mansergh 2010	randomised trial	no serious risk of bias	N/A	serious[1]	serious[2]	none	118/537 (22%)	103/542 (19%)	RR 1.16 (0.91 to 1.46)	30 more per 1000 (from 17 fewer to 87 more)	⊕⊕OO LOW
Drug use soon before or during UAI with a non-primary partner whose HIV status was unknown or serodiscordant, at 3 months											
Mansergh 2010	randomised trial	no serious risk of bias	N/A	serious[1]	very serious[3]	none	63/524 (12%)	64/537 (11.9%)	RR 1.01 (0.73 to 1.4)	1 more per 1000 (from 32 fewer to 48 more)	⊕OOO VERY LOW
Drug use soon before or during UAI with a non-primary partner whose HIV status was unknown or serodiscordant, at 6 months											
Mansergh 2010	randomised trial	no serious risk of bias	N/A	serious[1]	very serious[3]	none	52/520 (10%)	48/538 (8.9%)	RR 1.12 (0.77 to 1.63)	11 more per 1000 (from 21 fewer to 56 more)	⊕OOO VERY LOW

Drug use soon before or during UAI with a non-primary partner whose HIV status was unknown or serodiscordant, at 12 months											
Mansergh 2010	randomised trial	no serious risk of bias	N/A	serious[1]	very serious[3]	none	54/537 (10.1%)	60/542 (11.1%)	RR 0.91 (0.64 to 1.29)	10 fewer per 1000 (from 40 fewer to 32 more)	⊕OOO VERY LOW
Number of episodes of UAI with a HIV serodiscordant or status unknown partner, while using meth, in the past 3 months, at 3 months. MID = 1.03 (Better indicated by lower values)											
Mansergh 2010	randomised trial	no serious risk of bias	N/A	serious[1]	serious[2]	none	19	17	-	MD 0.9 lower (2.15 lower to 0.35 higher)	⊕⊕OO LOW
Number of episodes of UAI with a HIV serodiscordant or status unknown partner, while using meth, in the past 3 months, at 6 months. MID = 0.87 (Better indicated by lower values)											
Mansergh 2010	randomised trial	no serious risk of bias	N/A	serious[1]	serious[4]	none	21	19	-	MD 1.5 lower (2.38 to 0.62 lower)	⊕⊕OO LOW

[1] US study
[2] Downgraded once as 95%CI crosses line of no effect and 1 MID
[3] Downgraded twice as 95%CI crosses 2 MIDs
[4] Downgraded once as 95%CI crosses 1 MID

F.7.3 Culturally relevant Spanish language small group interventions

F.7.3.1 Condom use outcomes

Quality assessment							No of patients		Effect		Quality
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Intervention**	**Control**	**Relative (95% CI)**	**Absolute**	
Consistent condom use during past 3 months for MSM who report sex with men or women, at 6 months											
Rhodes 2017	randomised trial	no serious risk of bias	N/A	serious[1]	no serious imprecision	none	69/109 (63.3%)	37/108 (34.3%)	RR 1.85 (1.37 to 2.49)	291 more per 1000 (from 127 more to 510 more)	⊕⊕⊕O MODERATE
Consistent condom use during past 3 months among MSM who report sex with men only, at 6 months											
Rhodes 2017	randomised trial	no serious risk of bias	N/A	serious[1]	no serious imprecision	none	61/95 (64.2%)	34/94 (36.2%)	RR 1.78 (1.31 to 2.41)	282 more per 1000 (from 112 more to 510 more)	⊕⊕⊕O MODERATE

[1] US study

F.8 Young MSM

F.8.1 Group-based HIV prevention intervention

F.8.1.1 Condom use outcomes

Quality assessment							No of patients		Effect		Quality
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intervention	Control	Relative (95% CI)	Absolute	
Any UAI in prior 6 weeks, at 6 weeks											
Hidalgo 2015	randomised trial	serious[1]	N/A	serious[2]	very serious[3]	none	9/42 (21.4%)	7/33 (21.2%)	RR 1.01 (0.42 to 2.43)	2 more per 1000 (from 123 fewer to 303 more)	⊕OOO VERY LOW
Any UAI in prior 6 weeks, at 12 weeks											
Hidalgo 2015	randomised trial	serious[1]	N/A	serious[2]	very serious[3]	none	11/43 (25.6%)	8/31 (25.8%)	RR 0.99 (0.45 to 2.17)	3 fewer per 1000 (from 142 fewer to 302 more)	⊕OOO VERY LOW
Number of unprotected anal sex acts with male partners in prior 6 weeks, at 6 weeks (analyses restricted to those reporting any anal sex at baseline) (Better indicated by lower values). MID = 1.45											
Hidalgo 2015	randomised trial	serious[1]	N/A	serious[2]	serious[4]	none	34	33	-	MD 0.39 lower (1.5 lower to 0.72 higher)	⊕OOO VERY LOW
Number of unprotected anal sex acts with male partners in prior 6 weeks, at 12 weeks (analyses restricted to those reporting any anal sex at baseline) (Better indicated by lower values). MID = 1.15											
Hidalgo 2015	randomised trial	serious[1]	N/A	serious[2]	very serious[3]	none	34	33	-	MD 0.08 lower (1.33 lower to 1.17 higher)	⊕OOO VERY LOW
Condom use errors, at 6 weeks (Better indicated by lower values). MID = 1.15											
Hidalgo 2015	randomised trial	serious[1]	N/A	serious[2]	very serious[3]	none	42	33	-	MD 0.03 lower (0.24 lower to 0.18 higher)	⊕OOO VERY LOW
Condom use errors, at 12 weeks (Better indicated by lower values). MID = 0.24											
Hidalgo 2015	randomised trial	serious[1]	N/A	serious[2]	serious[4]	none	43	31	-	MD 0.18 lower (0.41 lower to 0.05 higher)	⊕OOO VERY LOW

[1] Downgraded once for some concerns of bias due to no information on participant blinding; ITT analyses not used; low intervention adherence; relatively high attrition
[2] US study
[3] Downgraded twice as 95%CI crosses 2 MIDs
[4] Downgraded once as 95%CI crosses line of no effect and 1 MID

F.8.1.2 Secondary outcomes

Quality assessment							No of patients		Effect		Quality
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intervention	Control	Relative (95% CI)	Absolute	
Self-efficacy for safer sex, at 6 weeks (Better indicated by lower values). MID = 2.35											
Hidalgo 2015	randomised trial	serious[1]	N/A	serious[2]	serious[3]	none	42	33	-	MD 1.1 higher (0.82 lower to 3.02 higher)	⊕OOO VERY LOW
Health protective communication, at 6 weeks (Better indicated by lower values). MID = 2.15											
Hidalgo 2015	randomised trial	serious[1]	N/A	serious[2]	serious[3]	none	42	33	-	MD 2.1 higher (0.01 lower to 4.21 higher)	⊕OOO VERY LOW
Health protective communication, at 12 weeks (Better indicated by lower values). MID = 2.35											
Hidalgo 2015	randomised trial	serious[1]	N/A	serious[2]	serious[3]	none	43	31	-	MD 1.5 lower (3.92 lower to 0.92 higher)	⊕OOO VERY LOW
Any UAI under the influence of alcohol or drugs in prior 6 weeks, at 6 weeks											
Hidalgo 2015	randomised trial	serious[1]	N/A	serious[2]	very serious[4]	none	2/42 (4.8%)	4/33 (12.1%)	RR 0.39 (0.08 to 2.02)	74 fewer per 1000 (from 112 fewer to 124 more)	⊕OOO VERY LOW
Any UAI under the influence of alcohol or drugs in prior 6 weeks, at 12 weeks											
Hidalgo 2015	randomised trial	serious[1]	N/A	serious[2]	serious[3]	none	2/43 (4.7%)	6/31 (19.4%)	RR 0.24 (0.05 to 1.11)	147 fewer per 1000 (from 184 fewer to 21 more)	⊕OOO VERY LOW

[1] No information on participant blinding; ITT analyses not used; low intervention adherence; relatively high attrition
[2] US study
[3] Downgraded once as 95%CI crosses line of no effect and 1 MID
[4] Downgraded twice as 95%CI crosses 2 MIDs

F.8.2 Motivational Interviewing intervention

F.8.2.1 Condom use outcomes

Quality assessment	No of patients	Effect	Quality

No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intervention	Control	Relative (95% CI)	Absolute	
Any UAI with a casual partner during prior 30 days; at 3 months											
Parsons 2014	randomised trial	serious[1]	N/A	serious[2]	very serious[3]	none	33/61 (54.1%)	35/62 (56.5%)	RR 0.96 (0.7 to 1.32)	23 fewer per 1000 (from 169 fewer to 181 more)	⊕OOO VERY LOW
Any UAI with a casual partner during prior 30 days, at 6 months											
Parsons 2014	randomised trial	serious[1]	N/A	serious[2]	very serious[3]	none	25/54 (46.3%)	29/55 (52.7%)	RR 0.88 (0.6 to 1.29)	63 fewer per 1000 (from 211 fewer to 153 more)	⊕OOO VERY LOW
Any UAI with a casual partner during prior 30 days, at 9 months											
Parsons 2014	randomised trial	serious[1]	N/A	serious[2]	serious[4]	none	25/55 (45.5%)	35/57 (61.4%)	RR 0.74 (0.52 to 1.06)	160 fewer per 1000 (from 295 fewer to 37 more)	⊕OOO VERY LOW
Any UAI with a casual partner during prior 30 days, at 12 months											
Parsons 2014	randomised trial	serious[1]	N/A	serious[2]	serious[4]	none	18/59 (30.5%)	22/54 (40.7%)	RR 0.75 (0.45 to 1.24)	102 fewer per 1000 (from 224 fewer to 98 more)	⊕OOO VERY LOW

[1] Downgraded for some concerns of bias due to no information on participant blinding and ITT not used, but deviations from intended intervention unlikely and intervention adherence good. Trial not registered
[2] US study; high recreational drug use
[3] Downgraded twice as 95%CI crosses 2 MIDs
[4] Downgraded once as 95%CI crosses line of no effect and 1 MID

F.8.2.2 Secondary outcomes

Quality assessment							No of patients		Effect		Quality
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intervention	Control	Relative (95% CI)	Absolute	
Any UAI with a casual partner while under the influence of drugs or alcohol during prior 30 days, at 3 months											
Parsons 2014	randomised trial	serious[1]	N/A	serious[2]	serious[3]	none	35/61 (57.4%)	42/62 (67.7%)	RR 0.85 (0.64 to 1.12)	102 fewer per 1000 (from 244 fewer to 81 more)	⊕OOO VERY LOW
Any UAI with a casual partner while under the influence of drugs or alcohol during prior 30 days, at 6 months											
Parsons 2014	randomised trial	serious[1]	N/A	serious[2]	serious[3]	none	31/54 (57.4%)	36/55 (65.5%)	RR 0.88 (0.65 to 1.18)	79 fewer per 1000 (from 229 fewer to 118 more)	⊕OOO VERY LOW
Any UAI with a casual partner while under the influence of drugs or alcohol during prior 30 days, at 9 months											
Parsons 2014	randomised trial	serious[1]	N/A	serious[2]	serious[3]	none	33/55 (60%)	43/57 (75.4%)	RR 0.8 (0.61 to 1.03)	151 fewer per 1000 (from 294 fewer to 23 more)	⊕OOO VERY LOW
Any UAI with a casual partner while under the influence of drugs or alcohol during prior 30 days, at 12 months											
Parsons 2014	randomised trial	serious[1]	N/A	serious[2]	serious[3]	none	28/59 (47.5%)	32/54 (59.3%)	RR 0.8 (0.57 to 1.13)	119 fewer per 1000 (from 255 fewer to 77 more)	⊕OOO VERY LOW

[1] Downgraded for some concerns of bias due to no information on participant blinding and ITT not used, but deviations from intended intervention unlikely and intervention adherence good. Trial not registered
[2] US study; high recreational drug use
[3] Downgraded once as 95%CI crosses line of no effect and 1 MID

F.9 Men from a Black African or Caribbean family background who have sex with men

F.9.1 IMB / Motivational Interviewing-based interventions

F.9.1.1 Condom use outcomes

Quality assessment							No of patients		Effect		Quality
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intervention	Control	Relative (95% CI)	Absolute	
Any unprotected anal or vaginal intercourse in past 3 months, at 3 months											
2[a]	randomised trials	serious[1]	no serious inconsistency	serious[2,3]	serious[4]	none	83/129 (64.3%)	103/134 (76.9%)	RR 0.84 (0.72 to 0.99)	123 fewer per 1000 (from 8 fewer to 215 fewer)	⊕OOO VERY LOW
Any UAI with males in past 3 months, at 3 months											
2[a]	randomised trials	serious[1]	no serious inconsistency	serious[2,3]	serious[4]	none	69/128 (53.9%)	91/134 (67.9%)	RR 0.8 (0.66 to 0.98)	136 fewer per 1000 (from 14 fewer to 231 fewer)	⊕OOO VERY LOW
Any unprotected anal or vaginal intercourse with females in past 3 months, at 3 months											
Fernandez 2016	randomised trial	serious[5]	N/A	serious[2,3]	very serious[6]	none	30/84 (35.7%)	33/82 (40.2%)	RR 0.89 (0.6 to 1.31)	44 fewer per 1000 (from 161 fewer to 125 more)	⊕OOO VERY LOW
Any serodiscordant anal or vaginal intercourse in past 3 months, at 3 months											
Fernandez 2016	randomised trial	serious[5]	N/A	serious[2,3]	serious[7]	none	34/84 (40.5%)	40/82 (48.8%)	RR 0.83 (0.59 to 1.17)	83 fewer per 1000 (from 200 fewer to 83 more)	⊕OOO VERY LOW
Any serodiscordant anal intercourse with males in past 3 months, at 3 months											
Fernandez 2016	randomised trial	serious[5]	N/A	serious[2,3]	serious[4]	none	17/84 (20.2%)	28/82 (34.1%)	RR 0.59 (0.35 to 1)	140 fewer per 1000 (from 222 fewer to 0 more)	⊕OOO VERY LOW
Any serodiscordant anal or vaginal intercourse with females in past 3 months, at 3 months											

Fernandez 2016	randomised trial	serious[5]	N/A	serious[2,3]	serious[7]	none	21/84 (25%)	27/82 (32.9%)	RR 0.76 (0.47 to 1.23)	79 fewer per 1000 (from 175 fewer to 76 more)	⊕OOO VERY LOW
Consistent condom use with HIV+ partners in past 3 months, at 3 months											
Tobin 2013	randomised trial	serious[8]	N/A	serious[2,3]	serious[7]	none	40/48 (83.3%)	37/53 (69.8%)	RR 1.19 (0.96 to 1.48)	133 more per 1000 (from 28 fewer to 335 more)	⊕OOO VERY LOW
Consistent condom use with HIV- or unknown status partners in past 3 months, at 3 months											
Tobin 2013	randomised trial	serious[8]	N/A	serious[2,3]	serious[7]	none	23/44 (52.3%)	23/54 (42.6%)	RR 1.23 (0.81 to 1.87)	98 more per 1000 (from 81 fewer to 371 more)	⊕OOO VERY LOW

[a] Fernandez 2016 and Tobin 2013
[1] Downgraded once for some concerns of bias for Fernandez 2016 due to no information on participant blinding; approx 25% of participants did not attend any intervention or control sessions; impact of adherence not assessed; approx 80% retention; comparisons of completers vs non-completers not reported; trial not registered; and some concerns of bias for Tobin 2013 due to no information on participant blinding and baseline differences between groups on HIV status and health insurance; and trial not registered
[2] US study
[3] High history of homelessness, incarceration, and recent drug use
[4] Downgraded once as 95%CI crosses 1MID
[5] Downgraded once for some concerns of bias due to no information on participant blinding; approx 25% of participants did not attend any intervention or control sessions; impact of adherence not assessed; approx 80% retention; comparisons of completers vs non-completers not reported; trial not registered
[6] Downgraded twice as 95%CI crosses 2 MIDs
[7] Downgraded once as 95%CI crosses line of no effect and 1 MID
[8] Downgraded once for some concerns of bias due to no information on participant blinding and baseline differences between groups on HIV status and health insurance; and trial not registered

F.9.1.2 Secondary outcomes

Quality assessment							No of patients		Effect		Quality
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Intervention**	**Control**	**Relative (95% CI)**	**Absolute**	
Drug use during last sex, at 3 months											
Tobin 2013	randomised trial	serious[1]	N/A	serious[2]	serious[3]	none	12/73 (16.4%)	23/71 (32.4%)	RR 0.51 (0.27 to 0.94)	159 fewer per 1000 (from 19 fewer to 236 fewer)	⊕OOO VERY LOW

[1] Downgraded once for some concerns of bias due to no information on participant blinding; approx 25% of participants did not attend any intervention or control sessions; impact of adherence not assessed; approx 80% retention; comparisons of completers vs non-completers not reported; trial not registered
[2] US study; high history of homelessness, incarceration, and recent drug use
[3] Downgraded once as 95%CI crosses 1 MID

F.9.2 Sexual risk decision making intervention

F.9.2.1 Condom use outcomes

Quality assessment							No of patients		Effect		Quality
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intervention	Control	Relative (95% CI)	Absolute	
Proportion of condom-protected anal sex acts in prior 3 months, at 3 months. MID = 1.01											
Eaton 2018	randomised trial	no serious risk of bias	N/A	serious[2]	no serious imprecision	none	267	252	-	MD 3.92 higher (3.53 to 4.31 higher)	⊕⊕⊕O MODERATE
Proportion of condom-protected anal sex acts in prior 3 months, at 6 months. MID = 1.23											
Eaton 2018	randomised trial	no serious risk of bias	N/A	serious[2]	no serious imprecision	none	255	258	-	MD 6.94 higher (6.55 to 7.33 higher)	⊕⊕⊕O MODERATE
Proportion of condom-protected anal sex acts in prior 3 months, at 12 months. MID = 1.22											
Eaton 2018	randomised trial	no serious risk of bias	N/A	serious[2]	no serious imprecision	none	246	252	-	MD 4.25 higher (3.83 to 4.67 higher)	⊕⊕⊕O MODERATE
Number of UAI acts in prior 3 months, at 3 months. MID = 0.33											
Eaton 2018	randomised trial	no serious risk of bias	N/A	serious[2]	serious[3]	none	267	252	-	MD 0.07 higher (0.04 lower to 0.18 higher)	⊕⊕OO LOW
Number of UAI acts in prior 3 months, at 6 months. MID = 0.41											
Eaton 2018	randomised trial	no serious risk of bias	N/A	serious[2]	no serious imprecision	none	255	258	-	MD 0.95 lower (1.07 to 0.83 lower)	⊕⊕⊕O MODERATE
Number of UAI acts in prior 3 months, at 12 months. MID = 0.45											
Eaton 2018	randomised trial	no serious risk of bias	N/A	serious[2]	no serious imprecision	none	246	252	-	MD 1.21 lower (1.34 to 1.08 lower)	⊕⊕⊕O MODERATE
Number of insertive UAI acts in prior 3 months, at 3 months. MID = 0.2											
Eaton 2018	randomised trial	no serious risk of bias	N/A	serious[2]	serious[4]	none	267	252	-	MD 0.13 higher (0.06 to 0.2 higher)	⊕⊕OO LOW
Number of insertive UAI acts in prior 3 months, at 6 months. MID = 0.33											
Eaton 2018	randomised trial	no serious risk of bias	N/A	serious[2]	no serious imprecision	none	255	258	-	MD 0.96 lower (1.05 to 0.87 lower)	⊕⊕⊕O MODERATE
Number of insertive UAI acts in prior 3 months, at 12 months. MID = 0.33											
Eaton 2018	randomised trial	no serious risk of bias	N/A	serious[2]	no serious imprecision	none	246	252	-	MD 1.2 lower (1.29 to 1.11 lower)	⊕⊕⊕O MODERATE
Number of receptive UAI acts in prior 3 months, at 3 months. MID = 0.16											
Eaton 2018	randomised trial	no serious risk of bias	N/A	serious[2]	serious[4]	none	267	252	-	MD 0.2 higher (0.14 to 0.26 higher)	⊕⊕OO LOW
Number of receptive UAI acts in prior 3 months, at 6 months. MID = 0.17											

Eaton 2018	randomised trial	no serious risk of bias	N/A	serious[2]	no serious	none	255	258	-	MD 0.08 higher (0.02 to 0.14 higher)	⊕⊕⊕O MODERATE
Number of receptive UAI acts in prior 3 months, at 12 months. MID = 0.16											
Eaton 2018	randomised trial	no serious risk of bias	N/A	serious[2]	serious[3]	none	246	252	-	MD 0.01 lower (0.07 lower to 0.05 higher)	⊕⊕OO LOW

[1] Eaton 2018
[2] US study; 50.1% of the sample reported depressive symptoms above the clinical threshold
[3] Downgraded once as 95%CI crosses line of no effect
[4] Downgraded once as 95%CI crosses 1 MID

F.9.2.2 STI incidence outcomes

Quality assessment							No of patients		Effect		Quality
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Intervention**	**Control**	**Relative (95% CI)**	**Absolute**	
Self-reported STI diagnosis in prior 3 months, at 3 months											
Eaton 2018	randomised trial	no serious risk of bias	N/A	serious[1]	serious[2]	none	42/267 (15.7%)	55/252 (21.8%)	RR 0.72 (0.5 to 1.04)	61 fewer per 1000 (from 109 fewer to 9 more)	⊕⊕OO LOW
Self-reported STI diagnosis in prior 3 months, at 6 months											
Eaton 2018	randomised trial	no serious risk of bias	N/A	serious[1]	very serious[3]	none	45/255 (17.6%)	50/258 (19.4%)	RR 0.91 (0.63 to 1.31)	17 fewer per 1000 (from 72 fewer to 60 more)	⊕OOO VERY LOW
Self-reported STI diagnosis in prior 3 months, at 12 months											
Eaton 2018	randomised trial	no serious risk of bias	N/A	serious[1]	serious[2]	none	32/246 (13%)	43/252 (17.1%)	RR 0.76 (0.5 to 1.16)	41 fewer per 1000 (from 85 fewer to 27 more)	⊕⊕OO LOW
Lab diagnosed gonorrhoea or chlamydia; urine sample, at 3 months											
Eaton 2018	randomised trial	no serious risk of bias	N/A	serious[1]	serious[4]	none	4/267 (1.5%)	12/252 (4.8%)	RR 0.31 (0.1 to 0.96)	33 fewer per 1000 (from 2 fewer to 43 fewer)	⊕⊕OO LOW
Lab diagnosed gonorrhoea or chlamydia; urine sample, at 6 months											
Eaton 2018	randomised trial	no serious risk of bias	N/A	serious[1]	very serious[3]	none	5/255 (2%)	6/258 (2.3%)	RR 0.84 (0.26 to 2.73)	4 fewer per 1000 (from 17 fewer to 40 more)	⊕OOO VERY LOW
Lab diagnosed gonorrhoea or chlamydia; urine sample, at 12 months											
Eaton 2018	randomised trial	no serious risk of bias	N/A	serious[1]	very serious[3]	none	6/246 (2.4%)	9/252 (3.6%)	RR 0.68 (0.25 to 1.89)	11 fewer per 1000 (from 27 fewer to 32 more)	⊕OOO VERY LOW

Lab diagnosed gonorrhoea or chlamydia; rectal swab, at 3 months											
Eaton 2018	randomised trial	no serious risk of bias	N/A	serious[1]	serious[2]	none	26/267 (9.7%)	15/252 (6%)	RR 1.64 (0.89 to 3.02)	38 more per 1000 (from 7 fewer to 120 more)	⊕⊕OO LOW
Lab diagnosed gonorrhoea or chlamydia; rectal swab, at 6 months											
Eaton 2018	randomised trial	no serious risk of bias	N/A	serious[1]	very serious[3]	none	16/255 (6.3%)	12/258 (4.7%)	RR 1.35 (0.65 to 2.79)	16 more per 1000 (from 16 fewer to 83 more)	⊕OOO VERY LOW
Lab diagnosed gonorrhoea or chlamydia; rectal swab, at 12 months											
Eaton 2018	randomised trial	no serious risk of bias	N/A	serious[1]	very serious[3]	none	19/246 (7.7%)	17/252 (6.7%)	RR 1.14 (0.61 to 2.15)	9 more per 1000 (from 26 fewer to 78 more)	⊕OOO VERY LOW

[1] US study; 50.1% of the sample reported depressive symptoms above the clinical threshold
[2] Downgraded once as 95%CI crosses line of no effect and 1 MID
[3] Downgraded twice as 95%CI crosses 2 MIDs
[4] Downgraded once as 95%CI crosses 1 MID

F.9.3 Condom-focused intervention

F.9.3.1 Condom use outcomes

Quality assessment							No of patients		Effect		Quality
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Intervention**	**Control**	**Relative (95% CI)**	**Absolute**	
Consistent condom use for every episode of vaginal or anal sex in prior 3 months, at 6 months											
Jemmott 2015	randomised trial	serious[1]	no serious inconsistency	serious[2]	serious[3]	none	128/203 (63.1%)	124/190 (65.3%)	RR 0.97 (0.83 to 1.12)	20 fewer per 1000 (from 111 fewer to 78 more)	⊕OOO VERY LOW
Consistent condom use for every episode of vaginal or anal sex in prior 3 months, at 12 months											
Jemmott 2015	randomised trial	serious[1]	no serious inconsistency	serious[2]	serious[4]	none	124/194 (63.9%)	112/190 (58.9%)	RR 1.08 (0.92 to 1.27)	47 more per 1000 (from 47 fewer to 159 more)	⊕OOO VERY LOW
Any unprotected vaginal or anal intercourse in prior 3 months, at 6 months											
Jemmott 2015	randomised trial	serious[1]	no serious inconsistency	serious[2]	serious[4]	none	74/202 (36.6%)	66/187 (35.3%)	RR 1.04 (0.8 to 1.35)	14 more per 1000 (from 71 fewer to 124 more)	⊕OOO VERY LOW
Any unprotected vaginal or anal intercourse in prior 3 months, at 12 months											

Jemmott 2015	randomised trial	serious[1]	no serious inconsistency	serious[2]	serious[4]	none	69/193 (35.8%)	76/188 (40.4%)	RR 0.88 (0.68 to 1.14)	49 fewer per 1000 (from 129 fewer to 57 more)	⊕OOO VERY LOW
Proportion of condom-protected sex acts in prior 90 days, at 6 months. MID = 0.19											
Jemmott 2015	randomised trial	serious[1]	no serious inconsistency	serious[2]	serious[3]	none	203	190	-	MD 0 higher (0.07 lower to 0.07 higher)	⊕OOO VERY LOW
Proportion of condom-protected sex acts in prior 90 days, at 12 months. MID = 0.2											
Jemmott 2015	randomised trial	serious[1]	no serious inconsistency	serious[2]	serious[3]	none	194	190	-	MD 0.05 higher (0.03 lower to 0.13 higher)	⊕OOO VERY LOW

[1] Downgraded once for some concerns of bias due to trial not registered
[2] US study, and high unemployment, history of incarceration, high alcohol and/or drug dependence, high history of intimate partner violence, and high history of childhood sexual abuse
[3] Downgraded once as 95%CI crosses line of no effect
[4] Downgraded once as 95%CI crosses line of no effect and 1 MID

F.9.3.2 STI/HIV knowledge-based outcomes

Quality assessment							No of patients		Effect		Quality
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Intervention**	**Control**	**Relative (95% CI)**	**Absolute**	
HIV risk reduction knowledge, at 6 months. MID = 1.35											
Jemmott 2015	randomised trial	serious[1]	N/A	serious[2]	serious[3]	none	254	251	-	MD 0.39 higher (0.07 lower to 0.85 higher)	⊕OOO VERY LOW
HIV risk reduction knowledge, at 12 months. MID = 1.48											
Jemmott 2015	randomised trial	serious[1]	N/A	serious[2]	serious[3]	none	254	241	-	MD 0.43 higher (0.08 lower to 0.94 higher)	⊕OOO VERY LOW
Condom use knowledge, at 6 months. MID = 0.48											
Jemmott 2015	randomised trial	serious[1]	N/A	serious[2]	serious[3]	none	254	251	-	MD 0.08 higher (0.07 lower to 0.23 higher)	⊕OOO VERY LOW
Condom use knowledge, at 12 months. MID = 0.55											
Jemmott 2015	randomised trial	serious[1]	N/A	serious[2]	serious[3]	none	254	241	-	MD 0.09 higher (0.09 lower to 0.27 higher)	⊕OOO VERY LOW

[1] Downgraded once for some concerns of bias due to trial not registered
[2] US study, and high unemployment, history of incarceration, high alcohol and/or drug dependence, high history of intimate partner violence, and high history of childhood sexual abuse
[3] Downgraded once as 95%CI crosses line of no effect

F.9.4 Coping-focused interventions addressing sociocultural issues

F.9.4.1 Condom use outcomes

Quality assessment							No of patients		Effect		Quality
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intervention	Control	Relative (95% CI)	Absolute	
Number of UAI acts with males in prior 3 months, at 6 months. MID = 4.64 (Better indicated by lower values)											
Harawa 2013	randomised trial	serious[1]	N/A	serious[2]	serious[3]	none	149	142	-	MD 0.26 lower (2.22 lower to 1.7 higher)	⊕OOO VERY LOW
Number of unprotected vaginal or anal intercourse acts with females in prior 3 months, at 6 months. MID = 8.23 (Better indicated by lower values)											
Harawa 2013	randomised trial	serious[1]	N/A	serious[2]	serious[3]	none	149	142	-	MD 1.71 lower (4.51 lower to 1.09 higher)	⊕OOO VERY LOW
Number of unprotected intercourse acts with males or females in prior 3 months, at 6 months. MID = 12.4 (Better indicated by lower values)											
Harawa 2013	randomised trial	serious[1]	N/A	serious[2]	serious[3]	none	149	142	-	MD 3.01 lower (7.32 lower to 1.3 higher)	⊕OOO VERY LOW
Number of participants reporting no change / increase in number of episodes of UAI with male partners in prior 3 months, at 3 months											
Lauby 2018	randomised trial	serious[4]	N/A	serious[5]	serious[6]	none	19/62 (30.6%)	43/81 (53.1%)	RR 0.58 (0.38 to 0.88)	223 fewer per 1000 (from 64 fewer to 329 fewer)	⊕OOO VERY LOW
Number of participants reporting a small to moderate decrease in number of episodes of UAI with male partners in prior 3 months, at 3 months											
Lauby 2018	randomised trial	serious[4]	N/A	serious[5]	serious[7]	none	30/62 (48.4%)	29/81 (35.8%)	RR 1.35 (0.92 to 1.99)	125 more per 1000 (from 29 fewer to 354 more)	⊕OOO VERY LOW
Number of participants reporting a large decrease in number of episodes of UAI with male partners in prior 3 months, at 3 months											
Lauby 2018	randomised trial	serious[4]	N/A	serious[5]	serious[7]	none	13/62 (21%)	9/81 (11.1%)	RR 1.89 (0.86 to 4.13)	99 more per 1000 (from 16 fewer to 348 more)	⊕OOO VERY LOW
Number of participants reporting no change / increase in number of episodes of UAI with female partners in prior 3 months, at 3 months											
Lauby 2018	randomised trial	serious[4]	N/A	serious[5]	very serious[8]	none	26/62 (41.9%)	36/81 (44.4%)	RR 0.94 (0.64 to 1.38)	27 fewer per 1000 (from 160 fewer to 169 more)	⊕OOO VERY LOW
Number of participants reporting a small to moderate decrease in number of episodes of UAI with female partners in prior 3 months, at 3 months											

Lauby 2018	randomised trial	serious[4]	N/A	serious[5]	very serious[8]	none	23/62 (37.1%)	25/81 (30.9%)	RR 1.2 (0.76 to 1.9)	62 more per 1000 (from 74 fewer to 278 more)	⊕OOO VERY LOW
Number of participants reporting a large decrease in number of episodes of UAI with female partners in prior 3 months, at 3 months											
Lauby 2018	randomised trial	serious[4]	N/A	serious[5]	very serious[8]	none	13/62 (21%)	20/81 (24.7%)	RR 0.85 (0.46 to 1.57)	37 fewer per 1000 (from 133 fewer to 141 more)	⊕OOO VERY LOW
Unprotected insertive anal sex in prior 3 months, at 3 months. MID = 3.6 (Better indicated by lower values)											
Williams 2013	randomised trial	serious[9]	N/A	serious[10]	serious[7]	none	44	44	-	MD 0.26 higher (3.5 lower to 4.02 higher)	⊕OOO VERY LOW
Unprotected insertive anal sex in prior 3 months, at 6 months. MID = 9.82 (Better indicated by lower values)											
Williams 2013	randomised trial	serious[9]	N/A	serious[10]	serious[3]	none	44	44	-	MD 0.44 lower (7.45 lower to 6.57 higher)	⊕OOO VERY LOW
Unprotected receptive anal sex in prior 3 months, at 3 months. MID = 3.45 (Better indicated by lower values)											
Williams 2013	randomised trial	serious[9]	N/A	serious[10]	serious[3]	none	44	44	-	MD 0.14 lower (2.83 lower to 2.55 higher)	⊕OOO VERY LOW
Any unprotected receptive anal sex in prior 3 months, at 6 months. MID = 6.3 (Better indicated by lower values)											
Williams 2013	randomised trial	serious[9]	N/A	serious[10]	serious[3]	none	44	44	-	MD 0.2 lower (4.34 lower to 3.94 higher)	⊕OOO VERY LOW
Any unprotected vaginal sex in prior 3 months, at 3 months. MID = 1.49 (Better indicated by lower values)											
Williams 2013	randomised trial	serious[9]	N/A	serious[10]	very serious[8]	none	44	44	-	MD 0.09 higher (1.57 lower to 1.75 higher)	⊕OOO VERY LOW
Any unprotected vaginal sex in prior 3 months, at 6 months. MID = 0.53 (Better indicated by lower values)											
Williams 2013	randomised trial	serious[9]	N/A	serious[10]	very serious[8]	none	44	44	-	MD 0.03 higher (0.66 lower to 0.72 higher)	⊕OOO VERY LOW

[1] Downgraded once for some concerns of bias due to baseline differences between groups on key variables; impact of adherence not assessed; high attrition and no comparison of completers vs non completers
[2] US study and high history of incarceration, plus a relatively high number were currently in substance abuse treatment
[3] Downgraded once as 95%CI crosses line of no effect
[4] Downgraded once for some concerns of bias due to baseline differences between groups on HIV status; session adherence was moderate and impact of adherence not assessed; some concerns over conversion of condom use outcome into categorial variable; trial not registered
[5] US study, and high history of incarceration, homelessness and recent drug use
[6] Downgraded once as 95%CI crosses 1 MID
[7] Downgraded once as 95%CI crosses line of no effect and 1 MID
[8] Downgraded twice as 95%CI crosses 2 MIDs
[9] Downgraded once for some concerns of bias due to no information on randomisation procedures or blinding; intervention adherence not assessed; moderate attrition but no differential attrition; trial not registered
[10] US study; high unemployment; and high history of incarceration

F.9.4.2 Secondary outcomes

Quality assessment							No of patients		Effect		Quality
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intervention	Control	Relative (95% CI)	Absolute	
Any risky drug use with sex in prior 3 months, at 6 months											
Harawa 2013	randomised trial	serious[1]	N/A	serious[2]	very serious[3]	none	22/149 (14.8%)	16/142 (11.3%)	RR 1.31 (0.72 to 2.39)	35 more per 1000 (from 32 fewer to 157 more)	⊕OOO VERY LOW

[1] Downgraded once for some concerns of bias due to baseline differences between groups on key variables; impact of adherence not assessed; high attrition and no comparison of completers vs non completers
[2] US study and high history of incarceration, plus a relatively high number were currently in substance abuse treatment
[3] Downgraded twice as 95%CI crosses 2 MIDs

F.10 Young men from a Black African or Caribbean family background who have sex with men

F.10.1 Condom focused intervention

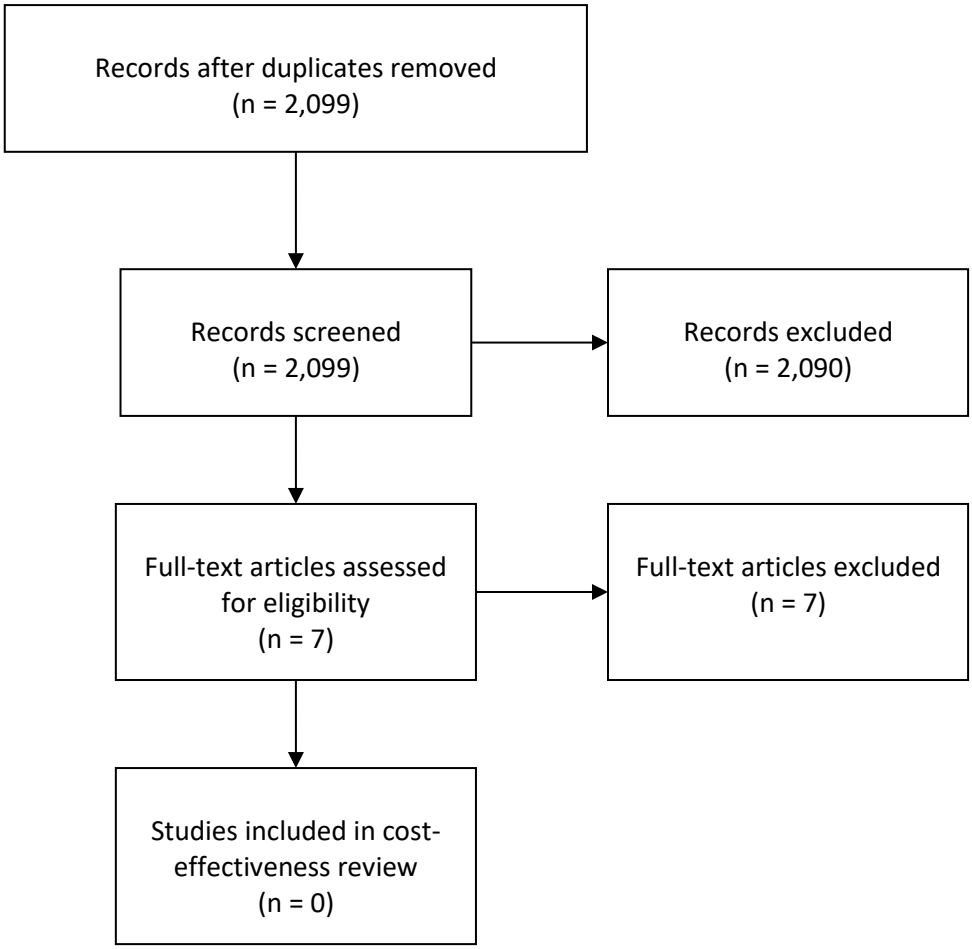
F.10.1.1 Condom use outcomes

Quality assessment							No of patients		Effect		Quality
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intervention	Standard care	Relative (95% CI)	Absolute	
Consistent condom use for anal sex with all partners in prior 3 months, at 12 months											
Crosby 2018a	randomised trial	serious[1]	N/A	serious[2]	serious[3]	none	103/200 (51.5%)	92/194 (47.4%)	RR 1.09 (0.89 to 1.33)	43 more per 1000 (from 52 fewer to 156 more)	⊕OOO VERY LOW
Consistent condom use for anal sex with 'side' (non-primary) partners in prior 3 months, at 12 months											
Crosby 2018a	randomised trial	serious[1]	N/A	serious[2]	serious[3]	none	24/51 (47.1%)	16/45 (35.6%)	RR 1.32 (0.81 to 2.16)	114 more per 1000 (from 68 fewer to 412 more)	⊕OOO VERY LOW
Any condomless insertive anal sex in prior 3 months, at 3 months (analyses restricted to HIV- participants)											

Crosby 2019	randomised trial	serious[1]	N/A	serious[2]	serious[4]	none	15/134 (11.2%)	27/131 (20.6%)	RR 0.54 (0.3 to 0.97)	95 fewer per 1000 (from 6 fewer to 144 fewer)	⊕OOO VERY LOW
Any condomless receptive anal sex in prior 3 months, at 3 months (analyses restricted to HIV- participants)											
Crosby 2019	randomised trial	serious[1]	N/A	serious[2]	serious[4]	none	17/142 (12%)	29/134 (21.6%)	RR 0.55 (0.32 to 0.96)	97 fewer per 1000 (from 9 fewer to 147 fewer)	⊕OOO VERY LOW
Any condomless anal sex in prior 3 months, at 3 months (analyses restricted to HIV- participants)											
Crosby 2019	randomised trial	serious[1]	N/A	serious[2]	serious[4]	none	26/142 (18.3%)	42/135 (31.1%)	RR 0.59 (0.38 to 0.9)	128 fewer per 1000 (from 31 fewer to 193 fewer)	⊕OOO VERY LOW
Any condomless oral sex in prior 3 months, at 3 months (analyses restricted to HIV- participants)											
Crosby 2019	randomised trial	serious[1]	N/A	serious[2]	serious[4]	none	33/72 (45.8%)	48/76 (63.2%)	RR 0.73 (0.54 to 0.98)	171 fewer per 1000 (from 13 fewer to 291 fewer)	⊕OOO VERY LOW

[1] Some concerns of bias due to baseline differences between groups; no information on participant blinding; high attrition (68% retention) but no differences between those retained and those not retained; unplanned analyses using stratification of groups by HIV status and multiple publications of the same trial.
[2] US study
[3] Downgraded once as 95%CI crosses line of no effect and 1 MID
[4] Downgraded once as 95%CI crosses 1 MID

Appendix G: Economic evidence study selection



Appendix H: Economic evidence tables

No economic evidence was included in this review.

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Appendix I: Health economic analysis

No economic analysis was undertaken for this review.

Appendix J: Excluded studies

Search 1

Study	Code [Reason]
Andrade, Elizabeth Louise, Evans, W Douglas, Barrett, Nicole et al. (2018) Strategies to Increase Latino Immigrant Youth Engagement in Health Promotion Using Social Media: Mixed-Methods Study. JMIR public health and surveillance 4(4): e71	- Mixed methods study on health promotion. Data on sexually transmitted disease prevention not usable
Arnold, Elizabeth Mayfield and Rotheram-Borus, Mary Jane (2009) Comparisons of prevention programs for homeless youth. Prevention science : the official journal of the Society for Prevention Research 10(1): 76-86	- Literature review. References checked for eligible studies
Ashdown, Heather; Jalloh, Chelsea; Wylie, John L (2015) Youth Perspectives on Sexual Health Workshops: Informing Future Practice. Qualitative health research 25(11): 1540-50	- Intrinsic case study approach on sexual health workshops
Barman-Adhikari, Anamika (2014) Social network norms and hiv risk behaviors among homeless youth in los angeles, california. Dissertation Abstracts International: Section B: The Sciences and Engineering 75(5be): no-specified	- Thesis or dissertation. References checked for eligible studies
Barman-Adhikari, Anamika, Hsu, Hsun-Ta, Begun, Stephanie et al. (2017) Condomless Sex Among Homeless Youth: The Role of Multidimensional Social Norms and Gender. AIDS and behavior 21(3): 688-702	- Cross-sectional study on gender and social norms around condomless sex among homeless youth
Beharie, N., Kalogerogiannis, K., McKay, M.M. et al. (2011) The HOPE family project: A family-based group intervention to reduce the impact of homelessness on HIV/STI and drug risk behaviors. Social Work with Groups 34(1): 61-78	- Review article
Bennett, Alex S, Aronson, Ian David, Guarino, Honoria et al. (2016) Perspectives on Tablet-based Multimedia Interventions for Behavioral Health: Populations, Venues, and Delivery Modalities. MMHealth'16 : proceedings of the 2016 ACM Workshop on Multimedia for Personal Health and Health Care : October 16, 2016, Amsterdam, The Netherlands. ACM Workshop on Multimedia for Personal Health and Health Care (1st : 2016 : Amsterdam,... 2016: 41-43	- Qualitative study on HIV/Hepatitis C virus testing and drug overdose
Bermudez, M Paz; Castro, Angel; Buela-Casal, Gualberto (2011) Psychosocial correlates of condom use and their relationship with worry about STI and HIV in native and immigrant adolescents in Spain. The Spanish journal of psychology 14(2): 746-54	- Cross-sectional study on psychological correlates of condom use
Bossard, K. and Song, Y. (2018) The impact of perceived barriers on self-efficacy for HPV preventive behavior. Asian Pacific Journal of Cancer Prevention 19(4): 983-988	- Cross-sectional study not pre-specidied high risk groups

Study	Code [Reason]
Boustani, Maya M, Frazier, Stacy L, Lesperance, Nephtalie et al. (2017) Sexual health programming for vulnerable youth: Improving knowledge, attitudes, and behaviors. Children and Youth Services Review 73: 375-383	- Survey type designon sexual health programme for vulnerable sheltred youth. Not RCT
Brondani, M.; Moniri, N.R.; Kerston, R.P. (2012) Community-based research among marginalized hiv populations: Issues of support, resources, and empowerment. Interdisciplinary Perspectives on Infectious Diseases 2012: 601027	- Qualitative study on spatial representation from marginalised community
Bungay, Vicky, Kolar, Kat, Thindal, Soni et al. (2013) Community-based HIV and STI prevention in women working in indoor sex markets. Health promotion practice 14(2): 247-55	- Cross-sectional survey on Community-Based HIV and STI Prevention for commercial sex workers
Carmona, J., Slesnick, N., Guo, X. et al. (2014) Reducing high risk behaviors among street living youth: Outcomes of an integrated prevention intervention. Children and Youth Services Review 43: 118-123	- RCT on street living youths receiving substance abuse treatement and HIV prevention. Data not usable
Cederbaum, Julie A, Wenzel, Suzanne L, Gilbert, Mary Lou et al. (2013) The HIV risk reduction needs of homeless women in Los Angeles. Women's health issues : official publication of the Jacobs Institute of Women's Health 23(3): e167-72	- HIV risk reduction needs of homeless sheltered women. Not on barriers, facilitators or acceptability of the approaches for reducing the acquisition and transmission of STIs. Not homeless people sleeping rough
Choi, S.K., LeGrand, S., Dong, W. et al. (2019) Condom use intentions mediate the relationships between psychosocial constructs and HIV sexual risk behavior in young Black men who have sex with men. AIDS Care - Psychological and Socio-Medical Aspects of AIDS/HIV 31(1): 53-60	- Cross-sectional study on condom use intentions
Cianelli, Rosina, Villegas, Natalia, McCabe, Brian E et al. (2017) Self-efficacy for HIV Prevention Among Refugee Hispanic Women in South Florida. Journal of immigrant and minority health 19(4): 905-912	- Cross-sectional study on HIV prevention. Not addressing specified outcomes
Coatsworth, Ashley M, Scheidell, Joy D, Wohl, David A et al. (2017) HIV-Related Sexual Risk among African American Men Preceding Incarceration: Associations with Support from Significant Others, Family, and Friends. Journal of urban health : bulletin of the New York Academy of Medicine 94(1): 136-148	- Cross-sectional study on HIV-Related risk. Not on reducing acquisition and transmission of STIs
Collins, J. and Slesnick, N. (2011) Factors associated with motivation to change HIV risk and substance use behaviors among homeless youth. Journal of Social Work Practice in the Addictions 11(2): 163-180	- Cross-sectional study on HIV risk and substance use

Study	Code [Reason]
Crawford, Pammie Renee (2014) The role of health information in reducing HIV transmission, reducing HIV stigma & achieving the right to health. Dissertation Abstracts International: Section B: The Sciences and Engineering 74(10be): no-specified	- Thesis or dissertation. References checked for eligible studies
Dang, Michelle T, Amos, Aaron, Dangerfield, Monique et al. (2019) A Youth Participatory Project to Address STIs and HIV among Homeless Youth. Comprehensive child and adolescent nursing 42(3): 222-240	- Qualitative. Not on homeless people sleeping rough
Daniel-Ulloa, Jason, Ulibarri, M, Baquero, B et al. (2016) Behavioral HIV Prevention Interventions Among Latinas in the US: A Systematic Review of the Evidence. Journal of immigrant and minority health 18(6): 1498-1521	- Systematic review. References checked for eligible studies
De Santis, J.P.; Martin, C.W.; Lester, A. (2010) An Educational Program on HIV Prevention for Male-to-Female Transgender Women in South Miami Beach, Florida. Journal of the Association of Nurses in AIDS Care 21(3): 265-271	- Review article
Deuba, Keshab, Kohlbrenner, Verena, Koirala, Sushil et al. (2018) Condom use behaviour among people living with HIV: a seven-country community-based participatory research in the Asia-Pacific region. Sexually transmitted infections 94(3): 200-205	- Non-OECD country
Dolwick Grieb, Suzanne M, Desir, Fidel, Flores-Miller, Alejandra et al. (2015) Qualitative assessment of HIV prevention challenges and opportunities among Latino immigrant men in a new receiving city. Journal of immigrant and minority health 17(1): 118-24	- Qualitative review. Not on short term or temporary migration
Drewry, Jonathan; Garces-Palacio, Isabel C; Scarinci, Isabel (2010) Awareness and knowledge about human papillomavirus among Latina immigrants. Ethnicity & disease 20(4): 327-33	- RCT. Not on short term or temporary migration
Drummond, Peter D, Mizan, Ayse, Brocx, Katie et al. (2011) Using peer education to increase sexual health knowledge among West African refugees in Western Australia. Health care for women international 32(3): 190-205	- Before and after survey workshop
Du, Hongfei and Li, Xiaoming (2015) Acculturation and HIV-related sexual behaviours among international migrants: a systematic review and meta-analysis. Health psychology review 9(1): 103-22	- Systematic review. References checked for eligible studies
Elford, J., McKeown, E., Doerner, R. et al. (2010) Sexual health of ethnic minority MSM in Britain (MESH project): design and methods. BMC public health 10: 419	- Internet based survey on sexual health of ethnic minority MSM

Study	Code [Reason]
Febres-Cordero, Belen, Brouwer, Kimberly C, Rocha-Jimenez, Teresita et al. (2018) Influence of peer support on HIV/STI prevention and safety amongst international migrant sex workers: A qualitative study at the Mexico-Guatemala border. PloS one 13(1): e0190787	- Qualitative review. Not on short term or temporary migration
Fiscella, K., Boyd, M., Brown, J. et al. (2015) Activation of persons living with HIV for treatment, the great study Health behavior, health promotion and society. BMC Public Health 15(1): 1056	- RCT on activation of persons living with HIV. Not on reducing acquisition and transmission of STIs
Fiscella, Kevin, Boyd, Michele, Brown, Julian et al. (2015) Activation of persons living with HIV for treatment, the great study. BMC public health 15: 1056	- RCT on activation of persons living with HIV. Not on reducing acquisition and transmission of STIs
Fletcher, Jesse B; Kisler, Kimberly A; Reback, Cathy J (2014) Housing status and HIV risk behaviors among transgender women in Los Angeles. Archives of sexual behavior 43(8): 1651-61	- Survey on housing status and HIV risk behaviours among trans people
Gagnon, Anita J, Merry, Lisa, Bocking, Jacqueline et al. (2010) South Asian migrant women and HIV/STIs: knowledge, attitudes and practices and the role of sexual power. Health & place 16(1): 10-5	- Cross-sectional survey. Not on short term or temporary migrant
Galvan, F.H., Bazargan, M., Gomez-Bastidas, E. et al. (2015) Using Peer Educators to Promote HIV Awareness Among Male Migrants in Mexico. Journal of HIV/AIDS and Social Services 14(1): 74-94	- Quasi-experimental pretest-posttest design on using peer educators to promote HIV awareness
Gao, Haijuan; Okoror, Titilayo A; Hyner, Gerald C (2016) Focus Group Study of Chinese International Students' Knowledge and Beliefs About HPV Vaccination, Before and After Reading an Informational Pamphlet About Gardasil(R). Journal of immigrant and minority health 18(5): 1085-1092	- Focus group study on HPV vaccination
Garofalo, Robert, Kuhns, Lisa M, Reisner, Sari L et al. (2016) Behavioral Interventions to Prevent HIV Transmission and Acquisition for Transgender Women: A Critical Review. Journal of acquired immune deficiency syndromes (1999) 72suppl3: 220-5	- Narrative review on Behavioral Interventions to Prevent HIV Transmission and Acquisition for Transgender Women. References checked for eligible studies
Ghimire, Sajana, Hallett, Jonathan, Gray, Corie et al. (2019) What Works? Prevention and Control of Sexually Transmitted Infections and Blood-Borne Viruses in Migrants from Sub-Saharan Africa, Northeast Asia and Southeast Asia Living in High-Income Countries: A Systematic Review. International journal of environmental research and public health 16(7)	- Systematic review. References checked for eligible studies

Study	Code [Reason]
Gosselin, A., Carillon, S., Coulibaly, K. et al. (2019) Participatory development and pilot testing of the Makasi intervention: a community-based outreach intervention to improve sub-Saharan and Caribbean immigrants' empowerment in sexual health. BMC public health 19(1): 1646	- Feasibility study on developing of a community-based and context-adapted intervention aimed at improving sub-Saharan and Caribbean immigrants' empowerment in sexual health,
Griffith, Derek M, Pichon, Latrice C, Campbell, Bettina et al. (2010) YOUR Blessed Health: a faith-based CBPR approach to addressing HIV/AIDS among African Americans. AIDS education and prevention : official publication of the International Society for AIDS Education 22(3): 203-17	- Descriptive review of the development of a community-based participatory project
Guarino, Honoria, Deren, Sherry, Mino, Milton et al. (2010) Training drug treatment patients to conduct peer-based HIV outreach: an ethnographic perspective on peers' experiences. Substance use & misuse 45(3): 414-36	- Qualitative review on Training Drug Treatment Patients. Not on reducing the acquisition and transmission of STIs
Henry-Akintobi, Tabia, Laster, Nastassia, Trotter, Jennie et al. (2016) The Health, Enlightenment, Awareness, and Living (HEAL) Intervention: Outcome of an HIV and Hepatitis B and C Risk Reduction Intervention. International journal of environmental research and public health 13(10)	- Pre-test and post-test survey on evaluating the HEAL intervention
Henwood, Benjamin F, Rhoades, Harmony, Hsu, Hsun-Ta et al. (2017) Changes in social networks and hiv risk behaviors among homeless adults transitioning into permanent supportive housing: A mixed methods pilot study. Journal of Mixed Methods Research 11(1): 124-137	- Mixed methods study design. Not on homeless people sleeping rough
Hsu, H.-T., Wenzel, S., Rice, E. et al. (2015) Understanding Consistent Condom Use Among Homeless Men Who Have Sex with Women and Engage in Multiple Sexual Partnerships: A Path Analysis. AIDS and behavior 19(9): 1676-1688	- Path model on understanding consistent condom use
Kendall, Tamil and Pelcastre, Blanca Estela (2010) HIV vulnerability and condom use among migrant women factory workers in Puebla, Mexico. Health care for women international 31(6): 515-32	- Qualitative study on vulnerability and condom use. Not on reducing the acquisition and transmission of STIs
Kennedy, David P, Hunter, Sarah B, Chan Osilla, Karen et al. (2016) A computer-assisted motivational social network intervention to reduce alcohol, drug and HIV risk behaviors among Housing First residents. Addiction science & clinical practice 11(1): 4	- Pilot trial on intervention to reduce high risk AOD use and HIV behaviors among the formerly homeless
Khosravi, N., Kolifarhood, G., Shoghli, A. et al. (2018) Effectiveness of peer education approach on improving HIV/AIDS related healthy	- Non-OECD country

Study	Code [Reason]
behaviors among immigrant street children: A randomized controlled trial. Clinical Epidemiology and Global Health 6(3): 115-121	
Lee, Christopher T, Winquist, Andrea, Wiewel, Ellen W et al. (2018) Long-Term Supportive Housing is Associated with Decreased Risk for New HIV Diagnoses Among a Large Cohort of Homeless Persons in New York City. AIDS and behavior 22(9): 3083-3090	- Retrospective study on permanent supportive housing intervention
Li, S, Huang, H, Cai, Y et al. (2010) Evaluation of a school-based HIV/AIDS peer-led prevention programme: The first intervention trial for children of migrant workers in China. International Journal of STD & AIDS 21(2): 82-86	- Non-OECD country
Li, Xiaoming, Lin, Danhua, Wang, Bo et al. (2014) Efficacy of theory-based HIV behavioral prevention among rural-to-urban migrants in China: A randomized controlled trial. AIDS Education and Prevention 26(4): 296-316	- Non-OECD country
Lin, D., Li, X., Stanton, B. et al. (2010) Theory-based HIV-related sexual risk reduction prevention for Chinese female rural-to-urban migrants. AIDS Education and Prevention 22(4): 344-355	- Non-OECD country
Loutfy, Mona, Greene, Saara, Kennedy, V Logan et al. (2016) Establishing the Canadian HIV Women's Sexual and Reproductive Health Cohort Study (CHIWOS): Operationalizing Community-based Research in a Large National Quantitative Study. BMC medical research methodology 16(1): 101	- Cohort study on establishing HIV women's sexual and reproductive health
Mayo-Wilson, Larissa Jennings, Glass, Nancy E, Ssewamala, Fred M et al. (2019) Microenterprise intervention to reduce sexual risk behaviors and increase employment and HIV preventive practices in economically-vulnerable African-American young adults (EMERGE): protocol for a feasibility randomized clinical trial. Trials 20(1): 439	- Protocol for a feasibility randomized trial
McMichael, C. and Gifford, S. (2009) "It is Good to Know Now...Before it's Too Late": Promoting sexual health literacy amongst resettled young people with refugee backgrounds. Sexuality and Culture 13(4): 218-236	- Qualitative review. Not on short term or temporary migration
McMichael, Celia and Gifford, Sandra (2010) Narratives of sexual health risk and protection amongst young people from refugee backgrounds in Melbourne, Australia. Culture, health & sexuality 12(3): 263-77	- Qualitative review. Not on short term or temporary migration
Mendelsohn, Joshua B, Calzavara, Liviana, Light, Lucia et al. (2015) Design and implementation of a sexual health intervention for migrant construction workers situated in Shanghai, China. Emerging themes in epidemiology 12: 16	- Non-OECD country

Study	Code [Reason]
Mileti, Francesca Poglia, Mellini, Laura, Sulstarova, Brikela et al. (2019) Exploring barriers to consistent condom use among sub-Saharan African young immigrants in Switzerland. AIDS care 31(1): 113-116	- Qualitative review. Not on short term or temporary migration
Moore, L., Chersich, M.F., Steen, R. et al. (2014) Community empowerment and involvement of female sex workers in targeted sexual and reproductive health interventions in Africa: A systematic review. Globalization and Health 10(1): 47	- Non-OECD country
Mosdøl, A, Lidal, IB, Straumann, GH et al. (2017) Targeted mass media interventions promoting healthy behaviours to reduce risk of non-communicable diseases in adult, ethnic minorities. Cochrane Database of Systematic Reviews	- Systematic review. References checked for eligible studies
Mueller, Noel T, Noone, Anne-Michelle, Luta, Gheorghe et al. (2012) Information channels associated with awareness of human papillomavirus infections and vaccination among Latino immigrants from safety net clinics. Journal of immigrant and minority health 14(1): 183-8	- Cross-sectional study on Awareness of Human Papillomavirus Infections and Vaccination among Latino Immigrants
Munene, Esther N (2012) Assessing knowledge, attitude, behavior, and practices related to Human Immunodeficiency Virus infection and Acquired Immunodeficiency Syndrome in a United States-based refugee population. Dissertation Abstracts International: Section B: The Sciences and Engineering 73(4b): 2156	- Thesis or dissertation. References checked for eligible studies
Naranbhai, Vivek; Abdool Karim, Quarraisha; Meyer-Weitz, Anna (2011) Interventions to modify sexual risk behaviours for preventing HIV in homeless youth. The Cochrane database of systematic reviews: cd007501	- Systematic review. References checked for eligible studies
Neville, Stephen and Adams, Jeffery (2016) Views about HIV/STI and health promotion among gay and bisexual Chinese and South Asian men living in Auckland, New Zealand. International journal of qualitative studies on health and well-being 11: 30764	- Qualitative review. Not on short term or temporary migration
Nostlinger, Christiana, Borms, Ruth, Dec-Pietrowska, Joanna et al. (2016) Development of a theory-guided pan-European computer-assisted safer sex intervention. Health promotion international 31(4): 782-792	- Review article
Nyamathi, Adeline, Kennedy, Barbara, Branson, Catherine et al. (2013) Impact of nursing intervention on improving HIV, hepatitis knowledge and mental health among homeless young adults. Community mental health journal 49(2): 178-84	- RCT on nurse led intervention. Data not usable

Study	Code [Reason]
Nyamathi, Adeline, Reback, Cathy J, Shoptaw, Steven et al. (2017) Impact of tailored interventions to reduce drug use and sexual risk behaviors among homeless gay and bisexual men. American Journal of Men's Health 11(2): 208-220	- Intervention on reducing drug use. Data on HIV/AIDS knowledge profile not usable
Oden, KaSaundra Mankins (2015) Predictors of condom use among African American transgender young adults. Dissertation Abstracts International: Section B: The Sciences and Engineering 76(5be): no-specified	- Thesis or dissertation. References checked for eligible studies
Osilla, Karen Chan, Kennedy, David P, Hunter, Sarah B et al. (2016) Feasibility of a computer-assisted social network motivational interviewing intervention for substance use and HIV risk behaviors for housing first residents. Addiction science & clinical practice 11(1): 14	- Qualitative study on the feasibility of a computer assited intervention. Not on reducing the acquisition and transmission of STIs
Parpouchi, M, Moniruzzaman, A, McCandless, L et al. (2016) Housing First and Unprotected Sex: a Structural Intervention. Journal of health care for the poor and underserved 27(3): 1278-1302	- Thesis or dissertation. References checked for eligible studies
Peragallo Montano, N., Cianelli, R., Villegas, N. et al. (2019) Evaluating a Culturally Tailored HIV Risk Reduction Intervention Among Hispanic Women Delivered in a Real-World Setting by Community Agency Personnel. American journal of health promotion : AJHP 33(4): 566-575	- RCT. Not on high risk groups identified
Prati, Gabriele, Mazzoni, Davide, Cicognani, Elvira et al. (2016) Evaluating the Persuasiveness of an HIV Mass Communication Campaign Using Gain-Framed Messages and Aimed at Creating a Superordinate Identity. Health communication 31(9): 1097-104	- Quasi-experimental study on Evaluating the Persuasiveness of an HIV Mass Communication
Rhodes, Scott D, Hergenrather, Kenneth C, Aronson, Robert E et al. (2010) Latino men who have sex with men and HIV in the rural south-eastern USA: findings from ethnographic in-depth interviews. Culture, health & sexuality 12(7): 797-812	- Qualitative study on HIV risk and potentially effective intervention characteristics. Not on barriers, facilitators or accetability of approaches to reduce acquisition and transmission of STIs
Rhodes, Scott D, Hergenrather, Kenneth C, Bloom, Fred R et al. (2009) Outcomes from a community-based, participatory lay health adviser HIV/STD prevention intervention for recently arrived immigrant Latino men in rural North Carolina. AIDS education and prevention : official publication of the International Society for AIDS Education 21(5suppl): 103-8	- Study on community-based, participatory lay health advisor HIV/STD prevention intervention. Not RCT
Rice, Eric (2010) The positive role of social networks and social networking technology in the condom-using behaviors of homeless young people. Public health reports (Washington, D.C. : 1974) 125(4): 588-95	- Cross-sectional study on homeless young people

Study	Code [Reason]
Rice, Eric, Tulbert, Eve, Cederbaum, Julie et al. (2012) Mobilizing homeless youth for HIV prevention: a social network analysis of the acceptability of a face-to-face and online social networking intervention. Health education research 27(2): 226-36	- Cross-sectional study on homeless young people
Rojas, P., Ramirez-Ortiz, D., Wang, W. et al. (2019) Testing the Efficacy of an HIV Prevention Intervention Among Latina Immigrants Living in Farmworker Communities in South Florida. Journal of immigrant and minority health	- Cohort study on testing the efficacy of an HIV Prevention Intervention Among Latina Immigrants
Sanchez, M., Rojas, P., Li, T. et al. (2016) Evaluating a Culturally Tailored HIV Risk Reduction Intervention Among Latina Immigrants in the Farmworker Community. World Medical and Health Policy 8(3): 245-262	- Cohort study on Evaluating a Culturally Tailored HIV Risk Reduction Intervention
Shehadeh, Nancy, Rubens, Muni, Attonito, Jennifer et al. (2018) Social Support and Its Impact on Ethnic Identity and HIV Risk among Migrant Workers. Journal of racial and ethnic health disparities 5(1): 96-103	- RCT. Not on short term or temporary migration
Sou, Julie, Shannon, Kate, Li, Jane et al. (2015) Structural determinants of inconsistent condom use with clients among migrant sex workers: findings of longitudinal research in an urban canadian setting. Sexually transmitted diseases 42(6): 312-6	- Cohort study on Structural Determinants of Inconsistent Condom Use
Swendeman, D., Arnold, E.M., Harris, D. et al. (2019) Text-messaging, online peer support group, and coaching strategies to optimize the HIV prevention continuum for youth: Protocol for a randomized controlled trial. Journal of Medical Internet Research 21(8): e11165	- Protocol for an RCT. Trial still recruiting
Taglieri, Filippo Maria, Colucci, Anna, Barbina, Donatella et al. (2013) Communication and cultural interaction in health promotion strategies to migrant populations in Italy: the cross-cultural phone counselling experience. Annali dell'Istituto superiore di sanita 49(2): 138-42	- Review article
Thompson, Ronald G Jr, Elliott, Jennifer C, Hu, Mei-Chen et al. (2017) Short-term effects of a brief intervention to reduce alcohol use and sexual risk among homeless young adults: Results from a randomized controlled trial. Addiction research & theory 25(1): 24-31	- Not on homeless people sleeping rough
Wenzel, Suzanne L, Cederbaum, Julie A, Song, Ahyoung et al. (2016) Pilot Test of an Adapted, Evidence-Based HIV Sexual Risk Reduction Intervention for Homeless Women. Prevention science : the official journal of the Society for Prevention Research 17(1): 112-21	- Quasi-experimental pilot study

Study	Code [Reason]
Wolitski, RJ, Kidder, DP, Pals, SL et al. (2010) Randomized trial of the effects of housing assistance on the health and risk behaviors of homeless and unstably housed people living with HIV. AIDS and behavior 14(3): 493-503	- RCT on improving housing status for homeless and housed people living with HIV

Search 2

Study	Code [Reason]
Achterbergh, Roeland Christiaan Alfons, van Rooijen, Martijn S, van den Brink, Wim et al. (2021) Enhancing help-seeking behaviour among men who have sex with men at risk for sexually transmitted infections: the syn.bas.in randomised controlled trial. Sexually transmitted infections 97(1): 11-17	- Exclude Data not useable
Adams, J. and Neville, S. (2012) Resisting the 'condom every time for anal sex' health education message. Health Education Journal 71(3): 386-394	- Exclude Intervention Type
Ahankari, A.S., Wray, J., Jomeen, J. et al. (2019) The effectiveness of combined alcohol and sexual risk taking reduction interventions on the sexual behaviour of teenagers and young adults: a systematic review. Public Health 173: 83-96	- Exclude Systematic Review - checked for primary papers
Aicken, Catherine R H, Sutcliffe, Lorna J, Gibbs, Jo et al. (2018) Using the eSexual Health Clinic to access chlamydia treatment and care via the internet: a qualitative interview study. Sexually transmitted infections 94(4): 241-247	- Exclude population
Alonzo, Jorge, Mann, Lilli, Tanner, Amanda E et al. (2016) Reducing HIV risk among Hispanic/Latino men who have sex with men: Qualitative analysis of behavior change intentions by participants in a small-group intervention. Journal of AIDS & clinical research 7(5)	- Exclude outcomes not relevant
Ames, H.M.R., Glenton, C., Lewin, S. et al. (2019) Clients' perceptions and experiences of targeted digital communication accessible via mobile devices for reproductive, maternal, newborn, child, and adolescent health: A qualitative evidence synthesis. Cochrane Database of Systematic Reviews 2019(10): cd013447	- Exclude Systematic Review - checked for primary papers
Andrasik, Michele Peake, Clad, Rachel, Bove, Joanna et al. (2015) A preliminary evaluation of a community-based campaign to increase awareness of concurrency and HIV transmission in African American and African-Born communities. AIDS and behavior 19(10): 1782-91	- Exclude Study design
Archibald, Cynthia M and Newman, David (2015) Pilot Testing HIV Prevention in an Afro Caribbean Faith-Based Community. The ABNF	- Exclude Parenting intervention

Study	Code [Reason]
journal : official journal of the Association of Black Nursing Faculty in Higher Education, Inc 26(2): 43-9	
Arnold, Emily A, Operario, Don, Cornwell, Stephanie et al. (2015) The Development of a Counseling-Based HIV Prevention Intervention for African American Men Who Have Sex With Men and Women: The Bruthas Project. AIDS education and prevention : official publication of the International Society for AIDS Education 27(6): 505-21	- Exclude Study design
Badawy, Sherif M and Kuhns, Lisa M (2017) Texting and Mobile Phone App Interventions for Improving Adherence to Preventive Behavior in Adolescents: A Systematic Review. JMIR mHealth and uHealth 5(4): e50	- Exclude Systematic Review - checked for primary papers
Bailey, JV, Murray, E, Rait, G et al. (2010) Interactive computer-based interventions for sexual health promotion. Cochrane Database of Systematic Reviews	- Exclude Systematic Review - checked for primary papers
Ballester-Arnal, Rafael, Gil-Llario, Maria Dolores, Gimenez-Garcia, Cristina et al. (2015) What Works Well in HIV Prevention Among Spanish Young People? An Analysis of Differential Effectiveness Among Six Intervention Techniques. AIDS and behavior 19(7): 1157-69	- Exclude Data not useable
Bangi, A., Dolcini, M.M., Harper, G.W. et al. (2013) Psychosocial Outcomes of Sexual Risk Reduction in a Brief Intervention for Urban African American Female Adolescents. Journal of HIV/AIDS and Social Services 12(2): 146-159	- Exclude Intervention Type
Barker, David H, Hadley, Wendy, McGee, Heather et al. (2019) Evaluating the Role of Family Context Within a Randomized Adolescent HIV-Risk Prevention Trial. AIDS and behavior 23(5): 1195-1209	- Exclude Intervention Type
Bassett, Shayna S., Delaney, Daniel J., Stein, L.A.R. et al. (2021) Motivational interviewing to reduce risky sexual behaviors among at-risk male youth: A randomized controlled pilot study. Psychological services	- Exclude Data not useable
Bauermeister, JA, Tingler, RC, Demers, M et al. (2019) Acceptability and Preliminary Efficacy of an Online HIV Prevention Intervention for Single Young Men Who Have Sex with Men Seeking Partners Online: the myDEx Project. AIDS and behavior 23(11): 3064-3077	- Exclude Intervention Type *Digital intervention*
Belgrave, F.Z., Corneille, M., Hood, K. et al. (2010) The impact of perceived group support on the effectiveness of an HIV prevention intervention for African American women. Journal of Black Psychology 36(2): 127-143	- Exclude Study design

Study	Code [Reason]
Berenson, Abbey B and Rahman, Mahbubur (2012) A randomized controlled study of two educational interventions on adherence with oral contraceptives and condoms. Contraception 86(6): 716-24	- Exclude Intervention Type
Berg, R (2009) The effectiveness of behavioural and psychosocial HIV/STI prevention interventions for MSM in Europe: A systematic review. Euro surveillance : bulletin Europeen sur les maladies transmissibles = European communicable disease bulletin 14(48)	- Exclude publication year
Berg, Rigmor C; Ross, Michael W; Tikkanen, Ronny (2011) The effectiveness of MI4MSM: how useful is motivational interviewing as an HIV risk prevention program for men who have sex with men? A systematic review. AIDS education and prevention : official publication of the International Society for AIDS Education 23(6): 533-49	- Exclude Systematic Review - checked for primary papers
Billings, Douglas W, Leaf, Samantha L, Spencer, Joy et al. (2015) A Randomized Trial to Evaluate the Efficacy of a Web-Based HIV Behavioral Intervention for High-Risk African American Women. AIDS and behavior 19(7): 1263-74	- Exclude Intervention Type *Digital intervention*
Boman, Jens, Lindqvist, Helena, Forsberg, Lars et al. (2018) Brief manual-based single-session Motivational Interviewing for reducing high-risk sexual behaviour in women - an evaluation. International journal of STD & AIDS 29(4): 396-403	- Exclude population
Bowring, A.L., Wright, C.J.C., Douglass, C. et al. (2018) Features of successful sexual health promotion programs for young people: findings from a review of systematic reviews. Health Promotion Journal of Australia 29(1): 46-57	- Exclude Systematic Review - checked for primary papers
Brawner, Bridgette M, Abboud, Sarah, Reason, Janaiya et al. (2019) The development of an innovative, theory-driven, psychoeducational HIV/STI prevention intervention for heterosexually active black adolescents with mental illnesses. Vulnerable children and youth studies 14(2): 151-165	- Exclude Intervention Type
Broaddus, Michelle R and Dickson-Gomez, Julia (2013) Text messaging for sexual communication and safety among African American young adults. Qualitative health research 23(10): 1344-53	- Exclude Intervention Type
Brookmeyer, Kathryn A; Hogben, Matthew; Kinsey, Jennine (2016) The Role of Behavioral Counseling in Sexually Transmitted Disease Prevention Program Settings. Sexually transmitted diseases 43(2suppl1): 102-12	- Exclude Systematic Review - checked for primary papers
Brown, G.; Sorenson, A.; Hildebrand, J. (2012) How they got it and how they wanted it: Marginalised young people's perspective on their	- Exclude Study design

Study	Code [Reason]
experiences of sexual health education. Sex Education 12(5): 599-612	
Brown, Larry K, Hadley, Wendy, Donenberg, Geri R et al. (2014) Project STYLE: a multisite RCT for HIV prevention among youths in mental health treatment. Psychiatric services (Washington, D.C.) 65(3): 338-44	- Exclude Data not useable
Brown, Larry K, Whiteley, Laura, Houck, Christopher D et al. (2017) The Role of Affect Management for HIV Risk Reduction for Youth in Alternative Schools. Journal of the American Academy of Child and Adolescent Psychiatry 56(6): 524-531	- Exclude School based intervention
Bull, Sheana S, Levine, Deborah K, Black, Sandra R et al. (2012) Social media-delivered sexual health intervention: a cluster randomized controlled trial. American journal of preventive medicine 43(5): 467-74	- Exclude Intervention Type *Digital intervention*
Bull, Sheana, Pratte, Katherine, Whitesell, Nancy et al. (2009) Effects of an Internet-based intervention for HIV prevention: the Youthnet trials. AIDS and behavior 13(3): 474-87	- Exclude publication year
Burns, Paul A, Williams, Michelle S, Mena, Leandro A et al. (2020) Leveraging Community Engagement: The Role of Community-Based Organizations in Reducing New HIV Infections Among Black Men Who Have Sex with Men. Journal of racial and ethnic health disparities 7(2): 193-201	- Exclude Study design *2 case studies*
Byron, Paul; Albury, Kath; Evers, Clifton (2013) "It would be weird to have that on Facebook": young people's use of social media and the risk of sharing sexual health information. Reproductive health matters 21(41): 35-44	- Exclude qualitative - digital intervention
Calderon, Yvette, Cowan, Ethan, Nickerson, Jillian et al. (2011) Educational effectiveness of an HIV pretest video for adolescents: a randomized controlled trial. Pediatrics 127(5): 911-6	- Exclude Intervention Type
Calderon, Yvette, Leider, Jason, Hailpern, Susan et al. (2009) A randomized control trial evaluating the educational effectiveness of a rapid HIV posttest counseling video. Sexually transmitted diseases 36(4): 207-10	- Exclude publication year
Calloway, Denyce S; Long-White, Deneen N; Corbin, Dennis E (2014) Reducing the risk of HIV/AIDS in African American college students: an exploratory investigation of the efficacy of a peer educator approach. Health promotion practice 15(2): 181-8	- Exclude Data not useable *Insufficient information to extract data relating to study design or outcomes*

Study	Code [Reason]
Cardoza, Vicky J, Documet, Patricia I, Fryer, Craig S et al. (2012) Sexual health behavior interventions for U.S. Latino adolescents: a systematic review of the literature. Journal of pediatric and adolescent gynecology 25(2): 136-149	- Exclude Systematic Review - checked for primary papers
Carey, Michael P, Senn, Theresa E, Vanable, Peter A et al. (2010) Brief and intensive behavioral interventions to promote sexual risk reduction among STD clinic patients: results from a randomized controlled trial. AIDS and behavior 14(3): 504-17	- Exclude population
Carpenter, Kelly M, Stoner, Susan A, Mikko, Aneke N et al. (2010) Efficacy of a web-based intervention to reduce sexual risk in men who have sex with men. AIDS and behavior 14(3): 549-57	- Exclude Intervention Type *Digital intervention with no HCP input*
Carrico, Adam W, Zepf, Roland, Meanley, Steven et al. (2016) Critical Review: When the Party is Over: A Systematic Review of Behavioral Interventions for Substance-Using Men Who Have Sex with Men. Journal of acquired immune deficiency syndromes (1999) 73(3): 299-306	- Exclude Systematic Review - checked for primary papers
Castillo-Arcos, Lubia Del Carmen, Benavides-Torres, Raquel Alicia, Lopez-Rosales, Fuensanta et al. (2016) The effect of an Internet-based intervention designed to reduce HIV/AIDS sexual risk among Mexican adolescents. AIDS care 28(2): 191-6	- Exclude population
Champion, JD and Collins, J (2011) African-and Mexican-American Adolescent women with sti and a history of abuse: biological outcome of a randomised trial of behavioural intervention. Sexually transmitted infections 87: a266	- Exclude Study design
Chandler-Coley, Rasheeta, Ross, Henry, Ozoya, Oluwatobi et al. (2017) Exploring Black College Females' Perceptions Regarding HIV Prevention Message Content. Journal of health communication 22(2): 102-110	- Exclude Qualitative paper not relevant *Discusses excluded intervention*
Chandwani, Sulachni, Abramowitz, Susan, Koenig, Linda J et al. (2011) A multimodal behavioral intervention to impact adherence and risk behavior among perinatally and behaviorally HIV-infected youth: description, delivery, and receptivity of adolescent impact. AIDS education and prevention : official publication of the International Society for AIDS Education 23(3): 222-35	- Exclude outcomes not relevant
Chavez, K. and Palfai, T.P. (2020) Feasibility of a Mobile Messaging-Enhanced Brief Intervention for High Risk Heavy Drinking MSM: A Pre-Pilot Study. Alcoholism Treatment Quarterly 38(1): 87-105	- Exclude Study design
Chen, Xinguang, Stanton, Bonita, Chen, Din et al. (2013) Intention to use condom, cusp modeling, and evaluation of an HIV prevention	- Exclude Study design

Study	Code [Reason]
intervention trial. Nonlinear dynamics, psychology, and life sciences 17(3): 385-403	
Cheng, W., Xu, H., Tang, W. et al. (2019) Online HIV prevention intervention on condomless sex among men who have sex with men: A web-based randomized controlled trial. BMC Infectious Diseases 19(1): 644	- Exclude not OECD
Chin, Helen B, Sipe, Theresa Ann, Elder, Randy et al. (2012) The effectiveness of group-based comprehensive risk-reduction and abstinence education interventions to prevent or reduce the risk of adolescent pregnancy, human immunodeficiency virus, and sexually transmitted infections: two systematic reviews for the Guide to Community Preventive Services. American journal of preventive medicine 42(3): 272-94	- Exclude Systematic Review - checked for primary papers
Chiou, P-Y, Liao, P-H, Liu, C-Y et al. (2019) Effects of mobile health on HIV risk reduction for men who have sex with men. AIDS care - psychological and socio-medical aspects of AIDS/HIV	- Exclude not OECD
Christensen, John L, Miller, Lynn Carol, Appleby, Paul Robert et al. (2013) Reducing shame in a game that predicts HIV risk reduction for young adult MSM: a randomized trial delivered nationally over the Web. Journal of the International AIDS Society 16(3suppl2): 18716	- Exclude Intervention Type
Coffin, Phillip O, Santos, Glenn-Milo, Colfax, Grant et al. (2014) Adapted personalized cognitive counseling for episodic substance-using men who have sex with men: a randomized controlled trial. AIDS and behavior 18(7): 1390-400	- Exclude Intervention Type
Coker-Appiah, Dionne Smith, Akers, Aletha Y, Banks, Bahby et al. (2009) In their own voices: rural African American youth speak out about community-based HIV prevention interventions. Progress in community health partnerships : research, education, and action 3(4): 301-12	- Exclude publication year
Coleman, Christopher Lance, Jemmott, Loretta, Jemmott, John B et al. (2009) Development of an HIV risk reduction intervention for older seropositive African American men. AIDS patient care and STDs 23(8): 647-55	- Exclude publication year
Conner, Laneshia R, Engstrom, Malitta, Junious, Eric et al. (2018) Woman to Woman (W2W): Adapting an HIV risk reduction intervention for older women. Journal of women & aging 30(5): 428-443	- Exclude Study design
Cooper, B, Toskin, I, Kulier, R et al. (2014) Brief sexuality communication--a behavioural intervention to advance sexually transmitted infection/HIV prevention: a systematic review. BJOG : an	- Exclude Systematic Review - checked for primary papers

Study	Code [Reason]
international journal of obstetrics and gynaecology 121suppl5: 92-103	
Cordova, D., Lua, F.M., Munoz-Velazquez, J. et al. (2019) A multilevel mHealth drug abuse and STI/HIV preventive intervention for clinic settings in the United States: A feasibility and acceptability study. PLoS ONE 14(8): e0221508	- Exclude qualitative - digital intervention
Cordova, David, Alers-Rojas, Francheska, Lua, Frania Mendoza et al. (2018) The usability and acceptability of an adolescent mHealth HIV/STI and drug abuse preventive intervention in primary care. Behavioral Medicine 44(1): 36-47	- Exclude qualitative - digital intervention
Cornelius, J.B., Whitaker-Brown, C., Neely, T. et al. (2019) Mobile phone, social media usage, and perceptions of delivering a social media safer sex intervention for adolescents: Results from two countries. Adolescent Health, Medicine and Therapeutics 10: 29-37	- Exclude not OECD
Cornelius, Judith B, Dmochowski, Jacek, Boyer, Cherrie et al. (2013) Text-messaging-enhanced HIV intervention for African American adolescents: a feasibility study. The Journal of the Association of Nurses in AIDS Care : JANAC 24(3): 256-67	- Exclude Study design
Cornelius, Judith B and St Lawrence, Janet S (2009) Receptivity of African American adolescents to an HIV-prevention curriculum enhanced by text messaging. Journal for specialists in pediatric nursing : JSPN 14(2): 123-31	- Exclude publication year
Cornelius, Judith B, St Lawrence, Janet S, Howard, Jacquelyn C et al. (2012) Adolescents' perceptions of a mobile cell phone text messaging-enhanced intervention and development of a mobile cell phone-based HIV prevention intervention. Journal for specialists in pediatric nursing : JSPN 17(1): 61-9	- Exclude qualitative - digital intervention
Crits-Christoph, Paul, Gallop, Robert, Sadicario, Jaclyn S et al. (2014) Predictors and moderators of outcomes of HIV/STD sex risk reduction interventions in substance abuse treatment programs: a pooled analysis of two randomized controlled trials. Substance abuse treatment, prevention, and policy 9: 3	- Exclude Study design
Crosby, Richard, DiClemente, Ralph J, Charnigo, Richard et al. (2009) A brief, clinic-based, safer sex intervention for heterosexual African American men newly diagnosed with an STD: a randomized controlled trial. American journal of public health 99suppl1: 96-103	- Exclude publication year
Danielson, Carla Kmett, McCauley, Jenna L, Gros, Kirstin Stauffacher et al. (2016) SiHLEWeb.com: Development and usability testing of an evidence-based HIV prevention website for female African-American adolescents. Health informatics journal 22(2): 194-208	- Exclude qualitative - digital intervention

Study	Code [Reason]
Davis, Wendy M, Shoveller, Jean A, Oliffe, John L et al. (2012) Young people's perspectives on the use of reverse discourse in web-based sexual-health interventions. Culture, health & sexuality 14(9): 1065-79	- Exclude qualitative - digital intervention
De Santis, J.P.; Martin, C.W.; Lester, A. (2010) An Educational Program on HIV Prevention for Male-to-Female Transgender Women in South Miami Beach, Florida. Journal of the Association of Nurses in AIDS Care 21(3): 265-271	- Exclude Study design
Debattista, Joseph (2015) Health promotion within a sex on premises venue: notes from the field. International journal of STD & AIDS 26(14): 1017-21	- Exclude Qualitative paper not relevant
DeMarco, Rosanna F and Chan, Keith (2013) The Sistah Powah structured writing intervention: a feasibility study for aging, low-income, HIV-positive Black women. American journal of health promotion : AJHP 28(2): 108-18	- Exclude Intervention Type
Dermen, Kurt H and Thomas, Sherilyn N (2011) Randomized controlled trial of brief interventions to reduce college students' drinking and risky sex. Psychology of addictive behaviors : journal of the Society of Psychologists in Addictive Behaviors 25(4): 583-94	- Exclude Study design
Deschepper, Reginald, Einav, Levy, Warner, Lisa M. et al. (2020) The effects of psychological inoculation on condom use tendencies and barriers; a randomized controlled trial. Psychology & health: 1-18	- Exclude Intervention Type *Exclusively digital*
DeSmet, Ann, Shegog, Ross, Van Ryckeghem, Dimitri et al. (2015) A Systematic Review and Meta-analysis of Interventions for Sexual Health Promotion Involving Serious Digital Games. Games for health journal 4(2): 78-90	- Exclude Systematic Review - checked for primary papers
DiClemente, Ralph J, Wingood, Gina M, Rose, Eve S et al. (2009) Efficacy of sexually transmitted disease/human immunodeficiency virus sexual risk-reduction intervention for african american adolescent females seeking sexual health services: a randomized controlled trial. Archives of pediatrics & adolescent medicine 163(12): 1112-21	- Exclude publication year
Dilley, James W, Schwarcz, Sandy, Murphy, Jessie et al. (2011) Efficacy of personalized cognitive counseling in men of color who have sex with men: secondary data analysis from a controlled intervention trial. AIDS and behavior 15(5): 970-5	- Exclude Study design
Dolcini, M Margaret, Harper, Gary W, Boyer, Cherrie B et al. (2010) Project ORE: A friendship-based intervention to prevent HIV/STI in urban African American adolescent females. Health education &	- Exclude Intervention Type

Study	Code [Reason]
behavior : the official publication of the Society for Public Health Education 37(1): 115-32	
Donenberg, Geri R, Kendall, Ashley D, Emerson, Erin et al. (2020) IMARA: A mother-daughter group randomized controlled trial to reduce sexually transmitted infections in Black/African-American adolescents. PloS one 15(11): e0239650	- Exclude Parenting intervention
Donenberg, Geri; Emerson, Erin; Kendall, Ashley D (2018) HIV-risk reduction intervention for juvenile offenders on probation: The PHAT Life group randomized controlled trial. Health psychology : official journal of the Division of Health Psychology, American Psychological Association 37(4): 364-374	- Exclude Data not useable *Study uses composite measure of consistent condom use combined with number of sexual partners; not possible to extract data only on consistent condom use.*
Downs, Julie S, Bruine de Bruin, Wandi, Fischhoff, Baruch et al. (2015) Behavioral Decision Research Intervention Reduces Risky Sexual Behavior. Current HIV research 13(5): 439-46	- Exclude Study design
Eaton, Lisa A, Cherry, Chauncey, Cain, Demetria et al. (2011) A novel approach to prevention for at-risk HIV-negative men who have sex with men: creating a teachable moment to promote informed sexual decision-making. American journal of public health 101(3): 539-45	- Exclude Intervention Type
Eaton, Lisa A, Huedo-Medina, Tania B, Kalichman, Seth C et al. (2012) Meta-analysis of single-session behavioral interventions to prevent sexually transmitted infections: implications for bundling prevention packages. American journal of public health 102(11): e34-44	- Exclude Systematic Review - checked for primary papers
Eaton, Lisa A, Kalichman, Seth C, Kenny, David A et al. (2013) A reanalysis of a behavioral intervention to prevent incident HIV infections: including indirect effects in modeling outcomes of Project EXPLORE. AIDS care 25(7): 805-11	- Exclude Study design
El-Bassel, Nabila, Jemmott, John B, Landis, J Richard et al. (2010) National Institute of Mental Health Multisite Eban HIV/STD Prevention Intervention for African American HIV Serodiscordant Couples: a cluster randomized trial. Archives of internal medicine 170(17): 1594-601	- Exclude Intervention Type
Enah, C.; Piper, K.; Moneyham, L. (2015) Qualitative Evaluation of the Relevance and Acceptability of a Web-Based HIV Prevention Game for Rural Adolescents. Journal of Pediatric Nursing 30(2): 321-328	- Exclude qualitative - digital intervention

Study	Code [Reason]
Escribano, Silvia, Espada, Jose P, Orgiles, Mireia et al. (2016) Implementation fidelity for promoting the effectiveness of an adolescent sexual health program. Evaluation and program planning 59: 81-87	- Exclude School based intervention
Espada, Jose P, Orgiles, Mireia, Morales, Alexandra et al. (2012) Effectiveness of a school HIV/AIDS prevention program for Spanish adolescents. AIDS education and prevention : official publication of the International Society for AIDS Education 24(6): 500-13	- Exclude School based intervention
Esposito-Smythers, Christianne, Hadley, Wendy, Curby, Timothy W et al. (2017) Randomized pilot trial of a cognitive-behavioral alcohol, self-harm, and HIV prevention program for teens in mental health treatment. Behaviour research and therapy 89: 49-56	- Exclude Parenting intervention
Evans, William D, Ulasevich, Alec, Hatheway, Megan et al. (2020) Systematic Review of Peer-Reviewed Literature on Global Condom Promotion Programs. International journal of environmental research and public health 17(7)	- Exclude Systematic Review - checked for primary papers
Fantus, Sophia, Souleymanov, Rusty, Lachowsky, Nathan J et al. (2017) The emergence of ethical issues in the provision of online sexual health outreach for gay, bisexual, two-spirit and other men who have sex with men: perspectives of online outreach workers. BMC medical ethics 18(1): 59	- Exclude Intervention Type
Febres-Cordero, Belen, Brouwer, Kimberly C., Jimenez, Teresita Rocha et al. (2020) Communication Strategies To Enhance HIV/STI Prevention, Sexual and Reproductive Health, and Safety Among Migrant Sex Workers at the Mexico-Guatemala Border. Journal of health care for the poor and underserved 31(2): 767-790	- Exclude Qualitative paper not relevant
Fernandez Cerdeno, Araceli, Martinez-Donate, Ana P, Zellner, Jennifer A et al. (2012) Marketing HIV prevention for heterosexually identified Latino men who have sex with men and women: the Hombres Sanos campaign. Journal of health communication 17(6): 641-58	- Exclude outcomes not relevant
Ferrer, R.A., Fisher, J.D., Buck, R. et al. (2011) Pilot Test of an Emotional Education Intervention Component for Sexual Risk Reduction. Health Psychology 30(5): 656-660	- Exclude outcomes not relevant
Fields, Errol L, Long, Amanda, Dangerfield, Derek T 2nd et al. (2020) There's an App for That: Using Geosocial Networking Apps to Access Young Black Gay, Bisexual, and other MSM at Risk for HIV. American journal of health promotion : AJHP 34(1): 42-51	- Exclude qualitative - digital intervention
Fiellin, Lynn E, Hieftje, Kimberly D, Pendergrass, Tyra M et al. (2017) Video Game Intervention for Sexual Risk Reduction in Minority	- Exclude population

Study	Code [Reason]
Adolescents: Randomized Controlled Trial. Journal of medical Internet research 19(9): e314	
Fiellin, Lynn E, Kyriakides, Tassos C, Hieftje, Kimberly D et al. (2016) The design and implementation of a randomized controlled trial of a risk reduction and human immunodeficiency virus prevention videogame intervention in minority adolescents: PlayForward: Elm City Stories. Clinical trials (London, England) 13(4): 400-8	- Exclude population
Fish, Julie, Papaloukas, Periklis, Jaspal, Rusi et al. (2016) Equality in sexual health promotion: a systematic review of effective interventions for black and minority ethnic men who have sex with men. BMC public health 16(1): 810	- Exclude Systematic Review - checked for primary papers
Flowers, Paul, Wu, Olivia, Lorimer, Karen et al. (2017) The clinical effectiveness of individual behaviour change interventions to reduce risky sexual behaviour after a negative human immunodeficiency virus test in men who have sex with men: systematic and realist reviews and intervention development. Health technology assessment (Winchester, England) 21(5): 1-164	- Exclude Systematic Review - checked for primary papers
Free, C., McCarthy, O., French, R.S. et al. (2016) Can text messages increase safer sex behaviours in young people? Intervention development and pilot randomized controlled trial. Health Technology Assessment 20(57): 1-81	- Exclude Intervention Type
Free, Caroline, McCarthy, Ona, French, Rebecca S et al. (2016) Can text messages increase safer sex behaviours in young people? Intervention development and pilot randomised controlled trial. Health technology assessment (Winchester, England) 20(57): 1-82	- Exclude duplicate paper
French, Rebecca S, Bonell, Chris, Wellings, Kaye et al. (2014) An exploratory review of HIV prevention mass media campaigns targeting men who have sex with men. BMC public health 14: 616	- Exclude Systematic Review - checked for primary papers
French, Rebecca Sophia, McCarthy, Ona, Baraitser, Paula et al. (2016) Young People's Views and Experiences of a Mobile Phone Texting Intervention to Promote Safer Sex Behavior. JMIR mHealth and uHealth 4(2): e26	- Exclude qualitative - digital intervention
Garcia-Retamero, Rocio and Cokely, Edward T (2015) Simple but powerful health messages for increasing condom use in young adults. Journal of sex research 52(1): 30-42	- Exclude Intervention Type
Garfein, Richard S, Metzner, Mitcheal, Cuevas, Jazmine et al. (2010) Formative Assessment of ARM-U: A Modular Intervention for Decreasing Risk Behaviors Among HIV-Positive and HIV-Negative Methamphetamine-Using MSM. The open AIDS journal 4: 105-15	- Exclude Intervention Type

Study	Code [Reason]
Garofalo, Robert, Johnson, Amy K, Kuhns, Lisa M et al. (2012) Life skills: evaluation of a theory-driven behavioral HIV prevention intervention for young transgender women. Journal of urban health : bulletin of the New York Academy of Medicine 89(3): 419-31	- Exclude Study design
Gause, Nicole K, Brown, Jennifer L, Welge, Jeffrey et al. (2018) Meta-analyses of HIV prevention interventions targeting improved partner communication: effects on partner communication and condom use frequency outcomes. Journal of behavioral medicine 41(4): 423-440	- Exclude Systematic Review - checked for primary papers
George, Sheba, Phillips, Robert, McDavitt, Bryce et al. (2012) The cellular generation and a new risk environment: implications for texting-based sexual health promotion interventions among minority young men who have sex with men. AMIA ... Annual Symposium proceedings. AMIA Symposium 2012: 247-56	- Exclude qualitative - digital intervention
Goesling, Brian, Colman, Silvie, Trenholm, Christopher et al. (2014) Programs to reduce teen pregnancy, sexually transmitted infections, and associated sexual risk behaviors: a systematic review. The Journal of adolescent health : official publication of the Society for Adolescent Medicine 54(5): 499-507	- Exclude Systematic Review - checked for primary papers
Gold, J, Aitken, C K, Dixon, H G et al. (2011) A randomised controlled trial using mobile advertising to promote safer sex and sun safety to young people. Health education research 26(5): 782-94	- Exclude population
Gold, Judy, Lim, Megan S C, Hellard, Margaret E et al. (2010) What's in a message? Delivering sexual health promotion to young people in Australia via text messaging. BMC public health 10: 792	- Exclude qualitative - digital intervention
Gold, Melanie A, Tzilos, Golfo K, Stein, L A R et al. (2016) A Randomized Controlled Trial to Compare Computer-assisted Motivational Intervention with Didactic Educational Counseling to Reduce Unprotected Sex in Female Adolescents. Journal of pediatric and adolescent gynecology 29(1): 26-32	- Exclude outcomes not relevant
Gollub, Erica L, Morrow, Kathleen M, Mayer, Kenneth H et al. (2010) Three city feasibility study of a body empowerment and HIV prevention intervention among women with drug use histories: Women FIT. Journal of women's health (2002) 19(9): 1705-13	- Exclude population
Greene, George J, Fisher, Kimberly A, Kuper, Laura et al. (2015) "Is this normal? Is this not normal? There is no set example": Sexual health intervention preferences of LGBT youth in romantic relationships. Sexuality Research & Social Policy: A Journal of the NSRC 12(1): 1-14	- Exclude population

Study	Code [Reason]
Greene, George J, Madkins, Krystal, Andrews, Katie et al. (2016) Implementation and Evaluation of the Keep It Up! Online HIV Prevention Intervention in a Community-Based Setting. AIDS education and prevention : official publication of the International Society for AIDS Education 28(3): 231-45	- Exclude Intervention Type
Grimley, Diane M and Hook, Edward W 3rd (2009) A 15-minute interactive, computerized condom use intervention with biological endpoints. Sexually transmitted diseases 36(2): 73-8	- Exclude publication year
Guse, Kylene, Levine, Deb, Martins, Summer et al. (2012) Interventions using new digital media to improve adolescent sexual health: a systematic review. The Journal of adolescent health : official publication of the Society for Adolescent Medicine 51(6): 535-43	- Exclude Systematic Review - checked for primary papers
Hallum-Montes, Rachel, Rhodes, Luella, Malone, Cassandra et al. (2016) 'Our only resource': Perspectives and Recommendations of Rural African American Youth on Adapting Sexual Health and Risk Reduction Interventions. Journal of health care for the poor and underserved 27(2): 622-35	- Exclude outcomes not relevant
Hawk, Mary (2013) The Girlfriends Project: Results of a pilot study assessing feasibility of an HIV testing and risk reduction intervention developed, implemented, and evaluated in community settings. AIDS education and prevention : official publication of the International Society for AIDS Education 25(6): 519-34	- Exclude outcomes not relevant
He, Jiayu, Wang, Ying, Du, Zhicheng et al. (2020) Peer education for HIV prevention among high-risk groups: a systematic review and meta-analysis. BMC infectious diseases 20(1): 338	- Exclude Systematic Review - checked for primary papers
Hemmige, Vagish, McFadden, Rachel, Cook, Scott et al. (2012) HIV prevention interventions to reduce racial disparities in the United States: a systematic review. Journal of general internal medicine 27(8): 1047-67	- Exclude Systematic Review - checked for primary papers
Hendrick, C Emily and Canfield, Caitlin (2017) HIV Risk-Reduction Prevention Interventions Targeting African American Adolescent Women. Adolescent research review 2(2): 131-149	- Exclude Systematic Review - checked for primary papers
Hightow-Weidman, Lisa B, LeGrand, Sara, Muessig, Kathryn E et al. (2019) A Randomized Trial of an Online Risk Reduction Intervention for Young Black MSM. AIDS and behavior 23(5): 1166-1177	- Exclude Intervention Type *Digital intervention*
Hightow-Weidman, Lisa B, Pike, Emily, Fowler, Beth et al. (2012) HealthMpowerment.org: feasibility and acceptability of delivering an internet intervention to young Black men who have sex with men. AIDS care 24(7): 910-20	- Exclude outcomes not relevant

Study	Code [Reason]
Hirshfield, S., Chiasson, M.A., Joseph, H. et al. (2012) An Online Randomized Controlled Trial Evaluating HIV Prevention Digital Media Interventions for Men Who Have Sex with Men. PLoS ONE 7(10): e46252	- Exclude Intervention Type *Digital intervention with no HCP input*
Hirshfield, Sabina, Downing, Martin J Jr, Chiasson, Mary Ann et al. (2019) Evaluation of Sex Positive! A Video eHealth Intervention for Men Living with HIV. AIDS and behavior 23(11): 3103-3118	- Exclude Intervention Type *Digital intervention with no HCP input*
Hoffman, Jenni L and Argeros, Grigoris (2020) An Online Sexual Health Educational Intervention Involving Young Adult Female Students: A Mixed Methods Study. Journal of community health 45(2): 407-411	- Exclude Study design *Not RCT*
Hoopes, A.J., Benson, S.K., Howard, H.B. et al. (2017) Adolescent Perspectives on Patient-Provider Sexual Health Communication: A Qualitative Study. Journal of primary care & community health 8(4): 332-337	- Exclude Intervention Type
Hosek, Sybil G, Lemos, Diana, Harper, Gary W et al. (2011) Evaluating the acceptability and feasibility of Project ACCEPT: an intervention for youth newly diagnosed with HIV. AIDS education and prevention : official publication of the International Society for AIDS Education 23(2): 128-44	- Exclude Intervention Type
Hosek, Sybil G, Lemos, Diana, Hotton, Anna L et al. (2015) An HIV intervention tailored for black young men who have sex with men in the House Ball Community. AIDS care 27(3): 355-62	- Exclude Study design
Jaganath, Devan, Gill, Harkiran K, Cohen, Adam Carl et al. (2012) Harnessing Online Peer Education (HOPE): integrating C-POL and social media to train peer leaders in HIV prevention. AIDS care 24(5): 593-600	- Exclude Study design
Jemmott, John B 3rd, Jemmott, Loretta S, Fong, Geoffrey T et al. (2010) Effectiveness of an HIV/STD risk-reduction intervention for adolescents when implemented by community-based organizations: a cluster-randomized controlled trial. American journal of public health 100(4): 720-6	- Exclude population
Jenner, E., Jenner, L.W., Walsh, S. et al. (2016) Impact of an intervention designed to reduce sexual health risk behaviors of african American adolescents: Results of a randomized controlled trial. American Journal of Public Health 106: 78-s84	- Exclude secondary publication of included trial *Secondary publication of excluded trial*
Jennings Mayo-Wilson, Larissa, Coleman, Jessica, Timbo, Fatmata et al. (2020) Acceptability of a feasibility randomized clinical trial of a microenterprise intervention to reduce sexual risk behaviors and	- Exclude Intervention Type

Study	Code [Reason]
increase employment and HIV preventive practices (EMERGE) in young adults: a mixed methods assessment. BMC public health 20(1): 1846	*Microenterprise intervention not included*
Jennings Mayo-Wilson, Larissa, Coleman, Jessica, Timbo, Fatmata et al. (2020) Microenterprise Intervention to Reduce Sexual Risk Behaviors and Increase Employment and HIV Preventive Practices Among Economically-Vulnerable African-American Young Adults (EMERGE): A Feasibility Randomized Clinical Trial. AIDS and behavior 24(12): 3545-3561	- Exclude Intervention Type *Microenterprise intervention excluded*
Johnson, Blair T, Scott-Sheldon, Lori A J, Smoak, Natalie D et al. (2009) Behavioral interventions for African Americans to reduce sexual risk of HIV: a meta-analysis of randomized controlled trials. Journal of acquired immune deficiency syndromes (1999) 51(4): 492-501	- Exclude publication year
Jones, Krista, Eathington, Patricia, Baldwin, Kathleen et al. (2014) The impact of health education transmitted via social media or text messaging on adolescent and young adult risky sexual behavior: a systematic review of the literature. Sexually transmitted diseases 41(7): 413-9	- Exclude Systematic Review - checked for primary papers
Jones, Krista, Williams, Jeff, Sipsma, Heather et al. (2019) Adolescent and emerging adults' evaluation of a Facebook site providing sexual health education. Public health nursing (Boston, Mass.) 36(1): 11-17	- Exclude qualitative - digital intervention
Jones, R; Hoover, DR; Lacroix, LJ (2013) A randomized controlled trial of soap opera videos streamed to smartphones to reduce risk of sexually transmitted human immunodeficiency virus (HIV) in young urban African American women. Nursing outlook 61(4): 205-215.e3	- Exclude Intervention Type
Kalichman, Seth C, Cherry, Chauncey, Kalichman, Moira O et al. (2018) Mobile Health Intervention to Reduce HIV Transmission: A Randomized Trial of Behaviorally Enhanced HIV Treatment as Prevention (B-TasP). Journal of acquired immune deficiency syndromes (1999) 78(1): 34-42	- Exclude Intervention Type
Kaufman, C.E., Schwinn, T.M., Black, K. et al. (2018) Impacting Precursors to Sexual Behavior Among Young American Indian Adolescents of the Northern Plains: A Cluster Randomized Controlled Trial. Journal of Early Adolescence 38(7): 988-1007	- Exclude population
Kennedy, D.P., Hunter, S.B., Osilla, K.C. et al. (2016) A computer-assisted motivational social network intervention to reduce alcohol, drug and HIV risk behaviors among Housing First residents. Addiction Science and Clinical Practice 11(1): 4	- Exclude Study design *Protocol only*

Study	Code [Reason]
Kennedy, Stephen B, Nolen, Sherry, Pan, Zhenfeng et al. (2013) Effectiveness of a brief condom promotion program in reducing risky sexual behaviours among African American men. Journal of evaluation in clinical practice 19(2): 408-13	- Exclude Data not useable *accurate n's by condition not reported*
Kerr, Jelani C, Valois, Robert F, DiClemente, Ralph J et al. (2015) The effects of a mass media HIV-risk reduction strategy on HIV-related stigma and knowledge among African American adolescents. AIDS patient care and STDs 29(3): 150-6	- Exclude Intervention Type
Kershaw, Trace S, Magriples, Urania, Westdahl, Claire et al. (2009) Pregnancy as a window of opportunity for HIV prevention: effects of an HIV intervention delivered within prenatal care. American journal of public health 99(11): 2079-86	- Exclude publication year
Kesten, Joanna M, Dias, Kaiseree, Burns, Fiona et al. (2019) Acceptability and potential impact of delivering sexual health promotion information through social media and dating apps to MSM in England: a qualitative study. BMC public health 19(1): 1236	- Exclude qualitative - digital intervention
King, C., Llewellyn, C., Shahmanesh, M. et al. (2019) Sexual risk reduction interventions for patients attending sexual health clinics: A mixed-methods feasibility study. Health Technology Assessment 23(12): 1-121	- Exclude Intervention Type
Kirby D, Raine T, Thrush G et al. (2010) Impact of an intervention to improve contraceptive use through follow-up phone calls to female adolescent clinic patients. Perspectives on sexual and reproductive health 42(4): 251-257	- Exclude Intervention Type *Intervention is focused on contraception and pregnancy prevention*
Klein, Charles H and Card, Josefina J (2011) Preliminary efficacy of a computer-delivered HIV prevention intervention for African American teenage females. AIDS education and prevention : official publication of the International Society for AIDS Education 23(6): 564-76	- Exclude Intervention Type *Digital intervention*
Klein, Charles H, Lomonaco, Carmela G, Pavlescak, Rik et al. (2013) WiLLOW: reaching HIV-positive African-American women through a computer-delivered intervention. AIDS and behavior 17(9): 3013-23	- Exclude Intervention Type *digital intervention*
Klein, Charles and Lomonaco, Carmela (2016) Real Talk: Developing a Computer-Delivered Sexual Health Program for Black Men Who Have Sex With Men. AIDS education and prevention : official publication of the International Society for AIDS Education 28(6): 455-471	- Exclude Study design
Knight, R., Karamouzian, M., Salway, T. et al. (2017) Online interventions to address HIV and other sexually transmitted and	- Exclude Systematic Review - checked for primary papers

Study	Code [Reason]
blood-borne infections among young gay, bisexual and other men who have sex with men: A systematic review. Journal of the International AIDS Society 20(3): e25017	
Kogan, Steven M, Yu, Tianyi, Brody, Gene H et al. (2012) Integrating condom skills into family-centered prevention: efficacy of the Strong African American Families-Teen program. The Journal of adolescent health : official publication of the Society for Adolescent Medicine 51(2): 164-70	- Exclude Parenting intervention
Koniak-Griffin, Deborah, Lesser, Janna, Takayanagi, Sumiko et al. (2011) Couple-focused human immunodeficiency virus prevention for young Latino parents: randomized clinical trial of efficacy and sustainability. Archives of pediatrics & adolescent medicine 165(4): 306-12	- Exclude Intervention Type *Couples focused intervention*
Krawczyk, Andrea, Lau, Elsa, Perez, Samara et al. (2012) How to inform: comparing written and video education interventions to increase human papillomavirus knowledge and vaccination intentions in young adults. Journal of American college health : J of ACH 60(4): 316-22	- Exclude outcomes not relevant
Kudo, Yoshiko (2013) Effectiveness of a condom use educational program developed on the basis of the Information-Motivation-Behavioral Skills model. Japan journal of nursing science : JJNS 10(1): 24-40	- Exclude Study design
Kurtz, Steven P, Stall, Ronald D, Buttram, Mance E et al. (2013) A randomized trial of a behavioral intervention for high risk substance-using MSM. AIDS and behavior 17(9): 2914-26	- Exclude Intervention Type *Primary aim of the intervention was substance misuse risk reduction*
L'Engle, Kelly L, Mangone, Emily R, Parcesepe, Angela M et al. (2016) Mobile Phone Interventions for Adolescent Sexual and Reproductive Health: A Systematic Review. Pediatrics 138(3)	- Exclude Systematic Review - checked for primary papers
Lan, Chiao-Wen, Lightfoot, Alexandra, Gere, David et al. (2019) Live or virtual? Comparing two versions of AMP!, a theater-based sexual health intervention for adolescents. American Journal of Sexuality Education 14(3): 292-314	- Exclude Intervention Type
LaSala, M.C., Fedor, J.P., Revere, E.J. et al. (2016) What Parents and Their Gay and Bisexual Sons Say About HIV Prevention. Qualitative health research 26(11): 1519-1530	- Exclude Parenting intervention
LeCroy, Craig Winston, McCullough Cosgrove, Jenny, Cotter, Katie et al. (2018) Go Grrrls: A Randomized Controlled Trial of a Gender-Specific Intervention to Reduce Sexual Risk Factors in Middle School	- Exclude School based intervention

Study	Code [Reason]
Females. Health education & behavior : the official publication of the Society for Public Health Education 45(2): 286-294	*Participants recruited from schools and intervention delivered in afterschool settings. Also participants were 11-15 years.*
Lelutiu-Weinberger, Corina, Pachankis, John E, Gamarel, Kristi E et al. (2015) Feasibility, Acceptability, and Preliminary Efficacy of a Live-Chat Social Media Intervention to Reduce HIV Risk Among Young Men Who Have Sex With Men. AIDS and behavior 19(7): 1214-27	- Exclude Study design
Letourneau, Elizabeth J, McCart, Michael R, Sheidow, Ashli J et al. (2017) First Evaluation of a Contingency Management Intervention Addressing Adolescent Substance Use and Sexual Risk Behaviors: Risk Reduction Therapy for Adolescents. Journal of substance abuse treatment 72: 56-65	- Exclude population
Lim, Megan S C, Hocking, Jane S, Aitken, Campbell K et al. (2012) Impact of text and email messaging on the sexual health of young people: a randomised controlled trial. Journal of epidemiology and community health 66(1): 69-74	- Exclude Intervention Type *Digital intervention*
Llewellyn, Carrie Diane, Abraham, Charles, Pollard, Alex et al. (2019) A randomised controlled trial of a telephone administered brief HIV risk reduction intervention amongst men who have sex with men prescribed post-exposure prophylaxis for HIV after sexual exposure in the UK: Project PEPSE. PloS one 14(5): e0216855	- Exclude Data not useable
Logie, Carmen H, Lys, Candice L, Schott, Nicole et al. (2018) 'In the North you can't be openly gay': Contextualising sexual practices among sexually and gender diverse persons in Northern Canada. Global public health 13(12): 1865-1877	- Exclude Qualitative paper not relevant *Population not relevant (Arctic and North West Territories) and no focus on intervention acceptability - focus on access to sexual health care in this region*
Lomotey, M.; Brown, J.L.; DiClemente, R.J. (2013) Targeting STD/HIV prevention interventions for heterosexual male adolescents in North and Central America: A review. Current Pediatric Reviews 9(4): 376-382	- Exclude Systematic Review - checked for primary papers
Long, L, Abraham, C, Paquette, R et al. (2016) Brief interventions to prevent sexually transmitted infections suitable for in-service use: A systematic review. Preventive medicine 91: 364-382	- Exclude Systematic Review - checked for primary papers

Study	Code [Reason]
Lopez, Laureen M, Otterness, Conrad, Chen, Mario et al. (2013) Behavioral interventions for improving condom use for dual protection. The Cochrane database of systematic reviews: cd010662	- Exclude Systematic Review - checked for primary papers
Lorimer, Karen, Kidd, Lisa, Lawrence, Maggie et al. (2013) Systematic review of reviews of behavioural HIV prevention interventions among men who have sex with men. AIDS care 25(2): 133-50	- Exclude Systematic Review - checked for primary papers
LoVette, A.; Kuo, C.; Harrison, A. (2019) Strength-based interventions for HIV prevention and sexual risk reduction among girls and young women: A resilience-focused systematic review. Global Public Health 14(10): 1454-1478	- Exclude Systematic Review - checked for primary papers
Lys, Candice and Reading, Charlotte (2012) Coming of age: how young women in the Northwest Territories understand the barriers and facilitators to positive, empowered, and safer sexual health. International journal of circumpolar health 71: 18957	- Exclude Qualitative paper not relevant *Does not ask about acceptability, experiences or preferences of sexual health interventions*
MacCarthy, Sarah, Barreras, Joanna L, Mendoza-Graf, Alexandra et al. (2019) Strategies for Improving Mobile Technology-Based HIV Prevention Interventions With Latino Men Who Have Sex With Men and Latina Transgender Women. AIDS education and prevention : official publication of the International Society for AIDS Education 31(5): 407-420	- Exclude qualitative - digital intervention
Madkins, Krystal, Moskowitz, David A, Moran, Kevin et al. (2019) Measuring Acceptability and Engagement of The Keep It Up! Internet-Based HIV Prevention Randomized Controlled Trial for Young Men Who Have Sex With Men. AIDS education and prevention : official publication of the International Society for AIDS Education 31(4): 287-305	- Exclude qualitative - digital intervention
Magee, J.C., Bigelow, L., DeHaan, S. et al. (2012) Sexual Health Information Seeking Online: A Mixed-Methods Study Among Lesbian, Gay, Bisexual, and Transgender Young People. Health Education and Behavior 39(3): 276-289	- Exclude qualitative - digital intervention
Mahat, Ganga and Scoloveno, Mary Ann (2018) Effectiveness of Adolescent Peer Education Programs on Reducing HIV/STI Risk: An Integrated Review. Research and theory for nursing practice 32(2): 168-198	- Exclude Systematic Review - checked for primary papers
Marcell, Arik V, Allan, Elizabeth, Clay, Eric A et al. (2013) Effectiveness of a brief curriculum to promote condom and health care use among out-of-school young adult males. Perspectives on sexual and reproductive health 45(1): 33-40	- Exclude Study design

Study	Code [Reason]
Marion, Lucy N, Finnegan, Lorna, Campbell, Richard T et al. (2009) The Well Woman Program: a community-based randomized trial to prevent sexually transmitted infections in low-income African American women. Research in nursing & health 32(3): 274-85	- Exclude publication year
Markham, Christine Margaret, Shegog, Ross, Leonard, Amy Dolph et al. (2009) +CLICK: harnessing web-based training to reduce secondary transmission among HIV-positive youth. AIDS care 21(5): 622-31	- Exclude publication year
Marrazzo, Jeanne M; Thomas, Katherine K; Ringwood, Kathleen (2011) A behavioural intervention to reduce persistence of bacterial vaginosis among women who report sex with women: results of a randomised trial. Sexually transmitted infections 87(5): 399-405	- Exclude population
Marsch, Lisa A, Grabinski, Michael J, Bickel, Warren K et al. (2011) Computer-assisted HIV prevention for youth with substance use disorders. Substance use & misuse 46(1): 46-56	- Exclude Intervention Type *Digital intervention*
Marsch, Lisa A, Guarino, Honoria, Grabinski, Michael J et al. (2015) Comparative Effectiveness of Web-Based vs. Educator-Delivered HIV Prevention for Adolescent Substance Users: A Randomized, Controlled Trial. Journal of substance abuse treatment 59: 30-7	- Exclude population
Martinez, Omar, Wu, Elwin, Frasca, Timothy et al. (2017) Adaptation of a Couple-Based HIV/STI Prevention Intervention for Latino Men Who Have Sex With Men in New York City. American journal of men's health 11(2): 181-195	- Exclude Study design
Maulsby, Cathy, Millett, Greg, Lindsey, Kali et al. (2013) A systematic review of HIV interventions for black men who have sex with men (MSM). BMC public health 13: 625	- Exclude Systematic Review - checked for primary papers
Mavedzenge, Sue Napierala; Luecke, Ellen; Ross, David A (2014) Effective approaches for programming to reduce adolescent vulnerability to HIV infection, HIV risk, and HIV-related morbidity and mortality: a systematic review of systematic reviews. Journal of acquired immune deficiency syndromes (1999) 66suppl2: 154-69	- Exclude Systematic Review - checked for primary papers
McCarthy, Ona L, French, Rebecca S, Baraitser, Paula et al. (2016) Safetxt: a pilot randomised controlled trial of an intervention delivered by mobile phone to increase safer sex behaviours in young people. BMJ open 6(12): e013045	- Exclude outcomes not relevant
McCarthy, Ona, Carswell, Kenneth, Murray, Elizabeth et al. (2012) What young people want from a sexual health website: design and development of Sexunzipped. Journal of medical Internet research 14(5): e127	- Exclude qualitative - digital intervention

Study	Code [Reason]
McCoy, Sandra I; Kangwende, Rugare A; Padian, Nancy S (2010) Behavior change interventions to prevent HIV infection among women living in low and middle income countries: a systematic review. AIDS and behavior 14(3): 469-82	- Exclude Systematic Review - checked for primary papers
McKee, Alan, Watson, Anne-Frances, Dore, Johanna et al. (2014) 'It's all scientific to me': Focus group insights into why young people do not apply safe-sex knowledge. Sex Education 14(6): 652-665	- Exclude Qualitative paper not relevant
McMahon, James M, Pouget, Enrique R, Tortu, Stephanie et al. (2015) Couple-based HIV counseling and testing: a risk reduction intervention for US drug-involved women and their primary male partners. Prevention science : the official journal of the Society for Prevention Research 16(2): 341-51	- Exclude population
Melendez-Torres, G J and Bonell, Chris (2014) Systematic review of cognitive behavioural interventions for HIV risk reduction in substance-using men who have sex with men. International journal of STD & AIDS 25(9): 627-35	- Exclude Systematic Review - checked for primary papers
Mendez-Ruiz, Martha Dalila, Villegas-Pantoja, Miguel Angel, Alarcon-Luna, Nohemi Selene et al. (2020) Prevention of alcohol consumption and transmission of human immunodeficiency virus: randomized clinical trial. Revista latino-americana de enfermagem 28: e3262	- Exclude Data not useable *Means only, no SDs*
Menza, Timothy W, Jameson, Damon R, Hughes, James P et al. (2010) Contingency management to reduce methamphetamine use and sexual risk among men who have sex with men: a randomized controlled trial. BMC public health 10: 774	- Exclude Intervention Type
Mercer Kollar, Laura M, Davis, Teaniese L, Monahan, Jennifer L et al. (2016) Do As I Say: Using Communication Role-Plays to Assess Sexual Assertiveness Following an Intervention. Health education & behavior : the official publication of the Society for Public Health Education 43(6): 691-698	- Exclude outcomes not relevant
Merlo, LJ; Naar-King, S; Green-Jones, M (2010) Computer-based motivational intervention promotes condom use among urban youth with HIV. Comprehensive psychiatry 51(6): e7	- Exclude Study design
Metsch, Lisa R, Feaster, Daniel J, Gooden, Lauren et al. (2013) Effect of risk-reduction counseling with rapid HIV testing on risk of acquiring sexually transmitted infections: the AWARE randomized clinical trial. JAMA 310(16): 1701-10	- Exclude population
Mevissen, Fraukje E F, Ruiter, Robert A C, Meertens, Ree M et al. (2011) Justify your love: testing an online STI-risk communication	- Exclude Intervention Type *Digital intervention*

Study	Code [Reason]
intervention designed to promote condom use and STI-testing. Psychology & health 26(2): 205-21	
Milam, Joel, Morris, Sheldon, Jain, Sonia et al. (2016) Randomized Controlled Trial of an Internet Application to Reduce HIV Transmission Behavior Among HIV Infected Men Who have Sex with Men. AIDS and behavior 20(6): 1173-1181	- Exclude Intervention Type *Digital intervention with no HCP input*
Milhausen, R.R., Wood, J., Sanders, S.A. et al. (2011) A novel, self-guided, home-based intervention to promote condom use among young men: A pilot study. Journal of Men's Health 8(4): 274-281	- Exclude Study design
Mimiaga, M.J.; Hughto, J.M.W.; Reisner, S.L. (2019) A Randomized Pilot Study of a Group-Delivered HIV Risk Reduction Intervention for At-Risk Urban Men Who Have Sex with Men Who Regularly Attend Private Sex Events. Archives of sexual behavior 48(4): 1059-1071	- Exclude Intervention Type
Miners, Alec, Llewellyn, Carrie, King, Carina et al. (2018) Designing a brief behaviour change intervention to reduce sexually transmitted infections: a discrete choice experiment. International journal of STD & AIDS 29(9): 851-860	- Exclude Intervention Type
Mitchell, J W, Lee, J-Y, Godoy, F et al. (2018) HIV-discordant and concordant HIV-positive male couples' recommendations for how an eHealth HIV prevention toolkit for concordant HIV-negative male couples could be improved to meet their specific needs. AIDS care 30(sup2): 54-60	- Exclude qualitative - digital intervention
Mitchell, Jason William, Lee, Ji-Young, Wu, Yanyan et al. (2020) Feasibility and Acceptability of an Electronic Health HIV Prevention Toolkit Intervention With Concordant HIV-Negative, Same-Sex Male Couples on Sexual Agreement Outcomes: Pilot Randomized Controlled Trial. JMIR formative research 4(2): e16807	- Exclude outcomes not relevant
Montgomery, Tiffany M, Mays, Vickie M, Heilemann, MarySue V et al. (2018) Acceptability and feasibility of a sexual health intervention for young adult Black women. Journal of Obstetric, Gynecologic, & Neonatal Nursing: Clinical Scholarship for the Care of Women, Childbearing Families, & Newborns 47(6): 862-873	- Exclude qualitative - digital intervention
Moore, Erin W; Smith, William E; Folsom, Ashlee R B (2012) F.O.R.E.play: the utility of brief sexual health interventions among college students. Journal of American college health : J of ACH 60(2): 175-7	- Exclude Intervention Type
Morales, A.; Espada, J.P.; Orgiles, M. (2019) Mediation of an efficacious HIV risk reduction intervention for adolescents: A cluster-randomised controlled trial. Journal of health psychology 24(13): 1884-1896	- Exclude School based intervention

Study	Code [Reason]
Morales, A., Espada, J.P., Orgiles, M. et al. (2018) Interventions to reduce risk for sexually transmitted infections in adolescents: A meta-analysis of trials, 2008-2016. PLoS ONE 13(6): e0199421	- Exclude Systematic Review - checked for primary papers
Morales, Alexandra; Orgiles, Mireia; Espada, Jose P (2020) Sexually Unexperienced Adolescents Benefit the Most From a Sexual Education Program for Adolescents: A Longitudinal Cluster Randomized Controlled Study. AIDS education and prevention : official publication of the International Society for AIDS Education 32(6): 493-511	- Exclude Intervention Type *School-based intervention*
Morgenstern, Jon, Bux, Donald A Jr, Parsons, Jeffrey et al. (2009) Randomized trial to reduce club drug use and HIV risk behaviors among men who have sex with men. Journal of consulting and clinical psychology 77(4): 645-56	- Exclude publication year
Morrison-Beedy, Dianne, Carey, Michael P, Seibold-Simpson, Susan M et al. (2009) Preliminary efficacy of a comprehensive HIV prevention intervention for abstinent adolescent girls: pilot study findings. Research in nursing & health 32(6): 569-81	- Exclude publication year
Morrison-Beedy, Dianne, Crean, Hugh F, Passmore, Denise et al. (2013) Risk reduction strategies used by urban adolescent girls in an HIV prevention trial. Current HIV research 11(7): 559-69	- Exclude secondary publication of included trial
Mthembu, Jacqueline, Hamilton, Alison B, Milburn, Norweeta G et al. (2020) "It Had a Lot of Cultural Stuff in It": HIV-Serodiscordant African American Couples' Experiences of a Culturally Congruent Sexual Health Intervention. Ethnicity & disease 30(2): 269-276	- Exclude Intervention Type
Muessig, Kathryn E, Pike, Emily C, Fowler, Beth et al. (2013) Putting prevention in their pockets: developing mobile phone-based HIV interventions for black men who have sex with men. AIDS patient care and STDs 27(4): 211-22	- Exclude Intervention Type
Munro-Kramer, Michelle L, Fava, Nicole M, Banerjee, Tanima et al. (2017) The Effect of a Youth-Centered Sexual Risk Event History Calendar (SREHC) Assessment on Sexual Risk Attitudes, Intentions, and Behavior. Journal of pediatric health care : official publication of National Association of Pediatric Nurse Associates & Practitioners 31(3): 302-313	- Exclude outcomes not relevant
Mustanski, Brian, Garofalo, Robert, Monahan, Colleen et al. (2013) Feasibility, acceptability, and preliminary efficacy of an online HIV prevention program for diverse young men who have sex with men: the keep it up! intervention. AIDS and behavior 17(9): 2999-3012	- Exclude Intervention Type *Digital intervention*
Mustanski, Brian, Parsons, Jeffrey T, Sullivan, Patrick S et al. (2018) Biomedical and Behavioral Outcomes of Keep It Up!: An eHealth HIV	- Exclude Intervention Type

Study	Code [Reason]
Prevention Program RCT. American journal of preventive medicine 55(2): 151-158	*Digital intervention*
Mustanski, Brian, Ryan, Daniel T, Sanchez, Travis et al. (2014) Effects of messaging about multiple biomedical and behavioral HIV prevention methods on intentions to use among US MSM: results of an experimental messaging study. AIDS and behavior 18(9): 1651-60	- Exclude outcomes not relevant
Muzny, C.A., Harbison, H.S., Pembleton, E.S. et al. (2013) Misperceptions regarding protective barrier method use for safer sex among African-American women who have sex with women. Sexual Health 10(2): 138-141	- Exclude outcomes not relevant
Nelson, Annabelle, Cordova, David, Walters, Andrew S et al. (2016) Storytelling for empowerment for Latino teens: Increasing HIV prevention knowledge and attitudes. Journal of Adolescent Research 31(2): 202-231	- Exclude School based intervention
Neumann, Mary Spink, O'Donnell, Lydia, Doval, Alexi San et al. (2011) Effectiveness of the VOICES/VOCES sexually transmitted disease/human immunodeficiency virus prevention intervention when administered by health department staff: does it work in the "real world"?. Sexually transmitted diseases 38(2): 133-9	- Exclude Study design
Neville, Stephen; Adams, Jeffery; Holdershaw, Judith (2014) Social marketing campaigns that promote condom use among MSM: a literature review. Nursing praxis in New Zealand inc 30(1): 5-16	- Exclude Systematic Review - checked for primary papers
Newcomb, Michael E, Macapagal, Kathryn R, Feinstein, Brian A et al. (2017) Integrating HIV Prevention and Relationship Education for Young Same-Sex Male Couples: A Pilot Trial of the 2GETHER Intervention. AIDS and behavior 21(8): 2464-2478	- Exclude population
Nguyen, Long Hoang, Tran, Bach Xuan, Rocha, Luis E C et al. (2019) A Systematic Review of eHealth Interventions Addressing HIV/STI Prevention Among Men Who Have Sex With Men. AIDS and behavior 23(9): 2253-2272	- Exclude Systematic Review - checked for primary papers
Nicholas, Angela, Bailey, Julia V, Stevenson, Fiona et al. (2013) The Sexunzipped trial: young people's views of participating in an online randomized controlled trial. Journal of medical Internet research 15(12): e276	- Exclude qualitative - digital intervention
Nielsen, A.M., De Costa, A., Gemzell-Danielsson, K. et al. (2019) The MOSEXY trial: Mobile phone intervention for sexual health in youth - A pragmatic randomised controlled trial to evaluate the effect of a smartphone application on sexual health in youth in Stockholm, Sweden. Sexually Transmitted Infections	- Exclude Intervention Type *Digital intervention*

Study	Code [Reason]
Noar, Seth M., Willoughby, Jessica Fitts, Crosby, Richard et al. (2020) Acceptability of a Computer-Tailored Safer Sex Intervention for Heterosexually Active African Americans Attending an STI Clinic. The journal of primary prevention 41(3): 211-227	- Exclude Intervention Type *Exclusively digital*
Nobles, W.W.; Goddard, L.L.; Gilbert, D.J. (2009) Culturecology, women, and African-centered HIV prevention. Journal of Black Psychology 35(2): 228-246	- Exclude publication year
Norton, Wynne E, Fisher, Jeffrey D, Amico, K Rivet et al. (2012) Relative efficacy of a pregnancy, sexually transmitted infection, or human immunodeficiency virus prevention-focused intervention on changing sexual risk behavior among young adults. Journal of American college health : J of ACH 60(8): 574-82	- Exclude study year
O'Cleirigh, Conall, Safren, Steven A, Taylor, S Wade et al. (2019) Cognitive Behavioral Therapy for Trauma and Self-Care (CBT-TSC) in Men Who have Sex with Men with a History of Childhood Sexual Abuse: A Randomized Controlled Trial. AIDS and behavior 23(9): 2421-2431	- Exclude population
O'Connor, Elizabeth A, Lin, Jennifer S, Burda, Brittany U et al. (2014) Behavioral sexual risk-reduction counseling in primary care to prevent sexually transmitted infections: a systematic review for the U.S. Preventive Services Task Force. Annals of internal medicine 161(12): 874-83	- Exclude Systematic Review - checked for primary papers
O'Donnell, Lydia, Bonaparte, Beverly, Joseph, Heather et al. (2009) Keep It Up: development of a community-based health screening and HIV prevention strategy for reaching young African American men. AIDS education and prevention : official publication of the International Society for AIDS Education 21(4): 299-313	- Exclude publication year
O'Grady, Megan A; Wilson, Kristina; Harman, Jennifer J (2009) Preliminary findings from a brief, peer-led safer sex intervention for college students living in residence halls. The journal of primary prevention 30(6): 716-31	- Exclude publication year
Okwumabua, Theresa M, Peasant, Courtney, Anderson, Mollie B et al. (2018) Using deep reasoning questions to improve an email-based sexually transmitted infection prevention intervention. American Journal of Sexuality Education 13(4): 452-469	- Exclude population
Operario, Don, Gamarel, Kristi E, Iwamoto, Mariko et al. (2017) Couples-Focused Prevention Program to Reduce HIV Risk Among Transgender Women and Their Primary Male Partners: Feasibility and Promise of the Couples HIV Intervention Program. AIDS and behavior 21(8): 2452-2463	- Exclude population

Study	Code [Reason]
Orozco-Olvera, V.; Shen, F.; Cluver, L. (2019) The effectiveness of using entertainment education narratives to promote safer sexual behaviors of youth: A meta-analysis, 1985-2017. PLoS ONE 14(2): e0209969	- Exclude Systematic Review - checked for primary papers
Ota, Erika, Wariki, Windy Mv, Mori, Rintaro et al. (2011) Behavioral interventions to reduce the transmission of HIV infection among sex workers and their clients in high-income countries. The Cochrane database of systematic reviews: cd006045	- Exclude population *Sex workers not a group of interest. SR - 4 trials included; 2 published 1999, 1 studied clients of SWs, 1 studied SWs but not from a population of interest.*
Owczarzak, Jill; Broaddus, Michelle; Tarima, Sergey (2018) Effectiveness of an evidence-based HIV prevention intervention when implemented by frontline providers. Translational behavioral medicine 8(6): 917-926	- Exclude Study design
Pantalone, D.W., Nelson, K.M., Batchelder, A.W. et al. (2020) A Systematic Review and Meta-Analysis of Combination Behavioral Interventions Co-Targeting Psychosocial Syndemics and HIV-Related Health Behaviors for Sexual Minority Men. Journal of sex research: 1-28	- Exclude Systematic Review - checked for primary papers
Perez, Ashley; Santamaria, E Karina; Operario, Don (2018) A Systematic Review of Behavioral Interventions to Reduce Condomless Sex and Increase HIV Testing for Latino MSM. Journal of immigrant and minority health 20(5): 1261-1276	- Exclude Systematic Review - checked for primary papers
Petrova, D. and Garcia-Retamero, R. (2015) Effective evidence-based programs for preventing sexually-transmitted infections: A meta-analysis. Current HIV Research 13(5): 432-438	- Exclude Systematic Review - checked for primary papers
Powell, Terrinieka W, Herbert, Ann, Ritchwood, Tiarney D et al. (2016) "Let Me Help You Help Me": Church-Based HIV Prevention for Young Black Men Who Have Sex With Men. AIDS education and prevention : official publication of the International Society for AIDS Education 28(3): 202-15	- Exclude Intervention Type
Prado, Guillermo, Pantin, Hilda, Huang, Shi et al. (2012) Effects of a family intervention in reducing HIV risk behaviors among high-risk Hispanic adolescents: a randomized controlled trial. Archives of pediatrics & adolescent medicine 166(2): 127-33	- Exclude population
Protogerou, Cleo and Johnson, Blair T (2014) Factors underlying the success of behavioral HIV-prevention interventions for adolescents: a meta-review. AIDS and behavior 18(10): 1847-63	- Exclude Systematic Review - checked for primary papers

Study	Code [Reason]
Qvarnstrom, Anna and Oscarsson, Marie G (2014) Perceptions of HIV/STI prevention among young adults in Sweden who travel abroad: a qualitative study with focus group and individual interviews. BMC public health 14: 897	- Exclude population
Randolph, Schenita D; Pleasants, Terrence; Gonzalez-Guarda, Rosa M (2017) Barber-led sexual health education intervention for Black male adolescents and their fathers. Public health nursing (Boston, Mass.) 34(6): 555-560	- Exclude Qualitative paper not relevant
Reback, Cathy J, Fletcher, Jesse B, Swendeman, Dallas A et al. (2019) Theory-Based Text-Messaging to Reduce Methamphetamine Use and HIV Sexual Risk Behaviors Among Men Who Have Sex with Men: Automated Unidirectional Delivery Outperforms Bidirectional Peer Interactive Delivery. AIDS and behavior 23(1): 37-47	- Exclude Intervention Type *Digital intervention*
Redding, Colleen A, Prochaska, James O, Armstrong, Kay et al. (2015) Randomized trial outcomes of a TTM-tailored condom use and smoking intervention in urban adolescent females. Health education research 30(1): 162-78	- Exclude population
Reisner, S.L., Mimiaga, M.J., Mayer, K.H. et al. (2009) Tricks of the trade: Sexual health behaviors, the context of hiv risk, and potential prevention intervention strategies for male sex workers. Journal of LGBT Health Research 4(4): 195-209	- Exclude publication year
Rinehart, D.J., Leslie, S., Durfee, M.J. et al. (2019) Acceptability and Efficacy of a Sexual Health Texting Intervention Designed to Support Adolescent Females. Academic Pediatrics	- Exclude Intervention Type *Digital intervention*
Rizzo, Christie J, Joppa, Meredith, Barker, David et al. (2018) Project Date SMART: a Dating Violence (DV) and Sexual Risk Prevention Program for Adolescent Girls with Prior DV Exposure. Prevention science : the official journal of the Society for Prevention Research 19(4): 416-426	- Exclude Intervention Type
Roffman, R.A., Picciano, J.F., Ryan, R. et al. (1997) HIV-Prevention Group Counseling Delivered by Telephone: An Efficacy Trial with Gay and Bisexual Men. AIDS and Behavior 1(2): 137-154	- Exclude publication year
Rojas, Patria, Ramirez-Ortiz, Daisy, Wang, Weize et al. (2020) Testing the Efficacy of an HIV Prevention Intervention Among Latina Immigrants Living in Farmworker Communities in South Florida. Journal of immigrant and minority health 22(4): 661-667	- Exclude Study design *Cohort study*
Rose, India D, Friedman, Daniela B, Spencer, S. Melinda et al. (2016) Health information-seeking practices of African American young men who have sex with men: A qualitative study. Youth & Society 48(3): 344-365	- Exclude outcomes not relevant

Study	Code [Reason]
Rosser, B R Simon, Hatfield, Laura A, Miner, Michael H et al. (2010) Effects of a behavioral intervention to reduce serodiscordant unsafe sex among HIV positive men who have sex with men: the Positive Connections randomized controlled trial study. Journal of behavioral medicine 33(2): 147-58	- Exclude Intervention Type
Rosser, B R Simon, Oakes, J Michael, Konstan, Joseph et al. (2010) Reducing HIV risk behavior of men who have sex with men through persuasive computing: results of the Men's INTernet Study-II. AIDS (London, England) 24(13): 2099-107	- Exclude Intervention Type *Digital intervention with no HCP input*
Roy, A., King, C., Gilson, R. et al. (2020) Healthcare provider and service user perspectives on STI risk reduction interventions for young people and MSM in the UK. Sexually Transmitted Infections 96(1): 26-32	- Exclude Study design
Ruiz-Perez, Isabel, Murphy, Matthew, Pastor-Moreno, Guadalupe et al. (2017) The Effectiveness of HIV Prevention Interventions in Socioeconomically Disadvantaged Ethnic Minority Women: A Systematic Review and Meta-Analysis. American journal of public health 107(12): e13-e21	- Exclude Systematic Review - checked for primary papers
Salam, R.A., Faqqah, A., Sajjad, N. et al. (2016) Improving Adolescent Sexual and Reproductive Health: A Systematic Review of Potential Interventions. Journal of Adolescent Health 59(2supplement): 11-s28	- Exclude Systematic Review - checked for primary papers
Salam, R.A., Haroon, S., Ahmed, H.H. et al. (2014) Impact of community-based interventions on HIV knowledge, attitudes, and transmission. Infectious Diseases of Poverty 3(1): 26	- Exclude Systematic Review - checked for primary papers
Saleh, Lena D, Operario, Don, Smith, Carla Dillard et al. (2011) "We're going to have to cut loose some of our personal beliefs": barriers and opportunities in providing HIV prevention to African American men who have sex with men and women. AIDS education and prevention : official publication of the International Society for AIDS Education 23(6): 521-32	- Exclude Study design
Sales, Jessica M, Lang, Delia L, DiClemente, Ralph J et al. (2012) The mediating role of partner communication frequency on condom use among African American adolescent females participating in an HIV prevention intervention. Health psychology : official journal of the Division of Health Psychology, American Psychological Association 31(1): 63-9	- Exclude Intervention Type
Sales, Jessica M, Lang, Delia L, Hardin, James W et al. (2010) Efficacy of an HIV prevention program among African American female adolescents reporting high depressive symptomatology. Journal of women's health (2002) 19(2): 219-27	- Exclude publication year *Secondary analysis of a main trial published in 2004 therefore excluded*

Study	Code [Reason]
Sales, JM; DiClemente, RJ; Monahan, JL (2013) An HIV-risk reduction intervention for alcohol-using african american youngwomen seeking std services. Alcoholism, clinical and experimental research 37: 285a	- Exclude Study design
Sanchez, John P, Guilliames, Conair, Sanchez, Nelson F et al. (2010) Video tool to promote knowledge of syphilis among black and Hispanic men recruited from clinical and non-clinical settings. Journal of community health 35(3): 220-8	- Exclude population
Sanchez, John Paul, Kaltwassar, Sydney, McClellan, Mary et al. (2010) Educational video tool to increase syphilis knowledge among black and Hispanic male patients. Journal of health care for the poor and underserved 21(1): 371-85	- Exclude population
Schmiege, SJ, Broaddus, MR, Levin, M et al. (2009) Randomized trial of group interventions to reduce HIV/STD risk and change theoretical mediators among detained adolescents. Journal of consulting and clinical psychology 77(1): 38-50	- Exclude publication year
Schnall, Rebecca, Travers, Jasmine, Rojas, Marlene et al. (2014) eHealth interventions for HIV prevention in high-risk men who have sex with men: a systematic review. Journal of medical Internet research 16(5): e134	- Exclude Systematic Review - checked for primary papers
Schonnesson, Lena Nilsson; Bowen, Anne M; Williams, Mark L (2016) Project SMART: Preliminary Results From a Test of the Efficacy of a Swedish Internet-Based HIV Risk-Reduction Intervention for Men Who Have Sex With Men. Archives of sexual behavior 45(6): 1501-11	- Exclude Intervention Type *Digital intervention with no HCP input*
Seidel, A., Wienholz, S., Michel, M. et al. (2014) Sexual knowledge among adolescents with physical handicaps: A systematic review. Sexuality and Disability 32(3): 429-441	- Exclude Systematic Review - checked for primary papers
Serovich, Julianne M, Laschober, Tanja C, Brown, Monique J et al. (2017) Longitudinal Findings on Changes in and the Link Between HIV-Related Communication, Risky Sexual Behavior, and Relationship Status in Men Who Have Sex With Men Living With HIV. Sexually transmitted diseases 44(12): 732-738	- Exclude Intervention Type
Serovich, Julianne M, Laschober, Tanja C, Brown, Monique J et al. (2018) Assessment of HIV disclosure and sexual behavior among Black men who have sex with men following a randomized controlled intervention. International journal of STD & AIDS 29(7): 673-679	- Exclude Intervention Type
Seth, Puja, Wingood, Gina M, Robinson, LaShun S et al. (2014) The impact of alcohol use on HIV/STI intervention efficacy in predicting	- Exclude outcomes not relevant

Study	Code [Reason]
sexually transmitted infections among young African-American women. AIDS and behavior 18(4): 747-51	
Shafii, Taraneh, Benson, Samantha K, Morrison, Diane M et al. (2019) Results from e-KISS: electronic-KIOSK Intervention for Safer Sex: A pilot randomized controlled trial of an interactive computer-based intervention for sexual health in adolescents and young adults. PloS one 14(1): e0209064	- Exclude Intervention Type *Digital intervention*
Shambley-Ebron, Donna Z (2009) My sister, myself: a culture- and gender-based approach to HIV/AIDS prevention. Journal of transcultural nursing : official journal of the Transcultural Nursing Society 20(1): 28-36	- Exclude publication year
Shepherd, Jonathan P; Frampton, Geoff K; Harris, Petra (2011) Interventions for encouraging sexual behaviours intended to prevent cervical cancer. The Cochrane database of systematic reviews: cd001035	- Exclude Systematic Review - checked for primary papers
Sherriff, N., McDonnell, E., Bogen-Johnston, L. et al. (2013) Engaging 'gay' businesses in HIV prevention 'Everywhere': Findings from a qualitative study in eight European cities. Health Education Journal 72(1): 13-23	- Exclude outcomes not relevant
Shoveller, Jean, Knight, Rod, Davis, Wendy et al. (2012) Online sexual health services: examining youth's perspectives. Canadian journal of public health = Revue canadienne de sante publique 103(1): 14-8	- Exclude Intervention Type
Sledge, Jennifer A, Jensen, Claire E, Cibulka, Nancy J et al. (2019) The Male Voice: A Qualitative Assessment of Young Men's Communication Preferences About HPV and 9vHPV. Journal of community health 44(5): 998-1008	- Exclude Qualitative paper not relevant
Snead, Margaret C, O'Leary, Ann M, Mandel, Michele G et al. (2014) Relationship between social cognitive theory constructs and self-reported condom use: assessment of behaviour in a subgroup of the Safe in the City trial. BMJ open 4(12): e006093	- Exclude population
Sophus, Amber I and Mitchell, Jason W (2021) Reducing HIV Risk Behaviors Among Black Women Living With and Without HIV/AIDS in the U.S.: A Systematic Review. AIDS and behavior 25(3): 732-747	- Exclude Systematic Review - checked for primary papers
Soscia, Isabella; Turrini, Alex; Tanzi, Emilio (2012) Non Castigat Ridendo Mores: evaluating the effectiveness of humor appeal in printed advertisements for HIV/AIDS prevention in Italy. Journal of health communication 17(9): 1011-27	- Exclude Intervention Type

Study	Code [Reason]
Stewart, Katharine E, Wright, Patricia B, Montgomery, Brooke E E et al. (2017) Reducing Risky Sex among Rural African American Cocaine Users: A Controlled Trial. Journal of health care for the poor and underserved 28(1): 528-547	- Exclude population
Stone, N., Graham, C., Anstee, S. et al. (2018) Enhancing condom use experiences among young men to improve correct and consistent condom use: Feasibility of a home-based intervention strategy (HIS-UK). Pilot and Feasibility Studies 4(1): 63	- Exclude Study design
Suffoletto, Brian, Akers, Aletha, McGinnis, Kathleen A et al. (2013) A sex risk reduction text-message program for young adult females discharged from the emergency department. The Journal of adolescent health : official publication of the Society for Adolescent Medicine 53(3): 387-93	- Exclude Intervention Type *Digital intervention*
Sun, Christina J, Anderson, Kirsten M, Mayer, Liat et al. (2019) Findings from Formative Research to Develop a Strength-Based HIV Prevention and Sexual Health Promotion mHealth Intervention for Transgender Women. Transgender health 4(1): 350-358	- Exclude Study design
Sun, Christina J, Stowers, Jason, Miller, Cindy et al. (2015) Acceptability and feasibility of using established geosocial and sexual networking mobile applications to promote HIV and STD testing among men who have sex with men. AIDS and behavior 19(3): 543-52	- Exclude Study design
Surratt, Hilary L, O'Grady, Catherine, Kurtz, Steven P et al. (2014) Outcomes of a behavioral intervention to reduce HIV risk among drug-involved female sex workers. AIDS and behavior 18(4): 726-39	- Exclude population
Sznitman, Sharon, Stanton, Bonita F, Vanable, Peter A et al. (2011) Long term effects of community-based STI screening and mass media HIV prevention messages on sexual risk behaviors of African American adolescents. AIDS and behavior 15(8): 1755-63	- Exclude Data not useable
Sznitman, Sharon, Vanable, Peter A, Carey, Michael P et al. (2011) Using culturally sensitive media messages to reduce HIV-associated sexual behavior in high-risk African American adolescents: results from a randomized trial. The Journal of adolescent health : official publication of the Society for Adolescent Medicine 49(3): 244-51	- Exclude Data not useable
Taylor, S Wade, Goshe, Brett M, Marquez, Samantha M et al. (2018) Evaluating a novel intervention to reduce trauma symptoms and sexual risk taking: qualitative exit interviews with sexual minority men with childhood sexual abuse. Psychology, health & medicine 23(4): 454-464	- Exclude population

Study	Code [Reason]
Thomas, R., Bekan Homawoo, B., McClamroch, K. et al. (2013) Community attitudes about discussing sexual health: assessing public opinion of local STD prevention campaigns. Public health reports (Washington, D.C. : 1974) 128(supplement1): 73-80	- Exclude Study design
Thurheimer, Jennifer, Sereika, Susan M, Founds, Sandra et al. (2016) Efficacy of the READY-Girls Program on General Risk-Taking Behaviors, Condom Use, and Sexually Transmitted Infections Among Young Adolescent Females With Type 1 Diabetes. The Diabetes educator 42(6): 712-720	- Exclude Intervention Type
Tingey, Lauren, Mullany, Britta, Chambers, Rachel et al. (2015) Respecting the circle of life: one year outcomes from a randomized controlled comparison of an HIV risk reduction intervention for American Indian adolescents. AIDS care 27(9): 1087-97	- Exclude population
Tobin, Karin, Davey-Rothwell, Melissa A, Nonyane, Bareng A S et al. (2017) RCT of an integrated CBT-HIV intervention on depressive symptoms and HIV risk. PloS one 12(12): e0187180	- Exclude Intervention Type
Tolli, M V (2012) Effectiveness of peer education interventions for HIV prevention, adolescent pregnancy prevention and sexual health promotion for young people: a systematic review of European studies. Health education research 27(5): 904-13	- Exclude Systematic Review - checked for primary papers
Tolou-Shams, Marina, Houck, Christopher, Conrad, Selby M et al. (2011) HIV prevention for juvenile drug court offenders: a randomized controlled trial focusing on affect management. Journal of correctional health care : the official journal of the National Commission on Correctional Health Care 17(3): 226-32	- Exclude Data not useable
US Preventive Services Task, Force, Krist, Alex H, Davidson, Karina W et al. (2020) Behavioral Counseling Interventions to Prevent Sexually Transmitted Infections: US Preventive Services Task Force Recommendation Statement. JAMA 324(7): 674-681	- Exclude Systematic Review - checked for primary papers
Velasquez, Mary M, von Sternberg, Kirk, Johnson, David H et al. (2009) Reducing sexual risk behaviors and alcohol use among HIV-positive men who have sex with men: a randomized clinical trial. Journal of consulting and clinical psychology 77(4): 657-67	- Exclude publication year
Villar-Loubet, Olga, Jones, Deborah, Waldrop-Valverde, Drenna et al. (2011) Sexual barrier acceptability among multiethnic HIV-positive and at-risk women. Journal of women's health (2002) 20(3): 365-73	- Exclude population
Villegas, N, Santisteban, D, Cianelli, R et al. (2014) The development, feasibility and acceptability of an Internet-based STI-HIV prevention intervention for young Chilean women. International nursing review 61(1): 55-63	- Exclude Study design

Study	Code [Reason]
von Sadovszky, Victoria; Draudt, Breana; Boch, Samantha (2014) A systematic review of reviews of behavioral interventions to promote condom use. Worldviews on evidence-based nursing 11(2): 107-17	- Exclude Systematic Review - checked for primary papers
Wadham, E., Green, C., Debattista, J. et al. (2019) New digital media interventions for sexual health promotion among young people: A systematic review. Sexual Health 16(2): 101-123	- Exclude Systematic Review - checked for primary papers
Walsh S, Jenner E, Leger R et al. (2015) Effects of a Sexual Risk Reduction Program for African-American Adolescents on Social Cognitive Antecedents of Behavior Change. American journal of health behavior 39(5): 610-622	- Exclude outcomes not relevant
Wechsberg, W.M., Novak, S.P., Zule, W.A. et al. (2010) Sustainability of intervention effects of an evidence-based HIV prevention intervention for African American women who smoke crack cocaine. Drug and Alcohol Dependence 109(13): 205-212	- Exclude outcomes not relevant
Wenzel, Suzanne L., Cederbaum, Julie A., Song, Ahyoung et al. (2016) Pilot Test of an Adapted, Evidence-Based HIV Sexual Risk Reduction Intervention for Homeless Women. Prevention Science 17(1): 112-121	- Exclude Study design *Quasi-experimental design - no randomisation*
Wernette, GT, Plegue, M, Kahler, CW et al. (2018) A Pilot Randomized Controlled Trial of a Computer-Delivered Brief Intervention for Substance Use and Risky Sex during Pregnancy. Journal of women's health 27(1): 83-92	- Exclude population
Whiteley, Laura B, Brown, Larry K, Curtis, Virginia et al. (2018) Publicly Available Internet Content as a HIV/STI Prevention Intervention for Urban Youth. The journal of primary prevention 39(4): 361-370	- Exclude Intervention Type *Digital intervention*
Whiting, W., Pharr, J.R., Buttner, M.P. et al. (2019) Behavioral Interventions to Increase Condom Use Among College Students in the United States: A Systematic Review. Health education & behavior : the official publication of the Society for Public Health Education 46(5): 877-888	- Exclude Systematic Review - checked for primary papers
Widman, Laura, Golin, Carol E, Kamke, Kristyn et al. (2018) Sexual Assertiveness Skills and Sexual Decision-Making in Adolescent Girls: Randomized Controlled Trial of an Online Program. American journal of public health 108(1): 96-102	- Exclude School based intervention
Widman, Laura, Nesi, Jacqueline, Kamke, Kristyn et al. (2018) Technology-Based Interventions to Reduce Sexually Transmitted Infections and Unintended Pregnancy Among Youth. The Journal of adolescent health : official publication of the Society for Adolescent Medicine 62(6): 651-660	- Exclude Systematic Review - checked for primary papers

Study	Code [Reason]
Wilkerson, J Michael, Danilenko, Gene P, Smolenski, Derek J et al. (2011) The role of critical self-reflection of assumptions in an online HIV intervention for men who have sex with men. AIDS education and prevention : official publication of the International Society for AIDS Education 23(1): 13-24	- Exclude Intervention Type *Digital intervention with no HCP input*
Williams, Mark, Bowen, Anne, Atkinson, John S et al. (2012) An assessment of brief group interventions to increase condom use by heterosexual crack smokers living with HIV infection. AIDS care 24(2): 220-31	- Exclude Data not useable *Results for relevant outcomes are for a subgroup of participants reporting being sexually active at follow up but ns not reported so cannot extract data*
Williams, Mark; Bowen, Anne; Ei, Sue (2010) An evaluation of the experiences of rural MSM who accessed an online HIV/AIDS health promotion intervention. Health promotion practice 11(4): 474-82	- Exclude outcomes not relevant
Wilton, Leo, Herbst, Jeffrey H, Coury-Doniger, Patricia et al. (2009) Efficacy of an HIV/STI prevention intervention for black men who have sex with men: findings from the Many Men, Many Voices (3MV) project. AIDS and behavior 13(3): 532-44	- Exclude publication year
Wingood, Gina M, DiClemente, Ralph J, Villamizar, Kira et al. (2011) Efficacy of a health educator-delivered HIV prevention intervention for Latina women: a randomized controlled trial. American journal of public health 101(12): 2245-52	- Exclude population
Wingood, Gina M, Robinson, LaShun R, Braxton, Nikia D et al. (2013) Comparative effectiveness of a faith-based HIV intervention for African American women: importance of enhancing religious social capital. American journal of public health 103(12): 2226-33	- Exclude Intervention Type
Wingood, Gina M, Simpson-Robinson, LaShun, Braxton, Nikia D et al. (2011) Design of a faith-based HIV intervention: successful collaboration between a university and a church. Health promotion practice 12(6): 823-31	- Exclude Intervention Type
Wong, T., Pharr, J.R., Bungum, T. et al. (2019) Effects of Peer Sexual Health Education on College Campuses: A Systematic Review. Health promotion practice 20(5): 652-666	- Exclude Systematic Review - checked for primary papers
Wray, Tyler B, Kahler, Christopher W, Simpanen, Erik M et al. (2019) A Preliminary Randomized Controlled Trial of Game Plan, A Web Application to Help Men Who Have Sex with Men Reduce Their HIV Risk and Alcohol Use. AIDS and behavior 23(6): 1668-1679	- Exclude Intervention Type *Digital intervention with no HCP input*

Study	Code [Reason]
Wright, Erin, Fortune, Thierry, Juzang, Ivan et al. (2011) Text messaging for HIV prevention with young Black men: formative research and campaign development. AIDS care 23(5): 534-41	- Exclude qualitative - digital intervention
Yang, Xing, Fang, Ting, Mobarak, Siam Ai et al. (2020) Social network strategy as a promising intervention to better reach key populations for promoting HIV prevention: a systematic review and meta-analysis. Sexually transmitted infections 96(7): 485-491	- Exclude Systematic Review - checked for primary papers
Ybarra, M.L., Prescott, T., Mustanski, B. et al. (2019) Feasibility, Acceptability, and Process Indicators for Guy2Guy, an mHealth HIV Prevention Program for Sexual Minority Adolescent Boys. Journal of Adolescent Health 65(3): 417-422	- Exclude Intervention Type *digital intervention*
Ybarra, Michele L, Liu, Weiwei, Prescott, Tonya L et al. (2018) The Effect of a Text Messaging Based HIV Prevention Program on Sexual Minority Male Youths: A National Evaluation of Information, Motivation and Behavioral Skills in a Randomized Controlled Trial of Guy2Guy. AIDS and behavior 22(10): 3335-3344	- Exclude Intervention Type *Digital intervention*
Ybarra, Michele L, Prescott, Tonya L, Philips, Gregory L 2nd et al. (2016) Iteratively Developing an mHealth HIV Prevention Program for Sexual Minority Adolescent Men. AIDS and behavior 20(6): 1157-72	- Exclude Study design
Ybarra, Michele L, Prescott, Tonya L, Phillips, Gregory L 2nd et al. (2017) Pilot RCT Results of an mHealth HIV Prevention Program for Sexual Minority Male Adolescents. Pediatrics 140(1)	- Exclude Intervention Type *Digital intervention*
Ye, Shaodong, Yin, Lu, Amico, Rivet et al. (2014) Efficacy of peer-led interventions to reduce unprotected anal intercourse among men who have sex with men: a meta-analysis. PloS one 9(3): e90788	- Exclude Systematic Review - checked for primary papers
Young, I; Flowers, P; McDaid, L M (2015) Key factors in the acceptability of treatment as prevention (TasP) in Scotland: a qualitative study with communities affected by HIV. Sexually transmitted infections 91(4): 269-74	- Exclude Intervention Type
Zellner Lawrence, Tiffany, Henry Akintobi, Tabia, Miller, Assia et al. (2016) Assessment of a Culturally-Tailored Sexual Health Education Program for African American Youth. International journal of environmental research and public health 14(1)	- Exclude Study design
Zhang, Jingwen, Cederbaum, Julie A, Jemmott, John B 3rd et al. (2018) Theory-Based Behavioral Intervention Increases Mother-Son Communication About Sexual Risk Reduction Among Inner-City African-Americans. The Journal of adolescent health : official publication of the Society for Adolescent Medicine 63(4): 497-502	- Exclude Parenting intervention

Study	Code [Reason]
Zule, William A, Bobashev, Georgiy V, Reif, Susan M et al. (2013) Results of a pilot test of a brief computer-assisted tailored HIV prevention intervention for use with a range of demographic and risk groups. AIDS and behavior 17(9): 3045-58	- Exclude population

J.1 Economic studies

Study	Reason for exclusion
Cooper, Keith, Shepherd, Jonathan, Picot, Jo et al. (2012) An economic model of school-based behavioral interventions to prevent sexually transmitted infections. International journal of technology assessment in health care 28(4): 407-14	- Not a relevant intervention setting (school-based)
Dealy, Bern C, Horn, Brady P, Callahan, Tiffany J et al. (2013) The economic impact of project MARS (motivating adolescents to reduce sexual risk). Health psychology : official journal of the Division of Health Psychology, American Psychological Association 32(9): 1003-12	- Not a relevant intervention setting (youth detention centre)
Juusola JL, Brandeau ML, Long EF, Owens DK, Bendavid E (2011) The cost-effectiveness of symptom-based testing and routine screening for acute HIV infection in men who have sex with men in the USA. AIDS 25(14): 1779-1787	- Focused on increasing uptake of HIV testing
Krebs, Emanuel, Zang, Xiao, Enns, Benjamin et al. (2020) The impact of localized implementation: determining the cost-effectiveness of HIV prevention and care interventions across six United States cities. AIDS (London, England) 34(3): 447-458	- Intervention does not match one specified in the review protocol
Long, Elisa F, Mandalia, Roshni, Mandalia, Sundhiya et al. (2014) Expanded HIV testing in low-prevalence, high-income countries: a cost-effectiveness analysis for the United Kingdom. PloS one 9(4): e95735	- Focused on increasing uptake of HIV testing
Shepherd, J, Kavanagh, J, Picot, J et al. (2010) The effectiveness and cost-effectiveness of behavioural interventions for the prevention of sexually transmitted infections in young people aged 13-19: a systematic review and economic evaluation. Health technology assessment (Winchester, England) 14(7): 1-iv	- Not a relevant intervention setting (school-based)
Song, Dahye L, Altice, Frederick L, Copenhaver, Michael M et al. (2015) Cost-effectiveness analysis of brief and expanded evidence-based risk reduction interventions for HIV-infected people who inject drugs in the United States. PloS one 10(2): e0116694	- Population does not match one of the risk groups specified in the review question