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Behavioral Counseling Interventions to Prevent Sexually Transmitted Infections: A Systematic Evidence Review for the U.S. Preventive Services Task Force

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Prepared by:

Kaiser Permanente Evidence-based Practice Center
Kaiser Permanente Center for Health Research
Portland, OR

Investigators:

Jillian T. Henderson, PhD, MPH
Michelle Henninger, Ph.D.
Sarah I. Bean, MPH
Caitlyn A. Senger, MPH
Nadia Redmond, M.S.P.H
Elizabeth A. O'Connor, PhD

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Structured Abstract

Objective: To support an update to the USPSTF’s previous recommendation on Behavioral Counseling Interventions to Prevent Sexually Transmitted Infections, we systematically reviewed evidence on behavioral counseling interventions aimed at primary risk reduction for adolescents and adults.

Data Sources: Studies from the previous review were evaluated for inclusion, and we performed a comprehensive search of MEDLINE, PubMed (publisher-supplied only), PsycINFO, and the Cochrane Collaboration Registry of Controlled Trials for studies published between January 2013 and June 2018. A research librarian developed and executed the search strategy.

Study Selection: Two researchers independently reviewed 4,649 abstracts and 273 full-text articles against prespecified inclusion criteria, then abstracted data from included studies. English-language controlled clinical trials published after 1999 were included to assess the direct health benefits, intermediate behavioral changes, and potential harms of interventions screening for STI prevention. Trials with control conditions of usual care, no treatment, attention control, or waitlist were included. Included study populations were pregnant and nonpregnant adolescents or adults of any sexual orientation, sexually active or not. Studies conducted in existing social networks (e.g., school classrooms, clubs, churches) were excluded, as were studies of interventions for HIV-positive individuals only. Included interventions included behavioral counseling to reduce STI risk, delivered alone or in combination with other sexual risk-reduction interventions, that were feasible to implement in or refer from primary care. Studies reporting incidence of STI or protective and risky sexual behaviors such as condom use or unprotected intercourse were eligible for inclusion if followup data at least 3 months from baseline were reported.

Data Analysis: Eligible studies assessed to have high risk of bias (e.g., > 40% loss to followup) were excluded for poor quality according to standard USPSTF procedures. Descriptions of the study populations and intervention characteristics were provided for all included studies. The most consistently reported health and behavioral outcomes were analyzed with random effects meta-analysis to calculate pooled intervention effects when data were sufficient. We conducted meta-analyses of STI incidence, condom use, and unprotected intercourse, using the Dersimonian and Laird method or, when fewer than 10 trials were available for pooling, restricted maximum likelihood (REML) models with the Knapp-Hartung correction for small samples. We also examined differences in intervention effects by population, intervention, and study design characteristics, using planned and exploratory metaregression to identify sources of statistical heterogeneity for the main outcome of STI incidence. Finally, funnel plots and Egger tests for small-study effects were generated for all pooled analyses that included 10 or more studies. Using established methods, we assessed the strength of evidence for each key question.

Results: We included 39 studies (54 intervention arms) reported in 63 articles (n = 65,888), including 17 new studies not in the previous review. All but five studies were conducted in the United States, and one-third were good-quality trials. Over half of the studies enrolled women or girls only; nearly two-thirds were among adolescents or young adults; and over two-thirds reported that more than half of participants identified as a racial or ethnic minority. The

behavioral counseling interventions tested in the trials employed a range of behavior change strategies, with individual or group counseling a component of over two-thirds of the intervention arms. Eight trials tested interventions with low contact times (<30 minutes), and high contact time interventions (>120 minutes) were included in over half of the included trials. Behavior change techniques based on cognitive behavioral therapy or motivational interviewing were included in over one-third of the interventions, and the content of the interventions was often derived from concepts outlined in behavior change theories. Twenty-one studies reported STI outcomes. Meta-analysis spanning all studies providing adequate data showed that the interventions were associated with one-third lower odds of STI (19 RCTs; n=52,072; odds ratio [OR], 0.66 [95% CI, 0.54 to 0.81]; I² 74%) but statistical and clinical heterogeneity was high among studies. Behavioral outcomes were reported in 34 trials (n = 21,417), but inconsistency in measures used and outcomes reported limited meta-analysis. Eighteen studies reported condom use outcomes (n = 9,205). There was evidence that interventions were associated with increased condom use in meta-analysis of dichotomous reports such as consistent condom use (13 RCTs; n=5,253; odds ratio [OR], 1.31 [95% CI, 1.10 to 1.56]; I² 40%) and greater percentage times condoms were used with sexual intercourse (7 trials; n randomized = 2,920; mean difference [MD], 10.75 [95% CI, 1.01 to 20.50]; I² 79%). For studies reporting counts of unprotected intercourse (i.e., without a condom), measures were inconsistently defined with regard to the types of intercourse (vaginal, anal, any), time period assessed, and partnerships (e.g., any partner, non-primary partner). Behavioral interventions tested in studies that reported this outcome also were associated with a reduction in sexual risk behaviors. Intervention was associated with fewer unprotected sexual acts (14 RCTs; n = 9,183; mean difference [MD], -0.94 [95% CI, -1.40 to -0.48]; I² 16%). There was not evidence of small study effects. Meta-regression to assess potential sources of statistical heterogeneity was limited by correlated study features and the number of studies reporting STI outcomes. There was limited evidence suggesting potentially stronger effects for interventions that included group counseling or higher contact times (> 2 hours).

Limitations: Our search was limited to English-language literature. We excluded trials with active comparators (i.e., comparative effectiveness), conducted in existing social networks (e.g., clubs, schools, workplaces), interventions focused on reducing transmission among HIV-positive individuals, and people very high STI risk behaviors requiring specialized preventive care (e.g., IV drug using, engaged in sex work). Statistical and clinical heterogeneity were high for the included evidence. The direct evidence for STI prevention was consistent and precise, but the diversity of study populations, interventions, and effect sizes contributed to a wide range of effects. Factors explaining the range of effects were difficult to disentangle because they tended to be highly correlated. For behavioral outcomes, the outcomes reported and specific measures used were highly variable, and limited the estimation of pooled effects across studies such that only a subset of fewer than half of the included studies could be combined. Furthermore, self-reported behavioral outcomes, particularly those involving sexual practices, are likely to be affected by social desirability and recall bias. Men, older adults, gay, bisexual, and transgender people were not well-represented in the included study populations.

Conclusions: For individuals at increased risk for STI, there are effective behavioral counseling interventions for reducing STI incidence, by increasing condom use, and reducing sexual risk behaviors. There was no evidence of intervention harms, but few studies reported on potential adverse effects. Research is needed to address gaps in the literature on primary care feasible

behavioral interventions that could apply to more heterogeneous populations seen in primary care and to address the needs of specific populations at heightened risk for STI not represented in this body of evidence.

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Chapter 1. Introduction

Condition Background

Condition Definition

Sexually transmitted infections (STIs) are infections that are principally transmitted through intimate physical contact and sexual activity.¹ STIs with the greatest extensive public health impact in the United States are human immunodeficiency virus (HIV), hepatitis B (HBV), herpes simplex virus (HSV) 1 and 2, human papillomavirus (HPV), *Chlamydia trachomatis*, *Neisseria gonorrhoea*, *Treponema pallidum* (syphilis), and *Trichomonas vaginalis*.¹ Other conditions that can be spread through sexual contact include granuloma inguinale, chancroid, pubic lice, and *Sarcoptes scabiei* var. *hominis* (scabies). Bacterial vaginosis (BV), while not caused by a specific sexually transmitted pathogen, is an imbalance in the growth of normal vaginal microorganisms that is associated with sexual activity and is included condition for this review.

Etiology and Natural History

STIs are caused by three main types of pathogens: bacteria, including *Chlamydia* (*C.*) *trachomatis*, *Neisseria* (*N.*) *gonorrhoea*, and *Treponema* (*T.*) *pallidum*; viruses, such as HIV, HSV, HBV, and HPV; and parasites, including *Trichomonas* (*T.*) *vaginalis*. More than 30 different bacteria, viruses, and parasites are known to be acquired and spread through sexual activity, which includes vaginal, anal, and oral intercourse.² STIs can also be transmitted nonsexually via direct contact with bodily fluids (blood, saliva, semen) from an infected person (e.g., using or sharing contaminated needles, syringes, body piercing, or tattooing equipment).² Some untreated STIs in pregnant women can be transmitted vertically from the placenta to the womb or through the cervix during vaginal delivery.

Depending on the STI and specific health outcome, incubation and latency periods between infection, first symptoms and serious sequelae can be quite variable. For gonorrhoea, the incubation period can be as short as one day after exposure,³ while the incubation period for syphilis can range from 1 week to 3 months.⁴ In acute HBV, the latency period can be relatively short, occurring within 4 to 24 weeks post exposure;⁵ whereas the latency period for an HPV infection to manifest into a precancerous lesion in the cervix may take as long as 10-20 years.⁶ In many cases, individuals can have an STI without any noticeable signs or symptoms of an infection. For instance, it is estimated that 10 percent of men and 5 to 30 percent of women with laboratory confirmed chlamydia develop symptoms;⁷⁻⁹ In acute HBV and trichomoniasis infections, approximately 70 percent of men and women are asymptomatic.^{10, 11} Clinically undiagnosed or untreated STIs can progress to more serious health complications, such as pelvic inflammatory disease (PID), chronic pelvic pain, cancer, and infertility.¹² Mother-to-child transmission of STIs carry a significant risk of infant morbidity and mortality, including ectopic pregnancy, low birth weight, and premature birth, and stillbirth.¹³

Prevalence and Burden

According to the Centers for Disease Control and Prevention (CDC), there are more than 110 million cases of STIs in the United States¹³ and it is estimated that roughly 20 million new STI infections occur nationwide each year.¹³ An accelerating rise in rates of STI has been observed in the United States, with the most recent CDC surveillance data for the year 2018 showing the highest rates yet observed for combined cases of syphilis, gonorrhea, and chlamydia.¹⁴ Of particular concern, congenital syphilis cases increased 40 percent above the previous year, accompanied by a rise in the number of associated newborn deaths of which there were nearly one hundred. Access to STI screening and treatment programs and effective behavioral interventions are the health care system tools for reducing the burden of STI in the United States. Community programs and the social and political context also contribute to the STI epidemic and determine the resources available for addressing the complex needs of populations most at risk for STI.

Of patients presenting to STI clinics for testing, 17.5 percent of men who have sex with men (MSM) test positive for chlamydia and 26.5 percent test positive for gonorrhea. In men who have sex with women (MSW), 15 percent test positive for chlamydia and 14.6 percent test positive for gonorrhea. Finally, 11.5 percent of women presenting to STI clinics test positive for chlamydia and 7.4 percent test positive for gonorrhea.¹³ Although positivity rates are higher among individuals presenting at STI clinics, the majority of STI infections reported in the United States are diagnosed in other primary care settings.¹³ Along with the adverse physical, social, and psychological consequences, STIs create a steep economic burden for the United States' healthcare system: \$16 billion in direct health care costs each year, according to the CDC.¹⁵

Bacterial

Chlamydia

Chlamydia is the most commonly reported bacterial STI in the United States.¹⁴ In 2018, 1,758,668 cases (539.9 cases per 100,000 population, an increase of 2.9 percent compared with the rate in 2017) of chlamydia were reported to the CDC.¹⁴ However, due to the asymptomatic nature of *C. trachomatis*, an estimated 2.86 million cases occur annually.⁷ From 2017-2018, rates of reported chlamydia increased in both females and males, in all regions of the United States, and among all racial and Hispanic ethnicity groups. However, the highest prevalence rates were observed among adolescents and young adults age 20 to 24 years. In 2018, there were 2,472.0 cases per 100,000 population of chlamydia among persons age 20 to 24 years.¹⁴

Women have a higher population prevalence of reported chlamydia (692.7 cases per 100,000 females) compared with males (380.6 cases per 100,000 males), but greater increases in reported cases have been observed for men; cases among men increased 37.8 percent during 2014-2018, compared with an 11.4 percent increase in women. The rate of reported cases among non-Hispanic Blacks was 5.6 times higher compared the rate among non-Hispanic Whites (1,192.5 and 212.1 cases per 100,000 population, respectively). Prevalence was also highest in the South (565.2 cases per 100,000 population).¹⁴

If left undiagnosed or untreated, chlamydia can result in PID, which causes inflammation and damage to the fallopian tubes. The progression of PID can lead to serious health outcomes, including infertility, ectopic pregnancy, endometritis, and chronic pelvic pain.¹² Data from prospective studies estimate that 10 to 15 percent of untreated chlamydial infections progress to clinically diagnosed, symptomatic PID.^{7, 16, 17} In men, untreated chlamydia can cause urethritis and, in rare cases, epididymitis.⁷

Gonorrhea

While the national rate of reported cases of gonorrhea reached a historic 40-year low in 2009 (98.1 cases per 100,000 population), rates have since increased and continue to do so.¹⁴ In 2018, 583,405 cases of gonorrhea (171.9 cases per 100,000 population) were reported to the CDC, reflecting a 82.6 percent increase from 2009.¹⁴ Although rates in both men and women increased, prevalence was higher in men (212.8 cases per 100,000 males) compared with women (145.8 cases per 100,000 females). The South had the highest rate of reported gonorrhea cases (194.4 per 100,000 population) in 2018, compared with the other three regions of the United States.¹⁴

N. gonorrhoeae infects the mucous membranes of the reproductive tract, including the cervix, uterus, and fallopian tubes in women, and the urethra in both men and women.³ Untreated gonorrhea can lead to PID, ectopic pregnancy, infertility, as well as an increased risk of HIV infection.³ The vertical transmission of gonorrhea can cause blindness, joint infection, or life-threatening infections in the infant.³ The increasing incidence and prevalence of antimicrobial resistant cases of gonorrhea have greatly contributed to its burden. The CDC estimates that 246,000 cases of *N. gonorrhoeae* infection are resistant to any antibiotic, including cefixime, ceftriaxone, azithromycin, and tetracycline).¹⁸ Moreover, in the event *N. gonorrhoeae* becomes widespread, the public health impact during a 10-year period is estimated to be 75,000 additional cases of PID, 15,000 cases of epididymitis, and 222 additional HIV infections.¹⁸

Syphilis

Primary and secondary (P&S). In 2000 and 2001, the rate of reported primary stage and secondary stage (defined below) syphilis cases reached a historic low. However, much like gonorrhea, P&S syphilis rates have risen almost every year since.¹⁴ In 2018, 35,063 cases of P&S syphilis (10.8 cases per 100,000 population) were reported to the CDC, up 14.9 percent from 2017.¹⁴ Rates increased in both men and women, in all racial and Hispanic ethnicity groups, and in all regions of the United States. Prevalence was higher among men (18.7 cases per 100,000 males) compared with women (3.0 cases per 100,000 females).¹⁴ Men accounted for 85.7 percent of P&S syphilis infections, and 53.5 percent of cases were MSM. Prevalence was highest among non-Hispanic Blacks (28.1 per 100,000 population) and Native Hawaiian/Other Pacific Islanders (16.3 per 100,000 population).¹⁴ From 2017-2018, P&S syphilis increased in every region of the United States; the West had the highest prevalence of reported cases (15.0 cases per 100,000 population).¹⁴

Undiagnosed and untreated P&S syphilis can lead to sores (primary stage), which can develop into rashes or lesions around the mouth, genitals, or anus (secondary stage). In severe cases, syphilis can infect the internal organs and result in death (tertiary stage).⁴ At any stage of the

infection, syphilis can impact the nervous system and cause a wide range of symptoms, such as difficulty coordinating muscle movement, sensory deficits, dementia, and paralysis.⁴

Congenital. In 2018, 1,306 cases (33.1 cases per 100,000 live births) of congenital syphilis were reported to the CDC, which included 78 syphilitic stillbirths and 16 infant deaths, and represents a 39.7 percent increase in cases from 2017. Rates of congenital syphilis were highest among non-Hispanic Blacks (86.6 cases per 100,000 live births), followed by American Indians/Alaska Natives (79.2 cases per 100,000 live births), and Hispanics (44.7 cases per 100,000 live births).¹⁴ In 2018, the highest congenital syphilis rates were reported in the West (48.5 cases per 100,000 live births).¹⁴ Untreated syphilis in pregnancy can gravely affect maternal and fetal outcomes, including stillbirth or fetal loss and premature birth, low birthweight, congenital syphilis, and neonatal death in live-born infants.⁴

Parasitic

Trichomoniasis Vaginalis

It is estimated that 3.7 million people are infected with trichomoniasis in the United States.¹⁰ Because trichomoniasis is not a nationally reported condition, current detailed trend data are limited.¹³ According to data from the National Health and Nutritional Examination Survey (NHANES) from 2013–2014, the estimated prevalence of *T. vaginalis* infection among adults age 18 to 59 years, was 0.5 percent among males and 1.8 percent among females with the highest prevalence among non-Hispanic Black males (4.2%) and females (8.9%).^{19, 20}

Roughly 70 percent of *T. vaginalis* cases are asymptomatic.¹⁰ In symptomatic persons, trichomoniasis may cause itching or irritation of the genitals, burning or discomfort with urination, and/or discharge from the penis or vagina that varies in color (clear, white, yellow, green), with an unusual fishy odor.¹⁰ Untreated trichomoniasis carries a significant risk of poor birth outcomes, such as preterm delivery, low birth weight, premature rupture of membranes, and PID.^{21, 22}

Viral

Human Immunodeficiency Virus (HIV)

Currently, more than 1.1 million people (age 13 years or older) are estimated to be living with HIV, including 162,500 persons (1 in 7) whose infections have not been diagnosed.²³ Since the height of the HIV epidemic in the mid-1980s, newly diagnosed HIV infections have declined in the United States. According to CDC's most recent HIV surveillance report, from 2012 to 2016, the annual rate of diagnoses of HIV infection decreased and the annual number of diagnoses remained stable.²⁴ In 2017, 38,739 people were diagnosed with HIV, down approximately 3 percent from the previous year's report. However, numbers and rates of diagnoses varied by subgroup; for example, HIV diagnoses decreased by 9 percent in women and increased by 13 percent in 25- to 34-year-olds and 25 percent in White people who injected drugs.²⁴ Diagnosis rates in MSM remained stable from 2012-2016, but still account for the majority (67%) of all diagnoses in 2017.²⁴ In terms of prevalence, male adolescents and adults are disproportionately

affected by HIV (303.0 per 100,000 population) compared with female adolescents and adults (89.8 per 100,000 population).²⁴ At the end of 2016, adults age 50 to 54 years had the highest prevalence (777.6 per 100,000 population).²⁴ Among racial/ethnic groups, non-Hispanic Blacks/African Americans made up the largest percentage (41%) of persons living with HIV, a rate of 538.8 per 100,000 population.²⁴

HIV weakens the immune system by specifically targeting CD4 lymphocytes (T cells), which aide the body in fighting off infections and diseases. If left untreated, HIV reduces the number of T cells, making the body more susceptible to illnesses and, in more advanced stages (i.e., AIDS), opportunistic infections or cancers.²⁵

Human Papillomavirus (HPV)

HPV is the most common sexually transmitted infection in the United States.²⁶ The CDC estimates that 79 million Americans are infected with HPV, and 14 million new HPV infections occur each year.²⁶ Based on data from NHANES from 2013 to 2014, any genital HPV among adults ages 18 to 69 years was 42.5 percent.²⁷ Men ages 18 to 59 years had a higher prevalence of genital HPV (45.2%), oral HPV (11.5%), and high-risk genital HPV (25.1%) compared with women age 18 to 59 years (39.9% genital HPV; 3.3% oral HPV; 20.4% high-risk genital HPV).²⁷ Non-Hispanic Black adults age 18 to 59 years had the highest prevalence of genital, oral, and high-risk HPV among the total population and among men and women.²⁷

Low-risk HPV infection can cause genital warts and cervical dysplasia, with a minimal risk of progressing to cancer. Persistent high-risk HPV infection can develop to HPV-associated cancers (specific cancers that are diagnosed at site of HPV infection).²⁶ The CDC estimates that 33,737 HPV-associated cancers occur in the United States each year, affecting roughly 20,260 women and 13,477 men.²⁸ Cervical cancer is the most common HPV-associated cancer among women; oropharyngeal cancers are the most common among men.²⁸ There is a vaccine to prevent infection from HPV-associated cancers and genital warts, but HPV is not treatable. HPV infections are often transitory, and spontaneously cleared by the immune system, but roughly 10 percent of women with high-risk HPV on their cervix will develop long-lasting HPV infections, which can increase their risk of cervical cancer.²⁹

Since the introduction of the HPV vaccine in 2006 for females and in 2011 for males, vaccination rates have steadily increased among adolescents age 13 to 17 years and adults age 19 to 26 years in the United States. From 2010 to 2015, HPV vaccination increased from 20.7 percent to 41.6 percent in females age 19 to 26 years.³⁰ Among males ages 19 to 26 years, HPV vaccination increased from 2.1 percent in 2011 to 10.1 percent in 2015.³⁰ In 2016, 60.4 percent (65.1% females; 56.0% males) of adolescents age 13 to 17 years received one or more doses of HPV vaccine, a 4 percent increase from 2015.³¹ Additionally, 43.4 percent of adolescents (49.5% females; 37.5% males) were up to date with the HPV vaccination series.³¹ However, despite the increase in vaccination rates, HPV vaccine uptake remains lower than the Healthy People goal of 80 percent coverage in the United States³² and racial/ethnic disparities in HPV prevalence, have been attributed to uneven vaccination rates, with lower coverage among non-Hispanic Black and Mexican-American adolescent and young adult females.³³

Herpes Simplex Virus (HSV) 1 & 2

The CDC estimates that 11.9 percent of men and women ages 14 to 49 years have HSV-2 (the most common cause of genital herpes); however, due to an increasing number of genital herpes infections caused by HSV-1 (the most common cause of oral herpetic lesions), the overall prevalence of genital herpes is likely higher.³⁴ Published estimates of the percentage of genital herpes infections caused by HSV-1 range from 32 to 43 percent.³⁵ HSV-2 infection is more prevalent in women age 14 to 49 years (15.9%), compared with men ages 14 to 49 years (8.2%).³⁴ Among racial/ethnic groups, the prevalence of HSV-2 infection is higher among non-Hispanic Blacks (34.6%) compared with non-Hispanic Whites (8.1%).³⁴ HSV-1 infection is more prevalent in women age 14 to 49 years (20.3%), compared with men age 14 to 49 years (10.6%).³⁴ In most cases, HSV-1 and HSV-2 infections are asymptomatic or have very mild symptoms that may go unnoticed or be mistaken for another skin condition.^{34, 36} It is estimated that 87.4 percent of individuals ages 14 to 49 with HSV-2 have never received a clinical diagnosis.³⁴

During a symptomatic infection, HSV-1 and HSV-2 can cause painful lesions on the genitals, which can be particularly severe and persistent in people with suppressed immune systems.³⁷ Small blisters or ulcers may also appear around the mouth, rectum, or on the buttocks, groin, thighs, fingers, or eyes. There is an estimated 2- to 4-fold increased risk of acquiring HIV infection if an open lesion is exposed to HIV.³⁸⁻⁴⁰ In rare cases, both HSV-1 and HSV-2 can cause blindness, encephalitis, and aseptic meningitis.³⁴ Pregnant women can pass herpes infection to their infants (neonatal herpes). The risk of perinatal transmission is higher during the first outbreak of symptoms (e.g., blisters) than with a recurrent outbreak of symptoms.³⁷

Hepatitis B (HBV)

Based on data from NHANES from 2007 to 2012, 3.9 percent of noninstitutionalized adults have ever been infected with HBV.⁴¹ It is estimated that 800,000 to 1.4 million people (0.3%) are currently living with chronic HBV in the United States.⁴² Since 1999, chronic HBV prevalence in non-Hispanic Blacks has been 2- to 3- fold greater compared with the general population.⁴¹ In 2012, 3.1 percent of non-Hispanic Asians were chronically infected with HBV, marking a 10-fold greater prevalence than the general population.⁴¹ The estimated prevalence of chronic HBV infection among pregnant women is 0.7 to 0.9 percent, placing more than 25,000 infants at risk for infection.⁴²

HBV is a blood borne virus that affects the liver by causing acute or chronic infections. Roughly 70 percent of people with acute infections are asymptomatic; the other 30 percent experience symptoms of liver disease (e.g., abnormal pain and swelling, jaundice, chronic fatigue).¹¹ A small subset of acute cases will progress to chronic HBV, which increases the odds of liver cancer 50 to 100 times.¹¹ Vaccination is the primary means for preventing HBV infection.⁴³ The CDC's Advisory Committee on Immunization Practices (ACIP) recommends testing all pregnant women for HBV; universal HBV vaccine for all infants within 24 hours of birth, followed by completion of the vaccine series; vaccination of children and adolescents <19 years of age who have not been previously vaccinated; and vaccination of adults at risk for HBV infection. In

infants HBV vaccine is typically given as a series of 2 to 4 injections typically completed by six months of age.⁴³

Risk Factors

The unequal distribution and patterns of STI rates are influenced by physiology, behaviors, and importantly, by social and structural inequalities.⁴⁴⁻⁴⁶ Unequal access to health care and limited resources for free or low cost clinical and public health programs to prevent STI contribute to differences in prevalence across subpopulations, as do historical and ongoing racial and ethnic disparities in the distribution of resources. Some communities and regions of the United States are at greater risk of STI based on the interaction of these and other factors. Individuals in sexual networks that have higher STI prevalence rates face a greater risk of exposure in each sexual encounter compared with those in lower prevalence sexual networks.⁴⁷ STI rates are highest in groups with less access to screening, diagnosis and treatment, more potential exposures (i.e., sexual partners), and lower use of protective interventions.

The terms female and male generally refer to the sex on one's birth certificate and therefore seemingly gendered terms used in this report and in the studies reviewed may include cisgender, transgender and gender nonbinary people. Nevertheless, a person's sex assigned at birth is an important determinant of sexual health outcomes. For instance, due to the asymptomatic nature of STIs, the female reproductive tract is uniquely vulnerable to the long-term complications of infection.³² In 2017, 1,127,651 cases of chlamydia were reported to the CDC among females (687.4 cases per 100,000 females), compared with 577,644 reported cases among males (363.1.5 cases per 100,000 males).¹³ Undiagnosed or untreated chlamydial infection in females can lead to PID, which can damage the fallopian tubes and increase the risk of infertility. It is estimated that tubal factor infertility accounts for 30 percent of female infertility in the United States, and much of this damage results from previous episodes of PID.³² Men can also be asymptomatic for both bacterial and viral STIs, which contributes to ongoing transmission in the absence of treatment. Uncircumcised males are at an increased risk for STIs. Randomized controlled trials (RCTs) conducted in sub-Saharan Africa found that male circumcision can reduce heterosexual HIV acquisition by 50 to 60 percent.⁴⁸⁻⁵² Additionally, male circumcision has been shown to decrease the risk of genital herpes and high-risk HPV infection.⁵³

Adolescents and young adults who are sexually active have higher rates of STIs, particularly chlamydia gonorrhea and HPV, compared with other age groups.¹³ Data from a recent systematic review by Falasinnu and colleagues reported that younger age was consistently associated with an increased risk of STIs.⁵⁴ Published incidence and prevalence estimates indicate that half of all new STIs occur in young people ages 15 to 24 years and one in four sexually active adolescent females has an STI.¹⁴ Risks of acquiring an STI are even higher among those who begin sexual activity earlier in adolescence, have multiple sexual partners (either concurrently or sequential sexual partners of limited duration), participate in other high-risk behaviors (such as alcohol or drug abuse), or live in detention facilities. Furthermore, adolescents may be more biologically susceptible to infection (for example, due to cervical ectopy in adolescent females) and may also lack adequate access to health care.^{13, 55} Stigma and shame, distrust in health care providers, and limited access to confidential reproductive health

services for adolescent boys and girls and young adults, can also contribute to higher prevalence of infection since STI information, screening, treatment may be more difficult to obtain.

Higher rates of STIs are observed in certain racial and ethnic groups. For example, while rates of chlamydia have been increasing among all groups, rates of chlamydia among Black women and men in 2017 were 5 times and 6.6 times higher, respectively, than among White women and men.¹³ Likewise, in 2017, the rate of chlamydia in American Indians/Alaska Natives was 3.7 times higher; in Native Hawaiians/Pacific Islanders, 3.4 times higher; and in Hispanics, 1.9 times higher than in Whites. Asians had the lowest rate of chlamydia in 2017; the rate among Whites was 1.6 times higher than among Asians. It is thought that race and ethnicity may be surrogate markers for other social characteristics (such as income, employment, insurance coverage, and educational level) and interpersonal networks related to sexual activity or drug-use that are associated with increased STI risk.⁵⁶ Even without these disparities, it is also possible that factors such as fear and distrust of health care organizations, language barriers, and perceived or actual discrimination may impact decisions to seek medical care in certain racial or ethnic groups.¹³

Rates of STIs are higher among men who have sex with men (MSM), compared with rates in heterosexual women and men.¹³ For example, MSM accounted for over 68 percent of reported cases of primary and secondary syphilis during 2017, and this percentage has been increasing over time. Factors that may contribute to higher rates of STIs in MSM include the number of lifetime partners, the number of recent or current sex partners, frequency of engaging in sex without using condoms, and experiences of stigma or discrimination that may increase high risk sexual behavior or barriers to STI preventive care and treatment.¹³ MSM, WSW, and gender minorities such as transgender individuals can encounter challenges accessing non-judgmental health care and inclusive health education. Data on STI rates among transgender individuals are not collected at the national level and gender identity data are not routinely collected, therefore data on MSM likely include STI rates for transgender women. In the United States, the prevalence of HIV among transgender women is 27.7% among all transgender women and 56.3% among black transgender women.⁵⁷ Lifetime rates of other STIs in transgender women have been reported as 1.4% for P&S syphilis in Whites compared to 21.6% and 14.7% in Hispanics and Blacks, respectively. Rates of HBV infection are 6.5% among Whites compared to 36.0% in Hispanics and 35.5% in Blacks.⁵⁸ There are limited data on HIV prevalence in transgender men. One study reported that only 2% of a national sample of transgender men were HIV-infected; however, 91% had been diagnosed with an STI at some point in the past.⁵⁹

Intravenous drug users demonstrate greater risk for HIV and HBV. They are also at greater risk for other STIs if they engage in transactional sex or engage in sex while using drugs or alcohol. A recent review by Medina-Perucha and colleagues found six primary factors that were associated with higher risk of STIs in women using heroin or other drugs.⁶⁰ These factors included lack of condom use, engaging in transactional sex, experiencing sexual violence, sexual activity (e.g., greater number of sexual partners, frequency of sexual activity), type and characteristics of sexual partners (e.g., heterosexual women reported less casual sex compared with bisexual or lesbian women), and engaging in drug use with sex partners.

Additional subpopulations that have higher STI risk include: ¹ transgender men and women,¹ current or former inmates,⁶¹ people with a history of sexual assault and/or abuse,¹ and sex

workers.⁶² Disproportionate rates of STIs among marginalized populations are closely tied to social and economic factors such as low economic status, insurance coverage, social stigma, and level of education, which limit access to healthcare services and hinder health literacy. Social barriers to prevention, such as intimate partner violence (IPV) and gender-based power imbalance, are also important predictors of STI.^{63, 64} Studies have shown that IPV, relationship power imbalances are associated with inconsistent condom use and subsequently higher STI risk.^{63, 65-68} Women and men experiencing partner abuse may be less likely to negotiate protected sex due to fear and power inequality within their relationships. Other risk factors for STIs include: commercial, survival or coerced sex;¹ high number of new or multiple sexual partners in recent months;⁶⁹ sex partner with concurrent partners;⁶⁹ sexual intercourse under the influence of mind-altering substances;¹ and sexual intercourse with a partner who has an STI or is at high risk for an STI.^{1, 54}

Individuals who continue to have sex with partners who have an STI, or their partners remain untreated are at greater risk of reinfection. The CDC STD Treatment Guidelines (2015)¹ recommend rescreening 3 months after treatment for chlamydia, gonorrhea, or trichomoniasis. Likewise, individuals who are diagnosed with syphilis should receive followup serologic syphilis testing. Unless prohibited by state laws or regulations, the CDC also recommends that health care providers offer STI Expedited Partner Therapy (EPT; also known as patient-delivered partner therapy) to patients who are diagnosed with a STI. EPT allows the patient to provide medications or prescriptions to their partners without requiring them to be examined by a medical provider. According to the CDC guidelines, there is substantial evidence that EPT results in decreased rates of reinfection of chlamydia (20% reduction of reinfection at followup) and gonorrhea (50% reduction).

High rates of STI in the United States and documented disparities arise from a host of factors beyond individual behaviors, as noted in the previous two sections. Nevertheless, individuals at risk that obtain health care might benefit from interventions aimed at increasing protective behaviors and providing support and skills for reducing potential STI exposure. Those most at risk for STI may require interventions that acknowledge and address the broader social context that frames their experience and needs.

Sexual Health History and Risk Assessment

Primary care physicians play a crucial role in evaluating a patient's risk of contracting STIs. They can accomplish this during primary care visits by conducting an inclusive and comprehensive sexual health history, which assesses an individual's sexual activity and related behaviors that increase their risk for developing an STI and becoming pregnant.^{70, 71} Key elements to a sexual health history include an individual's sexual orientation; frequency of sexual activity and the number of partners; and type of sexual engagement (e.g., penile-vaginal intercourse, oral sex, anal sex).⁷⁰ These are often referred to as the Five P's: partners, practices, prevention of pregnancy, protection from STIs, and past history of STIs.^{1, 70} Numerous national organizations, including the American Academy of Pediatrics,⁷² the Centers for Disease Control and Prevention (CDC),¹ the American Academy of Family Physicians (AAFP),⁷³ and the American College of Obstetrics and Gynecology (ACOG)^{74, 75} recommend that physicians periodically obtain a sexual history or sexual risk assessment and discuss risk reduction with all

patients. Additionally, these organizations and others have developed sexual history-taking or sexual risk assessment tools that providers can utilize in primary care to enable comprehensive, nonjudgmental risk assessment and obtain more complete and accurate information from patients.^{71, 76}

Behavioral Counseling Interventions to Prevent STIs

After determining STI risk, clinicians can reduce a patient's future risk of contracting an STI by providing or referring patients for behavioral counseling aimed at increasing their likelihood of engaging in safer sexual practices and reducing sexual risk behaviors. While the availability of biomedical interventions to reduce transmission of viral STI (e.g., HIV pre-exposure prophylaxis, hrHPV vaccination) and bacterial STI (expedited partner treatment with antibiotics) has increased, the emphasis of behavioral counseling is on supporting individual health protective behaviors such as increasing condom use and reducing sexual risk behaviors. Guidance from the CDC cautions that in order to be effective, prevention counseling must be done in a nonjudgmental and empathetic way that is suitable to the patient's culture, gender identity, language, age, and gender of sexual partners.¹ As part of the prevention message, health care providers should educate patients on how to reduce their risk of STI transmission, including abstinence, correct and consistent condom use, and limiting the number of sex partners.^{1, 77} An interactive approach that is tailored to the patient's personal risk has been shown to be effective, as well as behavioral counseling that utilizes personalized goal-setting, motivational interviewing, and client-centered counseling.¹ Motivational interviewing is a behavior change technique that is used to increase motivation and commitment to change, help patients identify the problematic behaviors that the individual is most willing and able to change, help patients feel a sense of agency for promoting their own health. The CDC maintains a website of interventions it considers effective for HIV risk-reduction, including over 25 behavioral interventions tailored for a variety of different populations.⁷⁸ They commonly include motivational and cognitive-behavioral elements such as skills development with role-play, communication or negotiation training, values clarification exercises, and problem-solving.

Current Clinical Practice and Recommendations of Others

In 2015 the CDC issued new prevention guidelines for STIs, recommending that all providers routinely obtain a sexual history from their patients and encourage risk-reduction strategies, including prevention counseling.¹ ACOG echoed this recommendation and encourages providers to discuss contraception and STI risks with both adolescent and adult patients.^{74, 75, 79} Similarly, the AAP recommends that pediatricians and other health care providers actively support and encourage the consistent and correct use of condoms with adolescent patients and promote communication between parents and adolescents regarding healthy sexual development and appropriate contraception use.⁷² NICE recommends that upon identifying patients at high-risk for contracting an STI, providers should have one-on-one structured discussions aimed at encouraging preventive behaviors to reduce their risk.⁸⁰ Among vulnerable adolescents, they recommend that when appropriate, health practitioners provide one-on-one counseling, which includes education on how to prevent and/or get tested for STIs. The Society of Adolescent Health and Medicine (SAHM) recommends that health care providers provide STI and HIV

education, counseling, and services to all adolescents, and that these services are incorporated into well-adolescent and contraception visits. A list of recommendations from other organizations can be found in **Appendix B Table 1**.

Surveys examining STI counseling practices among physicians in the United States have shown varied results. A survey of 508 pediatricians found that only 28 percent offered sexual risk reduction guidance to more than three-quarters of the parents of their adolescent patients.⁸¹ Similarly, a recent retrospective, cross-sectional study of 1000 randomly selected adolescent well-child visits found that only 21.2 percent had a documented sexual history⁸² and another study utilizing patient chart reviews found that sexuality-related education was provided to fewer than 20 percent of adolescent patients.⁸³ Conversely, 88 percent of 541 Pennsylvania primary care physicians reported asking their adolescent and young adult patients (ages 15 to 25 years) about sexual activity; 80 percent reported counseling those patients about STI/HIV transmission and prevention.⁸⁴ In the same study, however, 70 percent of the clinicians believed STI counseling in general to be ineffective. Higher compliance was also reported in a recent survey of 1,154 practicing OB/GYNs, which found that 63 percent reported routinely asking patients about their sexual activity and history.⁸⁵ Primary care physicians frequently reported insufficient time as the main barrier to providing STI and/or HIV counseling during a patient visit.^{77, 86, 87} Other barriers reported include insufficient staff, lack of comfort discussing sexual health-related topics, and inadequate knowledge.⁸⁶⁻⁸⁹

Previous USPSTF Recommendation

Identifying patients at risk for STIs and identifying effective behavioral interventions to reduce future infections is an important clinical step for primary and secondary preventive interventions in primary care. Screening and treatment are also important for secondary prevention of STIs, and the USPSTF provides several recommendations. For example, the USPSTF recommends early screening for syphilis infection in all pregnant women (A recommendation) as well as in nonpregnant adolescents and adults who are at increased risk for infection (A recommendation).^{90, 91} The USPSTF also recommends screening for chlamydia and gonorrhea in sexually active women aged 24 years and younger, as well as older women who are at increased risk for infection (B recommendations – currently being updated), but found insufficient evidence to recommend screening for chlamydia and gonorrhea screening in sexually active men. The USPSTF also recommends screening for hepatitis B infection in persons at high risk for infection (B recommendation).⁹² The USPSTF recommends against routine serologic screening for genital HSV in asymptomatic adolescents and adults, including those who are pregnant (D recommendation).⁹³ Finally, the USPSTF has previously concluded that there is insufficient evidence to recommend routine screening pelvic examinations for asymptomatic women who are not at increased risk for any specific gynecologic condition, including STIs (I recommendation).⁹⁴ An important opportunity to discuss sexual health risks and to recommend behavioral counseling interventions may occur when patients are identified for STI screening in primary care on the basis of existing USPSTF guidelines.

In 2014, the USPSTF recommended intensive behavioral counseling for all adolescents who are sexually active adolescents and for adults at an increased risk for sexually transmitted infections (B recommendation).⁹⁵ They found adequate evidence that intensive behavioral counseling

interventions reduced the likelihood of STIs in sexually active adolescents and among adults at increased risk for STI.⁹⁵ Additionally, the USPSTF found adequate evidence that intensive interventions reduced risky sexual behaviors and increased the likelihood of condom use and other protective sexual practices. They found adequate evidence that the harms of behavioral interventions to reduce the likelihood of STIs were small at most, with the primary harm being the opportunity cost associated with intensive behavioral counseling.⁹⁵ The USPSTF concluded with moderate certainty that intensive behavioral counseling interventions reduce the likelihood of STIs in sexually active adolescents and in adults who are at an increased risk, resulting in a moderate net benefit.

Chapter 2. Methods

Scope and Purpose

This systematic review will provide updated evidence regarding the effectiveness of behavioral counseling interventions to reduce risky sexual behavior and promote protective sexual behaviors in reducing STI incidence and/or related morbidity and mortality, as well as the potential harms associated with these interventions. The USPSTF will use this review to update its 2014 recommendation for primary care practices.⁹⁵ This review includes all trials from the previous review⁹⁶ that met current inclusion/exclusion criteria as well as newly identified studies.

Key Questions and Analytic Framework

Using the USPSTF's methods (detailed in **Appendix A**), we developed an analytic framework (**Figure 1**) and three Key Questions (KQs).

The KQs are:

1. Do behavioral counseling interventions that aim to decrease risky sexual behaviors or increase protective behaviors, or both, reduce sexually transmitted infections (STIs) or related morbidity and mortality?
 - a. Does the effectiveness of behavioral counseling interventions differ for subpopulations (e.g., defined by age, STI history, sexual orientation, gender, pregnancy status)?
 - b. Does the effectiveness of behavioral counseling interventions differ by intervention characteristics (e.g., intensity or mode)?
2. Do behavioral counseling interventions decrease risky sexual behaviors or increase protective behaviors that can reduce the risk of STIs?
 - a. Does the effectiveness of behavioral counseling interventions differ for subpopulations (e.g., defined by age, STI history, sexual orientation, gender, pregnancy status)?
 - b. Does the effectiveness of behavioral counseling interventions differ by intervention characteristics (e.g., intensity or mode)?
3. What potential harms are associated with behavioral counseling interventions to reduce STI infections?

Data Sources and Searches

In addition to considering all studies from the previous review for inclusion in the current review, we performed a comprehensive search of MEDLINE, PubMed (publisher-supplied only), PsycInfo, and the Cochrane Collaboration Registry of Controlled Trials for studies published between January 2013 and June 2018. This search was designed to partially overlap with the end search dates of the previous USPSTF commissioned review of this topic, and to identify new studies. Studies included in the previous USPSTF review were evaluated for inclusion against

the inclusion and exclusion criteria for the current review. A research librarian developed and executed the search, which was peer-reviewed by a second research librarian (**Appendix A**).

We also examined the reference lists of other previously published reviews, meta-analyses, and primary studies to identify additional potential studies for inclusion. We supplemented our searches with suggestions from experts and articles identified through news and table-of-contents alerts. We also searched ClinicalTrials.gov (<https://ClinicalTrials.gov/>) for ongoing trials (**Appendix G**). We imported the literature from these sources directly into EndNote® X9 (Thomson Reuters, New York, NY).

Study Selection

Two reviewers independently reviewed the titles and abstracts of all identified articles to determine whether studies met inclusion and exclusion criteria for design, population, intervention, and outcomes (**Appendix A Table 1**). Two reviewers then independently evaluated the full-text article(s) of all potentially included studies against the complete inclusion and exclusion criteria. Disagreements regarding the abstract and/or full-text review were resolved by discussion and consultation with a third reviewer if necessary. Excluded studies and reasons for exclusion are listed in **Appendix D**.

We developed an *a priori* set of criteria for inclusion and exclusion of studies based on our understanding of the literature (**Appendix A Table 1**). For all KQs, included studies were required to target sexual behavior change for the prevention of STI. The review included studies conducted among adults and adolescents of any sexual orientation, including pregnant individuals. We included randomized controlled trials (RCTs) and nonrandomized controlled trials reporting STI or behavioral outcomes assessed at 3 months postbaseline or longer. Comparative effectiveness trials were excluded; included studies compared the intervention to attention control, minimal intervention, usual care, or no treatment (e.g., waitlist) conditions. Included interventions involved behavioral counseling, including but not limited to the provision of education, skills training, or guidance on how to change sexual behaviors to prevent STI. Studies aimed solely at targeting behavior change to prevent unintended pregnancy or change behaviors associated with risky sexual behavior (e.g., substance use disorder, interpersonal violence) were not included, nor were those assessing the impact of circumcision to prevent HIV/STI, involving HIV/STI testing only, or testing biomedical prevention interventions. Included studies were conducted in or recruited from primary care settings, which included family planning clinics, STI clinics, and behavioral/mental health clinics. Studies recruited from the community involving individual media-based interventions (computer, email, text messages) were considered for inclusion if all other inclusion criteria were met, and a comparable population, recruitment approach, and intervention would be feasible in a primary care setting. Studies involving recruitment through or conducted within pre-existing social networks (e.g., worksites, school, classrooms, social clubs, churches) were not included. Studies enrolling individuals living with HIV were included, unless the study was entirely limited to this population since interventions designed solely for HIV positive populations predominantly focus on preventing STI transmission and increasing HIV treatment adherence and tend to include provision of specialized clinical care. We also did not include studies limited to populations

requiring complex, specialized interventions outside the scope of primary care to address their specific STI risk (e.g., HIV serodiscordant couples, commercial sex workers). The review was limited to studies conducted in countries categorized as “very high” on the Human Development Index (2016) published by the United Nations Development Programme.⁹⁷

We limited our included studies to those published in English and deemed good- or fair-quality based on USPSTF quality rating standards.⁹⁸ There were two minor but notable changes to the scope of this review relative to the previous 2014 review. The current review excluded studies providing only self-reported STI outcomes since laboratory-confirmed diagnosis of STI generally possible and commonly reported in studies evaluating behavioral interventions and is the key health outcome for determining effectiveness. In addition, in considering the medical and social context of STI risk and prevention, it was determined that studies conducted over 20 years ago may not be applicable to present-day United States population risks and prevention. Changes occurring in the past two decades include the development of effective prophylactic and treatment interventions for HIV, the resurgence and emergence of pathogens (e.g., syphilis, antibiotic-resistant gonorrhea), new contraceptive options (i.e., levonorgestrel intrauterine contraception, implant, injectibles), and shifts in the social and sexual environment, including widespread use of social media and applications. Therefore, studies from the 2014 review that were published in 1999 or prior were excluded from the current review. The outcomes that were included in the review are fully listed in **Appendix A Table 1**.

Quality Assessment and Data Abstraction

Two reviewers applied USPSTF design-specific criteria to assess the methodological quality of all eligible studies (**Appendix A Table 2**). We assigned each study a quality rating of “good,” “fair,” or “poor.” Discordant quality ratings were resolved by discussion or by a third reviewer and adjudicated as needed. Studies rated as poor quality were excluded from the review.

Good-quality RCTs were those that met all or nearly all of the specified quality criteria (e.g., comparable groups were assembled initially and maintained throughout the study, followup was 90 percent or higher, assessment procedures were described and blinded if they involved direct interview, randomization methods were described, allocation was concealed). Fair-quality studies did not meet all criteria but did not have serious threats to their internal validity related to design, execution, or reporting. Intervention studies rated as poor quality generally had several important limitations, including at least one of the following risks of bias: very high attrition (generally > 40%); differential attrition between intervention arms (generally > 20%); lack of baseline comparability between groups without adjustment; or problematic issues in trial conduct, analysis, or reporting of results (e.g., possible selective reporting; inappropriate exclusion of participants from analyses; questionable validity of allocation or assessment procedures).

For all of the included studies, one reviewer extracted key elements into standardized abstraction forms in DistillerSR (Evidence Partners, Ottawa, Canada). A second reviewer checked the data for accuracy. For each study, we abstracted general characteristics of the study (e.g., author,

year, study design), clinical and demographic characteristics of the sample and setting (e.g., age, race/ethnicity, baseline clinical characteristics, setting, country), analytic methods, and results.

For KQ1, we abstracted reported data of STI incidence based on testing or biologic confirmation and related morbidity and mortality outcomes (e.g., STI-related cancers, reproductive complications, perinatal and infant morbidity), as well as mental health and quality of life outcomes. For KQ2, which examined the behavioral outcomes of sexual risk and protective behaviors, we abstracted changes in STI risk behaviors, such as the current number of sexual partners; instances of unprotected vaginal or anal intercourse or other sexual contact; sex with partners with high STI risk; sex while intoxicated with alcohol or other substances; and sex in exchange for money or drugs. Additionally, we abstracted data indicating changes in protective factors, including sexual abstinence; delayed initiation of intercourse or age of sexual debut; use of condoms or other barrier methods; or other changes in sexual behavior. For harms of these behavioral counseling interventions we abstracted data indicating possible paradoxical effects; health care avoidance; psychological harms such as anxiety, shame, guilt, or stigma; and unintended or unwanted pregnancy.

Data Synthesis and Analysis

We synthesized data separately for each KQ and provided tables describing the study results for all included outcomes, with stratification by intervention and study population characteristics. Narrative summary and summary tables were used to describe important features of the included evidence, including study design and setting, interval validity, and important characteristics about patients and interventions. Based on *a priori* plans to evaluate differences in intervention effects by age, we present data tables for studies focused on adolescent and young adult populations separately from those focused primarily on adult populations. The included studies varied in the inclusion criteria used and the ages of participants recruited. The age categories used in this review were defined to represent the ages of the included populations as accurately as possible, but there is some overlap in the age ranges and included in each of the review age categories. The adolescent age category includes studies limited to participants ages 12 to 19 years. The combined adolescent and young adult age category applied to studies enrolling adolescents and adults that reported a mean age of the included population of <25 years. The young adult category includes studies with eligibility criteria limited to young adults (e.g., 18–25 years) reporting a study population mean age <25 years. The adult age category includes a mix of studies including those limited to adults ages 18 years and older, as well as studies with participants of any age, including adolescents, having a study population mean age ≥ 25 years. We abstracted within study age-specific subgroup analyses when available, regardless of the subgroup comparison methods (e.g., *a priori* hypotheses, statistical power).

Studies reporting diagnosed STIs were included for KQ1. The outcomes were based on laboratory-confirmed clinical tests that were conducted in the trial, recorded in the medical records of study participants, found in public health surveillance registries, or drawn from all of these sources. A few studies reported incidence of a specific STI (e.g., BV, chlamydia, hrHPV), while others considered intervention effects on the diagnosis of any STI or a specific subset (e.g., chlamydia and gonorrhea). For meta-analysis, we combined these outcomes, considering the

effects of the interventions on the acquisition of any STI in the followup period. The followup periods ranged from 3 to 24 months, and we selected the longest time point or that closest to 12 months when several time points were reported.

We computed random-effects models using the DerSimonian and Laird (DL) method. For analyses with fewer than 10 trials and with substantial statistical heterogeneity ($I^2=50\%$ and higher), we ran restricted maximum likelihood (REML) models with the Knapp-Hartung correction for small samples. The DL method tends to underestimate the width of the 95% CI interval when the number of studies is small or statistical heterogeneity is high (and I^2 were typically near or above 50% in this review).⁹⁹ Our meta-analysis summary tables reflect the results of the REML correction method. Finally, for outcomes with 10 or more trials in the meta-analysis, we generated funnel plots and ran regression tests (e.g., Egger, Peters, or Harbord's modified test) to explore small-study effects and potential publication bias.^{100, 101}

We conducted meta-analyses of STI incidence, condom use, and unprotected intercourse outcomes. Diagnosis of STI was the primary outcome for this review. For studies that reported STI outcomes, findings for behavioral outcomes were examined to assess whether they contradicted or agreed with STI results within the study. A pooled odds ratio (OR) was used to analyze the average effect of the interventions on STI incidence. We included adjusted study-reported ORs in meta-analysis if they were reported, and calculated ORs based on the reported proportion of participants with an STI in each group if adjusted differences were not reported or results were presented in a format that could not be combined with the outcomes available in the included studies (e.g., hazard ratios).^{100, 101} Additionally, we conducted meta-regression and stratified analyses to explore intervention, population, and study characteristics that might explain heterogeneity in the effects observed in the included evidence.⁹⁹ For these comparisons, we examined the following as potential effect modifiers: study quality (good vs. fair), publication year, country (United States vs. other), recruitment approach (primary care-based, broad media-based recruitment, or other), whether the intervention was conducted in an STI clinic, whether the study targeted a highest STI risk group defined by history or STI or recruitment at an STI clinic, whether the study was limited to a single sex or gender, study age populations (adolescent only vs. others, and the 4-level age group categorization of adolescent only, combined adolescents and young adults, young adults, adults), estimated minutes of contact with the intervention (as a continuous variable and also grouped into low contact (<30 minutes), moderate contact (30–120 minutes), and high contact (>120 minutes), group vs. individual counseling sessions, mode of intervention (e.g., technology-based only vs. others), number of intervention components (single vs. multiple), whether the intervention was delivered by a health care professional (i.e., nurse, physician, social worker, psychologist, mental health specialist), and type of control group (attention control, minimal intervention, or usual care/none/waitlist).

Condom use and unprotected outcomes were reported using a variety of measures. We conducted one pooled odds ratio (for binary data) for condom use measures, selecting any of the following available measures in order of preference: consistent condom use (variably defined, e.g., “percent consistent condom use,” “percent consistent condom use for every vaginal sex act in past 30 days”), condom use at last intercourse, any condom use, and condom used at first intercourse with new partners. Female condom use was included for this outcome and was reported in one trial.¹⁰² For continuous outcomes, we analyzed the effect sizes two ways: 1)

weighted mean difference (MD) of percentage or proportion of sex acts using a condom or of unprotected sex acts between intervention and control, and 2) standardized mean difference (Hedges' g) of sex acts using a condom or of unprotected sex acts, based on the differences in change between groups from baseline to followup.

After synthesizing the evidence, we created an implementation table according to Agency for Healthcare Research and Quality (AHRQ) specifications that provides examples and features of selected effective interventions identified in this review.

We used Stata version 15.1 (StataCorp LP, College Station, TX) for all analyses. All significance testing was 2-sided, and results were considered statistically significant if the p -value was 0.05 or less. The data on study numbers reported throughout this report are n randomized in the case of randomized controlled trials and the n allocated to the study conditions unless otherwise indicated.

Grading the Strength of the Body of Evidence

The strength of the overall body of evidence for each KQ was graded using an adaptation of the Evidence-based Practice Center approach,¹⁰³ which is based on a system developed by the Grading of Recommendations Assessment, Development and Evaluation (GRADE) Working Group.¹⁰⁴ This adaptation explicitly addresses four of the five Evidence-based Practice Center-required domains: consistency (similarity of effect direction and size), precision (degree of certainty around an estimate), reporting bias (potential for bias related to publication, selective outcome reporting, or selective analysis reporting), and study quality (i.e., study limitations, risk of bias). We do not evaluate the fifth domain—directness—as it is implied in the structure of the KQs (i.e., pertains to whether the evidence links the interventions directly to a health outcome).

Consistency was rated as reasonably consistent, inconsistent, or not applicable (e.g., single study). Precision was rated as reasonably precise, imprecise, or not applicable (e.g., no evidence). Reporting bias was rated as suspected, undetected, or not applicable (e.g., when there was insufficient evidence for a particular outcome). Study quality reflects the quality ratings of the individual trials and indicates the degree to which the included studies for a given outcome have a high likelihood of adequate protection against bias. The limitations field highlights important restrictions in answering the overall KQ (e.g., lack of replication of interventions, nonreporting of outcomes important to patients).

The overall strength of evidence was graded as “high,” “moderate,” “low,” or “insufficient.” “High” indicates high confidence that the evidence reflects the true effect and that further research is very unlikely to change our confidence in the estimate of effects. “Moderate” indicates moderate confidence that the evidence reflects the true effect and that further research may change our confidence in the estimate of effect and may change the estimate. “Low” indicates low confidence that the evidence reflects the true effect and that further research is likely to change our confidence in the estimate of effect and to change the estimate. A grade of “insufficient” indicates that evidence is either unavailable or does not permit estimate of an effect. At least two independent reviewers rated the overall strength of evidence for each

intervention type. We resolved discrepancies through consensus discussion involving more reviewers.

Expert Review and Public Comment

A draft Research Plan for this review was posted for public comment on the USPSTF Website from April 19, 2018, to May 15, 2018. In response to comments, the USPSTF revised the scope of the review to exclude studies solely enrolling HIV positive participants (studies including a mix of participants whose HIV infection status was negative, positive or unknown were included in the review). In addition, the USPSTF expanded the list of STIs to include the hepatitis C virus and Zika virus. The USPSTF made other minor changes to clarify the scope and intention of the review. Some commenters requested changes outside of the scope of the USPSTF, such as political and social policy approaches to STI prevention, including community-level interventions; the USPSTF made no changes in response to these comments. A final research plan was posted on the USPSTF's Web site on August 23, 2018.

A draft version of this report was reviewed by content experts, representatives of Federal partners, USPSTF members, and AHRQ Medical Officers. Reviewer comments were presented to the USPSTF during its deliberations and subsequently addressed in revisions of this report when appropriate. Additionally, a draft of this report was posted for public comment on the USPSTF Web site from December 17, 2019 through January 21, 2020. Few comments were received during this public comment period; minor clarifications and editorial changes were made to the report based on these comments, but no changes were made to the included evidence or to our conclusions.

USPSTF Involvement

We worked with four USPSTF members at key points throughout this review, particularly when determining the scope and methods for this review and developing the Analytic Framework and Key Questions. After revisions reflecting the public comment period, the USPSTF members approved the final analytic framework, KQs, and inclusion and exclusion criteria. AHRQ funded this review under a contract to support the work of the USPSTF. An AHRQ Medical Officer provided project oversight, reviewed the draft report, and assisted in the external review of the report.

Chapter 3. Results

Literature Search

We screened 4,649 abstracts and assessed 273 full-text articles for inclusion (**Appendix A Figure 1**). After screening the full-text articles, we included 39 studies (in 63 articles) in our systematic review.^{102, 105-159} The full list of included studies and their ancillary articles are available in **Appendix C**. The list of excluded studies (with reasons for exclusion) are available in **Appendix D**. The most common reasons that studies were not included were that they did not contain relevant outcomes to the review, were conducted in settings not relevant to primary care, or employed an active intervention as the comparison intervention rather than usual care, no treatment, or attention control conditions.

Description of Included Studies

Of the 39 included studies (n = 65,888) 22 are from the review conducted in 2014.^{102, 107, 108, 111, 112, 116, 118, 119, 125, 127-129, 135, 137, 145, 148-150, 154-156, 158} These met the inclusion and exclusion criteria set forth for the current synthesis and are combined with 17 newly identified studies.^{105, 110, 113, 117, 122, 132, 142, 144, 153, 159-166} Nine studies that were included in the previous review were dropped from the current review due to high risk of bias¹⁶⁷⁻¹⁶⁹ or having a publication date prior to 2000.¹⁷⁰⁻¹⁷⁵ **Figure 2** shows the distribution of the included age groups, study population STI risk levels, intervention contact times, and key outcomes reported for the included studies. The newly available studies included four conducted among adolescents,^{144, 159, 160, 163} five conducted among a mix of adolescents and young adults,^{117, 122, 153, 164, 166} and one focused solely on young adults.¹³² The remaining seven enrolled mostly adults and spanned a wider age range.^{105, 110, 113, 142, 161, 162, 165} Nearly all of the included evidence considers intervention effectiveness for individuals at an increased risk for STI, including some participants with recent STI diagnosis. Most provided high contact time interventions involving more than two hours of time spent engaging study participants. **Tables 1 and 2** provide summary information on study population, setting, design, and intervention characteristics of the included studies, described below.

Population and Setting

Seventeen trials examined STI or behavioral outcomes in populations of adolescents only (k=8)^{116, 119, 125, 127, 144, 159, 160, 163} or adolescents and young adults combined (k=9) (**Table 3**).^{107, 117, 122, 129, 148, 153, 155, 164, 166} Others focused primarily on young adults (k=7).^{102, 118, 132, 137, 150, 154, 158} The remaining trials enrolled adults spanning broader age ranges (k=7)^{108, 110-112, 128, 142, 145} or an even broader range including some adolescents (k=8).^{105, 113, 135, 149, 156, 161, 162, 165} Among the studies of adults and mixed-age population, the average age of participants was <30 years in most studies, and none reported an average age of 40 years or older. Thus, among studies that included adults, young adults (i.e., 18–25) were most commonly recruited. People age 40 and older are minimally represented in the body of evidence, and no trials focused on adults in older age ranges.

Over half of the included studies were among women or girls only (k=20)— including one focused on pregnant individuals—¹²⁹ or mostly women (k=3). Only seven studies targeted men or primarily men, and another seven studies enrolled similar numbers of men and women. Most studies were conducted in the United States (k=34), and among these three-quarters (k=27) enrolled study populations in which a majority of participants identified as a racial or ethnic minority.

Most of the included studies enrolled participants at increased risk of an STI (**Figure 2**, k=35). Several studies recruited individuals at increased risk for STI based on their sociodemographic characteristics (e.g., age, member of low-resource or high STI prevalence community), reported sexual behaviors, or personal history associated with higher STI risk (k=22). Among the increased risk study populations, those recruited from STI clinics or based on their recent STI history were considered highest risk (k=13). Only four included studies recruited populations at average risk for STI, as follows. One study conducted among individuals across the age spectrum did not have specific criteria aimed at enrolling the participants based on risk characteristics.¹⁴⁹ Two studies enrolled adolescent populations that include large proportions of sexually inexperienced or sexually inactive participants and were therefore considered to have low to average STI risk.^{125, 159} One newly added study included a mix of sexually active and non-sexually active, average-risk adolescents and young adults making primary care visits.¹⁵³

Study reported STI and sexual history characteristics of participants reflected the aim of most of the trials to provide interventions for individuals at increased risk for STI. Three studies recruited individuals presenting with a current STI,^{118, 135, 155} and nine additional studies reported rates of STIs at baseline greater than 15 percent.^{112, 119, 122, 127, 128, 137, 145, 156, 158, 163, 164} Self-reported sexual risk behaviors were also used to identify high-risk populations for study recruitment.

Only one study specifically reported the sex and gender of participants; this study enrolled adolescent cisgender males (e.g., gender identity matches sex assigned at birth) (**Table 3**).¹⁵⁹ In this study, the sexual orientation of study participants was a key recruitment criterion and the intervention was designed for individuals identifying as gay, bisexual or queer (72% identified as gay). A few studies recruited participants based on their sexual partnerships or orientation. For example, one study recruited WSW with a diagnosis of BV;¹³⁵ others limited the study population to heterosexual women.^{117, 143} In describing the study participants, a few studies described whether participants engaged in sex with the same-sex or same-gender partners or identified as gay or bisexual.^{122, 137, 145, 150, 156, 162, 164, 166} Only one study reported that the study population included transgender participants (<1% of sample).¹⁵⁶ The remainder did not report sexual identity or sexual orientation characteristics of the included populations, although several specified sexual practices in their inclusion/exclusion criteria (e.g., vaginal intercourse in previous 3 months).

Intervention Characteristics

Tables 1 and 2 provide brief descriptions of the interventions, and further detail is provided in (**Appendix E Tables 1 and 2; Table 9**). In total there were 54 intervention arms tested across the 39 studies. Most were conducted in health care settings including general primary care, obstetrics and gynecology, STI clinics, women's health clinics, adolescent medicine, and family

planning clinics (**Table 4**). Eleven of the interventions tested involved low contact times (<30 minutes), and about half involved high contact times (over 2 hours), ranging from 165 minutes to 1,750 minutes. Nine studies^{105, 112, 128, 132, 150, 154, 156, 164, 166} included a low-contact time intervention arm (<30 minutes), 13^{107, 110, 113, 117, 118, 122, 125, 135, 137, 145, 148, 149, 165} included a moderate contact time intervention arm (30-120 minutes), and over half^{102, 107, 108, 111, 112, 116, 117, 119, 127-129, 142, 144, 153, 155, 158-163} (21/39; 54%) tested a high-contact time intervention arm (over 2 hours).

The most common therapeutic or conceptual approach taken in the included interventions was motivational interviewing,^{176, 177} used in eleven studies (15 intervention arms).^{111-113, 116, 135, 149, 160, 163-165} Another seven studies (9 interventions arms) employed cognitive behavioral therapy approaches.^{107, 117, 127, 155, 158, 160, 162, 178} Social and behavioral theories were the foundation for several of the interventions, sometimes paired with specific therapeutic approaches. The most commonly cited theory was the Information-Motivation-Behavioral Skills (IMB) model,^{179, 180} which guided intervention development in eight studies.^{112, 113, 142, 143, 159, 160, 163, 164} Social cognitive theory¹⁸¹ was cited in three studies^{119, 128, 129} and the transtheoretical model¹⁸² in two.^{112, 148} The Health Belief Model¹⁸³ was cited as a source for one study.¹⁰⁷ The Theory of Gender and Power¹⁸⁴ was drawn upon for two of the interventions evaluated^{119, 142} and the AIDS Risk Reduction Model (ARRM)¹⁸⁵ in one study that focused on adolescent girls¹¹⁶ and another with adolescent girls and young adult women.¹⁵⁵ Several studies described general approaches but did not report designing the intervention according to any specific therapeutic approach or theory.^{102, 105, 110, 118, 122, 132, 137, 145, 150, 154, 156} We did not review the earlier qualitative work and pilot investigations for the included interventions, and it is likely there were theoretical underpinnings considered at early stages of program development.

Fourteen of the intervention arms primarily involved mobile-phone text or computer interventions, and all but two of these involved low or moderate contact times ranging from 5 to 90 minutes.^{105, 110, 111, 113, 122, 132, 148, 159, 163-166} In contrast, one recent study tested a text-based intervention involving 5-10 daily messages for five weeks, amounting to several hours of texting contact with adolescent males identifying as gay, bisexual, or queer.¹⁵⁹ These interventions using mobile and computer technology all took place in an STI clinic or at participants' homes via personal devices, and most were self-directed^{113, 159}

The most common intervention component was group counseling (25 intervention arms). Group counseling was frequently paired with other components, such as individual counseling, videos, video games, or phone contact. Interventions with group counseling involved more than 2 hours of contact in all but one study. That study recruited adult men and women at STI clinics for a single, mixed-gender group sessions with moderate contact time (40–60 minutes).¹⁴⁵ In most studies of group counseling, participants were of the same sex or gender. Clinic settings and involvement of trained health professionals were commonly employed for group counseling interventions.

Twenty-three study arms included individual counseling alone or combined with other components. Eleven study arms involved individual counseling only, delivered by a range health professionals (e.g., physicians, nurses, mental health professionals) or by health educators,^{108, 112, 128, 150, 160, 162} trained research staff, or trained lay peer counselors.^{107, 118, 135, 137, 149} Eight

intervention arms involved both group and individual counseling and sometimes also included video or phone components; these tended to involve high contact times (> 2 hours). In three studies, individual counseling was combined with print or phone components.^{107, 117, 125} Only four study arms (from three studies) tested low contact time interventions, ranging from 15 to 20 minutes, with trained health professionals.^{112, 128, 150}

Seven intervention arms (six studies) with low contact, ranging from 0 to 29 minutes, were self-directed with computer web-based educational sites^{105, 132, 164} or intervention via emails, texts, printed materials or video. One study of young adult women tested an intervention using print materials only,¹⁵⁴ and a study of adolescents and adults comprised a low contact time (~23 minutes), self-directed print and video intervention.¹⁵⁶ Another study of adolescents and young adults sent 8 emails containing links to internet contents.¹⁶⁶

Comparators and Outcomes

One third (k=13) of the studies employed attention control conditions involving an equivalent amount of contact time related to healthy lifestyle topics other than STI prevention (**Table 4**). The remainder used minimal intervention controls (k=10) or no intervention, usual care, or waitlist controls (k=16). The outcomes reported in the trials varied, both in the type of outcome reported and the specific measures used. Five trials reported STI outcomes, but not intermediate behavioral outcomes associated with the interventions. Another 16 trials reported both STI and behavioral outcomes, and 18 reported only behavioral outcomes. The longest followup times reported across the studies ranged from 3 to 24 months, with the majority (61%) reporting outcomes at 12 months or more.

Quality Assessment

Thirty-six of the included studies were RCTs; two were nonrandomized clinical trials,^{145, 156} including the largest study by Warner et al.,¹⁵⁶ (n = 40,282) and one was a cluster randomized trial.¹⁵³ Thirteen of the trials were “good quality” and the remaining 26 were “fair quality” based on risk of bias assessments. Thirteen newly identified studies otherwise eligible for inclusion were excluded from this review based on poor quality ratings in risk of bias assessment. The primary threats to internal validity that resulted in exclusion of studies were high loss to followup (>40%), differential attrition between treatment arms, and questionable handling of missing data.

Among the fair-quality studies included in this review, sources of bias most commonly encountered were lack of information reported on key quality domains (e.g., allocation concealment, blinding) and moderate loss to followup reported with no imputation or data substitution.

Key Question 1. Do Behavioral Counseling Interventions to Decrease Risky Sexual Behaviors, Increase Protective Behaviors, or Both Reduce STIs or Related Morbidity and Mortality?

Summary of Results

No studies reported intervention effects on STI morbidity or mortality, but 21 included studies reported on the effectiveness of behavioral interventions for preventing STI. Overall, the mostly moderate- and high-contact time interventions included in this body of evidence which focused on individuals at increased STI risk were effective in reducing the incidence of STI in followup, most commonly reported at 6 to 12 months. The overall pooled OR was 0.66 (95% CI 0.54, 0.81; I^2 74%, $n=52,072$). Only four studies reported higher absolute STI rates in the control condition, but the rates were not statistically different from rates in the intervention groups. Based on meta-regression comparisons, larger effect sizes were associated with studies conducted among adolescents ($p<0.01$), testing high-contact interventions (>120 minutes of contact) ($p=0.02$), or including group counseling sessions ($p=0.02$). Intervention effect sizes tended to be smaller in the largest studies and those published more recently, but the larger studies also tended to be among mixed-gender populations with broader age ranges, lower rates of STI, and tested shorter duration interventions. Overall, subgroup comparisons tended to be based on very few studies, however, study population and intervention characteristics tended to be confounded, limiting strong conclusions about the specific factors associated with greater intervention effectiveness.

Detailed Results

Prevention of Morbidity and Mortality From STIs

No studies reporting on the effects of interventions on morbidity or mortality sequelae from STI infection were identified.

STI Prevention

Twenty-one trials reported an STI outcome ($n = 59,328$) (**Appendix E, Tables 3 and 4**) and 19 reported measures that could be combined for meta-analysis (**Table 5 and Figure 3**).

The overall pooled effect of behavioral interventions for STI prevention in the included evidence suggested a statically significant 34 percent lower odds of STI with intervention compared with a control condition (pooled OR = 0.66, 95% CI 0.54, 0.81; I^2 74%) (**Table 5 and Figure 3**).

Results were predominantly in the direction of an intervention benefit; only four trials reported more STI diagnoses in the intervention group than in the control,^{113, 135, 137, 165} but none were statistically different. STI incidence rates were highly variable across studies; control group rates ranged from 0 to 50 percent, while intervention groups ranged from 0 to 53 percent. The absolute effects across studies ranged from 19 percentage points lower STI incidence in the intervention group to 10 percentage points higher incidence, with a median risk difference (IQR) of -0.3 (-3.4,

+1.0). Statistical heterogeneity was substantial, and there was also considerable clinical heterogeneity, particularly in terms of the populations and intervention characteristics. Sensitivity analyses were conducted to examine the pooled effect when excluding studies that were unique in terms of STI outcomes and study population, as for a study conducted with WSW that tested an intervention to prevent the spread of BV, and this did not change the overall result.¹³⁵

Six studies with the largest effect sizes reduced the odds of STI infection by 50 percent or more (50 to 96%), and shared common characteristics.^{116, 118, 119, 127, 128, 155} Most were provided to adolescents or young adults and involved group counseling sessions with high contact times. As well, most interventions were for girls or women, and one was provided to men and another to men and women. The analytic samples ranged from 199 to 490 participants, and all reported statistically significant findings of reduced STI associated with intervention. Two of these six interventions were associated with reduced odds of STI infection of greater than 80 percent; both were conducted with adolescent girls, recruited based on their race/ethnicity and increased or high STI risk.^{116, 119} The first of these two, the *Project Image* intervention for African American and Mexican American girls with a history of STI or abuse, involved multiple group and individual counseling sessions over the course of 1 year amounting to over 17 hours of contact time.¹¹⁶ The second intervention was for HIV prevention, and focused on sexually active adolescent African American girls at increased risk for STI.¹¹⁹ This was also a high-contact time intervention involving four 4-hour group counseling sessions over the course of one month. *Project Image* included motivational interviewing, and the HIV prevention intervention was based in social cognitive theory and theory of gender and power. Another intervention tested by Jemmott and colleagues¹²⁷ that focused on Black and Hispanic adolescent girls was also statistically significant. Consisting of a single group counseling session (250 minutes) that included a video and games, it focused on skills development and was based on CBT therapeutic approaches, and was associated with 56 percent reduced odds of STI.¹²⁷ An adaptation of this intervention was also effective when tested among adult African American women (ages 18–45); it had a similar effect size (52% reduced odds of STI).¹²⁸ Another intervention for Mexican American and African American women that was not limited to adolescents also was associated with reducing the odds of STI by half at followup.¹⁵⁵ This was also a high contact time intervention taking place over 2 months, and included individual and group counseling amounting to approximately 17 hours. Only one intervention among these studies with larger effect sizes focused on men. The *Focus on the Future* intervention for young adult African American men recently diagnosed with an STI involved a single individual counseling session and provision of a variety of condoms and lubricants (control condition received 12 free condoms).¹¹⁸ The intervention was conducted at an STI clinic and was provided by a trained layperson (peer counselor).

Eight studies with more modest estimates of effects,^{105, 107, 122, 129, 145, 156, 158, 164} ranging from 47 to 15 percent reductions in the odds of STI, included three with statistically significant effects among people making visits to STI clinics.^{145, 156, 158} Two of these were large nonrandomized controlled trials evaluating low or moderate contact interventions for adult populations, mostly over the age of 25^{145, 156} The low contact intervention for adults, *Safe in the City*, involved an STI clinic video intervention with educational pamphlets and condoms.¹⁵⁶ The moderate contact time intervention for adults, *VOICES/VOCES*, was a single 45-minute group counseling session

delivered in STI clinics.¹⁴⁵ The third study with sufficient precision to establish effectiveness was an RCT of an intervention for young adult African American women.¹⁵⁸ This intervention was two 4-hour group counseling sessions using CBT therapeutic approaches, conducted by health educators in a primary care setting over a 2-week period. The five remaining studies were not statistically significant, but effect sizes were similar. Two high contact time interventions, one for adolescent and young adult pregnant women¹²⁹ and another for adolescent and young adult women seeking contraception,¹⁰⁷ reported similar effect estimates and confidence intervals. The *Centering Pregnancy Plus* intervention (OR 0.72, 95% CI 0.38, 1.37) involved 10 group counseling sessions,¹²⁹ and the other intervention for those seeking contraception included an individual counseling session and more than six followup phone calls (OR 0.72, 95% CI 0.35, 1.48).¹⁰⁷ Two small trials conducted in Great Britain and published in 2016 were also not statistically precise, and evaluated lower contact approaches to STI prevention. One was a text message and email intervention for mixed-gender adolescents and young adult populations at high STI risk that involved 50 to 60 contacts over the course of a year (OR 0.57, 96% CI 0.24, 1.38).¹²² The other, *Men's Safer Sex*, focused on men of any age making visits to an STI clinic and involved a single 10-minute visit to a website (OR 0.64, 95% CI 0.23, 1.80).¹⁰⁵ A similar trial evaluated the electronic kiosk intervention for safer sex (*e-KISS*) for male and female adolescents and young adults making visits to a public STI clinic.¹⁶⁴ The intervention offered one 20-minute session with a tailored-interactive computer-based intervention. Fewer cases of diagnosed or self-reported chlamydia cases occurred in the intervention group (12%) compared to the control group (20%) after three months of followup, but the difference was not statistically significant (OR 0.53, 95% CI 0.26, 1.08).¹⁶⁴

The remaining studies reported similar STI incidence for the intervention and control groups or slightly higher STI incidence for intervention participants, and none approached statistical significance.^{112, 113, 135, 137, 148, 165} The main behavioral study outcomes were also no different between groups for the studies that did not show differences in STI rates (discussed below). A tailored web-based intervention for adolescent and young adult women that involved moderate contact (~90 minutes) with the intervention platform over the course of 2 months was not effective.¹⁴⁸ A large study (n=4,071) with brief individual counseling and HIV testing for a diverse population of young adult men and women visiting an STI clinic also was not effective,¹³⁷ nor was a very small trial (n=87) of an intervention to prevent BV among WSW.¹³⁵ A large study (n=1,010) of a video and survey intervention for a diverse population of men and women, adolescents, and adults conducted at an STI clinic did not prevent the incidence of STI.¹¹³ Another intervention study from the same team evaluating a high contact time intervention for adult men and women reported no difference in STI incidence between groups in the publication text, but did not provide details.¹¹²

The risk of bias rating (good vs. fair quality) was not associated with different intervention effects for STI in meta-regression (p=0.46) (data not shown). More recently published studies tended toward smaller effects than those published earlier, but there was not a statistically significant difference (p = 0.07). The six largest studies (n≥1000) also had smaller effects (p= 0.02) in meta-regression analysis. A statistically significant relationship was not observed, however, when looking at the linear relationship between study size and effect estimates (p=0.42). Statistical tests with Harbord's modified and Peter's tests also did not find a pattern of results suggesting the findings were driven by small study effects. However, there was

heterogeneity in the populations enrolled where studies enrolling 1,000 or more participants tended to include broader general populations at lower STI risk across a range of ages, including both men and women, and to deliver individual rather than group focused interventions.

Key Question 2. Do Behavioral Counseling Interventions Decrease Risky Sexual Behaviors or Increase Protective Behaviors That Can Reduce the Risk of STIs?

Summary of Results

In total, 34 studies contributed evidence on the effectiveness of behavioral counseling interventions in changing a variety of sexual risk and protective behaviors. Eighteen trials reported only behavioral outcomes, and 21 reported STI and behavioral outcomes. Results were generally consistent across STI and behavioral outcomes for studies reporting both outcomes. In pooled analysis, statistically significant effects of interventions for improving condom use ($k = 13$; pooled OR 1.31, 95% CI 1.10, 1.56, I^2 40%) and for reducing unprotected intercourse ($k=14$; pooled MD -0.94, 95% CI 0-1.40, -0.48, I^2 16%) were found across studies with reasonably comparable measures to accommodate pooling. Similar to the studies reporting STI outcomes, nearly all of the included evidence for pooled analysis was from studies of people at increased risk for STI; one study of average-risk adolescents reported no difference in unprotected intercourse. Most interventions involved moderate or high contact times. Followup ranged from 3 to 14 months (mode = 12 months), and for the few studies reporting extended followup beyond a year, effects tended to diminish. Statistical heterogeneity was modest, but clinical heterogeneity was high due to the diverse populations and intervention approaches. Behavioral outcomes were not consistently reported, and measures were variable among those reporting. This limited our ability to combine studies and to explore and identify specific study or intervention characteristics associated with differences in intervention effects. Other behavioral outcomes, such as the number of sexual partners and sexual abstinence, were reported by fewer of the total included studies and tended to be consistent with effects seen for other outcomes.

Detailed Results

Condom Use

Eighteen studies reported a variety of condom use measures ($n = 9,205$) (**Appendix E Tables 5 and 6**). The pooled effects in studies reporting dichotomous outcomes ($k= 13$, $n = 5,253$) and those reporting comparable continuous outcomes ($k=7$, $n =2,920$) were estimated separately (**Table 6**). One study, by Erhardt and colleagues,¹⁰² included female condom use, and the remainder reported male condom use only.

Thirteen studies reported dichotomous condom-use outcomes. The combined effect across these studies suggested increased odds of condom use associated with intervention (OR 1.31, 95% CI 1.10, 1.56, I^2 40%) (**Table 6 and Appendix G Figure 1**). The percentage reporting any condom use ranged from 4 to 81 percent in the intervention groups, compared with 4 to 77 percent in the

control groups, with absolute risk differences ranging from -7 to +27 percent. Seven studies reported a continuous condom-use measure comparing mean differences in the percentage of time condoms were used out of the total sexual acts, encounters, or days of sex. The interventions evaluated in these studies were associated with reports of condom use in just over 10 percent more of total sexual encounters, and statistically heterogeneity was fairly substantial (pooled MD 10.8, 95% CI 1.0, 20.5, I² 79%).

Eight of the studies reporting condom use outcomes also reported STI incidence, and effects were consistent in terms of the statistical significance and effect direction reported in each study. Among the eleven studies that only reported behavioral outcomes, three reported statistically significant benefits of the intervention.^{110, 117, 163} One of these reported a continuous condom use measure defined as the reported number of times condoms were used during the previous 4 sexual acts.¹¹⁷ In the intervention group the mean (SD) was 3.4 (2.0) and in the control group it was 2.4 (1.8, p=0.05). The study, conducted in Portugal, evaluated a high-contact time intervention for adolescent and young adult women at high risk for STI that included six 120-minute group counseling and skill building sessions conducted by psychologists using CBT techniques. The *Safe Sistah* intervention also was associated with statistically significant increases in condom use, which was measured as the proportion of sexual episodes in which condoms were used.¹¹⁰ *Safe Sistah*, which was developed and evaluated in the United States, was an intervention for adult Black women conducted at a community-based health clinic that employed a single computer-based educational session of moderate duration (~88 minutes). The mean percent (SD) condom use percentages measured at 4-month followup were 59.6 (40.4) in the intervention group and 31.6 (34.6) in the control group (p=0.03). A similar intervention, *Step by Step*, for adolescent females recruited from family planning or community health clinics in the United States administered four computer sessions (~25 minutes each) followed by individual counseling sessions. The study reported a significant increase in consistent condom use for the intervention group (51%) compared with the control group (39%) at 12-month followup (p=0.02).¹⁶³

Unprotected Intercourse

Twenty-one studies reported a measure of unprotected intercourse (n = 13,665). Of these, 14 reported the number of times participants engaged in unprotected sexual intercourse or intercourse without a condom over various time frames (e.g., past 30 days, past 3 months), with different degrees of specificity regarding the type of partner or sexual intercourse act. When combined to estimate an overall effect, there was a small but statistically significant difference between groups. Fewer unprotected intercourse occasions were reported among those assigned to the intervention conditions (pooled MD -0.94, 95% CI -1.40, -0.48, I² 16%) (**Table 6 and Appendix G Figure 2**). Overall, findings for individual studies reporting this outcome were mostly consistent when results were compared for other outcomes, including STI. The exception was the *Centering Pregnancy Plus* intervention: STI rates were not statistically different, but the intervention was associated with fewer reported acts of unprotected intercourse at 12-month followup (mean [SD] 3.9 [6.5] in the intervention group, 5.3 [7.8] in the control group (p=0.04).¹²⁹ Among studies that did not report STI outcomes, the *Safe Sistah* intervention, described above with the condom use results, also reported fewer unprotected acts of sexual intercourse at 4 months of followup.¹¹⁰

Two recent studies reported statistically significant differences in reported unprotected intercourse. A small study among adult males who mostly identified their sexual orientation as gay or bisexual evaluated reports of unprotected anal intercourse nine months after an intervention involving STI testing and counseling and ten individual therapy sessions. Fewer in the intervention group reported any unprotected anal intercourse (12%) compared to those in the control group (68%) ($p < 0.001$).¹⁶² Differences in reports of unprotected intercourse were also seen in a trial testing a low-contact computer-based intervention that provided numerous emails with internet links to informational and motivational content. The intervention was tested with sexually active adolescent and young adults of any gender, most of whom identified as Black or Hispanic. At 3 months followup, fewer reported any unprotected intercourse in the intervention group (17%) compared with the control group (48%) ($p < 0.05$).¹⁶⁶

A trial testing *Guy2Guy*, a high-contact-time text-message intervention for adolescent cisgender males identifying as gay, bisexual or queer, had null findings for this outcome.¹⁵⁹ Two newer studies with high-contact time also found no significant results with unprotected intercourse or condomless sex acts. One of these studies¹⁶⁰ was conducted among adolescents who received ten 60-minute individual sessions and the other study¹⁶¹ administered three 2.5-hour group sessions among refugee and immigrant populations of adult Hispanic females.^{162, 166} A trial conducted by Mittal and colleagues (2016)^{140, 142} that evaluated the *SUPPORT* intervention—which provided three individual counseling sessions (2 to 2.5 hours each) and five group counseling sessions (2 to 2.5 hours each) to women with a history of intimate partner violence—found no group differences in episodes of unprotected sex, although results suggested a trend toward fewer unprotected episodes with nonsteady partners for intervention participants. An additional study published by Jemmott et al. (2005),¹²⁸ which reported STI-prevention benefits associated with a high contact time group counseling intervention for African American and Latina adolescent girls, also reported on days of sex while high or on drugs and unprotected sex while high or on drugs. At 12 months of followup, there was no difference between groups in the number of days women had sex while high or on drugs (0.4 vs 0.6 days in the intervention and control groups, respectively), but those in the group intervention had lower mean reported days of unprotected sex while high or on drugs (0.1 vs 0.5 in the intervention and control groups, respectively, $p = 0.02$).

Other Behavioral Outcomes

Studies reported a wide range of additional behavioral outcomes, detailed results are shown in **Appendix E Tables 7 and 8**.

Number of Sexual Partners

Ten studies compared intervention and control groups on different measures of participants' reports of the number of sexual partners for recall periods ranging from 1 to 12 months. Dichotomous measures were reports of two or more sexual partners. Continuous measures were reported as the mean number of sexual partners or the absolute number of sexual partners. Four trials with statistically significant intervention benefits for STI, condom use, or unprotected intercourse also found reports of fewer sexual partners among intervention participants.^{111, 118, 127, 155, 164} Four of these trials tested interventions for adolescent and young adult single-gender populations (three for females,^{127, 155, 164} one for males¹¹⁸), and one was among mixed-sex/gender

adults receiving outpatient psychiatric treatment.¹¹¹ Four trials had null findings for the outcome, consistent with null findings for other reported outcomes.^{112, 113, 122, 144}

Abstinence

Trials of interventions that focused on younger populations also reported sexual abstinence outcomes and the initiation of new sexual partnerships. The *HipTeens* intervention evaluated in the study published by Morrison-Beedy and colleagues enrolled sexually active, predominantly African American, low-income adolescent females for a group counseling intervention.¹⁴⁴ The trial did not report an intervention benefit for STI prevention, condom use, or reductions in unprotected intercourse, nor was there a difference in the number reporting any vaginal sex (protected or unprotected) at 12 months' followup. An intervention effect on abstinence was observed at 6 months' followup, where the percent reporting any episodes of vaginal sex was lower in the intervention group.¹⁴³ The study also reported null effects for reports of abstaining from sex or avoiding drinking or drug use before sex as risk-reduction strategies. The *Guy2Guy* intervention for sexually experienced and unexperienced queer, bisexual, or gay cisgender adolescent males reported abstinence in the previous 90 days as a primary outcome, but did not find overall differences at 3 months of followup.¹⁵⁹ *Post hoc* subgroup analyses indicated that participants who were already sexually experienced were less likely to report abstinence after participating in the intervention (aOR 0.48, 95% CI 0.23, 1.00, $p < 0.05$), whereas there was no effect among not-yet sexually experienced individuals (OR 0.98, 95% CI 0.38, 2.53). Sexually experienced participants were, however, more likely than those in the control condition to have been tested for HIV (data not shown).

The HIV prevention intervention for adolescent African American girls at increased STI risk evaluated by DiClemente and colleagues (2004)¹¹⁹ found reduced STI infections and increased condom use (see above), and also was associated with a decline in reports of having a new vaginal sex partner in the past 30 days (OR 0.40, 95% CI 0.19, 0.82, $p = 0.01$). A study enrolling mother-child dyads attending pediatric care visits also reported vaginal intercourse as a primary outcome. The intervention evaluated by Guilamo-Ramos and colleagues (2011)¹²⁵ was designed to reduce sexual health risks in a population of African American and Latino adolescent girls and boys ages 11–14. Few of the adolescents in the mother-child dyads had ever had intercourse (6.4% reported vaginal sex). Mothers randomized to the moderate contact time intervention received a 30-minute individual counseling session, a program manual, and two followup phone calls. At followup (9 months) the adolescents with mothers assigned to the intervention were less likely to report having engaged in vaginal sexual intercourse (OR 0.24, 95% CI 0.11, 0.55).

Safer Sex Practices

A large cluster-randomized trial conducted in Australia, published by Sanci and colleagues (2015),¹⁵³ randomized general medical practice clinicians and their 14- to 24-year-old patients to an intervention aimed at improving screening and motivational interviewing for adolescent health risk behaviors. A self-reported outcome assessing risk of STI defined as engagement in safe sexual behaviors to prevent STI (response options were never, rarely, sometimes, most of the time, always) was measured 12 months after the clinician intervention; it found no difference between groups (OR 0.79, 95% CI 0.51, 1.24).

Consistently null findings were reported in a trial of an educational materials intervention for mixed-gender populations of young adults in primary care conducted by Proude and colleagues (2004);¹⁵⁰ null findings for condom use were consistent with null findings for participant reports of new sex partners in the previous 3 months.

Participants' reports of having any casual sexual partners in the previous month were compared for a trial by Lewis and colleagues (2018)¹³² using low-intensity interventions with computer and text messaging to generate personalized feedback for young adult women and men. They included one intervention with feedback related to alcohol use and sexual risk and another without alcohol use content. Neither intervention was associated with a statistically significant lower relative risk of reporting casual partnerships, although there was a between-group difference suggesting lower odds of reporting any casual partners versus none in the intervention arm that did not incorporate alcohol-related risk-reduction content (OR 0.31, 95% CI 0.12, 0.79).

Key Questions 1a and 2a. Does the Effectiveness of Behavioral Counseling Interventions Differ for Subpopulations (e.g., by Age, STI History, Sexual Orientation, Gender, or Pregnancy Status)?

Summary of Results

Rigorous tests of intervention effectiveness for different subpopulations within trials were not reported. One trial¹⁵⁶ reported prespecified several exploratory subgroup comparisons but did not test for interactions or account for multiple comparisons, while other trials presented *post hoc* exploratory subgroup comparisons¹⁵⁹ or secondary analyses on a subset of trial participants.¹¹⁹ Instead, most of the included evidence focused exclusively on a specific subpopulation defined by gender, age, sexual history, pregnancy status, and racial/ethnic identity. Some subpopulations were not well-represented in the body of evidence; for example, only two included studies recruited participants for interventions occurring during pregnancy. Many of the interventions were effective in the subpopulations for which they were designed and evaluated. For example, interventions designed for African American and Latina adolescents, adult minority women, and mixed-gender populations making visits to STI clinics were effective. Trials among men, adolescent boys, MSM, and average risk populations were not well-represented in the body of evidence, however, and when differences in effects were observed, other factors present could not be ruled out as the source of differential effects. We also explored differences in the pooled effect estimates for sets of studies defined by the study population and other characteristics using stratified meta-analysis and meta-regression. Meta-regression revealed a few subpopulations or study features statistically associated with intervention effectiveness. Isolating specific effects was hindered, however, by the presence of shared features among the most effective trials, such as group counseling interventions often being delivered to racial and ethnic minority women. Too few degrees of freedom and small numbers did not allow for more than one or two variables in meta-regression models, further limiting the disentanglement of subgroup effects.

Detailed Results

Results from within-study group comparisons were reported by several studies, and while some were planned and sufficiently powered, such as the large study by Warner and colleagues (2008) testing the *Safe in the City* intervention, the stratified analyses were exploratory in nature, without correction for multiple testing or reporting of interaction effects. The results of within-study subgroup comparisons, meta-analysis and meta-regression exploration of differences in effects, and results for studies conducted among focused subpopulations are discussed below.

Age

The Warner study described above suggested reduced intervention effectiveness for participants younger than age 25, relative to those aged 25 and older. Three trials limited to adolescents reported STI outcomes eligible for meta-analysis (n =1,763).^{116, 119, 127} Statistically significant differences were observed in meta-regression (p=0.002) when comparing the studies focused on adolescents with the studies focused on all other age groups. The pooled effect for trials limited to adolescents is statistically significant in Figure 3 using the DL pooling method, but highly imprecise when estimated with the Knapp-Hartung correction, as shown in Table 5. Specifically, the pooled effect for trials limited to adolescents indicated a greater reduction in the odds of infection (OR 0.22, 95% CI 0.02, 2.30; k=3, n = 1,166, REML method with the Knapp-Hartung correction for small number of studies, Table 5) and a smaller and statistically significant effect for trials that were not limited to adolescents (OR 0.79, 95% CI 0.67,0.93; k=14, n=50,627, DL method). This result does not offer conclusive evidence that the difference is due only to the ages of the trial participants, however, since the precision and number of studies for estimating this effect difference for adolescents was low. Moreover, all three of the studies limited to adolescents were conducted among sexually active minority females at increased STI risk and involved high-contact time interventions provided in a group counseling format.^{116, 119, 127} It is not possible to determine the extent to which differences in effect estimates for this age group comparison can be attributed to the age category per se, or to a combination of other factors, but within-study comparisons suggest that some interventions may be more effective for adolescents. The *Centering Pregnancy Plus* intervention reported statistically significantly reduced odds of STI for adolescent participants (OR 0.37, 95% CI 0.17, 0.77), but not overall (OR 0.72, 95% CI 0.38, 1.36).¹²⁹

Sex and Gender

One study fully characterized the gender of study participants, specifying that cisgender men were recruited.¹⁵⁹ The majority of studies recruited women or females, most recruiting either heterosexual women or women reporting sex with men. Five studies focused only on males or men, whereas 20 focused on adolescent and adult women and 14 included both men and women. Larger effect estimates for STI prevention in trials limited to women suggested a greater intervention benefit, but formal testing with meta-regression did not find a statistically significant difference in intervention effectiveness for studies conducted only among women (k=11) (p=0.17). Larger effect sizes were observed for trials targeted to a single gender (only men or only women) (k=13) compared to those including both men and women (k=6), but the test for intervention effect differences for STI incidence in meta-regression did not meet the

threshold for statistical significance ($p=0.06$). Studies focused on a single gender had many features in common, making it difficult to ascertain whether any one aspect could account for potentially larger effect sizes. Evidence from within study comparisons was mixed. For example, *VOICES/VOCES*—the single group-counseling session at an STI clinic for adults by Neumann and colleagues (2011)—reported a statistically significant effect of the intervention for STI prevention for women, but not for men. Conversely, the subgroup comparisons provided in the STI clinic *Safe in the City* intervention trial by Warner and colleagues (2008) showed an intervention effect for men but not for women.¹⁵⁶ Intervention effects also varied for men and women in the *e-KISS* trial, and were suggestive of a stronger effect for men than for women on the prevention of incident STI.¹⁶⁴

Sexual Orientation

Only 2 studies focused exclusively on MSM¹⁵⁹ or WSW¹³⁵ populations, and only a few other studies reported that more than ten percent of study participants were not heterosexual^{113, 122, 137, 150, 156, 162, 164, 166}. Most studies enrolled women who either identified as heterosexual or reported having intercourse with men.

The study among MSM was focused on adolescents that identified as gay, bisexual, or queer and did not enroll participants based on whether they had ever had sex (approximately half sexually inexperienced).¹⁵⁹ The text message-based intervention did not have a statistically significant main effect on the main behavioral outcome, condomless sex, regardless of sexual experience.

One trial of a moderate contact individual counseling and testing intervention conducted with STI clinic attendees by Metsch et al. (2013)¹³⁷ reported null findings overall, and in subgroup comparisons, there was some evidence of a potentially harmful effect for participating MSM; a statistically significant increase in STI was seen for the intervention group (OR 1.62, 95% CI 1.16, 2.26) in this subpopulation and the overall intervention effect was also in the direction of harm, (OR 1.12, 95% CI 0.92, 1.35).

History of Abuse

Two studies of interventions for adolescent girls^{116, 119} and one for adult women¹⁴² considered the effects of abuse history on sexual health risks. A small study ($n= 55$) by Mittal and colleagues¹⁴² recruited adult women with a history of intimate partner abuse/violence for an intervention including individual and group counseling sessions (high contact time of 1,080 minutes). The study, which did not report STI or condom use outcomes, found that unprotected intercourse was not statistically different between groups, but means were lower in the intervention group. Improvements in self-esteem and generalized anxiety were associated with the intervention. The study by Champion and colleagues¹¹⁶ actively recruited girls with either STIs or abuse history for their *Project Image* intervention, and a majority of participants reported sexual, physical, and emotional abuse histories. The study reported STIs (chlamydia, gonorrhea) among those reporting a history of sexual abuse and those without. The overall effect of the intervention across all participants was beneficial for STI prevention (OR 0.04, 95% CI 0, 0.53, $p=0.02$). However, among those reporting a history of sexual abuse ($n=241$) more STI cases occurred in the intervention group than in the control group (15.4% vs. 9.3%, respectively) and there was not

a statistically significant intervention effect ($p = 0.16$). Among those not reporting a history of sexual abuse, the intervention was associated with fewer STIs, similar to the overall effect ($p=0.02$). Finally, the study by DiClemente and colleagues¹¹⁹ reported a subanalysis of the intervention findings for adolescent African American girls reporting a history of gender-based violence. The intervention was effective overall and in this subpopulation for STI prevention (OR=0.47, 95% CI 0.25, 0.87), and also in increasing condom use.

Mental Health

The study by DiClemente and colleagues¹¹⁹ evaluating a group counseling intervention for adolescent African American girls reported a secondary subpopulation analysis among participants with depressive symptomatology at baseline. Higher reports of consistent condom use and reported condom use at last sex were associated with the intervention.

Two studies enrolled participants in treatment for mental health conditions. One intervention was tested among men with severe mental illness¹⁰⁸ and another among men and women with alcohol or drug use in the previous year who were undergoing outpatient psychiatric treatment.¹¹¹ Intervention participants were assigned to attend multiple group-counseling sessions. The intervention for men with severe mental illness found increased condom use (percent sexual acts using condoms) reported by intervention group participants at 14 months of followup, but the mean difference was small (6.4, 95% CI -8.0, 20.8) and not statistically different. The study by Carey and colleagues (2004) for men and women with a history of alcohol or drug use found reduced frequency of unprotected intercourse reported by intervention group participants in adjusted analyses ($p=0.004$), but a small absolute mean (SD) number with 7.2 (14.5) versus 8.0 (17.9).

Level of STI Risk

One of the studies conducted in general average-risk study populations reported in the text that they evaluated incident Chlamydia and found no difference between groups STI outcome.¹⁴⁹ No other studies among average-risk populations reported STI outcomes. Within the increased risk populations evaluated, there was not a statistically significant difference in effect estimates for studies enrolling individuals at highest risk, having been recruited from an STI clinic or recent history of STI ($p=0.18$). Stratified within-study comparisons conducted in the nonrandomized Warner trial¹⁵⁶ discussed above, however, suggested that individuals with an STI at the index visit may have obtained a more pronounced benefit from the brief *Safe in the City* video intervention.

Pregnancy

Only two studies eligible for inclusion in this review were conducted among pregnant individuals.^{129, 165} Both reported STI outcomes, and neither found a preventive benefit. One small trial ($n=50$) with very low precision for estimated differences in STI outcomes enrolled pregnant women at risk for STI/HIV and alcohol or drug use and provided a moderate contact time computer-based intervention.¹⁶⁵ A larger trial of the *Centering Pregnancy Plus* intervention was conducted with pregnant adolescents and young adults.¹²⁹ At 12 months followup, STI incidence

was not statistically different between groups, but was in the direction of a preventive benefit (OR 0.72, 95% CI 0.38, 1.36) and there were statistical differences in self-reported behavioral outcomes (condom use, unprotected intercourse). At extended followup, however, these differences were no longer present. The high contact time intervention tested in this trial consisted of an STI prevention component added to each of ten 120-minute group prenatal care sessions.

Key Questions 1b and 2b. Does the Effectiveness of Behavioral Counseling Interventions Differ by Intervention Characteristics (e.g., Intensity or Mode)?

As described above, the interventions tested in the trials varied considerably in their characteristics in terms of total contact time, duration of contact (single vs. multiple contacts over weeks or months), format (e.g., group counseling, individual counseling, in-person, telephone, text messages, computer-based), and behavioral change models and strategies. The heterogeneity of study populations and the interventions tested limited our ability to draw strong inferences about which components were associated with effectiveness. Most studies involved moderate or high contact times, and high contact times were more strongly associated with effectiveness for STI prevention in meta-regression ($p=0.02$) (**Table 5**). There was also evidence from meta-regression that interventions involving group counseling may be more effective than those without ($p=0.02$). There was, however, considerable correlation in the study populations and intervention characteristics, as well as among the different intervention components. For example, group counseling interventions tended to have the highest contact times and were more commonly conducted in interventions for adolescent girls and young adult women. There were also exceptions evident in the body of evidence, including evidence of a modest effect for STI prevention from a brief video intervention for men and women making STI clinic visits.¹⁵⁶ A single individual counseling intervention with moderate contact time (45 minutes) also was effective for men and women making STI clinic visits.¹⁴⁵ The most effective interventions were those involving high contact times and group counseling, but it can also be concluded that many types of behavioral counseling interventions can be effective for STI prevention. Exemplars of effective interventions for specific subpopulations are provided in **Appendix F Table 1**.

Key Question 3. What Potential Harms Are Associated With Behavioral Counseling Interventions to Reduce STI Infections?

Summary of Results

Few studies reported potential adverse consequences of the evaluated behavioral interventions to prevent STI, and no evidence of statistically significant intervention harms was identified.

Seven trials ($n=3,458$) reported potentially adverse consequences that might theoretically arise from the behavioral interventions evaluated (**Table 7**).^{107, 119, 122, 129, 142, 148, 164} A study conducted

among adolescents and young adults (primarily females) that involved a text-messaging intervention reported three driver-caused road traffic accidents related to texting: two in the intervention group and one in the control group. The study was too small to permit estimation of the difference with any precision. No other studies relying on text-messaging interventions reported adverse events related to driving and texting.

Detailed Results

Higher rates of unintended pregnancy could occur if female study participants used condoms for STI prevention but did not add a more effective method of birth control. Conversely, interventions could encourage consistent condom use and reduce unintended pregnancy rates for populations not using effective contraceptive methods. One study of young women who did not want to become pregnant in the following year reported higher proportions of pregnancies in the intervention group at 6 and 12 months, but the differences were not statistically significant.¹⁰⁷ Two other studies reporting pregnancy outcomes found statistically significant lower pregnancy rates in the intervention groups among adolescents¹¹⁹ and postpartum women¹²⁹ at 6 months, but the proportion with a pregnancy remained slightly lower and was no longer statistically different at 12 months. Finally, two studies found no differences in unplanned pregnancy at 2-year followup.^{148, 164}

Participation in an intervention could potentially impact mental health. Improvements could be seen, or the intervention could be harmful, if individuals had experienced sexual trauma or abuse, or the intervention raised awareness of difficult issues related to sexual health but did not offer adequate resources or support. Only one small pilot trial among women with a history of intimate partner violence reported mental health outcomes by study group. At 3 months of followup, the frequency of depressive symptoms in the prior week was similar between groups, and the frequency of PTSD symptoms was lower in the IG but not statistically different.

Chapter 4. Discussion

Summary of Evidence

The literature included in this systematic review provides evidence that among populations with increased risk for STI based on a range of factors, behavioral counseling interventions can be effective (**Table 8**). Thirty-nine trials, including 17 identified since the previous review, tested the effectiveness of 54 intervention arms for reducing sexual risk behaviors and STI infections. Quantitative pooling of intervention effects on STI prevention indicated that the interventions were associated with reduced odds of incident infections (pooled OR 0.66, 95% CI 0.54, 0.81, I² 74%). Effects were generally consistent; most studies reported lower STI incidence associated with assignment to the intervention condition, and these differences were statistically significant in nine of the studies (**Table 9**). Statistical heterogeneity was substantial, however, as was clinical heterogeneity. Interventions' effects on sexual risk behaviors were consistent with STI results among the studies reporting both outcomes. Overall, 34 studies reported behavioral outcomes, but the specific measures varied and were not consistently reported. The most commonly reported outcomes were condom use (18 trials, n=9,205) and unprotected intercourse (21 trials, n=13,665). The reported numbers of sexual partners and sexual abstinence were also reported in ten trials, including four aimed at delaying or reducing sexual activity among adolescents.^{125, 127, 144, 164}

For STI prevention, the largest effect sizes were observed for intensive group counseling interventions for adolescent girls identifying as African American and Mexican American,^{116, 119, 127} and analysis of intervention characteristics across the body of evidence supports the benefit of group counseling interventions, which was also sometimes paired with individual counseling. Looking at the evidence across studies not limited to adolescents suggests a more modest, but statistically significantly lower odds of STI (**Table 5**). Overall, the included study populations reporting KQ1 outcomes were mostly at increased risk for STI, including some at highest risk based on STI clinic visits or history, and skewed toward participants who were young and female and represented racial or ethnic minorities. In addition, most were focused on reducing STI from heterosexual contact, with a few exceptions.

The findings of this review are consistent with the conclusions from our previous review for the USPSTF, despite the addition of 17 new studies evaluating the evidence of effectiveness for behavioral counseling to prevent STIs. The effect size found for STI incidence in this review (pooled OR = 0.66, 95% CI 0.54, 0.81) is similar both to the findings of the previous review conducted for the USPSTF and other more recent reviews of sexual risk reduction counseling. The previous USPSTF review reported pooled ORs ranging from 0.38 (95% CI 0.24 to 0.60) for five trials of adolescents for interventions with more than 2 hours of estimated contact to 0.85 (95% CI 0.66 to 1.10) for six trials of interventions for adults with between 30 minutes and 2 hours of estimate contact.⁹⁶ Other reviews covering a wide range of settings have reported effects on STI incidence in a comparable range, such as a pooled RR of 0.70 (95% CI NR) for interventions that involved skill-building or communication and negotiation skills in a broad-based review of 289 interventions to reduce STI and sexual risk behavior in adolescents¹⁸⁶ and a pooled RR of 0.59 (95% CI 0.46 to 0.75) in a review of 43 interventions targeting ethnic

minority and economically disadvantaged women.¹⁸⁷ One review found a slightly smaller pooled effect when looking only at brief interventions (up to 60 minutes) in trials limited to males, with a pooled OR of 0.82 (95% CI 0.67 to 0.99).¹⁸⁸

Of the 17 additional studies contributing evidence to this update, only five reported STI outcomes^{105, 113, 122, 164, 165} and twelve reported only behavioral outcomes. Among the five new studies reporting STI outcomes, none were statistically significant but three recruiting from STI clinics had similar effect sizes in the direction of a preventive benefit;^{105, 122, 164} two of these were low-to-moderate contact time interventions using tailored computer-based¹⁶⁴ or text-messages¹²² delivered to male and female adolescent and young adult populations and the other was a small trial in Great Britain that evaluated a 10-minute website visit intervention for adult men (*Men's Safer Sex*).¹⁰⁵ Behavioral change outcomes reported for these trials were consistent with the effects for STI. Among the most effective previously included trials, statistically significant effects^{116, 118, 119, 127, 128, 145, 155, 156, 158} were reported for several. Most of these were high contact time interventions focused on somewhat narrowly defined populations at risk for STI, mainly delivering group counseling sessions to adolescent or young adult girls and women.

Five of the twelve added trials reporting behavioral outcomes reported statistically significant main effects for behavioral changes^{110, 117, 162, 163, 166} and the remainder had null findings with small differences between groups and mixed directions of the intervention effects. Among the statistically significant effective interventions added to the body of evidence, one reported increases in condom use and lower counts of unprotected sex with a moderate contact time, web-based intervention for African American women (*Safe Sistah*).¹¹⁰ Another email-based intervention that sent links to internet content was associated with reduced unprotected intercourse among participating adolescents and young adults.¹⁶⁶ These lower contact time interventions involving computer-based intervention that were effective for self-reported improvements in behavioral outcomes warrant further study to evaluate their effectiveness for STI prevention. Higher contact time intervention were also effective in three trials; one providing ten individual counseling sessions was effective for reducing reports of unprotected anal intercourse for MSM with a history of childhood sexual abuse,¹⁶² another pairing computer sessions with ongoing individual counseling was effective for increasing reported condom use among disadvantaged adolescent girls,¹⁶³ and another conducted in Portugal increased condom use among adolescent girls and young women,¹¹⁷ highlighting the need for further research to identify the approaches and modalities that are effecting changes to prevent STI for different populations.

Intervention Approaches for Sexual Risk Reduction

The evidence included a diversity of literature in terms of included intervention components, modes of delivery, and settings represented (**Appendix E Table 10 and Appendix F Table 1**). The interventions evaluated tended to be designed for and targeted to specific subpopulations defined by age, gender, STI risk behaviors, and STI history. Overall, the included studies were more heavily composed of participants who were young (two-thirds of studies focused on adolescent and young adult populations) and female (more than half of studies enrolled only women) and included high percentages of racial/ethnic minorities. Just as the study populations

varied, the interventions tested were highly variable in terms of the amount of contact time with participants, the number of contacts, the duration of the intervention, the guiding theories and therapeutic approaches, and providers or modalities for intervention delivery. Given that the statistical and clinical heterogeneity of the included evidence was substantial, our ability to identify specific study or intervention characteristics associated with differences in intervention effects was limited. Nevertheless, a few broad conclusions can be drawn based on the body of evidence we reviewed.

Overall, we found that interventions among individuals at increased risk for STIs tended to have large preventive effects if they involved more contact time, included group counseling sessions, and were conducted in more narrowly focused populations with respect to age, gender, and race/ethnicity. Other reviews have proposed moderators of effect size, including matching the gender or ethnicity of the facilitator to the intervention recipients,^{77, 189} targeting or tailoring and intervention to a particular ethnic or sociodemographic group^{77, 189} having theory-based interventions,^{189, 190} and providing skills training, such as regarding the use of condoms or strengthening interpersonal relations.^{77, 186, 189, 190} One of these reviews explored the efficacy of brief (1 or 2 sessions and no more than 60 minutes of contact), individual, face-to-face STI prevention interventions that took place in clinical settings in the United States, and found that many were effective and that the study populations primarily included high-risk heterosexuals, most of whom had STIs at the time of or prior to their participation in the studies.^{77, 191} Our review had similar findings despite the different scope and included many of the same trials.

Individuals were identified for the interventions as being at increased risk for STIs based on medical history (e.g., current or recent STI) or health care site (e.g., STI clinic), reported sexual risk behaviors such as unprotected sexual intercourse with multiple partners, or demographic characteristics associated with higher STI prevalence. There is evidence that behavioral interventions can be effective in reducing incident STIs in the populations included in the trials identified for inclusion in this review. In general, larger intervention effect estimates were observed in trials focused on a single-gender population (often for specific subpopulations defined by race/ethnicity) and involving group counseling and higher contact times. There were exceptions, however: Less intensive interventions targeting more broadly defined populations were also effective,^{145, 156} and given the diversity of study populations and intervention approaches, general conclusions about the necessary components of interventions were not drawn. In general, interventions among individuals at high risk for an STI that involved more contact time, included group counseling sessions, and were conducted in more narrowly focused populations with respect to age, gender, and race/ethnicity tended to have larger preventive effects. For example, the *HORIZONS* and *Project SAFE* and interventions were effective for minority adolescent girls and young women, and these were designed with specific demographic populations in mind; adolescent African American girls and African American and Mexican American girls and women, respectively.

Fourteen of the included trials evaluated interventions delivered to populations of men and women, rather than on a single gender. Of these, seven reported an STI outcome^{112, 113, 122, 137, 145, 156, 164} and seven reported only behavioral outcomes.^{111, 125, 132, 150, 153, 160, 166} Four of these trials reported statistically significant effects. Two conducted among individuals presenting for care at STI clinics^{145, 156} reported lower STI incidence. The other two trials (one among adult psychiatric

outpatients¹¹¹ and one among adolescents and young adults¹⁶⁶) reported reductions in unprotected intercourse and number of sexual partners.¹¹¹ In the STI clinic studies, the *VOICES/VOCES* counseling intervention,¹⁴⁵ and *Safe in the City*, the provision of condoms and a short video intervention¹⁵⁶ were both effective, but there may have been gender differences in effectiveness based on exploratory analyses, with women possibly obtaining more benefit in *VOICES/VOCES* and men more than women from the *Safe in the City* intervention. The more modest effects of these mixed-gender studies and the stratified gender analyses support the overall conclusion that sexual risk reduction counseling interventions are likely more effective when they are attentive to ways that the relational, social, and sexual context may differ for men and women.

Only eleven of 54 intervention arms (8 studies) evaluated low contact interventions (<30 minutes), and only two reported statistically significant effects. Statistically significant findings of reduced STI were reported for the nonrandomized trial of *Safe in the City*¹⁵⁶ and reduced unprotected vaginal and anal sex associated with an intervention consisting of emails with links to internet content.¹⁶⁶ There was evidence that interventions involving more than 2 hours of contact time, often taking place over weeks or months, and interventions involving group counseling were more effective than low and moderate contact time interventions. These higher contact time interventions tended to focus on specific populations defined by personal characteristics such as sex/gender, race/ethnicity, sexual orientation, and age. Several of the low and moderate contact time interventions were extended to broader populations of men and women visiting STI clinics. These included the *Safe in the City* intervention,¹⁵⁶ the *VOICES/VOCES* intervention,¹⁴⁵ a text messaging intervention in Great Britain,¹²² and the *e-KISS* computer-based intervention.¹⁶⁴ As noted, the confounding of intervention characteristics and study populations limited our ability to draw strong conclusions about specific behaviorally intervention features associated with preventive benefit from the body of literature we reviewed to evaluate efficacy.

Behavior Change Theories and Strategies

A broad body of literature suggests that interventions based on a theoretical model are more effective than those that lack one.¹⁸⁹ The most widely used theoretical models of health behavior are the Health Belief Model, the Transtheoretical Model, and Social Cognitive Theory. Additional theoretical or interventional approaches used specifically in the STI prevention literature include¹⁷⁶⁻¹⁷⁸ the Information-Motivational-Behavioral Skills Model,^{179, 180} the Theory of Gender and Power,¹⁸⁴ and the AIDs Risk Reduction Model.¹⁸⁵ Many of these theories share overlapping concepts that are a focus of intervention, such as attitudinal beliefs about positive and negative aspects of behavior, self-efficacy, normative beliefs, risk-related beliefs, and intentions.¹⁹² We did not identify any specific approaches or theories that independently accounted for differences in effect sizes. As noted above, however, other reviews designed to investigate the theories informing interventions have found evidence that theory-based interventions are more effective for sexual behavioral change and STI prevention.^{77, 189-191}

Several studies relied on specific therapeutic counseling approaches, such as cognitive behavioral therapy,¹⁷⁸ family therapy, and motivational interviewing^{176, 177} Cognitive behavioral therapy (CBT) is a problem-focused therapy approach designed to address maladaptive thoughts

(cognitions) and behaviors. CBT was originally developed to help patients manage psychological distress such as depression and anxiety. However, CBT strategies have also been applied more broadly for promoting healthy behavior and self-care.¹⁷⁸ Common therapeutic strategies include cognitive restructuring (identifying and modifying maladaptive thoughts), behavioral activation (activity monitoring and scheduling), and problem-solving. Given that many of the extended high-contact-time counseling interventions used CBT, we cannot quantify the importance of this aspect of the interventions. There is extensive literature, however, supporting the effectiveness of CBT for improving a wide range of health and mental health conditions.¹⁷⁸ Motivational interviewing is a behavior change technique that is used to increase motivation and commitment to change, help patients identify the problematic behaviors that the individual is most willing and able to change, help patients feel a sense of agency for promoting their own health.^{176, 177} This technique was used in seven trials, including the group and individual counseling intervention for adolescent girls evaluated by Champion and colleagues (2012), which had the largest effect size for STI prevention reported among the included studies.

Applicability of the Evidence to U.S.-Based Primary Care

Most of the included studies were conducted in the United States, and four studies were conducted in somewhat comparable international settings (Great Britain, Portugal, Australia). Nearly all of the interventions took place in clinical settings, with STI clinics most heavily represented, along with clinics delivering family planning and women's health services. Very few trials were conducted in general primary care settings. A group counseling intervention conducted in a primary care setting and led by health educators was effective in preventing STI among young adult Black women in a trial by Wingood and colleagues.¹⁵⁸ Three other interventions conducted in general primary care settings found no difference in reported behavioral outcomes between study groups.^{148, 150, 153} One was a brief intervention provided by physicians and aimed at young adult men and women,¹⁵⁰ another evaluated in Australia taught primary care clinicians motivational interviewing techniques for use in engaging with their adolescent and young adult patients,¹⁵³ and the third offered individual counseling with health educators during primary care visits to girls and women at risk for unintended pregnancy,¹⁴⁸ and focused primarily on increasing effective contraceptive use.

The high contact, group counseling interventions that were found effective in this review tended to be tailored to specific subpopulations at increased risk for STI. Similar patients to those enrolled in these interventions can be identified in routine care (e.g., presenting for STI testing). The ongoing, facilitated, group counseling that appears to be most effective will require extra resources to implement in primary care settings that do not have established behavioral health programs. In particular, maintenance of inclusive, effective programs for diverse patient populations may be most important in health systems and settings serving the most low-resourced and vulnerable populations. Usual care comparators may differ depending on the site of care. For example, interventions conducted at STI clinics may provide condoms to all visitors and engage in partner treatment services and counseling with people in the control condition as the standard of care. Group differences between study arms may therefore not reflect what would be seen if interventions were implemented in general primary care settings where usual care would not necessarily offer this standard of care. Furthermore, attendees at STI clinics may

be more motivated to change behaviors following an STI diagnosis or an exposure that led them to seek care in a specialized setting. We did not find evidence that intervention effects differed according to the recruitment setting, possibly because of attenuated effects from to enhanced control conditions were offset by higher motivation of study participants. There is a need for evidence from replication studies of effective interventions evaluated in STI clinics. This would help to ascertain their transferability to primary care settings that see patients at increased and even highest risk for infection but are not solely focused on this health concern.

Other important primary care settings for women and men at risk of STIs and unintended pregnancy were represented in this body of evidence. In addition to STI clinics, much of the evidence on intervention effectiveness comes from studies in focused reproductive health provision centers, such as family planning clinics and women's health centers. One included trial was implemented in a pediatric health care setting and was found to be effective for delaying self-reported initiation of sexual intercourse. The *Families Talking Together* intervention enrolled mother-child dyads and was designed for African-American and Hispanic youth before they became sexually active.¹²⁵ Few studies in the review attempted to identify and recruit individuals at increased STI risk from large health care systems. Instead, the studies selected settings based on the presence of specific increased risk or vulnerable populations. It remains to be seen whether the intensive interventions, often involving multiple group counseling encounters and focused on specific populations at risk, can be made available and will be effective in other clinical settings or among more with heterogeneous populations.

The review was limited to interventions evaluated over the past 20 years, and over one-third were published more than a decade ago. Population changes in sexual risk behaviors and risks over this time period may have implications for the applicability of evidence. Specifically, the development of effective treatments and a prophylactic agent for HIV infection may have shifted population risk perceptions. In addition, the emergence of social networking and dating app platforms has altered the landscape that defines sexual networks and sexual practices.¹⁹³ Research is needed to better understand risk factors and to develop interventions that can attend to current sexual, social and interpersonal contexts that adolescents and young adults most at risk for STIs must navigate.

Because we limited our review to this time frame, interventions that were evaluated for efficacy prior to 2000 were not included. Notably, a large multicenter trial of *Project RESPECT* that was included in the previous USPSTF review, published in 1998 by Kamb and colleagues,¹⁷³ was not included in the current review. This large trial of heterosexual men and women (including some adolescents) making STI clinic visits evaluated high- and moderate-duration individual counseling interventions. The counseling interventions evaluated were effective compared with STI clinic standard-of-care didactic messages. The study results were consistent with the overall results of the current review. For individuals making visits to STI clinics, there are evidence-based interventions to prevent future STIs.

The emergence of new pathogens (e.g., treatment-resistant gonorrhea) and reemergence of old ones (e.g., syphilis) necessitates ongoing efforts to strengthen public health initiatives to prevent STIs. Preventive strategies for individuals are similar for sexually transmitted infections, although the risk of transmission of different pathogens is affected by sexual activities and the

amount of exposure. In addition to the individual protective behaviors that can be addressed with behavioral interventions, public policy and medical practices also have important bearing on the prevalence of disease and risk of exposure. Access to health care, to adequate sexual history-taking and STI screening, and to effective treatments and followup are critical for reducing the scope of the STI epidemic in the United States.¹⁹⁴ While interventions targeting individual sexual behaviors are important, the unequal risks of STI borne by vulnerable subpopulations are in part owing to social inequality in the distribution of health and community resources.

Limitations of the Literature

The diverse behavioral outcome measures and reporting inconsistency among the studies was the main shortcoming of the included literature. The inconsistency in measures of condom use reported across the body of evidence meant that we combined outcomes that have qualitatively different effects on STI prevention; specifically, STI prevention requires consistent condom use, but many studies reported condom use at last sex or any condom use. Further, behavioral outcomes were self-reported and subject to recall bias, Hawthorne effects, and social desirability bias. For the very intensive interventions that tended to be more effective, participants who invested substantial time and developed relationships with the study staff may have felt more acute pressure to conform to socially desirable sexual behaviors. There is evidence that social desirability effects can bias trial results.¹⁹⁵ It was reassuring, nevertheless, that in studies reporting the incidence of diagnosed STI, results for behavioral measures were generally consistent in the degree and direction of effects with the findings for reported STI outcomes; higher levels of condom use or lower levels of unprotected intercourse occurred alongside reduced STI acquisition. This is reassuring with respect to the validity of self-reported behavioral measures available in the included literature. Other observational studies also have shown that self-reported sexual behaviors are often associated with reductions in STI risk,¹⁸⁶ but that self-report of condom use is not always valid.¹⁹⁶ A study by Rose and colleagues (2015)¹⁹⁶ among African American teens and young adults sought to validate condom use self-reports. Considerable discordance between participants' reports and actual condom use validated with testing for sperm in vaginal fluid was observed. The authors suggested that either incorrect use or social desirability bias could account for the result.

The number of studies, their heterogeneity, and correlations in study characteristics limited our ability to draw conclusions about the differential effects of interventions across important subpopulations. For the most part, the included literature evaluated intervention effectiveness within narrowly defined population groups, and it is uncertain whether the reported effect estimates would also be observed for these interventions if adapted to other populations. Overall, the studies tended to conduct stratified analyses comparing subpopulations, and did not often specify *a priori* primary and secondary outcomes or correct for multiple comparisons, which could increase the occurrence of statistical differences attributable to chance. Examination of intervention effectiveness for important subpopulation was also limited by scant included evidence; there were only two studies conducted among pregnant individuals. No studies focused on certain populations known to be at increased risk for STI, such as young heterosexual men with a history of unprotected sex and transgender individuals.

Relatively few of the included studies presented replications or adaptations of effective interventions.¹⁴⁵ Once effectiveness has been established, replication often is conducted using comparative effectiveness study designs to ensure vulnerable patients at high STI risk receive the effective intervention. For example, the DiClemente trial (2004)¹¹⁹ included in this review and tested among adolescent African American girls, *HORIZONS*, has been further developed and evaluated, with additional evidence supporting its effectiveness relative to enhanced sexual health services.¹⁹⁷ These types of studies were not included in this review however, because of our focus on efficacy studies without an active comparator. A trial replicating the *Families Talking Together* intervention¹²⁵ for African-American and Hispanic youth being seen in pediatric care settings was identified during ongoing literature surveillance (published May 2020). The trial tested the intervention among a larger sample of Hispanic, African-American, and mixed race youth, providing additional evidence that the intervention was effective for reducing self-reported behavioral risk factors for STI (i.e., delayed sexual debut, increased condom use).¹⁹⁸ Overall, however, there were few replication studies for the interventions summarized in this review, raising questions as to whether the evaluated interventions are likely to be effective when transferred to different times, places, or populations.

A majority of studies provided 12 or more months of followup, and several of these reported differences at 6 months that were no longer observed at one year. Among the studies reporting shorter followup times, it is possible that effects would have diminished if longer followup had occurred. For this reason, the sustainability of effects remains uncertain. Few of the studies evaluated the extent to which intervention effects last beyond the followup time periods reported. Establishing new sexual habits and skills may have lasting effects or may require reinforcement to have continued health benefits. The study by Shain and colleagues (2004)¹⁵⁵ provided STI incidence data for 2 years of followup and found persistent reductions for standard and enhanced intervention arms. The study was a replication of the *Project SAFE* intervention that was found effective in an earlier trial for adolescent Mexican American and African American girls.¹⁷⁴ The recent test of the intervention adaptation was designed to include eligible participants ages 15 to 45 years old but enrolled mostly adolescents and young adults. Interventions to bolster and extend intervention effects can be effective. A comparative effectiveness trial of a maintenance intervention involving ongoing telephone reinforcement found benefits for African American adolescents receiving the *HORIZONS* intervention.¹⁹⁷ Improvements in ongoing effectiveness were observed with a telephone followup component added.¹⁹⁹ The *HORIZONS* intervention is an adaptation of the group counseling intervention for adolescent African American girls included in this review and found to be effective for STI prevention and improving protective sexual practices.¹¹⁹

Limitations of Our Approach

This review was conducted in accordance with USPSTF Procedures, and decisions about topic scope were made in advance of the review to include studies that would inform evidence-based clinical recommendations. The review was therefore limited to studies of effectiveness and did not evaluate studies designed to assess comparative effectiveness of different types of behavioral counseling interventions. Several studies that were excluded for this reason focused on high-risk populations that were not well-represented in the included body of evidence, such as African

American boys and men,^{200, 201} MSM,²⁰²⁻²⁰⁶ bisexual Black men,^{207, 208} transgender women,²⁰⁹ and homeless young adults.²¹⁰ Given the high STI risk, stigma, and vulnerability among some study populations, investigators may be hesitant to conduct randomized trials without an active STI prevention control condition. Further research aimed at demonstrating the effectiveness of these interventions, however, may be possible using study designs that ensure all identified participants eventually receive the active intervention (stepped wedge, waitlist, attention control addressing other health risks) conditions would be valuable for informing future USPSTF recommendations.

The scope of this review was defined to identify evidence for interventions that can be feasibly implemented in or referred from U.S.-based primary care health care settings. This excluded much of the rich evidence on STI prevention that has been generated in the United States and globally. Because our review was limited to settings applicable to primary care, we did not review evidence on interventions evaluated in among people affiliated through social groups or institutions (e.g., schools, churches, worksites). For example, an effective intervention with Latino MSM that recruited individuals from social settings such as bars or dance clubs and involving recruitment of friends, was not included.²¹¹ Importantly, this review does not provide a comprehensive examination of all effective interventions for STI prevention. Other resources and evidence-reviews, such as those provided through the Community Guide and the Community Preventive Services Task Force consider preventive interventions occurring in a broader range of community settings. The absence of studies included in this review for some at-risk populations does not mean other effective STI prevention programs are not available, but they are designed for application outside of primary health care.

We did not include studies limited to or primarily for HIV-positive patients, but evidence suggests that counseling approaches may help reduce high-risk behaviors. For example, a recent systematic review of STI prevention interventions targeting individuals living with HIV found a similarly modest intervention effect for behavioral counseling interventions to reduce sexual risk behaviors in HIV-positive populations (SMD -0.35, 95% CI -0.49, -0.20, k=14).²¹²

Future Research Needs

We identified only 17 eligible new trials of behavioral interventions without an active comparator that are feasible for primary care published since the previous review. There is a gap in the literature for behavioral interventions in primary care settings, where clinicians must address a range of health concerns and levels of STI risk. The existing evidence on behavioral counseling is, quite understandably, focused on prevention for patients most at risk for STIs, and trials have mostly been conducted in enriched populations with high baseline rates of STIs. There remains a need for research to develop and test lower-intensity behavioral interventions that might be applied in primary care settings serving patients with a range of levels of STI risk. For example, studies in large health systems could provide important evidence on intervening in the context of routine primary care, for example when patients screen positive for an STI or report sexual risk behaviors such as multiple concurrent partners and unprotected intercourse. Pragmatic trials might also be designed to strengthen the evidence base with respect to subpopulation effects. While there are several studies targeting specific groups in this review,

and several presented exploratory stratified analyses, none was designed and powered to test interactions to ascertain what types of interventions are most effective for whom. Larger studies including heterogeneous populations, powered to test differences in effectiveness for different subpopulations could further inform clinical practice. The assignment of patients in primary care to interventions most effective for specific sociodemographic groups and personal STI risk factors may necessitate readily tailored interventions or a menu of interventions for clinicians to prescribe.²¹³

Few studies tested web-enabled or interactive telemedicine modalities that could be used to extend the group counseling format found effective in this review to more remote or otherwise isolated settings. Interventions that included an ongoing group counseling format were associated with the largest effect sizes in this review, and research is needed to make this type of intensive contact intervention more widely available. Newer intervention modalities might be used to complement or boost in-person counseling and show promise for reaching broader patient populations.

Our review identified only one intervention focusing on dyads rather than individuals, in this case an intervention with mothers to reduce the risk for STI in their adolescent children.¹²⁵ None of the included studies were conducted with sexual partnership dyads. For women, the primary means of STI prevention, condom use, requires negotiation and joint decision-making with a male partner. Condom use may depend on intrapersonal and relationship factors.²¹⁴ These can be intervened upon in interventions with women only, as shown in the studies included in this review. Nevertheless, the absence of trials evaluating interventions with sexual partners suggests an area for future research. A comparative effectiveness trial conducted with young adult Latina women and their male partners found improvements in condom use over time for both study groups, suggesting possible benefits of couple interventions.^{215, 216} However, there is evidence from another trial that included an arm delivering an intervention to women only versus to couples, and the effect was no different between these two groups.²¹⁷

Clinician risk assessment is a necessary step for identifying patients who would be eligible for behavioral counseling interventions intended for patients at increased risk of STI, yet few of the included studies incorporated risk assessment by primary care providers into the study design. Tests of interventions among populations of patients identified using clearly defined sexual health risk assessment procedures could strengthen the applicability of evidence to primary care populations. Given that there may be considerable variation in sexual history-taking practices in primary care, the implementation of behavioral counseling interventions for increased risk populations will likely require greater attention to this aspect of provider training and health care delivery. Overall, there is a need for further research on how best to implement behavioral counseling interventions into the course of routine primary care. Pragmatic trials might include clinical identification of eligible patients using standardized approaches, and test different approaches for connecting patients to appropriate and effective interventions.

There are notable gaps in the included evidence. Two studies in this review were conducted among pregnant women, despite the clinical importance of preventing vertical transmission of STI and complications that can be associated with STI during delivery. Most studies primarily included heterosexual participants, and only two studies tested interventions for STI prevention

among gay or bisexual populations. Despite considerable diversity within and across the body of evidence, several groups that also can experience increased risk for STIs were underrepresented, including older adults, gay boys and men, gender minority and transgender populations. This may reflect gaps in the evidence or the limitations related to our review scope discussed above, but the shortage of efficacy research on behavioral interventions for these populations is of concern given the public health imperative to prevent STI and the need for evidence-based resources for intervention.

Conclusions

Our systematic review, which covered nearly two decades of published trials on behavioral counseling interventions that are primary-care feasible or referable, reiterated the findings of previous reviews. There are effective behavioral counseling interventions to prevent STIs by helping individuals increase condom use and reduce sexual risk behaviors. The diversity in study populations, interventions, and reported outcomes included in this evidence does not permit conclusions about the most effective or necessary components of interventions. For some populations at increased STI risk, there are focused interventions that have demonstrated benefit for the intended recipients. Intensive group-counseling interventions and individual counseling interventions were effective in some trials, particularly with young women at increased STI risk based on socioeconomic or racial/ethnic characteristic. There were, however, also trials showing modest intervention benefits for less intensive approaches, especially when tested among individuals presenting to STI clinics or with recent history of STI. The therapeutic approaches and theoretical underpinnings of effective interventions varied but generally included educational, skill development, motivational, and supportive elements. No intervention harms or unintended consequences were identified, although few studies reported potential adverse consequences. This review was designed to support the USPSTF recommendation for preventive clinical services and did not include behavioral counseling interventions that could not be provided in or referred from primary care. Thus, community-level interventions, school-based interventions, and other types of interventions taking place within established social networks were not included. Nevertheless, for some populations at increased risk for STI, there is clear evidence that behavioral counseling provided in the context of primary health care settings can improve sexual health.

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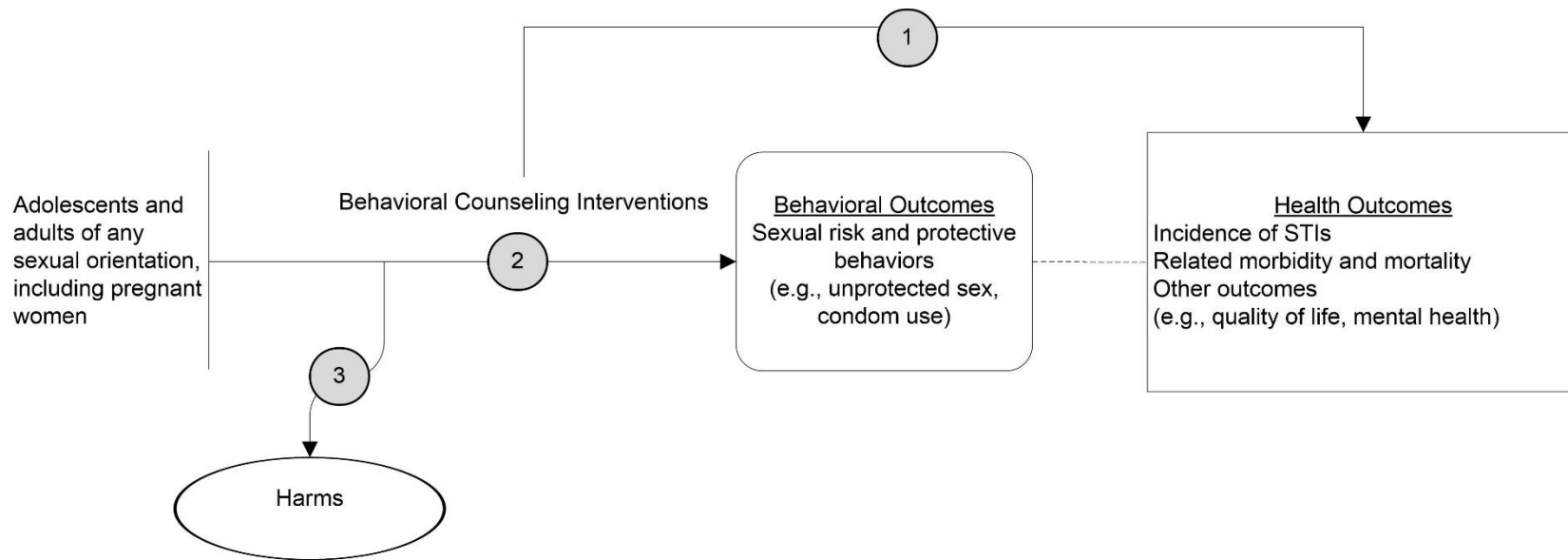
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Figure 1. Analytic Framework



Abbreviation: STI = sexually transmitted infection.

Figure 2. Studies Included in Evidence Review, by Subpopulation (k=39)

	Adolescents*	Adolescents & Young Adults†	Young Adults‡	Adults§
Increased STI Risk - Highest¶	Champion, 2012 ¹¹⁶ (STI)	<u>Costa, 2017</u> ¹¹⁷ <u>Free, 2016</u> ¹²² (STI) Shain, 2004 ¹⁵⁵ (STI)	<u>Crosby, 2009</u> ^{118b} (STI) <u>Metch, 2013</u> ^{137b} (STI)	<u>Bailey, 2016</u> ¹⁰⁵ (STI) <u>Carey, 2010</u> ¹¹² (STI) <u>Carey, 2015</u> ¹¹³ (STI) <u>Marrazzo, 2011</u> ¹³⁵ (STI) <u>O’Cleirigh, 2019</u> ¹⁶² <u>Neumann, 2011</u> ¹⁴⁵ (STI) <u>Warner, 2008</u> ¹⁵⁶ (STI)
Increased STI Risk¶	<u>Bai, 2018</u> ¹⁶⁰ DiClemente, 2004 ¹¹⁹ (STI) Jemmott, 2005 ¹²⁷ (STI) <u>Morrison-Beedy, 2013</u> ¹⁴⁴ Redding, 2014 ¹⁶³	Berenson, 2012 ¹⁰⁷ (STI) Kershaw, 2009 ¹²⁹ (STI) <u>Peipert, 2008</u> ¹⁴⁸ (STI) <u>Shafii, 2019</u> ¹⁶⁴ (STI) <u>Whiteley, 2018</u> ¹⁶⁶	Ehrhardt, 2002 ¹⁰² <u>Lewis, 2018</u> ^{132a} <u>Proude, 2004</u> ¹⁵⁰ <u>Scholes, 2003</u> ^{154a} Wingood, 2013 ¹⁵⁸ (STI) ¹⁰²	Berkman, 2007 ¹⁰⁸ <u>Billings, 2015</u> ¹¹⁰ Carey, 2004 ¹¹¹ <u>Jemmott, 2007</u> ¹²⁸ (STI) <u>Mittal, 2017</u> ¹⁴² <u>Peragallo Montano, 2019</u> ¹⁶¹ <u>Tzilos Wernette, 2018</u> ¹⁶⁵ (STI)
Average STI Risk	<u>Guilamo-Ramos, 2011</u> ¹²⁵ <u>Ybarra, 2017</u> ¹⁵⁹	<u>Sanci, 2015</u> ¹⁵³		<u>Petersen, 2007</u> ¹⁴⁹ (STI)

(STI) = Study reported at least one diagnosed sexually transmitted infection outcome by study group and is included for KQ1.

Study evaluated only high intervention contact times (>120 minutes) unless otherwise indicated: ^ included arms testing low contact intervention (<30 minutes) or ^^ arms testing moderate contact interventions (30-120 minutes).

Underline indicates newly identified study since prior evidence review

* Study participants ranged in age from 12 to 19 years

† Study participants ranged in age from 12 to 25 or study included adolescents and adults with population mean age < 25 years

‡ Study participants ranged in age from 18 to 25 only or study enrolled adults of all ages with population mean age <25 years

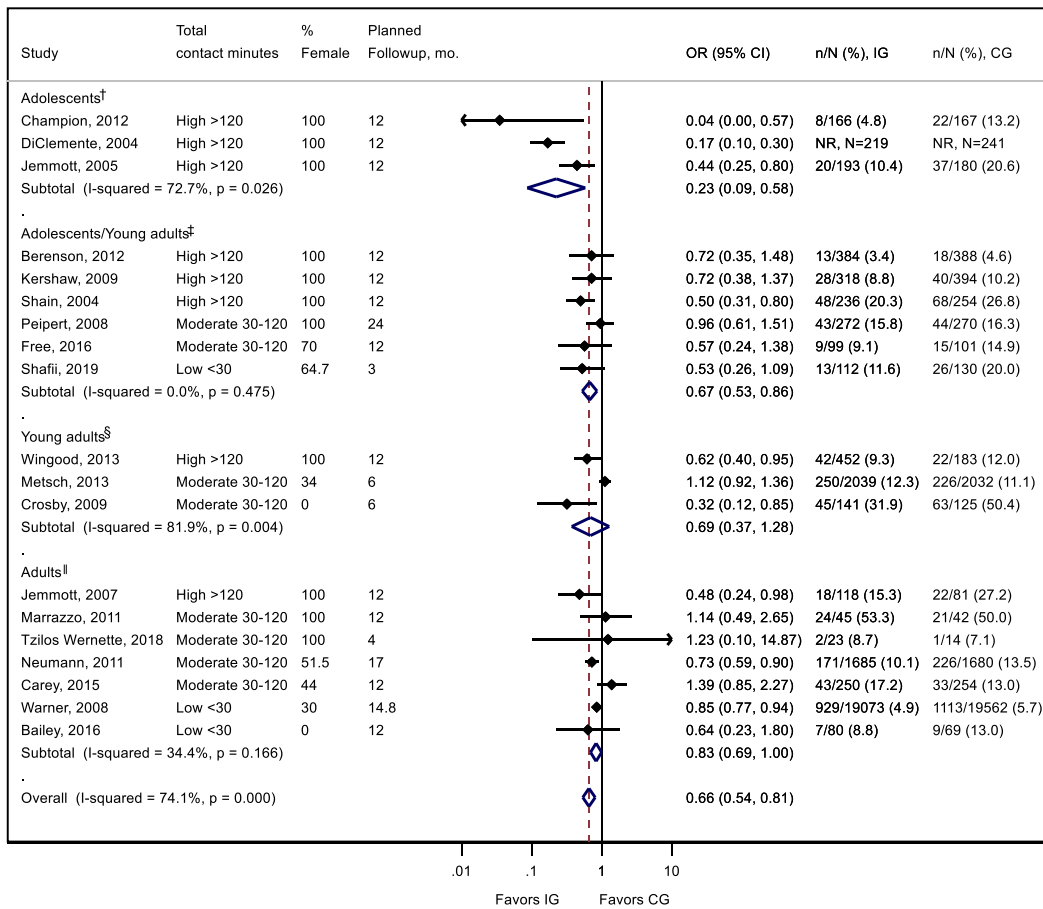
§ Study participants ages 18 and older or enrolled broad age range population with mean age ≥25 years

¶ Recent STI history, diagnosis or visit to STI clinic

¶ Based on reported sexual risk behaviors and/or sociodemographic characteristics associated with higher community STI prevalence

Abbreviation: STI = sexually transmitted infection.

Figure 3. Combined Effects of Interventions on Diagnosed Sexually Transmitted Infections, Stratified by Age Groups*



* Confidence intervals provided in this plot are estimated with the DerSimonian and Laird method. Table 5 provides conservative confidence intervals for the subgroup pooled effects that are estimated by the Restricted Maximum Likelihood method with Knapp Hartung correction that accounts for greater uncertainty when pooling few studies

† Study participants ranged in age from 12 to 19 years

‡ Study participants ranged in age from 12 to 25 or study included adolescents and adults with population mean age < 25 years

§ Study participants ranged in age from 18 to 25 only or study enrolled adults of all ages with population mean age <25 years

|| Study participants ages 18 and older or enrolled broad age range population with mean age ≥25 years

Abbreviations: CG = control group; CI = confidence interval; IG = intervention group; mo = month; n = number of observations; NR = not reported; OR = odds ratio.

Table 1. Design and Baseline Population Characteristics of Included Studies—Adolescents and Young Adults*

Author, year Quality	Country Recruitment setting	Risk	N rand	Population description	Intervention name Intervention description	Control condition	Mean age (range), yrs	% Female	% Race/Ethnicity	Sexual/STI history
Bai, 2018 ¹⁶⁰ Good	US Primary care clinic, community-based health clinic	Increased	187	Adolescents aged 13-18 yrs, with depressive symptoms	<i>Healthy Teens</i> IG1: Ten 60 minute in-person sessions	Usual care	16.06 (13-18)	57	White: 8.6 Black: 11.3 Hispanic: 73.1 Other: 7.0	NR
Berenson, 2012 ¹⁰⁷ Fair	US Prenatal or OBGYN	Increased	1155	Sexually active women, aged 16–24 yrs, not pregnant, seeking oral contraception	IG1: One 45 minute, individual, clinic-based counseling session + >6 phone calls IG2: One 45 minute, individual, clinic-based counseling session	Usual care	19.9 (16-24)	100	White: 24.8 Black: 18.6 Hispanic: 54.2 Other: 2.3	Mean sex partners in past 12 months: 1.6 Lifetime STI: 26.1%
Champion, 2012 ¹¹⁶ Fair	US Community-based health clinic	High	559	African and Mexican American adolescent women, aged 14 to 18 yrs, history of abuse or STI	<i>Project SAFE</i> Two 3-4-hour group counseling sessions, 2 or more individual counseling sessions, 3-5 optional support group sessions	Minimal intervention	16.5 (14-18)	100	Black: 16.4 Hispanic: 83.6	Sexual abuse history: 58.9% Mean age first intercourse: 13.8 yrs Sex with IDU: 11% Mean lifetime number male partners: 7.2 Lifetime STI†: ~100%
Costa, 2017 ¹¹⁷ Fair	Portugal Family planning clinic	High	177	Women 16 to 26 yrs of age at high risk for STI	IG1: Six 120-minute group counseling sessions IG2: Two 15-minute individual counseling sessions, informational	Waitlist	20 (16-26)	100	White: 93.8	Range in mean (SD) times condom used during last 4 sex acts: 1.7-2.1 (1.8-1.9)
Crosby, 2009 ¹¹⁸ Fair	US STI clinic	High	266	African American men, aged 18-29 yrs, newly diagnosed with STI	<i>Focus on the Future</i> One 45-50-minute individual counseling session, variety of condoms and water-based lubricant	Minimal intervention	23.2 (18-29)	0	Black: 100	Condom use at last sex: 48% Current nonmonogamous sexual relationship: 42% BL STI: 100%

Table 1. Design and Baseline Population Characteristics of Included Studies—Adolescents and Young Adults*

Author, year Quality	Country Recruitment setting	Risk	N rand	Population description	Intervention name Intervention description	Control condition	Mean age (range), yrs	% Female	% Race/Ethnicity	Sexual/STI history
DiClemente, 2004 ¹¹⁹ Good	US Community- based health clinic	Increased	522	African American adolescent girls, aged 14-18 yrs, reported vaginal intercourse in past 6 mos	<i>HORIZONS</i> Four 4-hour group counseling sessions	Attention control	15.98 (14-18)	100	Black: 100.0	History of nonconsexual sex: 13.9% Condom use at last sex: 30.3% BL CT: 17.4% BL GC: 5.2% BL Trich: 12.6%
Ehrhardt, 2002 ¹⁰² Good	US Women's health clinic	Increased	360	Sexually active women, aged 18 to 30 yrs	IG1: Eight 2-hour group counseling sessions IG2: Four 2-hour group counseling sessions	None (risk assessment only)	22.3 (18-30)	100	Black: 72.5 Hispanic: 16.9 Other: 10.6	>2 current male partners 23.4% Never/sometimes used condom during sex in past 3 months.: 75.2% STI past 3 months: 16.9% Lifetime STI: 58.3%
Free, 2016 ¹²² Fair	GBR STI clinic, University health clinic	High	200	People aged 16-24 yrs, diagnosed with STI or reporting >1 partner in past year and condomless sex	49 to 63 text messages tailored to participant characteristics (gender, STI)	Attention control	20.5 (16-24)	70.0	White: 57.0 Black: 26.5 Asian: 1.0 Other: 15.5	Condom use at last sex: 33.5% >2 sex partners in past 12 months.: 92.5% BL STI: 44.5%
Guilamo- Ramos, 2011 ¹²⁵ Fair	US Community- based health clinic	Average	264	Mother-child dyads, African American or Latino/a adolescents aged 11-14 yrs, resident mother attending child's healthcare visit	Mother received one 30- minute individual counseling session + program manual + 2 phone calls	Usual care	12.9 (NR)	52.3	Black: 15.5 Hispanic: 84.5	Sexually active: 6.4%

Table 1. Design and Baseline Population Characteristics of Included Studies—Adolescents and Young Adults*

Author, year Quality	Country Recruitment setting	Risk	N rand	Population description	Intervention name Intervention description	Control condition	Mean age (range), yrs	% Female	% Race/Ethnicity	Sexual/STI history
Jemmott, 2005 ¹²⁷ Good	US Hospital- based adolescent medicine clinic	Increased	682	Sexually experienced African American and Latina adolescent women, aged 12-19 yrs	IG1: One 250 minutes group counseling session, skills-based IG2: One 250-minute group counseling session, information-based	Attention control	15.5 (12-19)	100.0	Black: 67.9 Hispanic: 32.1	Unprotected sex in past 3 months: 52% Multiple sex partners in past 3 months.: 16% BL STI: 21.6%
Kershaw, 2009 ¹²⁹ Fair	US Prenatal or OB/GYN	Increased	712	Pregnant adolescent and young women without serious medical problems, aged 14 to 25 yrs	<i>Centering Pregnancy Plus</i> Ten 120-minute group counseling sessions	Usual care	20.4 (14-25)	100.0	White: 6.0 Black: 80.0 Hispanic: 13.0 Other: 1.0	NR
Lewis, 2018 ¹³² Fair	US Advertisements or media, general community	Increased	402	Sexually active young adults aged 18-25 yrs, report drinking alcohol	IG1: One 5-minute computer web-based personalized feedback session IG2: One 5-minute computer web-based integrated personalized feedback session	Attention control	22.4 (18–25)	54.0	White: 68.0 Black: 11.0 Asian: 8.0 AI/NA: 1.0 Hispanic: 14.0 Other: 12.0	NR
Metsch, 2013 ¹³⁷ Good	US STI clinic	High	5012	Adults aged 18+ yrs	One 30-minute individual counseling session + HIV testing	Minimal intervention	NR (2 ranges: 18-25, 68.5%; 25+, 31.5%)	34.0	White: 31.8 Black: 41.9 Hispanic: 15.3 Other: 11.1	Predicted mean number unprotected sex acts in past 6 months.: 23.2 Predicted mean number of sex partners in past 6 months.: 4.65 BL STI: 44.3% BL HIV: 1.1%

Table 1. Design and Baseline Population Characteristics of Included Studies—Adolescents and Young Adults*

Author, year Quality	Country Recruitment setting	Risk	N rand	Population description	Intervention name Intervention description	Control condition	Mean age (range), yrs	% Female	% Race/Ethnicity	Sexual/STI history
Morrison- Beedy, 2013 ¹⁴⁴ Good	US School health clinic, community- based health clinic, hospital- based adolescent medicine clinic, general community	Increased	639	Adolescent females aged 15-19 yrs, majority low-income African American	<i>HIPTeens</i> Four 120-minute information-motivation- behavioral group counseling sessions + two 90-minute group counseling sessions	Attention control	16.42 (15-19)	100	White: 8 Black: 73 Hispanic: 16 Other: 20	Sex in past 3 months: 100% Mean age first sex, yrs: 14.4
Peipert, 2008 ¹⁴⁸ Fair	US Primary care clinic, Family planning clinic, Prenatal or OB/GYN, Advertisements or media	Increased	542	Sexually active adolescent and young women aged 13-24 yrs and women aged 25-35 yrs at "high risk" for STI or unintended pregnancy; desire to avoid pregnancy next 2 yrs	Three 30 minute individually tailored computer web-based sessions	Minimal intervention	22 (13-35)	100	White: 45 Black: 26 Hispanic: 17 Other: 12	>11 lifetime number sex partners: 28% >2 sex partners in past 1 months: 15% Forced sex in past 12 months: 10% Lifetime STI: 47%
Proude, 2004 ¹⁵⁰ Fair	AUS Primary care clinic	Increased	312	Young adults aged 18-25 yrs	One 15-minute physician counseling session + informational resource pamphlets, 2 condoms, lubricant	Attention control	(18-25)	71	NR	Ever had sexual partner: 78%
Redding, 2015 ¹⁶³ Good	US Family planning clinic, Community- based health clinic	Increased	828	Adolescent females	<i>Step by Step</i> IG1: Four 25-minute computer sessions followed by individual counseling	Minimal intervention	16.4 (14-17)	100	White: 7.8 Black: 83.9 Asian: 0.8 AI/NA: 1.5 Hispanic: 7.8	Had vaginal or anal sex: 95.9% Mean total number of sex partners: 5 BL Syph: 1.7% BL GC: 10.4% BL CT: 20.6% BL hrHPV: 5.9% BL Herpes: 1.8%
Sanci, 2015 ¹⁵³ Fair	AUS Primary care clinic	Average	901	Healthy youth aged 14-24 yrs	Clinicians received 9 hours of training + 2 practice visits	Minimal intervention	(14-24)	75.7	NR	NR

Table 1. Design and Baseline Population Characteristics of Included Studies—Adolescents and Young Adults*

Author, year Quality	Country Recruitment setting	Risk	N rand	Population description	Intervention name Intervention description	Control condition	Mean age (range), yrs	% Female	% Race/Ethnicity	Sexual/STI history
Scholes, 2003 ¹⁵⁴ Fair	US Primary care clinic	Increased	1210	Sexually active women aged 18-24 yrs, not sexually monogamous, at risk for HIV/AIDS	2 tailored print mailings	Usual care	21 (18-25)	100	White: 69 Black: 19 Other: 12	>2 sex partners in past 12 months: 56.5% Sex with nonprimary partner in past 3 months: 19% Lifetime STI: 27%
Shafii, 2019 ¹⁶⁴ Fair	US STI clinic, advertisements or media	Increased	272	Adolescents and young adults aged 14-24 yrs with a history of risky sexual behavior	<i>e-KISS (electronic-KIOSK Intervention for Safer Sex)</i> IG1: One computer-based tailored feedback session	None	21 (15-24)	64.7	White: 37.4 Black: 34.1 Asian: 10.0 AI/NA: 2.2 Hisp: 7.0 Other: 9.3	NR
Shain, 2004 ¹⁵⁵ Fair	US STI clinic	High	775	Mexican-American and African American women aged 15-45 yrs, STI diagnosis	IG1: One individual counseling session + three 3-hour group counseling sessions + option to attend five 90-minute group counseling sessions IG2: One individual counseling session + three 3-hour group counseling sessions	Minimal intervention	21.0 (15-45)	100	Black: 23.2 Hisp: 76.8	>1 sex partner in past 3 months: 25.7% BL STI: 100% BL CT: 77.8% BL Syph: 4.6%
Whiteley, 2018 ¹⁶⁶ Fair	US General community	Increased	60	Sexually active adolescents aged 15-24 yrs	IG1: Eight emails containing 19 links to internet content	Waitlist	18.6 (15-24)	38	Black: 52 Hisp: 36	NR
Wingood, 2013 ¹⁵⁸ Good	US Primary care clinic	Increased	848	African American women aged 18-29 yrs	Two 4-hour group counseling sessions	Attention control	22 (18-29)	100	Black: 100	BL STI: 17% BL CT: 10.4% BL hrHPV: 38.9%
Ybarra, 2017 ¹⁵⁹ Good	US Advertisements or media	Average	302	Adolescent cisgender males aged 14-18 yrs, identify as gay, bisexual, or queer	<i>Guy2Guy Intervention Group</i> Text messages 5-10 times/day five consecutive weeks + text messages for one week	Attention control	NR (14-18)	0.00	White: 67.1 Black: 14.8 Other: 18.0	Ever had sex: 70%

* All studies were randomized trials, except: Sanci, 2015 = Cluster RCT

† Participants recruited based on history of STI or abuse

Table 1. Design and Baseline Population Characteristics of Included Studies—Adolescents and Young Adults*

Abbreviations: AI/NA = Alaska Native/Native American; AUS = Australia; BL = baseline; CT = chlamydia trachomatis; GBR = Great Britain; GC = gonorrhea; Hisp = Hispanic; HIV = human immunodeficiency virus; hrHPV = high-risk humanpapilloma virus; IDU = intravenous drug user; IG = intervention group; NR = not reported; OBGYN = obstetrics & gynecology; Rand = randomized; RESPECT = Recovery, Empowerment, Social Services, Prenatal care, Education, Community, and Treatment; RCT = randomized controlled trial; SD = standard deviation; STI = sexually transmitted infection; Syph = syphilis; Trich = trichomoniasis; US = United States; Yrs = years.

Table 2. Design and Baseline Population Characteristics of Included Studies—Adults*†

Author, year Quality	Country Recruitment setting	Risk	N rand	Population description	Intervention name Brief description	Control condition	Mean age (range), yrs	% Female	% Race/Ethnicity	Sexual/STI history
Bailey, 2016 ¹⁰⁵ Good	GBR STI clinic	High	176	Men aged ≥16 yrs	<i>Men's Safer Sex</i> One 10-minute website visit	Usual care	29.4 (≥16)	0	White: 69.2 Black: 14.5 Asian: 7.5 Other: 8.2	BL STI: 3.4%
Berkman, 2007 ¹⁰⁸ Good	US Behavioral health clinic	Increased	149	Men aged 18 to 59 yrs, psychiatric outpatients with severe mental illness diagnosis and history of psychosis	<i>Enhanced SexG (E- SexG)</i> Thirteen 60-minute, group counseling sessions	Attention control	38.6 (18- 56)	0.0	White: 11.0 Black: 54.0 Hispanic: 28.0 Other: 7.0	NR
Billings, 2015 ¹¹⁰ Fair	US Community- based health clinic	Increased	83	African American women, aged 18-50 yrs, at high risk for STI	<i>Safe Sistah</i> One computer-based educational session	Waitlist	35.1 (18- 50)	100	Black: 100	>1 sexual partner in past 2 months: 34.5%
Carey, 2004 ¹¹¹ Fair	US Behavioral health clinic	Increased	268	Women and men, aged 18+ yrs, psychiatric outpatients with alcohol or drug use in the past year	Ten group counseling sessions	Usual care	36.5 (≥18)	54	White: 67 Black: 21 Other: 12	Lifetime STI: 38%

Table 2. Design and Baseline Population Characteristics of Included Studies—Adults*†

Author, year Quality	Country Recruitment setting	Risk	N rand	Population description	Intervention name Brief description	Control condition	Mean age (range), yrs	% Female	% Race/Ethnicity	Sexual/STI history
Carey, 2010 ¹¹² Fair	US STI clinic	High	1,483	Women and men, aged 18+ yrs, sexual risk behavior in past 3 months, willing to be tested for HIV	IG1: One 15-minute individual counseling session + 4-hour intensive motivational, behavioral, skills workshop IG2: One 15-minute individual counseling session + 4-hour intensive informational workshop IG3: One 15-minute individual counseling session IG4: One 15-minute informational video + 4-hour intensive informational workshop IG5: One 15-minute informational video + 4-hour intensive motivational, behavioral, skills workshop	Minimal intervention	29.2 (≥18)	46.4	White: 24.3 Black: 63.9 Hisp: 8.7 Other: 11.9	Condom use at last intercourse: 27% Lifetime history of sex trade: 22% Age at first intercourse <13 yrs: 18% BL STI: 18.1%
Carey, 2015 ¹¹³ Fair	US STI clinic	High	1,010	Men and women aged 16+ yrs, sexual risk behavior in past 3 months	IG1: One 22-minute video + sexual health questionnaire IG2: One 22-minute video + general health questionnaire IG3: One 22-minute video + sexual health questionnaire	Attention control	28.5 (NR)	44	White: 19 Black: 69 Hisp: 8 Other: 13	>1 concurrent sexual partners in past 3 months.: 47%

Table 2. Design and Baseline Population Characteristics of Included Studies—Adults*†

Author, year Quality	Country Recruitment setting	Risk	N rand	Population description	Intervention name Brief description	Control condition	Mean age (range), yrs	% Female	% Race/Ethnicity	Sexual/STI history
Jemmott, 2007 ¹²⁸ Good	US Women's health clinic	Increased	564	Sexually experienced African American women, aged 18-45 yrs	<i>Sister-to-Sister</i> IG1: One 200-minute group counseling session, skills-based IG2: One 200-minute group counseling session, information- based IG3: One 20-minute individual counseling session, skills-based IG4: One individual, 20- minute counseling session, information- based	Attention control	27.2 (18- 45)	100	Black: 100	Condom use at last sex: 38.7% BL STI: 20.3%
Marrazzo, 2011 ¹³⁵ Fair	US Advertisements or media	High	89	WSW aged 16- 30 yrs, positive BV diagnosis, reported sex with woman in past 60 days	One 30-minute individual counseling session	Minimal intervention	25.4 (16- 30)	100	Black: 8	>1 female sex partner: 24.7% BL BV: 100%
Mittal, 2017 ¹⁴² Fair	US Community- based health clinic, women's health clinic, community agencies	Increased	55	Women aged 18+ yrs, history of intimate partner violence	<i>Supporting positive and healthy relationships (SUPPORT)</i> Three 135-minute individual counseling sessions + five 135- minute group counseling sessions	Minimal intervention	34.5 (18- 49)	100	White: 33.0 Black: 51.0 Other: 16.0	Median number lifetime sex partners: 19 Mean (SD) sex partners in past 3 months: 1.5 (1.2) Mean (SD) episodes unprotected sex in past 3 months: 21 (27.2)

Table 2. Design and Baseline Population Characteristics of Included Studies—Adults*†

Author, year Quality	Country Recruitment setting	Risk	N rand	Population description	Intervention name Brief description	Control condition	Mean age (range), yrs	% Female	% Race/Ethnicity	Sexual/STI history
Neumann, 2011 ¹⁴⁵ Fair	US STI clinic	High	3,365	Adults aged 18+ yrs	<i>VOICES/VOCES</i> One 45-minute group counseling session	Usual care	29.3 (18- 71)	51.5	White: 0.8 Black: 40.1 Hisp: 50.9 Other: 8.2	Ever used condoms: 80.8% BL STI: 22.2%
O'Cleirigh, 2019 ¹⁶² Fair	US Community- based health clinic, advertisements or media	High	43	Adult MSM with a history of childhood sexual abuse	IG1: HIV/STI counseling and testing plus 10 in-person therapy sessions	Usual care	39.2	0	White: 62.8 Black: 25.6 Hisp: 7.0 Other: 4.7	NR
Peragallo Montano ¹⁶¹ Fair	US Community- based health clinic, advertisements or media, community agencies	Increased	320	Refugee and immigrant Hispanic women (>95% born outside U.S.) aged 18- 50 yrs with any recent sexual activity	<i>Salud, Educacion, Prevencion y Autocuidado (SEPA)</i> IG1: Three 2.5-hour sessions	Waitlist	35.5 (18- 50)	100	Hisp: 100	Any sexual activity in past 3 mos.: 100%
Petersen, 2007 ¹⁴⁹ Fair	US Primary care clinic	Average	764	Women aged 16-44 yrs at risk of unintended pregnancy	<i>Women's Reproductive Assessment Program (WRAP)</i> One individual counseling + followup phone call or visit	Attention control	NR (16- 44)	100	White: 62 Black: 27 Other: 10	Sex in past 30 days: 70%
Tzilos Wernette, 2018 ¹⁶⁵ Fair	US Prenatal or OBGYN	Increased	50	Pregnant women at risk for STI/HIV and alcohol/drug use.	IG1: One 60-minute computer session plus a 15 min booster session	Attention control	24.4	100	White: 30 Black: 26 AI/NA: 4 Hisp: 32 Other: 40	NR
Warner, 2008 ¹⁵⁶ Good	US STI clinic	High	40,282	Individuals making visits to STI clinics	<i>Safe in the City</i> One 23-minute video + educational pamphlets and condoms	Usual care	NR (NR)	30.0	Black: 18.5 Hispanic: 25.0 White: 46 Other: 11.0	BL STI: 15.5%

* Four studies did not exclude adolescents, but primarily recruited adults and the mean age in the study populations was above 25 years

† All studies were randomized trials, except: Neumann, 2011 = nonrandomized controlled trial; Warner, 2008 = nonrandomized controlled trial

Table 2. Design and Baseline Population Characteristics of Included Studies—Adults*†

Abbreviations: BL = baseline; BV = bacterial vaginosis; CT = chlamydia trachomatis; E-SexG = Enhanced Sex, Games, and Videotape intervention; GBR = Great Britain; Hisp = Hispanic; HIV = human immunodeficiency virus; IG = intervention group; NR = not reported; Rand = randomized; SD = standard deviation; STI = sexually transmitted infection; SWE = Sweden; US = United States; WSW = women who have sex with women; Yrs = years; VOICES/VOCES = Video Opportunities for Innovative Condom Education and Safer Sex.

Table 3. Summary of Study Population Characteristics

Characteristics	No. studies	% studies
All studies	39	100
Ages groups in studies		
Adolescents*	8	21
Adolescents and Young Adults†	9	23
Young Adults‡	7	18
Adults§	15	38
Sex or gender of study population		
Women only	20	51
Men only	5	13
Men & Women	14	36
Majority of study population racial or ethnic minority	27	69
Defined STI Risk Populations		
Unselected, average risk populations¶	4	10
Increased STI risk#	22	56
Increased STI risk - Highest**	13	33
Reported at least 10% of study population were not heterosexual (e.g., gay, bisexual, lesbian, MSM, WSW)	10	26

* Study participants ranged in age from 12 to 19 years

† Study participants ranged in age from 12 to 25 or study included adolescents and adults with population mean age < 25 years

‡ Young Adults – Study participants ranged in age from 18 to 25 only or study enrolled adults of all ages with population mean age <25 years

§ Adults – Study participants ages 18 and older or enrolled broad age range population with mean age ≥25 years

|| Of the 27 studies conducted in the United States

¶ General risk population, attending primary care or family planning clinic, not targeting specific sexual risk behaviors or people in high STI prevalence communities. Includes studies with a mix of abstinent and sexually active adolescents

Increased STI risk population defined based on study enrollment of individuals belonging to a population known to have higher rates of STI (sexually active adolescent and young adult populations) or engaging in sexual behaviors associated with higher STI risk (e.g., unprotected intercourse, multiple concurrent partners). Many studies in this category enrolled participants with several risk factors.

** High STI risk population defined as individuals seeking care at STI clinic or having recent, suspected, or current STI

Abbreviations: CCT = controlled clinical trial; MSM = men who have sex with men; MSW = men who have sex with women; No. = number; RCT = randomized controlled trial; STI = sexually transmitted infection; US = United States; WSM = women who have sex with men; WSW = women who have sex with women.

Table 4. Summary of Study Design Characteristics

Characteristics	No. studies	% studies
All studies	39	100
Study design		
RCT	36	92
Cluster RCT	1	3
Nonrandomized CCT	2	5
Quality Rating*		
Good	13	33
Fair	26	67
Included in previous review (2014)	22	56
Conducted in US	34	87
Conducted more than 10 years ago (before 2009)	12	31
Recruitment Setting†		
Community health clinic, primary care clinic, school clinic	12	31
STI Clinic	9	23
Women’s health, OBGYN or family planning clinic	6	15
Other specialty health clinic (behavioral health, adolescent health)	3	8
Online, media, advertisements	9	23
Intervention provided by health professional (i.e., nurse, physician, social worker, psychologist, mental health specialist)	11	28
Intervention time‡		
Low contact (<30 minutes)	7	18
Moderate contact (30-120 minutes)	11	28
High contact (>120 minutes)	21	54
Intervention included group counseling	17	44
Control group		
No intervention/usual care/waitlist	16	41
Minimal intervention	10	26
Attention control	13	33
Longest followup time point reported		
3-5 months	7	18
6-11 months	8	21
12 months	18	46
>12 months (range 14-24)	6	15

* K additional studies were rated as poor quality and excluded from the review.

† Studies with multiple recruitment settings were categorized according to the most specialized.

‡ Studies with more than one intervention arm were categorized according to the longest contact-time.

Abbreviations: CCT = controlled clinical trial; No. = number; OBGYN = obstetrics and gynecology; RCT = randomized controlled trial; STI = sexually transmitted infection; US = United States.

Table 5. Meta-Analysis Results for Outcome of Sexually Transmitted Infection

	No. studies (n randomized or allocated)	Pooled Analysis No. studies (n analyzed)	Effect Estimate	Pooled result (95% CI)	I ² %	Tau ²	Effect Range*	Effect Median (IQR) [†]
All trials reporting STI	21 (59,328) [†]	19 (52,072)	OR	0.66 (0.54, 0.81)	74.1	0.11	0.02 to 3.07 ARD: -18.5 to +9.5	0.94 (0.62 to 1.13) ARD: -0.3 (-3.4 to +1.0)
Sensitivity analysis: excluding trial of BV prevention among WSW ^{135‡}	--	18 (51,985)	OR	0.65 (0.52, 0.80)	75.3	0.11	--	--
Statistically significant subgroup effect comparisons								
Trials limited to adolescents	3 (1,763)	3 (1,166)	OR	0.22 (0.02, 2.30) [§]	72.7	0.46	0.02 to 1.72 ARD: -8.4 to +9.1	0.76 (0.14 to 1.17) ARD: +0.8 (-5.3 to +2.15)
Trials <u>not</u> limited to adolescents	18 (57,565) [†]	16 (50,906)	OR	0.78 (0.67, 0.91)	50.9	0.03	0.32 to 3.07 ARD: -18.5 to +9.5	0.94 (0.66 to 1.12) ARD: -0.4 (-2.5 to +1.0)
High contact time interventions (>120 minutes)	9 (7,300) [†]	8 (3,974)	OR	0.46 (0.28, 0.75) [§]	65.4	0.17	0.02 to 1.72 ARD: -15.8 to +9.1	0.72 (0.47 to 0.99) ARD: -1.9 (-5.3 to +1.0)
Moderate contact time interventions (30-120 minutes)	9 (11,298) [†]	8 (9,072)	OR	0.90 (0.66, 1.25) [§]	58.8	0.06	0.32 to 3.07 ARD: -18.5 to +7.0	1.05 (0.9 to 1.12) ARD: 0 (-1.0 to +1.8)
Low contact time interventions (<30 minutes)	4 (41,294)	4 (39,230)	OR	0.66 (0.36, 1.24) [§]	43.6	0.07	0.43 to 1.62 ARD: -13.0 to +9.5	0.85 (0.64 to 1.08) ARD: -1.1 (-6.2 to 2.0)
Trials including group counseling	9 (9,510) [†]	8 (6,567)	OR	0.47 (0.28, 0.78) [§]	74.9	0.19	0.02 to 1.72 ARD: -15.8 to +9.1	0.72 (0.47 to 0.99) ARD: -2.2 (-5.3 to +1.0)
Trials <u>not</u> including group counseling	12 (49,818) [†]	11 (45,505)	OR	0.90 (0.74, 1.08)	42.7	0.03	0.32 to 3.07 ARD: -18.5 to +9.5	1.01 (0.77 to 1.18) ARD: 0 (-1.4 to +2.0)

* Range of effects for all study arms and timepoints, i.e., not limited to records in the meta-analysis

[†] Number of trials reporting an STI outcome does not add up to the total number of trials included in the pooled analyses because some trials did not provide sufficient data for inclusion in the meta-analysis

[‡] Sensitivity analysis conducted because the STI outcome and population were qualitatively different than the rest of the included evidence.

[§] Effect based on restricted maximum likelihood model with the Knapp-Hartung adjustment for small samples. Remaining effects based on DerSimonian and Laird method.

Confidence intervals for subgroup estimates shown in the stratified forest plot figures are also based on the DerSimonian and Laird method and are narrower than the confidence limits obtained with statistical adjustments for pooling a small number of studies.

^{||} Number of trials for low contact subgroup includes an additional intervention arm¹²⁸ focusing on the same skills as the high contact time subgroup.

Abbreviations: ARD = absolute risk difference; CI = confidence interval; IQR = interquartile range; k = number of studies; n = number of observations; OR = odds ratio; WSW = women who have sex with women.

Table 6. Meta-Analysis Results for Outcome of Condom Use and Unprotected Intercourse Outcomes

Outcome No. studies (n randomized)	Type of outcome measure	Pooled analysis No. studies (n analyzed)	Effect Estimate	Pooled result (95% CI)*	I ² %	Tau ²	Effect Range [†]	Effect Median (IQR) [†]
Condom Use All trials reporting condom use 18 (9,205) [§]	Dichotomous (e.g., consistent, at last sex)	13 (5,253)	OR	1.31 (1.10, 1.56)	39.9	0.04	0.54 to 5.08	1.17 (0.87 to 1.58)
		13(5,253)	ARD	--	--	--	-6.50 to +26.60	2.00 (-2.00 to +12.00)
	Continuous (proportion of sexual intercourse with condom use)	7 (2,920)	MD	10.75 (1.01, 20.50)	79.2	79.39	-8.42 to 27.88	5.65 (0.23 to 8.00)
		7 (1,914)	SMD	0.34 (0.06, 0.63)	78.9	0.07	-0.24 to 0.73	0.27 (0.05 to 0.37)
Unprotected Intercourse All studies reporting unprotected intercourse 21 (13,665) [¶]	Continuous (e.g., number of unprotected sex acts/episodes/days)	14 (9,183)	SMD	-0.11 (-0.19, -0.03)	58.8	0.01	-0.71 to +0.25	-0.05 (-0.20 to +0.04)
		14 (9,183)	MD	-0.94 (-1.40, -0.48)	16.4	0.11	-11.90 to +4.5	-0.44 (-1.97 to 0.43)

*For analyses with <10 studies the REML method was used to calculate the CI.

[†] Range and median of effects for all study arms and timepoints, i.e., not limited to records in the meta-analysis

[‡] Measures vary and include proportion condom used for sex acts, sex days, or sexual intercourse episodes across a range of time frames (30 days to 6 months).

[§] Number of trials reporting the condom use outcomes does not add up to the total number of trials reporting any outcome because some trials did not provide data to calculate the effect for either dichotomous or continuous score.

[|] MD and SMD analyses have same number of studies but differed by one study due to available statistical measures. Thus, the total number of participants differed.

[¶] Number of trials reporting the unprotected intercourse outcomes does not add up to the total number of trials reporting any outcome because some trials reported only a dichotomous scale score and are not shown in this table

Abbreviations: ARD = absolute risk difference; CI = confidence interval; IQR = interquartile range; MD = mean difference between groups; OR = odds ratio; SMD = standardized mean difference (Hedges' g).

Table 7. Results From Studies Reporting Intervention Harms

Author, year	Outcome	Outcome description	Recall period	Int arm	Group	F/U mos	IG n (%) or Mean (SD), n	CG n (%) or Mean (SD), n	Result (95% CI)	P-value
Berenson, 2012 ¹⁰⁷	Pregnancy	Pregnancy	1 month	IG1	Overall	12	52/384 (13.5)	48/388 (12.4)	OR: 1.11 (0.73 to 1.69)*	0.22
				IG2	Overall	12	63/383 (16.4)	48/388 (12.4)	OR: 1.39 (0.93 to 2.09)*	0.22
DiClemente, 2004 ¹¹⁹	Pregnancy	Pregnancy	NR	IG1	Overall	6	8/226 (3.5)	17/243 (7.0)	OR: 0.38 (0.15 to 0.36)	0.04
						12	13/219 (5.9)	20/241 (8.3)	OR: 0.53 (0.27 to 1.03)	0.06
Kershaw, 2009 ¹²⁹	Pregnancy	Percent repeat pregnancy	6 months	IG1	Overall	6	18/318 (5.7)	51/394 (12.9)	OR: 0.49 (0.27 to 0.91)	0.02
						12	73/318 (23.0)	102/394 (25.9)	OR: 0.95 (0.63 to 1.78)	0.79
Peipert, 2008 ¹⁴⁸	Pregnancy	Unplanned pregnancy	2 years	IG1	Overall	24	60/272 (22.1)	62/270 (23.0)	OR: 0.95 (0.63 to 1.42)*	NSD
Shafii, 2019 ¹⁶⁴	Pregnancy	Incident pregnancy	NA	IG1	Overall	3	5/112 (4.5)	10/130 (7.7)	OR: 0.56 (0.19 to 1.69)	0.10
Free, 2016 ¹²²	Intervention harm	Involved in a driver-caused road traffic accident as result of text messaging	1 year	IG1	Overall	12	2/77 (2.6)	1/80 (1.3)	OR: 2.11 (0.19 to 23.72)*	0.548
Mittal, 2017 ¹⁴²	Depression	Frequency of depressive symptoms during the preceding week	1 week	IG1	Overall	3	3.6 (2.8), 19	2.6 (2.6), 21	MeanDiff: 0.95 (-0.73 to 2.63)*	NSD
	Generalized anxiety	Bothered by certain problems within the past 2 weeks	2 weeks	IG1	Overall	3	7 (6.4), 19	10.2 (5), 21	MeanDiff: -3.04 (-6.65 to 0.57)*	NSD
	PTSD symptoms	Frequency of PTSD symptoms in the past 2 weeks	1 week	IG1	Overall	3	21 (14), 19	23.4 (13), 21	MeanDiff: -2.37 (-10.81 to 6.07)*	NSD

* Calculated estimate from reported raw study data. P-values are based on statistical analyses reported in the published study results

Abbreviations: BL = baseline; Calc = calculated; CG = control group; Diff = difference; F/U = followup; IG = intervention group; Int = intervention; Mos = months; n = number of participants; NR = not reported; NSD = no significant difference; OR = odds ratio; SD = standard deviation.

Table 8. Summary of Evidence for Behavioral Counseling Interventions to Prevent Sexually Transmitted Infections

Key Question	No. of Studies (No. of observations) Study Designs	Summary of Findings	Consistency and Precision	Other Limitations	Strength of Evidence	Applicability
<p>KQ1. Effectiveness of Behavioral Counseling Interventions for Reducing STI</p> <p>a. By study subpopulations</p> <p>b. By intervention characteristics</p>	<p>k = 21 studies (n= 59,328) [12 newly identified since previous review]</p>	<p>Behavioral interventions delivered to individuals at increased risk for STI were effective in pooled analysis (pooled OR 0.66, 95% CI 0.54, 0.81, I² 74%; k = 19, n = 52,072).</p> <p>Substantial statistical heterogeneity could not be attributed to specific factors since the most effective interventions generally shared similar characteristics. Larger preventive effects tended to be observed for interventions that included group counseling sessions, involved high contact times (>120 minutes), and focused on adolescent girls at increased risk for STI.</p>	<p>Reasonably consistent</p> <p>Reasonably precise</p>	<p>Seven trials were assessed good quality with low risk of bias and the remainder were deemed fair quality due to modest risk of bias associated mainly with modest loss to followup and incomplete outcome ascertainment.</p> <p>Statistical heterogeneity could not be readily explained by any independent factor as there was considerable overlap in the features of effective interventions (e.g., group counseling, higher contact times, age group, sex/gender of participants)</p>	<p>Moderate for benefit</p>	<p>Most trials were conducted in the US among populations at increased risk for STI. Increased risk populations were defined by STI clinic attendance or history (highest risk), sexual risk behaviors, or demographic characteristics.</p> <p>Most studies focused on specific subpopulations defined by race/ethnicity, sexual orientation, age, gender, pregnancy, or other factors.</p> <p>More than half of the studies were limited to girls or women (k=11). Two studies were limited to men.</p>

Table 8. Summary of Evidence for Behavioral Counseling Interventions to Prevent Sexually Transmitted Infections

Key Question	No. of Studies (No. of observations) Study Designs	Summary of Findings	Consistency and Precision	Other Limitations	Strength of Evidence	Applicability
<p>KQ2. Effectiveness of Behavioral Counseling Interventions for Reducing Sexual Risk Behaviors</p> <p>a. By study subpopulations</p> <p>b. By intervention characteristics</p>	<p>k = 34 (n= 21,417)</p>	<p>Among 18 studies reporting a variety of condom use measures and 21 studies reporting unprotected intercourse, there was evidence of intervention effectiveness. Intervention was associated with increased odds of reported condom use for dichotomous measures (pooled OR 1.31, 95% CI 1.10 to 1.56, I² 40%; k = 13, n = 5,253) and a decrease in reported unprotected intercourse measured as counts (pooled MD -0.94, 95%CI -1.40 to -0.48, I² 16%; k = 14, n = 9,183). Studies reporting STI and behavioral outcomes were internally consistent suggesting reductions in sexual risk behaviors contributed to lower STI incidence. One study of adolescents (mostly not yet sexually active) found reduced reports of vaginal sex associated with the intervention.</p>	<p>Reasonably consistent</p> <p>Imprecise due to variability in reported measures and effect sizes across measures</p>	<p>Measures of behavioral outcomes were heterogeneous and inconsistently reported, limiting the ability to quantitatively summarize intervention effects on sexual risk behaviors.</p> <p>Self-reported behavioral outcomes are subject to respondent recall and social desirability bias which can lead to overestimation of intervention effects.</p>	<p>Low for benefit</p>	<p>Most trials were conducted in the US among populations at increased risk for STI. Increased risk populations were defined by STI clinic attendance or history (highest risk), sexual risk behaviors, or demographic characteristics.</p> <p>Most studies focused on specific subpopulations defined by race/ethnicity, sexual orientation, age, gender, pregnancy, or other factors.</p>
<p>KQ3. Harms of Behavioral Counseling Interventions</p>	<p>k = 7 (n = 3,458)</p>	<p>No evidence of harms in the few studies reporting adverse events or possible harms related to unintended pregnancy risk or mental health. One study reported car crashes associated with text messages to evaluate this potential adverse effect of the intervention, but numbers were too small for inference.</p>	<p>Imprecise</p> <p>Consistency NA</p>	<p>Very limited reporting of potential adverse effects of behavioral counseling intervention to prevent STI.</p>	<p>Insufficient</p>	<p>Most trials were conducted in the US among populations at increased risk for STI. Increased risk populations were defined by STI clinic attendance or history (highest risk), sexual risk behaviors, or demographic characteristics.</p> <p>Most studies focused on specific subpopulations defined by race/ethnicity, sexual orientation, age, gender, pregnancy, or other factors.</p>

Abbreviations: CI = confidence interval; K = number of studies; KQ = key question; MD = mean difference; N = number of participants; NA = not applicable; No. = number; OR = odds ratio; STI = sexually transmitted infection; US = United States.

Table 9. Overall Direction of Intervention Effects on Health and Behavioral Outcomes, by Author*

Author, Year	Participant Age Groups [†]	Participant Gender/Sex	Intervention contact time [‡]	Direction of Intervention Effects			
				KQ1	KQ2: Behavioral Outcomes [§]		
				STI incidence	Condom use [¶]	Unprotected intercourse	Number of sexual partners
Bai, 2018 ¹⁶⁰	Adol	F-M	High			↔	
Bailey, 2016 ¹⁰⁵	Adult	M	Low	↑			
Berenson, 2012 ¹⁰⁷	Adol-YA	F	High	↑	↔		
Berkman, 2007 ¹⁰⁸	Adult	M	High		↑		
Billings, 2015 ¹¹⁰	Adult	F	Moderate		↑↑	↑ [#]	
Carey, 2004 ¹¹¹	Adult	F-M	High			↑↑	↑↑
Carey, 2010 ¹¹²	Adult	F-M	High	↔ ^{**}		↓	↔
Carey, 2015 ¹¹³	Adult	F-M	Moderate	↓		↔	↔
Champion, 2012 ¹¹⁶	Adol	F	High	↑↑			
Costa, 2017 ¹¹⁷	Adol-YA	F	High		↑↑ ^{**}		
Crosby, 2009 ¹¹⁸	YA	M	Moderate	↑↑	↑↑	↑	↑↑
DiClemente, 2004 ¹¹⁹	Adol	F	High	↑↑	↑↑	↑↑	
Ehrhardt, 2002 ¹⁰²	YA	F	High		↔ ^{††}	↑ ^{**}	
Free, 2016 ¹²²	Adol-YA	F-M	Moderate	↑	↑		↔
Guilamo-Ramos, 2011 ¹²⁵	Adol	F-M	Moderate				↑↑ ^{‡‡}
Jemmott, 2005 ¹²⁷	Adol	F	High	↑↑		↑↑	↑↑
Jemmott, 2007 ¹²⁸	Adult	F	High	↑↑	↑↑	↑	
Kershaw, 2009 ¹²⁹	Adol-YA	F	High	↑	↑↑	↑↑	
Lewis, 2018 ¹³²	YA	F-M	Low		↓		
Marrazzo, 2011 ¹³⁵	Adult	F	Moderate	↔			
Metsch, 2013 ¹³⁷	YA	F-M	Moderate	↔		↔	
Mittal, 2017 ¹⁴²	Adult	F	High			↑ ^{**}	
Morrison-Beedy, 2013 ¹⁴⁴	Adol	F	High		↔	↔	↑
Neumann, 2011 ¹⁴⁵	Adult	F-M	Moderate	↑↑			
O'Cleirigh, 2019 ¹⁶²	Adult	M	High			↑↑	
Peipert, 2008 ¹⁴⁸	Adol-YA	F	Moderate	↔	↔		
Peragallo Montano, 2019 ¹⁶¹	Adult	F	High		↔		
Petersen, 2007 ¹⁴⁹	Adult	F	Moderate	↔ ^{**}	↔ ^{**}		
Proude, 2004 ¹⁵⁰	YA	F-M	Low		↔		
Redding, 2014 ¹⁶³	Adol	F	High		↑↑		
Sanci, 2015 ^{153§§}	Adol-YA	F-M	High				
Scholes, 2003 ¹⁵⁴	YA	F	Low		↔		
Shafii, 2019 ¹⁶⁴	Adol-YA	F-M	Low	↑		↑	↔
Shain, 2004 ¹⁵⁵	Adol-YA	F	High	↑↑		↑↑	↑↑
Tzilos Wernette, 2018 ¹⁶⁵	Adult	F	Moderate	↔		↔	
Warner, 2008 ¹⁵⁶	Adult	F-M	Low	↑↑			
Whiteley, 2018 ¹⁶⁶	Adol-YA	F-M	Low			↑↑	

Table 9. Overall Direction of Intervention Effects on Health and Behavioral Outcomes, by Author*

Author, Year	Participant Age Groups [†]	Participant Gender/Sex	Intervention contact time [‡]	Direction of Intervention Effects			
				KQ1	KQ2: Behavioral Outcomes [§]		
				STI incidence	Condom use [¶]	Unprotected intercourse	Number of sexual partners
Wingood, 2013 ¹⁵⁸	YA	F	High	↑↑			↑↑
Ybarra, 2017 ¹⁵⁹	Adol	M	High			↔	

Symbol Legend:

- ↑↑ = Statistically significant between-group difference in favor of intervention group
- ↑ = Between-group difference in favor of intervention group (OR, RR, or Hedges' g > 0.15 or 1.15 of null); difference not statistically significant
- ↔ = No clear between-group difference (OR, RR, or Hedges' g within 0.15 of null).
- ↓ = Between-group difference in favor of control group (OR, RR or Hedges' g > 0.15 or 1.15 of null); difference not statistically significant
- ↓↓ = Statistically significant between-group difference in favor of control group

* All studies were randomized control trials, except: Sanci, 2015 = cluster randomized controlled trial; Neumann, 2011 = nonrandomized controlled clinical trial; Warner, 2008 = nonrandomized controlled clinical trial

† Age groups: Adol: Study participants ranged in age from 12 to 19 years; Adol-YA: Study participants ranged in age from 12 to 25 or study included adolescents and adults with population mean age < 25 years; YA: Study participants ranged in age from 18 to 25 only or study enrolled adults of all ages with population mean age <25 years; Adults: Study participants ages 18 and older or enrolled broad age range population with mean age ≥25 years

‡ Intervention contact time: Low: <30 min; Moderate contact: ≥30 to ≤120 min; High contact: >120 min

§ For majority of outcomes. See **Appendix E, Table 3, Table 4, Table 5, Table 6, Table 7, Table 8** for all detailed outcome results.

¶ Self-reported

¶¶ Condom use = Condom-protected sexual intercourse or condom-protected sexual acts

Based on study reported p-value

** Not included in meta-analysis

†† First time female condom use, all other outcomes are male condom use

‡‡ Any vaginal intercourse

§§ Study outcome was STI risk measured as self-report of frequency of “safe sex practices”; there was not a statistically significant difference between groups at 12-month followup but the effect estimate favored the intervention group (↑)

|| Based on assumed 15 minutes per text so this likely is an upper estimate, but with assumptions of shorter text message contact, the intervention involved over 2.5 hours of texting contact and was therefore considered a high-contact time intervention

Abbreviations: Adol = adolescent; F = female; KQ = key question; M = male; OR = odds ratio; RR = relative risk; STI = sexually transmitted infection; YA = young adult.

Appendix A. Detailed Methods

Literature Search Strategies for Primary Literature

Databases searched:

Cochrane Central Register of Controlled Trials (CENTRAL)

MEDLINE

PsycInfo

PubMed, publisher-supplied records

Key:

/ = MeSH subject heading

\$ = truncation

* = truncation

ab = word in abstract

adj# = adjacent within x number of words

hw = subject heading word

id = key phrase identifier

kf= keyword heading [word not phrase indexed]

kw = keyword

md = methodology

pt = publication type

ti = word in title

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#1 (hiv or "human immune deficiency" or "human immunodeficiency" or "acquired immune deficiency" or "acquired immunodeficiency" or hepatitis or herpes* or hpv or papilloma* or warts or condyloma* or trichomonas or trichomoniasis or chlamydia* or gonorrh* or syphil*):ti,ab,kw 45685

#2 (std or stds or sti or stis):ti,ab,kw 1861

#3 sexual*:ti,ab,kw next transmi*:ti,ab,kw 2143

#4 ("safe sex" or "unsafe sex" or "risky sex" or "risky sexual"):ti,ab,kw 924

#5 #1 or #2 or #3 or #4 47000

#6 ("health promotion" or "health education" or "patient education"):ti,ab,kw 24715

#7 (counsel* or advise or advice):ti,ab,kw 20469

#8 (motivational next interview*):ti,ab,kw 2460

#9 (prevent* next intervention*):ti,ab,kw 2648

#10 ("cognitive therapy" or CBT):ti,ab,kw 12452

#11 (physician* near/2 role):ti,ab,kw 278

#12 "preventive health services":ti,ab,kw 655

#13 "student health services":ti,ab,kw 65

#14 "teaching materials":ti,ab,kw 461

#15 "client education":ti,ab,kw 8

#16 (behavio* next intervention*):ti,ab,kw 4046

#17 (behavio* next therapy):ti,ab,kw 14148

#18 (behavio* next change*):ti,ab,kw 5217

#19 (behavio* next modification*):ti,ab,kw 1023

#20 "preventive medicine":ti,ab,kw 594

#21 (health next behavio*):ti,ab,kw 6300

#22 intervention*:ti,ab,kw 186690

#23 #21 and #22 4586

#24 (lifestyle next change*):ti,ab,kw 1275

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#25 #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #23 or #24 69192

#26 #5 and #25 Publication Year from 2013 to 2018 1702

MEDLINE (via Ovid)

Database: Ovid MEDLINE(R) <1946 to June Week 3 2018>, Ovid MEDLINE(R) Epub Ahead of Print <June 20, 2018>, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations <June 20, 2018>, Ovid MEDLINE(R) Daily Update <June 20, 2018>

-
- 1 HIV Infections/ (174246)
 - 2 Acquired Immunodeficiency Syndrome/ (75170)
 - 3 Hepatitis B/ (40887)
 - 4 Hepatitis B, Chronic/ (13618)
 - 5 Hepatitis C/ (37300)
 - 6 Hepatitis C, Chronic/ (21801)
 - 7 Herpes Simplex/ (13711)
 - 8 Herpes Genitalis/ (4482)
 - 9 Herpes Labialis/ (1149)
 - 10 Condylomata Acuminata/ (5012)
 - 11 Warts/ (4363)
 - 12 Chlamydia Infections/ (14641)
 - 13 Gonorrhoea/ (13176)
 - 14 Syphilis/ (20855)
 - 15 Papillomavirus Infections/ (21862)
 - 16 Human papillomavirus 6/ (387)
 - 17 Human papillomavirus 11/ (346)
 - 18 Human papillomavirus 16/ (4034)
 - 19 Human papillomavirus 18/ (1600)
 - 20 Trichomonas Infections/ (3134)
 - 21 Trichomonas Vaginitis/ (3412)
 - 22 Sexually Transmitted Diseases/ (23085)
 - 23 Sexually Transmitted Diseases, Bacterial/ (973)
 - 24 Sexually Transmitted Diseases, Viral/ (1397)
 - 25 (hiv or human immune deficiency or human immunodeficiency or acquired immune deficiency or acquired immunodeficiency).ti,ab,kf. (313255)
 - 26 (hepatitis or herpes or warts or chlamydia or gonorrh\$ or syphilis).ti,ab,kf. (323151)
 - 27 (sexually transmitted or std or stds or sti or stis).ti,ab,kf. (39014)
 - 28 (papilloma\$ or hpv or trichomonas or trichomoniasis).ti,ab,kf. (68847)
 - 29 condyloma\$.ti,ab,kf. (4209)
 - 30 or/1-29 (764140)
 - 31 health promotion/ (66451)
 - 32 Health Education/ (57715)
 - 33 patient education/ (79706)
 - 34 counseling/ (33085)
 - 35 directive counseling/ (2103)
 - 36 "Acceptance and Commitment Therapy"/ (234)

Appendix A. Detailed Methods

- 37 Mindfulness/ (1844)
- 38 Cognitive Remediation/ (128)
- 39 cognitive therapy/ (21903)
- 40 behavior therapy/ (26196)
- 41 physician's role/ (28594)
- 42 preventive health services/ (12452)
- 43 student health services/ (3035)
- 44 teaching materials/ (6261)
- 45 counsel\$.ti,ab,kf. (94968)
- 46 advice.ti,ab,kf. (42272)
- 47 advise.ti,ab,kf. (8327)
- 48 motivational interview\$.ti,ab,kf. (3422)
- 49 prevent\$ intervention\$.ti,ab,kf. (11766)
- 50 (physician\$ adj2 role).ti,ab,kf. (2555)
- 51 preventive health services.ti,ab,kf. (667)
- 52 student health services.ti,ab,kf. (246)
- 53 teaching materials.ti,ab,kf. (690)
- 54 client education.ti,ab,kf. (205)
- 55 health promotion.ti,ab,kf. (28016)
- 56 health education.ti,ab,kf. (30382)
- 57 patient education.ti,ab,kf. (16217)
- 58 cognitive therapy.ti,ab,kf. (2742)
- 59 behavio\$ therapy.ti,ab,kf. (18209)
- 60 behavio\$ intervention\$.ti,ab,kf. (8774)
- 61 behavio\$ change\$.ti,ab,kf. (29944)
- 62 behavio\$ modification\$.ti,ab,kf. (4296)
- 63 preventive medicine.ti,ab,kf. (7684)
- 64 (health behavio\$ and intervention\$).ti,ab,kf. (6406)
- 65 lifestyle change\$.ti,ab,kf. (6713)
- 66 or/31-65 (511424)
- 67 30 and 66 (35207)
- 68 Safe Sex/ (2779)
- 69 Unsafe Sex/ (4226)
- 70 Sexual Behavior/ (50951)
- 71 safe sex.ti,ab,kf. (1268)
- 72 unsafe sex.ti,ab,kf. (689)
- 73 risky sex\$.ti,ab,kf. (2912)
- 74 68 or 69 or 70 or 71 or 72 or 73 (57281)
- 75 66 and 74 (10251)
- 76 HIV Infections/pc (33258)
- 77 Acquired Immunodeficiency Syndrome/pc (13392)
- 78 Hepatitis B/pc (10080)
- 79 Hepatitis B, Chronic/pc (619)
- 80 Hepatitis C/pc (3150)
- 81 Hepatitis C, Chronic/pc (335)
- 82 Herpes Simplex/pc (963)
- 83 Herpes Genitalis/pc (786)
- 84 Herpes Labialis/pc (106)

Appendix A. Detailed Methods

- 85 Condylomata Acuminata/pc (424)
- 86 Warts/pc (37)
- 87 Chlamydia Infections/pc (1572)
- 88 Gonorrhoea/pc (1114)
- 89 Syphilis/pc (1249)
- 90 Papillomavirus Infections/pc (5034)
- 91 Trichomonas Infections/pc (78)
- 92 Trichomonas Vaginitis/pc (109)
- 93 Sexually Transmitted Diseases/pc (8704)
- 94 Sexually Transmitted Diseases, Bacterial/pc (180)
- 95 Sexually Transmitted Diseases, Viral/pc (458)
- 96 76 or 77 or 78 or 79 or 80 or 81 or 82 or 83 or 84 or 85 or 86 or 87 or 88 or 89 or 90 or 91 or 92 or 93 or 94 or 95 (71292)
- 97 intervention\$.ti,ab,kf,hw. (857306)
- 98 96 and 97 (10230)
- 99 67 or 75 or 98 (42929)
- 100 (clinical trial or controlled clinical trial or randomized controlled trial or adaptive clinical trial or equivalence clinical trial or pragmatic clinical trial or meta analysis).pt. (868580)
- 101 clinical trials as topic/ or controlled clinical trials as topic/ or randomized controlled trials as topic/ or adaptive clinical trials as topic/ or equivalence clinical trials as topic/ or pragmatic clinical trials as topic/ (301422)
- 102 Meta-Analysis as Topic/ (16255)
- 103 Random allocation/ (94679)
- 104 clinical trial\$.ti,ab,kf. (314050)
- 105 (control\$ adj3 (study or studies or trial\$)).ti,ab,kf. (450888)
- 106 random\$.ti,ab,kf. (982943)
- 107 trial.ti. (183333)
- 108 100 or 101 or 102 or 103 or 104 or 105 or 106 or 107 (1963179)
- 109 99 and 108 (6612)
- 110 limit 109 to (english language and yr="2013 -Current") (2412)
- 111 remove duplicates from 110 (2407)

PsycINFO (via Ovid)

Database: PsycINFO <1806 to June Week 3 2018>

-
- 1 sexually transmitted diseases/ (4203)
 - 2 Acquired Immune Deficiency Syndrome/ (15045)
 - 3 Human Immunodeficiency Virus/ (32806)
 - 4 GONORRHEA/ (155)
 - 5 HERPES GENITALIS/ (155)
 - 6 HERPES SIMPLEX/ (962)
 - 7 AIDS Prevention/ (8200)
 - 8 SYPHILIS/ (404)
 - 9 HEPATITIS/ (2499)
 - 10 Human Papillomavirus/ (1162)
 - 11 Sexual Risk Taking/ (7752)

Appendix A. Detailed Methods

- 12 safe sex/ (1405)
- 13 Psychosexual Behavior/ (24060)
- 14 sexually transmitted.ti,ab,id. (7451)
- 15 (hiv or human immune deficiency or human immunodeficiency or acquired immune deficiency or acquired immunodeficiency).ti,ab,id. (50028)
- 16 hepatitis b.ti,ab,id. (1106)
- 17 hepatitis c.ti,ab,id. (2556)
- 18 herpes.ti,ab,id. (2009)
- 19 condyloma\$.ti,ab,id. (28)
- 20 warts.ti,ab,id. (336)
- 21 chlamydia.ti,ab,id. (844)
- 22 gonorrh\$.ti,ab,id. (730)
- 23 papillomavirus.ti,ab,id. (1303)
- 24 hpv.ti,ab,id. (1452)
- 25 (trichomonas or trichomoniasis).ti,ab,id. (171)
- 26 syphilis.ti,ab,id. (1604)
- 27 (safe sex or unsafe sex or risky sex or risky sexual).ti,ab,id. (4433)
- 28 or/1-27 (82914)
- 29 Health Education/ (12222)
- 30 Health Promotion/ (22491)
- 31 Cognitive behavior therapy/ (17112)
- 32 Behavior Therapy/ (13373)
- 33 Behavior Change/ (11343)
- 34 Behavior Modification/ (10248)
- 35 Client Education/ (3672)
- 36 Counseling/ (22129)
- 37 Preventive Medicine/ (2023)
- 38 Motivational interviewing/ (2157)
- 39 student personnel services/ (2223)
- 40 Lifestyle Changes/ (1176)
- 41 advice.ti,ab,id. (18998)
- 42 advise.ti,ab,id. (2042)
- 43 counsel\$.ti,ab,id,hw. (117277)
- 44 motivational interview\$.ti,ab,id. (3318)
- 45 prevention intervention\$.ti,ab,id. (4524)
- 46 preventive health services.ti,ab,id. (185)
- 47 (physician\$ adj2 role).ti,ab,id. (805)
- 48 student health services.ti,ab,id. (61)
- 49 teaching materials.ti,ab,id. (642)
- 50 client education.ti,ab,id. (205)
- 51 health promotion.ti,ab,id. (17905)
- 52 health education.ti,ab,id. (9566)
- 53 patient education.ti,ab,id. (3219)
- 54 cognitive therapy.ti,ab,id. (6340)
- 55 behavio\$ therapy.ti,ab,id. (30155)
- 56 behavio\$ intervention\$.ti,ab,id. (10809)
- 57 behavio\$ change\$.ti,ab,id. (24459)
- 58 behavio\$ modification\$.ti,ab,id. (5943)

Appendix A. Detailed Methods

- 59 preventive medicine.ti,ab,id. (827)
 60 Health Behavior/ and intervention\$.ti,ab,id,hw. (6589)
 61 lifestyle change\$.ti,ab,id. (2075)
 62 or/29-61 (276332)
 63 28 and 62 (14307)
 64 random\$.ti,ab,id,hw. (179259)
 65 (control\$ adj3 (study or studies or trial\$)).ti,ab,id,hw. (73591)
 66 clinical trial\$.ti,ab,id,hw. (34378)
 67 trial.ti. (26134)
 68 (treatment outcome or clinical trial).md. (39450)
 69 64 or 65 or 66 or 67 or 68 (244261)
 70 63 and 69 (1941)
 71 limit 70 to english language (1908)
 72 limit 71 to yr="2013 -Current" (728)

Pubmed, publisher-supplied

#15	Search #14 AND English[Language] AND ("2013/01/01"[Date - Publication] : "3000"[Date - Publication])
#14	Search #13 AND publisher[sb]
#13	Search #12 AND (trial[tiab] OR trials[tiab] OR random*[tiab] OR metaanaly*[tiab] OR "meta analysis"[tiab] OR "meta analyses"[tiab] OR "meta analytic"[tiab] OR systematic[tiab])
#12	Search #1 AND #11
#11	Search #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10
#10	Search motivational[tiab] AND interview*[tiab]
#9	Search (prevention[tiab] OR preventive[tiab]) AND intervention*[tiab]
#8	Search advice[tiab] or advise[tiab]
#7	Search "preventive health services"[tiab] OR "student health services"[tiab]
#6	Search "behavior change"[tiab] OR "behavioral change"[tiab] OR "behaviour change"[tiab] OR "behavioural change"[tiab] OR "behavior modification"[tiab] OR "behavioral modification"[tiab] OR "behaviour modification"[tiab] OR "behavioural modification"[tiab] OR lifestyle change*[tiab]
#5	Search behavio*[tiab] AND (therapy[tiab] OR intervention*[tiab])
#4	Search "cognitive therapy"[tiab] OR cbt[tiab]
#3	Search counsel*[tiab]
#2	Search "health promotion"[tiab] OR "Health Education"[tiab] OR "patient education"[tiab] OR "client education"[tiab] OR "teaching materials"[tiab] OR "physician role"[tiab] OR "physician's role"[tiab] OR "physicians' role"[tiab]

Appendix A. Detailed Methods

#1	Search hiv[tiab] OR "human immunodeficiency"[tiab] OR "human immune deficiency"[tiab] OR "acquired immunodeficiency"[tiab] OR "acquired immune deficiency"[tiab] OR "Hepatitis B"[tiab] OR "Hepatitis C"[tiab] OR Herpes[tiab] OR warts[tiab] OR condyloma*[tiab] OR Papilloma*[tiab] OR hpv[tiab] OR Chlamydia[tiab] OR Gonorrhoea[tiab] OR Gonorrhoea[tiab] OR Syphilis[tiab] OR Trichomonas[tiab] OR trichomoniasis[tiab] OR "safe sex"[tiab] OR "unsafe sex"[tiab] OR "risky sex"[tiab] OR "risky sexual"[tiab] OR "Sexually Transmitted"[tiab] OR std[tiab] OR stds[tiab] OR sti[tiab] OR stis[tiab]
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Appendix A Table 1. Inclusion and Exclusion Criteria

Category	Included	Excluded
Aim	Studies targeting sexual behavior change to prevent STIs	Studies aimed solely at targeting behavior change to prevent unintended pregnancy or solely to change behaviors associated with risky sexual behavior (e.g., substance use disorders, interpersonal violence)
Condition	Any infection that is transmitted through sexual contact (i.e., oral, vaginal, or anal), including, but not limited to: HIV, human papillomavirus (HPV), herpes simplex virus (HSV) type 1 and 2, hepatitis b and c viruses, Zika virus, chlamydia, gonorrhea, syphilis, and trichomoniasis.	Infections acquired through non-sexual transmission routes (e.g., maternal-fetal transmission, blood transfusions, inadvertent needle sticks, sharing needles or injection equipment with an infected person)
Population	Adolescents and adults of any sexual orientation People who are sexually active Pregnant women People who are not sexually active (e.g., adolescents before sexual debut)	Studies limited to populations requiring specialized health care or interventions to address STI health risks (e.g., HIV sero-discordant couples, commercial sex workers)
Interventions	Interventions involving behavioral counseling to prevent or reduce STIs (i.e., some provision of education, skills training, or guidance on how to change sexual behaviors) delivered alone or in combination with other interventions intended to promote sexual risk reduction or risk avoidance, which can feasibly be implemented in or referred from primary care. Interventions may include, but are not limited to: Individual-, family-, couple-, or group-based counseling (e.g., motivational interviewing, cognitive behavioral therapy) Waiting room, multimedia, or other health system-based behavior change interventions Telemedicine or technology-based behavior change interventions (e.g., text messages, Internet-based)	Trials within closed pre-existing social networks (e.g., worksite or church programs) Social marketing (e.g., media campaigns) Policy (e.g., State or local public or health policy; health care delivery) Circumcision to prevent HIV/STI; circumcision counseling Solely focused on biomedical prevention interventions (e.g., HPV vaccination, Pre-exposure Prophylaxis for HIV) STI testing only Sexual abuse prevention Cash and voucher reward-based incentives for behavior change (e.g., condom use) Counseling to increase partner referral/notification only Promoting non-condom contraceptive use only
Comparators	No intervention (e.g., waitlist) Usual care Minimal intervention (e.g., usual care limited to ≤15 minutes of information) Attention control (e.g., similar in format and intensity but intervention is on a different content area, such as general sex education, wellness promotion, or nutrition education)	Active intervention (i.e., comparative effectiveness)

Appendix A Table 1. Inclusion and Exclusion Criteria

Category	Included	Excluded
<p>Outcomes</p>	<p>KQ 1 (Health outcomes):</p> <p>STI incidence (based on testing/biologic confirmation)</p> <p>Morbidity and mortality, including:</p> <p>STI related cancers (e.g., liver, oral, cervical, vulvar, vaginal, anal, penile)</p> <p>Oral and genital lesions</p> <p>Pelvic and genitourinary pain</p> <p>Chronic conditions (e.g., AIDS, neurosyphilis, chronic liver disease)</p> <p>Reproductive complications (e.g., pelvic inflammatory disease, ectopic pregnancy, spontaneous abortion, infertility)</p> <p>Perinatal and infant morbidity/mortality (e.g., neonatal infection, stillbirth, low birth weight, ophthalmia neonatorum, neurologic damage, congenital abnormalities)</p> <p>Mental health</p> <p>Quality of life</p> <p>KQ 2 (Behavioral outcomes):</p> <p>Changes in STI risk behaviors (e.g., multiple sexual partners, concurrent sexual partners, sexual partners with high STI risk, unprotected sexual intercourse or contact, sex while intoxicated with alcohol or other substances, sex in exchange for money or drugs)</p> <p>Changes in protective behaviors (e.g., sexual abstinence, mutual monogamy, delayed initiation of intercourse or age of sexual debut, use of condoms, other barrier methods, chemical barriers, or other changes in sexual behavior)</p> <p>KQ 3 (Harms):</p> <p>Increase in STI incidence or risky sexual behaviors or decrease in protective behaviors</p> <p>Health care avoidance</p> <p>Psychological harms (e.g., anxiety, shame, guilt, feelings of stigma)</p> <p>Unintended pregnancy</p>	<p>Self-reported measures of infection, attitude, knowledge, ability, or self-efficacy, including:</p> <p>Knowledge of risks and protective behaviors</p> <p>Perception of STI risk in self or partners</p> <p>Perceived relationship power</p> <p>Sexual negotiation skills</p> <p>Scheduling a health care appointment</p> <p>Intention to use protective barriers</p> <p>Carrying barrier protection</p>

Appendix A Table 1. Inclusion and Exclusion Criteria

Category	Included	Excluded
Setting	Conducted in or recruited from primary care settings, including: Health care systems STI clinics Family planning clinics School-based health clinics Prenatal care clinics Military health clinics Obstetrics-gynecology clinics Behavioral/mental health clinics.	Research laboratories Correctional facilities School classrooms Worksites Substance abuse treatment facilities or methadone maintenance clinics Inpatient/residential facilities Emergency departments
Study design	Randomized, controlled trials and nonrandomized, controlled trials (controlled clinical trials)	Observational studies; comparative effectiveness trials without a control group
Timing of outcome assessment	≥ 3 months postbaseline	< 3 months postbaseline
Publication date	Published after 1999 (2000 to present)	Published in or before 1999
Country	Studies conducted in countries categorized as “Very High” on the 2016 Human Development Index (as defined by the United Nations Development Programme)	Countries with a Human Development Index other than “Very High”
Language	English only	Non-English publications
Study quality	Fair- or good-quality studies	Poor-quality studies (according to design-specific USPSTF criteria)

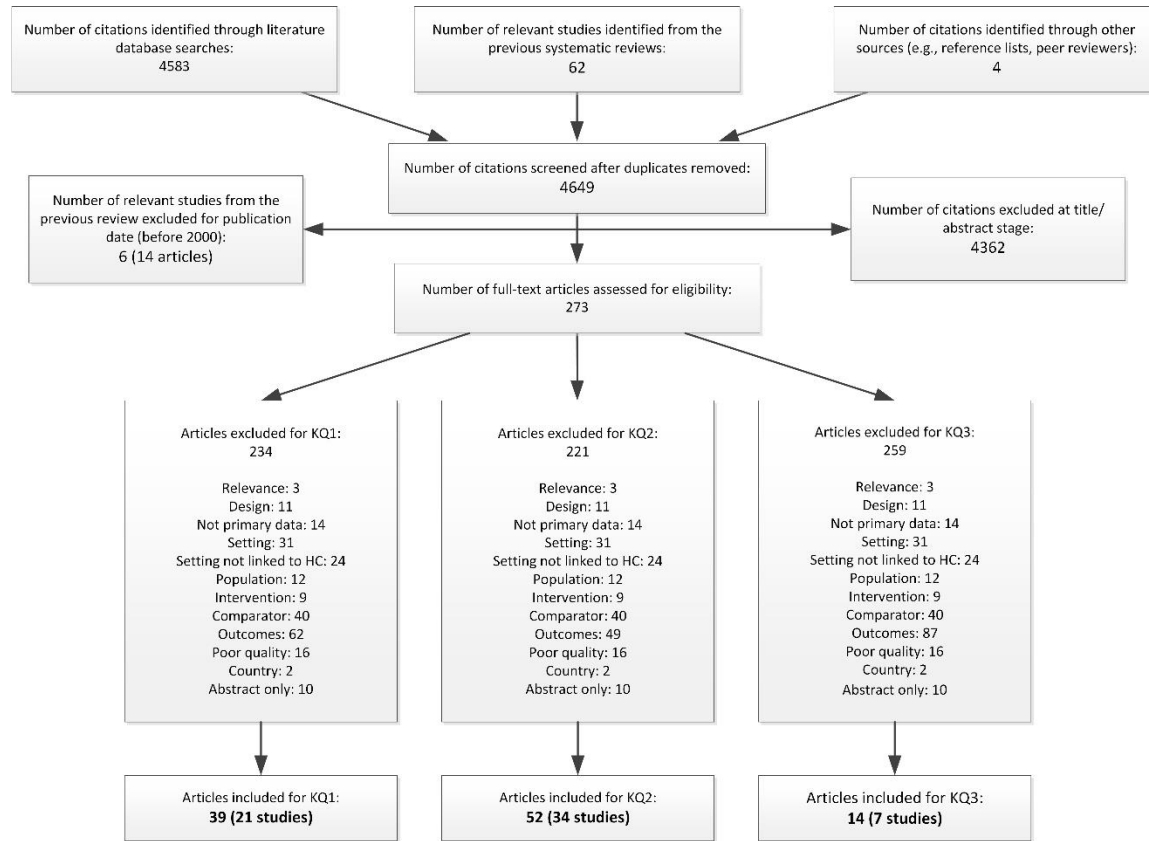
Abbreviations: AIDS = acquired immunodeficiency syndrome; HIV = human immunodeficiency virus; HSV = herpes simplex virus; KQ = key question; STI = sexually transmitted infections; USPSTF = U.S. Preventive Services Task Force.

Appendix A Table 2. Quality Assessment Criteria*

Study Design	Adapted Quality Criteria
Randomized and non-randomized controlled trials, adapted from the U.S. Preventive Services Task Force methods	<p>Bias arising in the randomization process or due to confounding Valid random assignment/random sequence generation method used Allocation concealed Balance in baseline characteristics</p> <p>Bias in selecting participants into the study CCT only: No evidence of biased selection of sample</p> <p>Bias due to departures from intended interventions Fidelity to the intervention protocol Low risk of contamination between groups Participants were analyzed as originally allocated</p> <p>Bias from missing data No, or minimal, post-randomization exclusions Outcome data are reasonably complete and comparable between groups Reasons for missing data are similar across groups Missing data are unlikely to bias results</p> <p>Bias in measurement of outcomes Blinding of outcome assessors Outcomes are measured using consistent and appropriate procedures and instruments across treatment groups No evidence of inferential statistics</p> <p>Bias in reporting results selectively No evidence that the measures, analyses, or subgroup analyses are selectively reported</p>

* Good quality studies generally meet all quality criteria. Fair quality studies do not meet all the criteria but do not have critical limitations that could invalidate study findings. Poor quality studies have a single fatal flaw or multiple important limitations that could invalidate study findings. Critical appraisal of studies using *a priori* quality criteria are conducted independently by at least two reviewers. Disagreements in final quality assessment are resolved by consensus, and, if needed, consultation with a third independent reviewer.

Appendix A Figure 1. Literature Flow Diagram



Appendix B Table 1. Recommendations of Other Organizations for Sexual Risk Reduction Counseling to Prevent Sexually Transmitted Infections

Organization, Year	Recommendation
American Academy of Family Physicians, 2014 ⁷³	The AAFP recommends high-intensity behavioral counseling to prevent STIs in all sexually active adolescents and high-risk adults. The AAFP concludes the current evidence is insufficient to assess the benefits and harms of behavioral counseling to prevent STIs in pre-sexually active adolescents and in adults not at increased risk for STIs. These recommendations were based on the USPSTF 2014 Recommendation Statement.
American Academy of Pediatrics, 2014 ⁷²	The AAP targets several recommendations to pediatricians and other clinicians, including (1) clinicians should actively support and encourage the consistent and correct use of condoms as part of anticipatory guidance in adolescents; (2) Clinicians should promote communication between parents and adolescents about healthy sexual development and effective use of condoms; (3) Clinicians should raise awareness that making condoms available does not increase the onset or frequency of adolescent sexual activity; (4) Clinicians should provide and support parental education programs to help parents develop communication skills with their adolescent children around preventions of STIs and proper use of condoms.
American College of Obstetricians and Gynecologists, 2009-2014	The ACOG recommends discussing contraception and STIs during an adolescent's initial reproductive health visits and provides time-based coding recommendations for individual counseling in preventive medicine or risk factor reduction or both in individuals without a specific illness to promote health and prevention illness or injury or both. ⁷⁴ The ACOG recognizes that an annual well-women visit provides an excellent opportunity to counsel patients about maintaining a healthy lifestyle and minimizing health risks and it should include screening, evaluation and counseling and immunizations based on the patients age and risk factors. ⁷⁵ Applying principles of motivational interviewing (e.g., prompting patients to use safe sex practices and to use contraception more consistently) to daily patient practices has been proved effective in eliciting behavior change that contributes to positive health outcomes and improved patient-physician communication. ²¹⁷ Among lesbian and bisexual patients, comprehensive care including prevention of STIs is recommended. ⁷⁹ Education about the risks of STIs and dispelling the perception that transmission STIs between women is negligible will help patients make informed decisions. All patients should be encouraged to use safe sex practices to reduce the risk of transmitting or acquiring STIs and HIV such as using condoms on sex toys, gloves and dental dams as well as avoidance of sharing other sex paraphernalia. Among women of color, several approaches (e.g., gender-tailored and culturally appropriate interventions to reduce risk-taking behavior) can reduce the rate of HIV infection and optimize health. ²¹⁸ For women participating in non-coital activities, clinicians should assess patient STI risk and provide risk reduction counseling. ²¹⁹ When engaging in oral and anal sex, most individuals, including adolescents, are unlikely to use barrier protection for a variety of reasons, including a greater perceived safety of noncoital sexual activity compared with vaginal sex. Clinicians should encourage and counsel patients in the correct and consistent use of condoms, barrier protection during oral sex, and cleaning of sex toys.
Centers for Disease Control and Prevention, 2015 ¹	The CDC recommends that all providers should routinely obtain a sexual history from their patients and encourage risk-reduction using various strategies (e.g., prevention counseling). The CDC also recommends that HIV prevention counseling should be offered and encouraged in all health care facilities that serve patients at high risk (e.g., STI clinics).
National Health Care for the Homeless Council, 2010 ²²⁰	The National Health Care for the Homeless Council recommends to counsel at-risk clients to adopt safer sexual behavior to prevent STIs (e.g., use of interactive counseling that focuses on preventing unwanted pregnancy and transmission of disease).
National Institute for Health and Clinical Excellence, 2007 ⁸⁰	After identifying individuals at high risk for STIs, NICE recommends having one-to-one structured discussions with these individuals (if the health professional is trained in sexual health) or arrange for these discussions to take place with a trained practitioner. Among vulnerable young people aged under 18 years including pregnant women and mothers, when appropriate, practitioners should provide one-to-one sexual advice on how to prevent and/or get tested for STIs.
The Society for Adolescent Health and Medicine ²²¹	SAHM recommends that health care providers provide STI and HIV education, counseling, and services to all adolescents, and that these services are incorporated into well-adolescent and contraception visits.

Abbreviations: AAFP = American Academy of Family Physicians; ACOG = American College of Obstetricians and Gynecologists; HIV = human immunodeficiency virus; NICE = National Institute for Health and Clinical Excellence; SAHM = Society for Adolescent Health and Medicine; STI = sexually transmitted infection; USPSTF = U.S. Preventive Services Task Force.

Appendix C. Included Studies

Below is a list of included studies and their ancillary publications (indented below main results publication):

Bai, S., et al. (2018). "Reducing health risk behaviors and improving depression in adolescents: A randomized controlled trial in primary care clinics." *Journal of Pediatric Psychology* **43**(9): 1004-1016. PMID: 30016473 <https://doi.org/10.1093/jpepsy/jsy048>

Bailey JV, Webster R, Hunter R, et al. The Men's Safer Sex project: intervention development and feasibility randomised controlled trial of an interactive digital intervention to increase condom use in men. *Health Technology Assessment (Winchester, England)*. 2016;20(91):1-124. PMID: 27966409. <https://dx.doi.org/10.3310/hta20910>

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Billings DW, Leaf SL, Spencer J, et al. A Randomized Trial to Evaluate the Efficacy of a Web-Based HIV Behavioral Intervention for High-Risk African American Women. *AIDS Behav*. 2015;19(7):1263-74. PMID: 25616838. <https://dx.doi.org/10.1007/s10461-015-0999-9>

Carey MP, Carey KB, Maisto SA, et al. Reducing HIV-risk behavior among adults receiving outpatient psychiatric treatment: results from a randomized controlled trial. *J Consult Clin Psychol*. 2004;72(2):252-68. PMID: 15065959. <https://dx.doi.org/10.1037/0022-006X.72.2.252>

Carey MP, Senn TE, Vanable PA, et al. Brief and intensive behavioral interventions to promote sexual risk reduction among STD clinic patients: results from a randomized controlled trial. *AIDS & Behav*. 2010;14(3):504-17. PMID: 19590947. <https://dx.doi.org/10.1007/s10461-009-9587-1>

Carey MP, Vanable PA, Senn TE, et al. Evaluating a two-step approach to sexual risk reduction in a publicly-funded STI clinic: rationale, design, and baseline data from the Health Improvement Project-Rochester (HIP-R). *Contemp Clin Trials*. 2008;29(4):569-86. PMID: 18325853. <https://dx.doi.org/10.1016/j.cct.2008.02.001>

Mittal M, Senn TE, Carey MP. Mediators of the relation between partner violence and sexual risk behavior among women attending a sexually transmitted disease clinic. *Sex Transm Dis*. 2011;38(6):510-5. PMID: 21258269. <https://dx.doi.org/10.1097/OLQ.0b013e318207f59b>

Mittal M, Senn TE, Carey MP. Fear of violent consequences and condom use among women attending an STD clinic. *Women & Health*. 2013;53(8):795-807. PMID: 24215273. <https://dx.doi.org/10.1080/03630242.2013.847890>

Carey MP, Senn TE, Walsh JL, et al. Evaluating a Brief, Video-Based Sexual Risk Reduction Intervention and Assessment Reactivity with STI Clinic Patients: Results from a Randomized Controlled Trial. *AIDS Behav*. 2015;19(7):1228-46. PMID: 25433653. <https://dx.doi.org/10.1007/s10461-014-0960-3>

Appendix C. Included Studies

Champion JD. Behavioural interventions and abuse: secondary analysis of reinfection in minority women. *Int J STD AIDS*. 2007;18(11):748-53. PMID: 18005508. <https://doi.org/10.1258/095646207782212180>

Recto P, Champion JD. Psychological Distress and Associated Factors Among Mexican American Adolescent Females. *Hisp Health Care Int*. 2016;14(4):170-6. PMID: 27852947. <https://doi.org/10.1177/1540415316676224>

Costa EC, McIntyre T, Trovisqueira A, et al. Comparison of two psycho-educational interventions aimed at preventing HIV and promoting sexual health among Portuguese women. *International Journal of Sexual Health*. 2017;29(3):258-72. PMID: 2017-42146-006. <http://dx.doi.org/10.1080/19317611.2017.1307300>

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DiClemente RJ, Wingood GM, Harrington KF, et al. Efficacy of an HIV prevention intervention for African American adolescent girls: a randomized controlled trial. *JAMA*. 2004;292(2):171-9. PMID: 15249566. <https://doi.org/10.1001/jama.292.2.171>

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Lang DL, DiClemente RJ, Hardin JW, et al. Threats of cross-contamination on effects of a sexual risk reduction intervention: fact or fiction. *Prev Sci*. 2009;10(3):270-5. PMID: 19241171. <https://doi.org/10.1007/s11121-009-0127-z>

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Wingood GM, DiClemente RJ, Harrington KF, et al. Efficacy of an HIV prevention program among female adolescents experiencing gender-based violence. *Am J Public Health*. 2006;96(6):1085-90. PMID: 16670238. <https://doi.org/10.2105/AJPH.2004.053595>

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- Enrhardt AA, Exner TM, Hoffman S, et al. HIV/STD risk and sexual strategies among women family planning clients in New York: Project FIO. *AIDS Behav.* 2002;6(1):1-13. PMID: None.
- Hoffman S, Exner TM, Leu CS, et al. Female-condom use in a gender-specific family planning clinic trial. *Am J Public Health.* 2003;93(11):1897-903. PMID: 14600063.
- Melendez RM, Hoffman S, Exner T, et al. Intimate partner violence and safer sex negotiation: effects of a gender-specific intervention. *Arch Sex Behav.* 2003;32(6):499-511. PMID: 14574094.
- Miller S, Exner TM, Williams SP, et al. A gender-specific intervention for at-risk women in the USA. *AIDS Care.* 2000;12(5):603-12. PMID: 11218546. <https://dx.doi.org/10.1080/095401200750003789>
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- O'Leary A, Jemmott LS, Jemmott JB. Mediation analysis of an effective sexual risk-reduction intervention for women: the importance of self-efficacy. *Health Psychol.* 2008;27(2 Suppl):S180-S4. PMID: 18377160. [https://dx.doi.org/10.1037/0278-6133.27.2\(Suppl.\).S180](https://dx.doi.org/10.1037/0278-6133.27.2(Suppl.).S180)
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- Marrazzo JM, Thomas KK, Ringwood K. A behavioural intervention to reduce persistence of bacterial vaginosis among women who report sex with women: results of a randomised trial. *Sex*

Appendix C. Included Studies

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Marrazzo JM, Thomas KK, Fiedler TL, et al. Relationship of specific vaginal bacteria and bacterial vaginosis treatment failure in women who have sex with women. *Ann Intern Med.* 2008;149(1):20-8. PMID: 18591634.

Metsch LR, Feaster DJ, Gooden L, et al. Effect of risk-reduction counseling with rapid HIV testing on risk of acquiring sexually transmitted infections: the AWARE randomized controlled trial. *JAMA.* 2013;310(16):1701-10. PMID: 24150466.
<https://dx.doi.org/10.1001/jama.2013.280034>

Mittal M, Thevenet-Morrison K, Landau J, et al. An Integrated HIV Risk Reduction Intervention for Women with a History of Intimate Partner Violence: Pilot Test Results. *AIDS & Behavior.* 2017;21(8):2219-32. PMID: 27172976. <https://dx.doi.org/10.1007/s10461-016-1427-5>
Morrison-Beedy D, Jones SH, Xia Y, et al. Reducing sexual risk behavior in adolescent girls: results from a randomized controlled trial. *Journal of Adolescent Health.* 2013;52(3):314-21. PMID: 23299011. <https://dx.doi.org/10.1016/j.jadohealth.2012.07.005>

Morrison-Beedy D, Crean HF, Passmore D, et al. Risk reduction strategies used by urban adolescent girls in an HIV prevention trial. *Current HIV Research.* 2013;11(7):559-69. PMID: 24476350.

Neumann MS, O'Donnell L, Doval AS, et al. 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"? *Sex Transm Dis.* 2011;38(2):133-9. PMID: 20729794. <https://dx.doi.org/10.1097/OLQ.0b013e3181f0c051>

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Petersen R, Albright J, Garrett JM, et al. Pregnancy and STD prevention counseling using an adaptation of motivational interviewing: a randomized controlled trial. *Perspect Sex Reprod Health*. 2007;39(1):21-8. PMID: 17335378.

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Sanci L, Chondros P, Sawyer S, et al. Responding to Young People's Health Risks in Primary Care: A Cluster Randomised Trial of Training Clinicians in Screening and Motivational Interviewing. *PLoS ONE*. 2015;10(9):e0137581. PMID: 26422235.

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Scholes D, McBride CM, Grothaus L, et al. A tailored minimal self-help intervention to promote condom use in young women: results from a randomized trial. *AIDS*. 2003;17(10):1547-56. PMID: 12824793.

Shafii T, Benson S, Morrison D, et al. 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*. 2019;14(1). PMID: 30673710.

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Gallo MF, Margolis AD, Malotte CK, et al. Sexual abstinence and other behaviours immediately following a new STI diagnosis among STI clinic patients: Findings from the Safe in the City

Appendix C. Included Studies

trial. *Sexually Transmitted Infections*. 2016;92(3):206-10. PMID: 26670913.
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Ybarra ML, Prescott TL, Phillips GL, 2nd, et al. Pilot RCT Results of an mHealth HIV Prevention Program for Sexual Minority Male Adolescents. *Pediatrics*. 2017;140(1). PMID: 28659456. <https://dx.doi.org/10.1542/peds.2016-2999>

Appendix D. Excluded Studies

Reason for Exclusion*
E1. Relevance: Not applicable/relevant to key question
E2. Design (e.g., observational studies, comparative effectiveness trials without control group)
E2a. Not primary data (e.g., editorials, narrative reviews)
E3. Setting: Otherwise outside of scope (e.g., emergency departments, research laboratories, school classrooms, worksites, inpatient/residential departments)
E3a. Interventions not linked to healthcare excluded at full text (except online only)
E4. Population: Otherwise outside of scope (e.g., serodiscordant couples, commercial sex workers)
E5. Intervention (e.g., STI testing only, sexual abuse prevention, cash and reward-based incentives, PrEP or vaccine only)
E6. Comparator (e.g., comparative effectiveness)
E7. Outcomes: No relevant outcomes (e.g., knowledge of HIV/STI risk, knowledge of protective behaviors, risk perception)
E7a. Self-reported STI outcomes (KQ1)
E8. Study Quality: Poor
E9. Publication type: Abstract-only, Non-English publication
E10. Country: Countries with an HDI other than “Very High”
E11. Publication Date: Published before 2000
E12. Abstract only

*Assigned at full-text phase

Appendix D. Excluded Studies

Code	Reference	Code	Reference
E7	Albarracin, D, Wilson, K, et al. A meta-intervention to increase completion of an HIV-prevention intervention: Results from a randomized controlled trial in the state of Florida. <i>J Consult Clin Psychol.</i> 84(12): 1052-1065. 2016.	E3	Barker, DH, Hadley, W, et al. Evaluating the Role of Family Context Within a Randomized Adolescent HIV-Risk Prevention Trial. <i>AIDS Behav.</i> 23(5): 1195-1209. 2019. https://dx.doi.org/10.1007/s10461-019-02400-3
E3a	Amirkhanian, YA, Kelly, JA, et al. Effects of a social network HIV/STD prevention intervention for MSM in Russia and Hungary: a randomized controlled trial. <i>AIDS.</i> 29(5): 583-93. 2015. https://dx.doi.org/10.1097/QAD.0000000000000558	E2a	Bauermeister, J, Sullivan, PS, et al. Reducing HIV Vulnerability Through a Multilevel Life Skills Intervention for Adolescent Men (The iREACH Project): Protocol for a Randomized Controlled Trial. <i>JMIR Res Protoc.</i> 7(7): e10174. 2018. https://dx.doi.org/10.2196/10174
E6	Anderson, Mollie Blair. The Condom Carnival: Assessment of a novel group intervention aimed to decrease sexual risk and increase condom use among college students. <i>Dissertation Abstracts International: Section B: The Sciences and Engineering.</i> 78(8-B(E)): No Pagination Specified. 2018. https://dx.doi.org/	E7	Bodin, M, Tyden, T, et al. Can Reproductive Life Plan-based counselling increase men's fertility awareness?. <i>Ups J Med Sci.</i> 123(4): 255-263. 2018. https://dx.doi.org/10.1080/03009734.2018.1541948
E7	Archibald, CM, Newman, D. Pilot Testing HIV Prevention in an Afro Caribbean Faith-Based Community. <i>ABNF Journal.</i> 26(2): 43-9. 2015. PMID:	E3a	Boekeloo, B, Geiger, T, et al. Evaluation of a socio-cultural intervention to reduce unprotected sex for HIV among African American/Black women. <i>AIDS Behav.</i> 19(10): 1752-62. 2015. https://dx.doi.org/10.1007/s10461-015-1004-3
E6	Arnold, EA, Kegeles, SM, et al. A Randomized Controlled Trial to Reduce HIV-Related Risk in African American Men Who Have Sex with Men and Women: the Bruthas Project. <i>Prevention Science.</i> 20(1): 115-125. 2019. https://dx.doi.org/10.1007/s11121-018-0965-7	E7	Booth, BM, Wright, PB, et al. Trajectory of substance use after an HIV risk reduction intervention. <i>Am J Drug Alcohol Abuse.</i> 41(4): 345-52. 2015. https://dx.doi.org/10.3109/00952990.2015.1043437
E2a	Arnold, EA, Operario, D, et al. The Development of a Counseling-Based HIV Prevention Intervention for African American Men Who Have Sex With Men and Women: The Bruthas Project. <i>AIDS Educ Prev.</i> 27(6): 505-21. 2015. https://dx.doi.org/10.1521/aeap.2015.27.6.505	E8	Boman, J, Lindqvist, H, et al. Brief manual-based single-session Motivational Interviewing for reducing high-risk sexual behaviour in women - an evaluation. <i>Int J STD AIDS.</i> 29(4): 396-403. 2018. https://dx.doi.org/10.1177/0956462417729308
E3	Bannink, R, Broeren, S, et al. Effectiveness of a Web-based tailored intervention (E-health4Uth) and consultation to promote adolescents' health: randomized controlled trial. <i>J Med Internet Res.</i> 16(5): e143. 2014. https://dx.doi.org/10.2196/jmir.3163	E7	Brawner, BM, Jemmott, LS, et al. Project GOLD: A pilot randomized controlled trial of a novel psychoeducational HIV/STI prevention intervention for heterosexually-active black youth. <i>Res Nurs Health.</i> 42(1): 8-28. 2019. https://dx.doi.org/10.1002/nur.21930
E3a	Barbee, AP, Cunningham, MR, et al. Impact of Two Adolescent Pregnancy Prevention Interventions on Risky Sexual Behavior: A Three-Arm Cluster Randomized Control Trial. <i>Am J Public Health.</i> 106(S1): S85-s90. 2016. https://dx.doi.org/10.2105/ajph.2016.303429	E6	Brown, JL, Sales, JM, et al. Added benefits: reduced depressive symptom levels among African-American female adolescents participating in an HIV prevention intervention. <i>J Behav Med.</i> 37(5): 912-20. 2014. https://dx.doi.org/10.1007/s10865-013-9551-4
		E3	Brown, LK, Hadley, W, et al. Project STYLE: a multisite RCT for HIV prevention among youths in mental health treatment. <i>Psychiatr Serv.</i> 65(3): 338-44. 2014. https://dx.doi.org/10.1176/appi.ps.201300095

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Code	Reference	Code	Reference
E2a	Browne, FA, Wechsberg, WM, et al. mHealth versus face-to-face: study protocol for a randomized trial to test a gender-focused intervention for young African American women at risk for HIV in North Carolina. <i>BMC Public Health</i> . 18(1): 982. 2018. https://dx.doi.org/10.1186/s12889-018-5796-8	E12	Cherian, Av, Lasopa, So, et al. Reductions in high risk sexual behavior among depressed and non-depressed women in the community participating peer delivered randomized controlled field trial. <i>Comprehensive psychiatry</i> . 54(8): e18. 2013. https://dx.doi.org/10.1016/j.comppsy.2013.07.011
E6	Bryan, Ad, Magnan, Re, et al. Moderation of alcohol-related sexual risk reduction intervention with adolescents: the role of neurocognitive and genetic factors. <i>Alcohol Alcohol</i> . 50(): i37-. 2015. https://dx.doi.org/10.1093/alcalc/agv079.07	E7	Choi, SK, LeGrand, S, et al. Condom use intentions mediate the relationships between psychosocial constructs and HIV sexual risk behavior in young Black men who have sex with men. <i>AIDS Care</i> . 31(1): 53-60. 2019. https://dx.doi.org/10.1080/09540121.2018.1492695
E3	Bull, S, Devine, S, et al. Text Messaging, Teen Outreach Program, and Sexual Health Behavior: A Cluster Randomized Trial.[Erratum appears in Am J Public Health. 2016 Dec;106(12):e14; PMID: 27831783]. <i>Am J Public Health</i> . 106(S1): S117-S124. 2016.	E8	Christensen, JL, Miller, LC, et al. Reducing shame in a game that predicts HIV risk reduction for young adult MSM: a randomized trial delivered nationally over the Web. <i>J Int AIDS Soc</i> . 16(3 Suppl 2): 18716. 2013. https://dx.doi.org/10.7448/IAS.16.3.18716
E10	Castillo-Arcos Ldel, C, Benavides-Torres, RA, et al. The effect of an Internet-based intervention designed to reduce HIV/AIDS sexual risk among Mexican adolescents. <i>AIDS Care</i> . 28(2): 191-6. 2016. https://dx.doi.org/10.1080/09540121.2015.1073663	E8	Cianelli, R, Ferrer, L, et al. Mano a Mano-Mujer: an effective HIV prevention intervention for Chilean women. <i>Health Care Women Int</i> . 33(4): 321-341. 2012. PMID: 22420675. https://dx.doi.org/
E2	Champion, JD, Young, C, et al. Substantiating the need for primary care-based sexual health promotion interventions for ethnic minority adolescent women experiencing health disparities. <i>J Am Assoc Nurse Pract</i> . 28(9): 487-92. 2016. https://dx.doi.org/10.1002/2327-6924.12346	E2	Cianelli, R, Villegas, N, et al. Self-efficacy for HIV Prevention Among Refugee Hispanic Women in South Florida. <i>Journal of Immigrant & Minority Health</i> . 19(4): 905-912. 2017. https://dx.doi.org/10.1007/s10903-016-0462-7
E7	Chandler, R, Ross, H, et al. The HIP LADIES: A Pilot Health Improvement Project for HIV Prevention in Black College Women. <i>J Assoc Nurses AIDS Care</i> . (): . 2019. https://dx.doi.org/10.1097/jnc.0000000000000058	E3a	Coffin, Phillip O, Santos, Glenn-Milo, et al. Adapted personalized cognitive counseling for episodic substance-using men who have sex with men: a randomized controlled trial. <i>AIDS Behav</i> . 18(7): 1390-1400. 2014.
E1	Charron-Prochownik, D, Sereika, SM, et al. Long-term effects of the booster-enhanced READY-Girls preconception counseling program on intentions and behaviors for family planning in teens with diabetes. <i>Diabetes Care</i> . 36(12): 3870-4. 2013. https://dx.doi.org/10.2337/dc13-0355	E7	Cordova, D. The preliminary efficacy of a HIV preventive intervention app in an urban youth-centered community health clinic. <i>Journal of adolescent health. Conference: society for adolescent health and medicine annual meeting 2018. United states</i> . 62(2 Supplement 1): S10-s11. 2018.
		E8	Cortes-Bordoy, J, Vidart, JA, et al. Usefulness of an educational leaflet to modify sexual risk behaviour in women with external genital warts. <i>Eur J Dermatol</i> . 20(3): 339-344. 2010. PMID: 20146965.

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Code	Reference	Code	Reference
E5	Crawford, MJ, Sanatinia, R, et al. The clinical and cost-effectiveness of brief advice for excessive alcohol consumption among people attending sexual health clinics: a randomised controlled trial. <i>Sex Transm Infect.</i> 91(1): 37-43. 2015. https://dx.doi.org/10.1136/sextrans-2014-051561	E6	DiClemente, RJ, Brown, JL, et al. Rate of decay in proportion of condom-protected sex acts among adolescents after participation in an HIV risk-reduction intervention. <i>Journal of Acquired Immune Deficiency Syndromes: JAIDS.</i> 63 Suppl 1(): S85-9. 2013. https://dx.doi.org/10.1097/QAI.0b013e3182920173
E6	Crosby, RA, Charnigo, RJ, et al. Enhancing condom use among Black male youths: a randomized controlled trial. <i>Am J Public Health.</i> 104(11): 2219-25. 2014. https://dx.doi.org/10.2105/AJPH.2014.302131	E6	DiClemente, RJ, Wingood, GM, et al. Efficacy of a telephone-delivered sexually transmitted infection/human immunodeficiency virus prevention maintenance intervention for adolescents: a randomized clinical trial. <i>JAMA Pediatr.</i> 168(10): 938-46. 2014. https://dx.doi.org/10.1001/jamapediatrics.2014.1436
E8	Crosby, RA, Mena, L, et al. 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. <i>Sex Transm Dis.</i> 45(3): 169-176. 2018. https://dx.doi.org/https://dx.doi.org/10.1097/OLQ.0000000000000721	E3	Dinaj-Koci, V, Lunn, S, et al. Adolescent age at time of receipt of one or more sexual risk reduction interventions. <i>J Adolesc Health.</i> 55(2): 228-34. 2014. https://dx.doi.org/10.1016/j.jadohealth.2014.01.016
E12	Crosby, RA, Mena, L, et al. Promoting positive condom use experiences among young black MSM: a randomized controlled trial of a brief, clinic-based intervention. <i>Health Educ Res.</i> 33(3): 197-204. 2018. https://dx.doi.org/10.1093/her/cyy010	E7	Downs, JS, Ashcraft, AM, et al. Video Intervention to Increase Perceived Self-Efficacy for Condom Use in a Randomized Controlled Trial of Female Adolescents. <i>J Pediatr Adolesc Gynecol.</i> 31(3): 291-298.e2. 2018. https://dx.doi.org/10.1016/j.jpag.2017.10.008
E6	Crosby, RA, Mena, L, et al. 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. <i>Sex Health.</i> 16(2): 187-191. 2019. https://dx.doi.org/10.1071/SH18156	E2a	Downs, JS, Bruine de Bruin, W, et al. Behavioral Decision Research Intervention Reduces Risky Sexual Behavior. <i>Curr HIV Res.</i> 13(5): 439-46. 2015.
E12	Crosby, R, Salazar, LF. Reduction of condom use errors from a brief, clinic-based intervention: a secondary analysis of data from a randomised, controlled trial of young black males. <i>Sex Transm Infect.</i> 91(2): 111-5. 2015. https://dx.doi.org/10.1136/sextrans-2013-051492	E12	Downs, Js, Ashcraft, Am, et al. Can you get an STI from a virgin? The answer might surprise you intervention improves knowledge about sexual risk perceptions. <i>Journal of adolescent health.</i> 56(2 suppl. 1): S76-s77. 2015. https://dx.doi.org/10.1016/j.jadohealth.2014.10.311
E3a	D'Amico, EJ, Houck, JM, et al. Group motivational interviewing for homeless young adults: Associations of change talk with substance use and sexual risk behavior. <i>Psychology of Addictive Behaviors.</i> 31(6): 688-698. 2017. https://dx.doi.org/10.1037/adb0000288	E6	Eaton, LA, Kalichman, SC, et al. A reanalysis of a behavioral intervention to prevent incident HIV infections: including indirect effects in modeling outcomes of Project EXPLORE. <i>AIDS Care.</i> 25(7): 805-11. 2013. https://dx.doi.org/10.1080/09540121.2012.748870
		E6	Eaton, Lisa A, Kalichman, Seth C, et al. Randomised controlled trial of a sexual risk reduction intervention for STI prevention among men who have sex with men in the USA. <i>Sex Transm Infect.</i> 94(1): 40-45. 2018.

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Code	Reference	Code	Reference
E3	Espada, JP, Morales, A, et al. Short-term evaluation of a skill-development sexual education program for Spanish adolescents compared with a well-established program. <i>J Adolesc Health.</i> 56(1): 30-7. 2015. https://dx.doi.org/10.1016/j.jadohealth.2014.08.018	E2a	Gamarel, KE, Darbes, LA, et al. The Development and Testing of a Relationship Skills Intervention to Improve HIV Prevention Uptake Among Young Gay, Bisexual, and Other Men Who Have Sex With Men and Their Primary Partners (We Prevent): Protocol for a Randomized Controlled Trial. <i>JMIR Res Protoc.</i> 8(1): e10370. 2019. https://dx.doi.org/10.2196/10370
E7	Esposito-Smythers, C, Hadley, W, et al. Randomized pilot trial of a cognitive-behavioral alcohol, self-harm, and HIV prevention program for teens in mental health treatment. <i>Behav Res Ther.</i> 89(): 49-56. 2017. https://dx.doi.org/10.1016/j.brat.2016.11.005	E3	Garofalo, R, Kuhns, LM, et al. Efficacy of an Empowerment-Based, Group-Delivered HIV Prevention Intervention for Young Transgender Women: The Project LifeSkills Randomized Clinical Trial. <i>JAMA Pediatr.</i> 172(10): 916-923. 2018. https://dx.doi.org/10.1001/jamapediatrics.2018.1799
E3	Estrada, Y, Rosen, A, et al. Efficacy of a Brief Intervention to Reduce Substance Use and Human Immunodeficiency Virus Infection Risk Among Latino Youth. <i>J Adolesc Health.</i> (): . 2015. https://dx.doi.org/10.1016/j.jadohealth.2015.07.006	E3a	Gil-Llario, MD, Ballester-Arnal, R, et al. Effectiveness of HIV prevention for women: what is working?. <i>AIDS Behav.</i> 18(10): 1924-33. 2014. https://dx.doi.org/10.1007/s10461-014-0703-5
E2a	Ewing, AC, Kottke, MJ, et al. 2GETHER - The Dual Protection Project: Design and rationale of a randomized controlled trial to increase dual protection strategy selection and adherence among African American adolescent females. <i>Contemp Clin Trials.</i> 54(): 1-7. 2017. https://dx.doi.org/10.1016/j.cct.2016.12.014	E6	Gimenez-Garcia, C, Ballester-Arnal, R, et al. Peer-Led or Expert-Led Intervention in HIV Prevention Efficacy? A Randomized Control Trial Among Spanish Young People to Evaluate Their Role. <i>Health Promot Pract.</i> 19(2): 277-286. 2018. https://dx.doi.org/10.1177/1524839917733966
E7	Feinstein, BA, Bettin, E, et al. The Influence of Internalized Stigma on the Efficacy of an HIV Prevention and Relationship Education Program for Young Male Couples. <i>AIDS Behav.</i> (): . 2018. https://dx.doi.org/10.1007/s10461-018-2093-6	E6	Gold, MA, Tzilos, GK, et al. A Randomized Controlled Trial to Compare Computer-assisted Motivational Intervention with Didactic Educational Counseling to Reduce Unprotected Sex in Female Adolescents. <i>J Pediatr Adolesc Gynecol.</i> 29(1): 26-32. 2016. https://dx.doi.org/10.1016/j.jpag.2015.06.001
E6	Fernandez, M, Hosek, SybilG, et al. A randomized controlled trial of POWER: An Internet-based HIV prevention intervention for Black bisexual men. <i>AIDS Behav.</i> 20(9): 1951-1960. 2016. http://dx.doi.org/10.1007/s10461-016-1403-0	E7	Gollub, EL, Cyrus-Cameron, E, et al. Basic body knowledge in street-recruited, active drug-using women enrolled in a "body empowerment" intervention trial. <i>AIDS Care.</i> 25(6): 732-7. 2013. https://dx.doi.org/10.1080/09540121.2012.748167
E3	Fernandez-Santos, DM, Miranda-Diaz, C, et al. Impact of ASUMA Intervention on HIV Risk Behaviors among Puerto Rican Adolescents. <i>International Journal of Environmental Research & Public Health [Electronic Resource].</i> 13(1): ijerph13010060. 2015. https://dx.doi.org/10.3390/ijerph13010060	E3a	Gollub, E, Cyrus-Cameron, E, et al. Active Drug-Using Women Use Female-Initiated Barrier Methods to Reduce HIV/STI Risk: Results from a Randomized Trial. <i>ISRN Addiction.</i> 2013(): 768258. 2013. https://dx.doi.org/10.1155/2013/768258
E3a	Fiellin, LE, Hieftje, KD, et al. Video Game Intervention for Sexual Risk Reduction in Minority Adolescents: Randomized Controlled Trial. <i>J Med Internet Res.</i> 19(9): e314. 2017. https://dx.doi.org/10.2196/jmir.8148	E3	Gooden, Lauren, Metsch, LisaR, et al. Examining the efficacy of HIV risk-reduction counseling on the sexual risk behaviors of a national sample of drug abuse treatment clients: Analysis of subgroups. <i>AIDS Behav.</i> 20(9): 1893-1906. 2016. https://dx.doi.org/10.1007/s10461-016-1300-6

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Code	Reference	Code	Reference
E2a	Gousse, Y, McFarlane, D, et al. Lessons Learned from the Implementation of a Shared Community-Academic HIV Prevention Intervention. <i>Progress in Community Health Partnerships</i> . 12(4): 451-461. 2018. https://dx.doi.org/10.1353/cpr.2018.0070	E6	Hatch-Maillette, MaryA, Beadnell, Blair, et al. Heterosexual anal sex among men and women in substance abuse treatment: Secondary analysis of two gender-specific HIV-prevention trials. <i>J Sex Res</i> . 54(1): 33-41. 2017. https://dx.doi.org/10.1080/00224499.2015.1118426
E3	Green, J, Oman, RF, et al. Long-Term Improvements in Knowledge and Psychosocial Factors of a Teen Pregnancy Prevention Intervention Implemented in Group Homes. <i>J Adolesc Health</i> . 60(6): 698-705. 2017. https://dx.doi.org/10.1016/j.jadohealth.2017.01.004	E5	Hawk, M. 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. <i>AIDS Educ Prev</i> . 25(6): 519-34. 2013. https://dx.doi.org/10.1521/aeap.2013.25.6.519
E7	Grossman, SL, Campagna, B, et al. Improving body image and sexual health behaviors among college women. <i>J Am Coll Health</i> . (): 1-5. 2018. https://dx.doi.org/10.1080/07448481.2018.1454927	E2a	Herbst, JH, Raiford, JL, et al. Adaptation and National Dissemination of a Brief, Evidence-Based, HIV Prevention Intervention for High-Risk Men Who Have Sex with Men. <i>MMWR: Morbidity & Mortality Weekly Report - Supplement</i> . 65(1): 42-50. 2016. https://dx.doi.org/10.15585/mmwr.su6501a7
E3	Hadley, W, Barker, D, et al. Relationship Between Unsupervised Time and Participation in an Emotion Regulation Intervention and Risk Outcomes. <i>J Dev Behav Pediatr</i> . 38(9): 714-722. 2017. https://dx.doi.org/10.1097/DBP.0000000000000498	E6	Hidalgo, MA, Kuhns, LM, et al. 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. <i>Arch Sex Behav</i> . 44(2): 475-85. 2015. https://dx.doi.org/10.1007/s10508-014-0347-6
E6	Hadley, W, Brown, LK, et al. Work It Out Together: Preliminary Efficacy of a Parent and Adolescent DVD and Workbook Intervention on Adolescent Sexual and Substance Use Attitudes and Parenting Behaviors. <i>AIDS Behav</i> . 20(9): 1961-72. 2016. https://dx.doi.org/10.1007/s10461-016-1418-6	E6	Hightow-Weidman, LB, LeGrand, S, et al. A Randomized Trial of an Online Risk Reduction Intervention for Young Black MSM. <i>AIDS Behav</i> . 23(5): 1166-1177. 2019. https://dx.doi.org/10.1007/s10461-018-2289-9
E3	Harawa, NT, Guentzel-Frank, H, et al. Efficacy of a Small-Group Intervention for Post-Incarcerated Black Men Who Have Sex with Men and Women (MSMW). <i>Journal of Urban Health</i> . 95(2): 159-170. 2018. https://dx.doi.org/10.1007/s11524-018-0227-9	E3a	Houck, CD, Barker, DH, et al. Sexual Risk Outcomes of an Emotion Regulation Intervention for At-Risk Early Adolescents. <i>Pediatrics</i> . 141(6): 06. 2018. https://dx.doi.org/10.1542/peds.2017-2525
E6	Harawa, NT, Williams, JK, et al. Efficacy of a culturally congruent HIV risk-reduction intervention for behaviorally bisexual black men: results of a randomized trial. <i>AIDS</i> . 27(12): 1979-88. 2013.	E3a	Jemmott, JB, 3rd, Jemmott, et al. 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. <i>AIDS Behav</i> . 19(7): 1247-62. 2015. https://dx.doi.org/10.1007/s10461-014-0961-2
E2	Hart, TA, Stratton, N, et al. A Pilot Trial of a Sexual Health Counseling Intervention for HIV-Positive Gay and Bisexual Men Who Report Anal Sex without Condoms. <i>PLoS ONE [Electronic Resource]</i> . 11(4): e0152762. 2016. https://dx.doi.org/10.1371/journal.pone.0152762	E3	Jenner, E, Jenner, LW, et al. Impact of an Intervention Designed to Reduce Sexual Health Risk Behaviors of African American Adolescents: Results of a Randomized Controlled Trial. <i>Am J Public Health</i> . 106(S1): S78-s84. 2016. https://dx.doi.org/10.2105/ajph.2016.303291

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Code	Reference	Code	Reference
E6	Jones, DL, Kashy, D, et al. The impact of substance use, sexual trauma, and intimate partner violence on sexual risk intervention outcomes in couples: a randomized trial. <i>Annals of Behavioral Medicine</i> . 45(3): 318-28. 2013. https://dx.doi.org/10.1007/s12160-012-9455-5	E8	Klein, CH, Kuhn, T, et al. C-SAFE: A Computer-Delivered Sexual Health Promotion Program for Latinas. <i>Health Promot Pract</i> . 18(4): 516-525. 2017. https://dx.doi.org/10.1177/1524839917707791
E10	Jones, HE, Kirtadze, I, et al. Feasibility and initial efficacy of a culturally sensitive women-centered substance use intervention in Georgia: Sex risk outcomes. <i>Subst Abuse Treat Prev Policy</i> . 10(): 47. 2015. https://dx.doi.org/10.1186/s13011-015-0043-0	E6	Koblin, BA, Bonner, S, et al. A randomized trial of a behavioral intervention for black MSM: the DiSH study. <i>AIDS</i> . 26(4): 483-488. 2012. PMID: 22156967. https://dx.doi.org/
E6	Jones, R, Hoover, DR, et al. 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.[Erratum appears in Nurs Outlook. 2013 Nov-Dec;61(6):383]. <i>Nurs Outlook</i> . 61(4): 205-215.e3. 2013. https://dx.doi.org/10.1016/j.outlook.2013.03.006	E6	Kurth, AE, Chhun, N, et al. Linguistic and Cultural Adaptation of a Computer-Based Counseling Program (CARE+ Spanish) to Support HIV Treatment Adherence and Risk Reduction for People Living With HIV/AIDS: A Randomized Controlled Trial. <i>J Med Internet Res</i> . 18(7): e195. 2016. https://dx.doi.org/10.2196/jmir.5830
E2	Kanamori, M, De La Rosa, M, et al. A Brief Report: Lessons Learned and Preliminary Findings of Progreso en Salud, an HIV Risk Reduction Intervention for Latina Seasonal Farmworkers. <i>International Journal of Environmental Research & Public Health [Electronic Resource]</i> . 14(1): 30. 2016. https://dx.doi.org/10.3390/ijerph14010032	E6	Kurtz, SP, Stall, RD, et al. A randomized trial of a behavioral intervention for high risk substance-using MSM. <i>AIDS Behav</i> . 17(9): 2914-26. 2013. https://dx.doi.org/10.1007/s10461-013-0531-z
E3	Kaufman, CE, Whitesell, NR, et al. Effectiveness of Circle of Life, an HIV-preventive intervention for American Indian middle school youths: a group randomized trial in a Northern Plains tribe. <i>Am J Public Health</i> . 104(6): e106-12. 2014. https://dx.doi.org/10.2105/AJPH.2013.301822	E3	Kurtz, Sp, Buttram, Me, et al. A randomized trial of brief assessment interventions for young adults who use drugs in the club scene. <i>J Subst Abuse Treat</i> . 78(): 64-73. 2017. https://dx.doi.org/10.1016/j.jsat.2017.05.008
E3	Kelsey, Meredith, Layzer, Carolyn, et al. Replicating Cuidate!: 6-month impact findings of a randomized controlled trial. <i>Am J Public Health</i> . 106(Suppl 1): S70-S77. 2016. https://dx.doi.org/10.2105/AJPH.2016.303371	E12	Lau, JT, Lee, AL, et al. A Randomized Control Trial for Evaluating Efficacies of Two Online Cognitive Interventions With and Without Fear-Appeal Imagery Approaches in Preventing Unprotected Anal Sex Among Chinese Men Who Have Sex with Men. <i>AIDS Behav</i> . 20(9): 1851-62. 2016. https://dx.doi.org/10.1007/s10461-015-1263-z
E6	Kennedy, SB, Nolen, S, et al. Effectiveness of a brief condom promotion program in reducing risky sexual behaviours among African American men. <i>J Eval Clin Pract</i> . 19(2): 408-13. 2013. https://dx.doi.org/10.1111/j.1365-2753.2012.01841.x	E6	Lauby, J, Milnamow, M, et al. Evaluation of Project RISE, an HIV Prevention Intervention for Black Bisexual Men Using an Ecosystems Approach. <i>AIDS Behav</i> . 22(1): 164-177. 2018. https://dx.doi.org/10.1007/s10461-017-1892-5
		E7	Lewis, MA, Patrick, ME, et al. Randomized controlled trial of a web-delivered personalized normative feedback intervention to reduce alcohol-related risky sexual behavior among college students. <i>J Consult Clin Psychol</i> . 82(3): 429-40. 2014. https://dx.doi.org/10.1037/a0035550

Appendix D. Excluded Studies

Code	Reference	Code	Reference
E8	Llewellyn, CD, Abraham, C, et al. 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. <i>PLoS ONE [Electronic Resource]</i> . 14(5): e0216855. 2019. https://dx.doi.org/10.1371/journal.pone.0216855	E7	McMahon, JM, Chimenti, R, et al. Risk of Intimate Partner Violence and Relationship Conflict Following Couple-Based HIV Prevention Counseling: Results From the Harlem River Couples Project. <i>J Interpers Violence</i> . (): . 2015. https://dx.doi.org/10.1177/0886260515600878
E2	Logie, CarmenH, Lacombe-Duncan, Ashley, et al. A pilot study of a group-based HIV and STI prevention intervention for lesbian, bisexual, queer, and other women who have sex with women in Canada. <i>AIDS Patient Care STDS</i> . 29(6): 321-328. 2015. https://dx.doi.org/http://dx.doi.org/10.1089/apc.2014.0355	E3a	McMahon, JM, Pouget, ER, et al. Couple-based HIV counseling and testing: a risk reduction intervention for US drug-involved women and their primary male partners. <i>Prevention Science</i> . 16(2): 341-51. 2015. https://dx.doi.org/10.1007/s11121-014-0540-9
E5	Lyson, HC, Le, GM, et al. Social Media as a Tool to Promote Health Awareness: Results from an Online Cervical Cancer Prevention Study. <i>J Cancer Educ</i> . (): . 2018. https://dx.doi.org/10.1007/s13187-018-1379-8	E3a	McMahon, JM, Tortu, S, et al. Effectiveness of Couple-Based HIV Counseling and Testing for Women Substance Users and Their Primary Male Partners: A Randomized Trial. <i>Adv Prev Med</i> . 2013(): 286207. 2013. https://dx.doi.org/10.1155/2013/286207
E3	Mallory, C, Hesson-McInnis, M. Pilot test results of an HIV prevention intervention for high-risk women. <i>West J Nurs Res</i> . 35(3): 313-29. 2013. https://dx.doi.org/10.1177/0193945911416134	E3a	McMahon, James M, Tortu, Stephanie, et al. Recruitment of heterosexual couples in public health research: a study protocol. . 3(1): 24. 2003. https://dx.doi.org/
E2	Marcell, AV, Allan, E, et al. Effectiveness of a brief curriculum to promote condom and health care use among out-of-school young adult males. <i>Perspect Sex Reprod Health</i> . 45(1): 33-40. 2013. https://dx.doi.org/10.1363/4503313	E3	Mimiaga, MJ, Hughto, JMW, et al. 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. <i>Arch Sex Behav</i> . 48(4): 1059-1071. 2019. https://dx.doi.org/10.1007/s10508-018-1326-0
E8	Marion, LN, Finnegan, L, et al. The Well Woman Program: a community-based randomized trial to prevent sexually transmitted infections in low-income African American women. <i>Res Nurs Health</i> . 32(3): 274-285. 2009. PMID: 19373824.	E2a	Mimiaga, MJ, Pantalone, DW, et al. A randomized controlled efficacy trial of behavioral activation for concurrent stimulant use and sexual risk for HIV acquisition among MSM: project IMPACT study protocol. <i>BMC Public Health</i> . 18(1): 914. 2018. https://dx.doi.org/10.1186/s12889-018-5856-0
E2a	McCabe, BE, Gonzalez-Guarda, RM, et al. Mechanisms of Partner Violence Reduction in a Group HIV-Risk Intervention for Hispanic Women. <i>J Interpers Violence</i> . 31(13): 2316-37. 2016. https://dx.doi.org/10.1177/0886260515575608	E2	Moniz, MH, Meyn, LA, et al. Text Messaging to Improve Preventive Health Attitudes and Behaviors During Pregnancy: A Prospective Cohort Analysis. <i>J Reprod Med</i> . 60(9-10): 378-82. 2015. https://dx.doi.org/
E2	McCabe, BE, Schaefer Solle, N, et al. Alcohol misuse, depressive symptoms, and HIV/STI risks of US Hispanic women. <i>Ethn Health</i> . 22(5): 528-540. 2017. https://dx.doi.org/10.1080/13557858.2016.1244738	E12	Montanaro, ErikaA. What are the 'active ingredients' of change in the theory of planned behavior? evaluating the relative effectiveness of attitudes, norms, and perceived behavioral control/self-efficacy. <i>Dissertation Abstracts International: Section B: The Sciences and Engineering</i> . 76(1-B(E)): No Pagination Specified. 2015.

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Code	Reference	Code	Reference
E7	Montgomery, TM, Mays, VM, et al. Acceptability and Feasibility of a Sexual Health Intervention for Young Adult Black Women. <i>J Obstet Gynecol Neonatal Nurs.</i> (): . 2018. https://dx.doi.org/10.1016/j.jogn.2018.04.136	E12	Murray, P, Ashcraft, A, et al. Evaluation of video intervention on sex-related psychosocial and behavioral outcomes in a randomized controlled trial of female adolescents. <i>Sexually transmitted diseases. Conference: 2016 sexually transmitted diseases prevention conference. United states.</i> 43(10 Supplement 2): S205-s206. 2016. https://dx.doi.org/10.1097/01.olq.0000503358.65329.6f
E3	Morales, A, Espada, JP, et al. Mediation of an efficacious HIV risk reduction intervention for adolescents: A cluster-randomised controlled trial. <i>J Health Psychol.</i> (): 1359105317707256. 2017. https://dx.doi.org/10.1177/1359105317707256	E6	Mustanski, B, Garofalo, R, et al. 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. <i>AIDS Behav.</i> 17(9): 2999-3012. 2013. https://dx.doi.org/10.1007/s10461-013-0507-z
E3	Morales, A, Espada, JP, et al. The short-term impact of peers as co-facilitators of an HIV prevention programme for adolescents: a cluster randomised controlled trial. <i>European Journal of Contraception & Reproductive Health Care.</i> 19(5): 379-91. 2014. https://dx.doi.org/10.3109/13625187.2014.919445	E6	Mustanski, B, Parsons, JT, et al. Biomedical and Behavioral Outcomes of Keep It Up!: An eHealth HIV Prevention Program RCT. Am J Prev Med. 55(2): 151-158. 2018. https://dx.doi.org/10.1016/j.amepre.2018.04.026
E3a	Morgenstern, J, Bux, DA, et al. Randomized trial to reduce club drug use and HIV risk behaviors among men who have sex with men. <i>J Consult Clin Psychol.</i> 77(4): 645-656. 2009. PMID: 19634958. https://dx.doi.org/	E12	Negash, Sesen. Sexual health education in college: The impact of sexual negotiation training on sexual risk reduction. <i>Dissertation Abstracts International Section A: Humanities and Social Sciences.</i> 74(2-A(E)): No Pagination Specified. 2013.
E7	Morrison-Beedy, D, Grove, L. Adolescent Girls' Experiences With Sexual Pressure, Coercion, and Victimization: #MeToo. <i>Worldviews on Evidence-Based Nursing.</i> 15(3): 225-229. 2018. https://dx.doi.org/10.1111/wvn.12293	E2a	Newby, KV, French, DP, et al. Increasing young adults' condom use intentions and behaviour through changing chlamydia risk and coping appraisals: study protocol for a cluster randomised controlled trial of efficacy. <i>BMC Public Health.</i> 13(): 528. 2013. https://dx.doi.org/10.1186/1471-2458-13-528
E6	Motley, DN, Hammond, S, et al. Strategies Chosen by YMSM During Goal Setting to Reduce Risk for HIV and Other Sexually Transmitted Infections: Results From the Keep It Up! 2.0 Prevention Trial. <i>AIDS Educ Prev.</i> 29(1): 1-13. 2017. https://dx.doi.org/10.1521/aeap.2017.29.1.1	E8	Ng, JYS, Chan, RKW, et al. An Abstinence and Safer Sex Intervention for Adolescents Attending the Public Sexually Transmitted Infection Clinic in Singapore. <i>J Adolesc Health.</i> 62(6): 737-746. 2018. https://dx.doi.org/10.1016/j.jadohealth.2017.12.014
E2a	Munro-Kramer, ML, Fava, NM, et al. What are we missing? Risk behaviors among Arab-American adolescents and emerging adults. <i>J Am Assoc Nurse Pract.</i> 28(9): 493-502. 2016. https://dx.doi.org/10.1002/2327-6924.12352	E7	Nostlinger, C, Borms, R, et al. Development of a theory-guided pan-European computer-assisted safer sex intervention. <i>Health Promot Int.</i> 31(4): 782-792. 2016.
		E5	Nyamathi, A, Reback, CJ, et al. Impact of Tailored Interventions to Reduce Drug Use and Sexual Risk Behaviors Among Homeless Gay and Bisexual Men. <i>American Journal of Mens Health.</i> 11(2): 208-220. 2017. https://dx.doi.org/10.1177/1557988315590837

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Code	Reference	Code	Reference
E3a	O'Donnell, L, Stueve, A, et al. Adapting the VOICES HIV behavioral intervention for Latino men who have sex with men. <i>AIDS Behav.</i> 18(4): 767-75. 2014. https://dx.doi.org/10.1007/s10461-013-0653-3	E3	Peskin, MF, Shegog, R, et al. Efficacy of It's Your Game-Tech: A Computer-Based Sexual Health Education Program for Middle School Youth. <i>J Adolesc Health.</i> 56(5): 515-21. 2015. https://dx.doi.org/10.1016/j.jadohealth.2015.01.001
E12	Operario, D, Arnold, E, et al. A forgotten drug in the hiv epidemic: alcohol use and unprotected sexual behavior in high-risk african american men. <i>Alcoholism: clinical and experimental research.</i> 37(): 295a. 2013. https://dx.doi.org/10.1111/acer.12163	E2a	Prado, G, Estrada, Y, et al. Rationale and design for eHealth Familias Unidas Primary Care: A drug use, sexual risk behavior, and STI preventive intervention for hispanic youth in pediatric primary care clinics. <i>Contemp Clin Trials.</i> 76(): 64-71. 2019. https://dx.doi.org/10.1016/j.cct.2018.11.005
E6	Operario, D, Gamarel, KE, et al. 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. <i>AIDS Behav.</i> 21(8): 2452-2463. 2017. https://dx.doi.org/10.1007/s10461-016-1462-2	E3	Prado, G, Huang, S, et al. Ecodevelopmental and intrapersonal moderators of a family based preventive intervention for Hispanic youth: a latent profile analysis. <i>Prevention Science.</i> 14(3): 290-9. 2013. https://dx.doi.org/10.1007/s11121-012-0326-x
E2	Owczarzak, J, Broaddus, M, et al. Effectiveness of an evidence-based HIV prevention intervention when implemented by frontline providers. <i>Transl Behav Med.</i> (): . 2018. https://dx.doi.org/10.1093/tbm/ibx041	E6	Raghupathy, S, Klein, C, et al. Online Activities for Enhancing Sex Education Curricula: Preliminary Evidence on the Effectiveness of the Abstinence and Contraception Education Storehouse. <i>J HIV AIDS Soc Serv.</i> 12(2): 160-171. 2013. https://dx.doi.org/10.1080/15381501.2013.790749
E6	Parsons, JT, Lelutiu-Weinberger, C, et al. A randomized controlled trial utilizing motivational interviewing to reduce HIV risk and drug use in young gay and bisexual men. <i>J Consult Clin Psychol.</i> 82(1): 9-18. 2014. https://dx.doi.org/10.1037/a0035311	E5	Reback, CJ, Peck, JA, et al. Contingency management among homeless, out-of-treatment men who have sex with men. <i>J Subst Abuse Treat.</i> 39(3): 255-263. 2010. PMID: 20667681. https://dx.doi.org/
E8	Pearson, CR, Kaysen, D, et al. Randomized Control Trial of Culturally Adapted Cognitive Processing Therapy for PTSD Substance Misuse and HIV Sexual Risk Behavior for Native American Women. <i>AIDS Behav.</i> 23(3): 695-706. 2019. https://dx.doi.org/10.1007/s10461-018-02382-8	E6	Reback, CathyJ, Veniegas, Rosemary, et al. Getting off: Development of a model program for gay and Bisexual Male Methamphetamine Users. <i>J Homosex.</i> 61(4): 540-553. 2014. https://dx.doi.org/10.1080/00918369.2014.865459
E7	Pellowski, JA, Kalichman, SC. Mixing it Up: Integrating Men and Women Living with HIV/AIDS in Prevention Groups. <i>J HIV AIDS Soc Serv.</i> 12(2): 190-204. 2013. https://dx.doi.org/10.1080/15381501.2013.790751	E3a	Rhodes, SD, Alonzo, J, et al. 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. <i>Am J Public Health.</i> 107(6): 969-976. 2017. https://dx.doi.org/10.2105/AJPH.2017.303814
E3a	Perez-Jimenez, D, Seal, DW, et al. A Pilot Intervention to Promote Safer Sex in Heterosexual Puerto Rican Couples. <i>Couple Family Psychol.</i> 3(3): 193-206. 2014. https://dx.doi.org/10.1037/cfp0000022	E3	Rizzo, CJ, Joppa, M, et al. Project Date SMART: a Dating Violence (DV) and Sexual Risk Prevention Program for Adolescent Girls with Prior DV Exposure. <i>Prevention Science.</i> 19(4): 416-426. 2018. https://dx.doi.org/10.1007/s11121-018-0871-z

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Code	Reference	Code	Reference
E7	Roux, P, Le Gall, JM, et al. Innovative community-based educational face-to-face intervention to reduce HIV, hepatitis C virus and other blood-borne infectious risks in difficult-to-reach people who inject drugs: results from the ANRS-AERLI intervention study. <i>Addiction</i> . 111(1): 94-106. 2016. https://dx.doi.org/10.1111/add.13089	E2	Scott-Sheldon, La, Senn, Te, et al. Quantity, not frequency, of alcohol use moderates the association between multiple sexual partners and <i>Trichomonas vaginalis</i> among women attending an urban STD clinic. <i>Sex Transm Infect</i> . 89(6): 498-503. 2013. https://dx.doi.org/10.1136/sextrans-2012-050983
E6	Safren, SA, O'Cleirigh, CM, et al. 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. <i>Health Psychol</i> . 32(2): 171-9. 2013. https://dx.doi.org/10.1037/a0028581	E7	Scull, TM, Kupersmidt, JB, et al. Examining the efficacy of an mHealth media literacy education program for sexual health promotion in older adolescents attending community college. <i>Journal of American College Health</i> . 66(3): 165-177. 2018. https://dx.doi.org/10.1080/07448481.2017.1393822
E7	Sales, Jm, Brown, JI, et al. A pilot study of a combination STD prevention intervention for african-american mothers and their adolescent daughters. <i>Sexually transmitted diseases</i> .. 41(): S9. 2014. https://dx.doi.org/	E8	Seth, P, Wingood, GM, et al. Abuse Impedes Prevention: The Intersection of Intimate Partner Violence and HIV/STI Risk Among Young African American Women. <i>AIDS Behav</i> . 19(8): 1438-45. 2015. https://dx.doi.org/10.1007/s10461-014-0940-7
E3a	Sanchez, J, De La Rosa, M, et al. Project Salud: Efficacy of a community-based HIV prevention intervention for Hispanic migrant workers in south Florida. <i>AIDS Educ Prev</i> . 25(5): 363-75. 2013. https://dx.doi.org/10.1521/aeap.2013.25.5.363	E2a	Shrestha, R, Krishnan, A, et al. A non-inferiority trial of an evidence-based secondary HIV prevention behavioral intervention compared to an adapted, abbreviated version: Rationale and intervention description. <i>Contemp Clin Trials</i> . 44(): 95-102. 2015. https://dx.doi.org/10.1016/j.cct.2015.08.002
E8	Sanderson, M, Khabele, D, et al. Results of a Health Education Message Intervention on HPV Knowledge and Receipt of Follow-up Care among Latinas Infected with High-risk Human Papillomavirus. <i>J Health Care Poor Underserved</i> . 26(4): 1440-55. 2015. https://dx.doi.org/10.1353/hpu.2015.0131	E7	Sieving, RE, Allen, ML, et al. Encuentro: Feasibility, Acceptability, and Outcomes of a Culturally Tailored Teen-Parent Health Promotion Program. <i>Health Promot Pract</i> . 18(5): 751-762. 2017. https://dx.doi.org/10.1177/1524839916654462
E7	Schonnesson, LN, Bowen, AM, et al. 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. <i>Arch Sex Behav</i> . 45(6): 1501-11. 2016. https://dx.doi.org/10.1007/s10508-015-0608-z	E5	Sieving, RE, McMorris, BJ, et al. Prime Time: 12-month sexual health outcomes of a clinic-based intervention to prevent pregnancy risk behaviors. <i>J Adolesc Health</i> . 49(2): 172-9. 2011. https://dx.doi.org/10.1016/j.jadohealth.2010.12.002
E6	Schwarcz, SK, Chen, YH, et al. A randomized control trial of personalized cognitive counseling to reduce sexual risk among HIV-infected men who have sex with men. <i>AIDS Care</i> . 25(1): 1-10. 2013. https://dx.doi.org/10.1080/09540121.2012.674095	E5	Sieving, RE, McRee, AL, et al. Prime time: sexual health outcomes at 24 months for a clinic-linked intervention to prevent pregnancy risk behaviors. <i>JAMA Pediatr</i> . 167(4): 333-40. 2013. https://dx.doi.org/10.1001/jamapediatrics.2013.1089
		E5	Sieving, RE, McRee, AL, et al. Prime Time: long-term sexual health outcomes of a clinic-linked intervention. <i>Perspect Sex Reprod Health</i> . 46(2): 91-100. 2014. https://dx.doi.org/10.1363/46e0914

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Code	Reference	Code	Reference
E6	Sikkema, KJ, Abler, L, et al. Positive choices: outcomes of a brief risk reduction intervention for newly HIV-diagnosed men who have sex with men. <i>AIDS Behav.</i> 18(9): 1808-19. 2014. https://dx.doi.org/10.1007/s10461-014-0782-3	E6	Sun, WH, Wong, CKH, et al. A Peer-Led, Social Media-Delivered, Safer Sex Intervention for Chinese College Students: Randomized Controlled Trial. <i>J Med Internet Res.</i> 19(8): e284. 2017. https://dx.doi.org/10.2196/jmir.7403
E6	Snead, MC, O'Leary, AM, et al. Relationship between social cognitive theory constructs and self-reported condom use: assessment of behaviour in a subgroup of the Safe in the City trial.[Erratum appears in <i>BMJ Open.</i> 2016 Jun 22;6(6):e006093corr1; PMID: 27334880]. <i>BMJ Open.</i> 4(12): e006093. 2014. https://dx.doi.org/10.1136/bmjopen-2014-006093	E4	Takahashi, LM, Tobin, KE, et al. Chieh Mei Ching Yi: A randomized controlled trial of a culturally tailored HIV prevention intervention for Chinese massage parlor women in Los Angeles. <i>AIDS Educ Prev.</i> 25(6): 508-18. 2013. https://dx.doi.org/10.1521/aeap.2013.25.6.508
E3	Spoth, R, Clair, S, et al. Universal family-focused intervention with young adolescents: effects on health-risking sexual behaviors and STDs among young adults. <i>Prevention Science.</i> 15 Suppl 1(): S47-58. 2014. https://dx.doi.org/10.1007/s11121-012-0321-2	E7	Thomas, KA, Sorenson, SB, et al. "Consent is Good, Joyous, Sexy": A banner campaign to market consent to college students. <i>Journal of American College Health.</i> 64(8): 639-650. 2016. https://dx.doi.org/
E3	Stanton, B, Dinaj-Koci, V, et al. Adolescent HIV Risk Reduction in the Bahamas: Results from Two Randomized Controlled Intervention Trials Spanning Elementary School Through High School. <i>AIDS Behav.</i> 20(6): 1182-96. 2016. https://dx.doi.org/10.1007/s10461-015-1225-5	E6	Thompson, RG, Jr, Elliott, et al. Short-term effects of a brief intervention to reduce alcohol use and sexual risk among homeless young adults: Results from a randomized controlled trial. <i>Addict Res Theory.</i> 25(1): 24-31. 2017. https://dx.doi.org/10.1080/16066359.2016.1193165
E6	Starks, TJ, Parsons, JT. Drug Use and HIV Prevention With Young Gay and Bisexual Men: Partnered Status Predicts Intervention Response. <i>AIDS Behav.</i> (): . 2018. https://dx.doi.org/10.1007/s10461-018-2091-8	E1	Thurheimer, J, Sereika, SM, et al. 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. <i>Diabetes Educator.</i> 42(6): 712-720. 2016.
E8	Starosta, AJ, Cranston, E, et al. Safer sex in a digital world: A Web-based motivational enhancement intervention to increase condom use among college women. <i>Journal of American College Health.</i> 64(3): 184-93. 2016. https://dx.doi.org/10.1080/07448481.2015.1107835	E1	Thurheimer, JenniferL. Examining short- and long-term effects of preconception counseling delivered during adolescence on risk-taking behaviors, condom use, and sexually transmitted infections among females with type 1 diabetes. <i>Dissertation Abstracts International: Section B: The Sciences and Engineering.</i> 77(1-B(E)): No Pagination Specified. 2016. https://dx.doi.org/
E7	Stern, J, Larsson, M, et al. Introducing the Reproductive Life Plan in midwifery counselling-a randomised controlled trial. <i>European journal of contraception and reproductive health care.</i> 18(): S195. 2013. https://dx.doi.org/10.3109/13625187.2013.793038	E3	Tingey, L, Mullany, B, et al. The Respecting the Circle of Life trial for American Indian adolescents: rationale, design, methods, and baseline characteristics. <i>AIDS Care.</i> 27(7): 885-91. 2015. https://dx.doi.org/10.1080/09540121.2015.1015481
E3a	Stewart, KE, Wright, PB, et al. Reducing Risky Sex among Rural African American Cocaine Users: A Controlled Trial. <i>J Health Care Poor Underserved.</i> 28(1): 528-547. 2017. https://dx.doi.org/10.1353/hpu.2017.0038	E3a	Tobin, K, Davey-Rothwell, MA, et al. RCT of an integrated CBT-HIV intervention on depressive symptoms and HIV risk. <i>PLoS ONE [Electronic Resource].</i> 12(12): e0187180. 2017. https://dx.doi.org/10.1371/journal.pone.0187180

Appendix D. Excluded Studies

Code	Reference	Code	Reference
E3a	Tobin, K, Kuramoto, SJ, et al. 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. <i>Health Education & Behavior</i> . 40(3): 286-95. 2013. https://dx.doi.org/10.1177/1090198112452125	E3	Williams, SP, Myles, RL, et al. An Intervention for Reducing the Sexual Risk of Men Released From Jails. <i>Journal of Correctional Health Care</i> . 24(1): 71-83. 2018. https://dx.doi.org/10.1177/1078345817745537
E2	Toland, Rebecca. Reduction of risky sexual behavior through behavioral modification based curriculum. <i>Dissertation Abstracts International Section A: Humanities and Social Sciences</i> . 74(12-A(E)): No Pagination Specified. 2014. https://dx.doi.org/	E6	Witte, SS, Wu, E, et al. Implementation of a couple-based HIV prevention program: a cluster randomized trial comparing manual versus Web-based approaches. <i>Implementation Science</i> . 9(): 116. 2014. https://dx.doi.org/10.1186/s13012-014-0116-x
E3a	Tucker, JS, D'Amico, EJ, et al. A group-based motivational interviewing brief intervention to reduce substance use and sexual risk behavior among homeless young adults. <i>J Subst Abuse Treat</i> . 76(): 20-27. 2017. https://dx.doi.org/10.1016/j.jsat.2017.02.008	E8	Wong, ML, Ng J YS, Chan R KW, et al. Randomized controlled trial of abstinence and safer sex intervention for adolescents in Singapore: 6-month follow-up. <i>Health Educ Res</i> . 32(3): 233-243. 2017. https://dx.doi.org/10.1093/her/cyx040
E12	Van Orden, Onna Rose. The influence of event-level factors and processes of change on safe sex and alcohol use among HIV+ men who have sex with men. <i>Dissertation Abstracts International: Section B: The Sciences and Engineering</i> . 75(1-B(E)): No Pagination Specified. 2014.	E5	Wray, TB, Chan, PA, et al. A Pilot, Randomized Controlled Trial of HIV Self-Testing and Real-Time Post-Test Counseling/Referral on Screening and Preventative Care Among Men Who Have Sex with Men. <i>AIDS Patient Care STDS</i> . 32(9): 360-367. 2018. https://dx.doi.org/10.1089/apc.2018.0049
E3a	Wechsberg, Wendee M, Browne, Felicia A, et al. Efficacy of the Young Women's CoOp: An HIV Risk-Reduction Intervention for Substance-Using African-American Female Adolescents in the South. <i>J Child Adolesc Subst Abuse</i> . 26(3): 205-218. 2017.	E3	Wray, TB, Kahler, CW, et al. 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. <i>AIDS Behav</i> . 23(6): 1668-1679. 2019. https://dx.doi.org/10.1007/s10461-019-02396-w
E7	Wenzel, SL, Cederbaum, JA, et al. Pilot Test of an Adapted, Evidence-Based HIV Sexual Risk Reduction Intervention for Homeless Women. <i>Prevention Science</i> . 17(1): 112-21. 2016. https://dx.doi.org/10.1007/s11121-015-0575-6	E7	Ybarra, ML, Liu, W, et al. 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. <i>AIDS Behav</i> . (): . 2018. https://dx.doi.org/10.1007/s10461-018-2118-1
E7	Widman, L, Golin, CE, et al. Sexual Assertiveness Skills and Sexual Decision-Making in Adolescent Girls: Randomized Controlled Trial of an Online Program. <i>Am J Public Health</i> . 108(1): 96-102. 2018. https://dx.doi.org/10.2105/AJPH.2017.304106	E8	Young, SD, Cumberland, WG, et al. Social networking technologies as an emerging tool for HIV prevention: a cluster randomized trial. <i>Ann Intern Med</i> . 159(5): 318-24. 2013. https://dx.doi.org/10.7326/0003-4819-159-5-201309030-00005
E7	Widman, L, Golin, CE, et al. Feasibility and acceptability of a web-based HIV/STD prevention program for adolescent girls targeting sexual communication skills. <i>Health Educ Res</i> . 32(4): 343-352. 2017. https://dx.doi.org/10.1093/her/cyx048	E7	Young, SD, Holloway, I, et al. Project HOPE: online social network changes in an HIV prevention randomized controlled trial for African American and Latino men who have sex with men. <i>Am J Public Health</i> . 104(9): 1707-12. 2014. https://dx.doi.org/10.2105/AJPH.2014.301992

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Code	Reference
E3a	<p>Zellner, T, Trotter, J, et al. Color It Real: A Program to Increase Condom Use and Reduce Substance Abuse and Perceived Stress. <i>International Journal of Environmental Research & Public Health [Electronic Resource]</i>. 13(1): ijerph13010051. 2015. https://dx.doi.org/10.3390/ijerph13010051</p>
E3	<p>Zhang, J, Cederbaum, JA, et al. Theory-Based Behavioral Intervention Increases Mother-Son Communication About Sexual Risk Reduction Among Inner-City African-Americans. <i>J Adolesc Health</i>. 63(4): 497-502. 2018. https://dx.doi.org/10.1016/j.jadohealth.2018.04.017</p>
E3	<p>Zhang, J, Jemmott, JB, et al. Mediation and moderation of an efficacious theory-based abstinence-only intervention for African American adolescents. <i>Health Psychol</i>. 34(12): 1175-84. 2015. https://dx.doi.org/10.1037/hea0000244</p>
E7	<p>Zhang, J, Jemmott, JB, et al. Efficacy and Mediation of a Theory-Based Physical Activity Intervention for African American Men Who Have Sex with Men: A Randomized Controlled Trial. <i>Annals of Behavioral Medicine</i>. 51(1): 106-116. 2017. https://dx.doi.org/10.1007/s12160-016-9832-6</p>
E8	<p>Zule, WA, Bobashev, GV, et al. Results of a pilot test of a brief computer-assisted tailored HIV prevention intervention for use with a range of demographic and risk groups. <i>AIDS Behav</i>. 17(9): 3045-58. 2013. https://dx.doi.org/10.1007/s10461-013-0557-2</p>

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Author, year Quality	Int arm	Int name	Brief description	Control	Theoretical or Therapeutic approach	Delivery	Months duration of Int	Total number of contacts	Est total min	Setting	Provider
Bai, 2018 ¹⁶⁰ Good	IG1	Healthy Teens	Ten 60-minute in-person counseling sessions	Usual care	CBT, Motivational Interviewing	Individual	2.5	10	600	Primary care clinic	Psychologists
Berenson, 2012 ¹⁰⁷ Fair	IG1	NA	One 45 minute, individual, clinic-based counseling session + >6 phone calls	Usual care	CBT, Health belief model	Individual, Phone	6	9	165	Prenatal or OB-GYN	Research staff
	IG2	NA	One 45 minute, individual, clinic-based counseling session	Usual care	Health belief model	Individual	0.03	1	45	Prenatal or OB-GYN	Research staff
Champion, 2012 ¹¹⁶ Fair	IG1	Project SAFE	Two 3-4-hour group counseling sessions, 2 or more individual counseling sessions, 3-5 optional support group sessions	Minimal intervention (one session of clinical counseling surrounding STI treatment [time NR] with nurse practitioner)	ARRM	Individual, Group	12	11	1035	Research clinic	Nursing professionals
Costa, 2017 ¹¹⁷ Fair	IG1	NA	Six 120-minute group counseling sessions	Waitlist	CBT	Group	2	6	720	Family planning clinic	Psychologists
	IG2	NA	Two 15-minute individual counseling sessions, informational	Waitlist	Psycho-educational intervention	Individual, Print	0.5	2	30	Family planning clinic	NR
Crosby, 2009 ¹¹⁸ Fair	IG1	Focus on the Future	One 45-50-minute individual counseling session, variety of condoms and water-based lubricant	Minimal intervention ("few minutes" of messaging based on CDC guidelines with nurse + 12 free condoms)	NR	Individual	0.03	1	50	STI clinic	Lay person
DiClemente, 2004 ¹¹⁹ Good	IG1	HORIZONS	Four 4-hour group counseling sessions	Attention control (four 4-hour health promotion group sessions)	Social cognitive theory, theory of gender and power	Group	1	4	240	Family planning clinic	Health educators
Ehrhardt, 2002 ¹⁰² Good	IG1	NA	Eight 2-hour group counseling sessions	None	NR	Group	2	8	960	Women's health clinic	Research staff
	IG2	NA	Four 2-hour group counseling sessions	None	NR	Group	1	4	480	Women's health clinic	Research staff
Free, 2016 ¹²² Fair	IG1	NA	49 to 63 text messages tailored to participant characteristics (gender, STI)	Attention control (13 text messages spaced 30 days apart)	Text messaging intervention functions and behavior change techniques	Email, Text	12	49-63	31.5	Personal device	NA

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Author, year Quality	Int arm	Int name	Brief description	Control	Theoretical or Therapeutic approach	Delivery	Months duration of Int	Total number of contacts	Est total min	Setting	Provider
Guilamo-Ramos, 2011 ¹²⁵ Fair	IG1	Families Talking Together (FTT)	Mother received one 30-minute individual counseling session + program manual + 2 phone calls	Usual care	Family therapy	Individual, Phone, Print	5	3	40	Home, Community-based health clinic	Physicians, Social work professionals
Jemmott, 2005 ¹²⁷ Good	IG1	Be Proud! Be responsible!	One 250 minutes group counseling session, skills-based	Attention control (one 4-hour group health promotion session)	CBT	Group, Video, Games	0.03	1	250	Hospital-based adolescent medicine clinic	Facilitator
	IG2	Be Proud! Be responsible!	One 250-minute group counseling session, information-based	Attention control (one 4-hour group health promotion session)	CBT	Group, Video, Games	0.03	1	250	Hospital-based adolescent medicine clinic	Facilitator
Kershaw, 2009 ¹²⁹ Fair	IG1	Centering Pregnancy Plus	Ten 120-minute group counseling sessions	Usual care	Social cognitive theory	Group	9	10	1200	Prenatal or OB-GYN	Physicians
Lewis, 2018 ¹³² Fair	IG1	NA	One 5-minute computer web-based personalized feedback session	Attention control (feedback on health-related behaviors [e.g., nutrition, exercise])	Personalized feedback	Computer web-based, Email, Text, Print	0.03	1	5	Personal device, Home	Self-directed
	IG2	Na	One 5-minute computer web-based integrated personalized feedback session	Attention control (feedback on health-related behaviors [e.g., nutrition, exercise])	Personalized feedback	Computer web-based, Email, Text	0.03	1	5	Personal device	Self-directed
Metsch, 2013 ¹³⁷ Good	IG1	RESPECT-2	One 30-minute individual counseling session + HIV testing	Minimal intervention (HIV testing, brief information about HIV according to CDC)	STI testing with counseling	Individual	0.03	1	30	STI clinic	Counselor
Morrison-Beedy, 2013 ¹⁴⁴ Good	IG1	HIPTeens	Four 120-minute information-motivation-behavioral group counseling sessions + two 90-minute group counseling sessions	Attention control (Four, weekly, 120-minute sessions and 2 90-minute booster sessions at 3- and 6-months post-intervention)	Fisher and Fishers' IMB	Group	6	6	660	School health clinic, Community-based health clinic, Hospital-based adolescent medicine clinic	Health educators

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Author, year Quality	Int arm	Int name	Brief description	Control	Theoretical or Therapeutic approach	Delivery	Months duration of Int	Total number of contacts	Est total min	Setting	Provider
Peipert, 2008 ¹⁴⁸ Fair	IG1	NA	Three 30-minute individually tailored computer web-based sessions	Minimal intervention (one computer session of standardized contraceptive and STI prevention information [time NR])	Transtheoretical model	Computer web-based	2	3	90	Home	NA
Proude, 2004 ¹⁵⁰ Fair	IG1	NA	One 15-minute physician counseling session + informational resource pamphlets, 2 condoms, lubricant	Attention control (tobacco screening and counseling)	NR	Individual	0.03	1	15	Primary care clinic	Physicians
Redding, 2014 ¹⁶³ Good	IG1	Step by Step	Four 25-minute computer sessions followed by individual counseling	Minimal intervention	Transtheoretical model	Individual, Computer web-based	9	4	220	Family planning clinic, Community-based health clinic	Counselor
Sanci, 2015 ¹⁵³ Fair	IG1	NA	Clinicians received 9 hours of training + 2 practice visits	Minimal intervention (3- hour seminar on youth-friendly care)	Motivational Interviewing	Individual, Group	1	5	660	Primary care clinic	Health educators, Research staff
Scholes, 2003 ¹⁵⁴ Fair	IG1	NA	2 tailored print mailings	Usual care	NR	Print	3	0	0	NA	NA
Shafii, 2019 ¹⁶⁴ Fair	IG1	<i>e-KISS</i>	One computer-based tailored feedback session	None	Motivational Interviewing	Computer web-based	0.03	1	20	STI clinic	NA
Shain, 2004 ¹⁵⁵ Fair	IG1	NA	One individual counseling session + three 3-hour group counseling sessions + option to attend five 90-minute group counseling sessions	Minimal intervention (one 10-to15-minute standardized STI presentation + STI test and referral to treatment)	ARRM, CBT	Individual, Group	2	9	1010	STI clinic	Research staff
	IG2	NA	One individual counseling session + three 3-hour group counseling sessions	Minimal intervention (one 10-to15-minute standardized STI presentation + STI test and referral to treatment)	ARRM, CBT	Individual, Group	1	4	560	STI clinic	Research staff

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Author, year, Quality	Int arm	Int name	Brief description	Control	Theoretical or Therapeutic approach	Delivery	Months duration of Int	Total number of contacts	Est total min	Setting	Provider
Whiteley, 2018 ¹⁶⁶ Fair	IG1	NA	Eight emails containing 19 links to internet content	Waitlist	IMB	Email	1	8	12	Personal device	NA
Wingood, 2013 ¹⁵⁸ Good	IG1	SISTA	Two 4-hour group counseling sessions	Attention control (nutrition health promotion)	CBT	Group	0.5	2	480	Primary care clinic	Health educators
Ybarra, 2017 ¹⁵⁹ Good	IG1	Guy2Guy Intervention Group	Text messages 5-10 times/day five consecutive weeks + text messages for one week	Attention control (text messages)	IMB of HIV preventive behavior	Text	1.25	125-350	1750*	Personal device	Research staff

* Estimate based on assumed 15 minutes per text so this likely is an upper estimate, but with assumptions of shorter text message contact, the intervention involved over 2.5 hours of texting contact and was therefore considered a high-contact time intervention

Abbreviations: ARRM = Aids Risk Reduction Model; CBT = cognitive behavioral therapy; CDC = Centers for Disease Control and Prevention; Est = estimated; HIV = human immunodeficiency virus; IG = intervention group; IMB = Information-Motivation Behavior Skills Model; Int = intervention; Min = minutes; NA = not applicable; NR = not reported; OB-GYN = obstetrician-gynecologist; RESPECT = Recovery, Empowerment, Social Services, Prenatal care, Education, Community, and Treatment; STI = sexually transmitted infection.

Appendix E Table 2. Intervention Characteristics: Adults*

Author, year Quality	Int arm	Int name	Brief description	Control	Theoretical or Therapeutic approach	Delivery	Mos	Total number of contacts	Est total min	Setting	Provider
Bailey, 2016 ¹⁰⁵ Good	IG1	Men's Safer Sex	One 10-minute website visit	Usual care	NR	Computer we-based	0.03	1	10	STI clinic	Self-directed
Berkman, 2007 ¹⁰⁸ Good	IG1	Enhanced SexG (E-SexG)	Thirteen 60-minute, group counseling sessions	Attention control (one HIV presentation that emphasized condom use [time NR] + 13 money management sessions)	NA	Group	11	13	780	Mental health	Mental or behavioral health specialists
Billings, 2015 ¹¹⁰ Fair	IG1	Safe Sistah	1 computer-based educational session	Waitlist	NR	Computer web-based	0.03	1	88	NA	NA
Carey, 2004 ¹¹¹ Fair	IG1	NA	Ten group counseling sessions	Usual care	Motivational Interviewing	Group	1.25	10	600	Mental health	Research staff
Carey, 2010 ¹¹² Fair	IG1	NA	One 15-minute individual counseling session + 4 hour intensive motivational, behavioral, skills workshop	Minimal intervention (one 15-minute education intervention with clinic nurse)	IMB, Motivational Interviewing, Transtheoretical Model	Individual, Group, Video	0.3	2	255	STI clinic	Nursing professionals, Facilitator
	IG2	NA	One 15-minute individual counseling session + 4-hour intensive informational workshop	Minimal intervention (one 15-minute education intervention with clinic nurse)	Motivational Interviewing, Transtheoretical Model	Individual Group	0.03	2	255	STI clinic	Nursing professionals, Facilitator
	IG3	NA	One 15-minute individual counseling session	Minimal intervention (one 15-minute education intervention with clinic nurse)	Motivational Interviewing, Transtheoretical Model	Individual	0.03	1	15	STI clinic	Nursing professionals
	IG4	NA	One 15-minute informational video + 4-hour intensive informational workshop	Minimal intervention (one 15-minute education intervention with clinic nurse)	Motivational Interviewing, Transtheoretical Model	Group, Video	0.03	2	255	STI clinic	Nursing professionals, Facilitator
	IG5	NA	One 15-minute informational video + 4 hour intensive motivational, behavioral, skills workshop	Minimal intervention (one 15-minute education intervention with clinic nurse)	NA	Individual, Group, Video	0.03	2	255	STI clinic	Nursing professionals
Carey, 2015 ¹¹³ Fair	IG1	NA	One 22 min video + sexual health questionnaire	Attention control (general health video + general health questionnaire)	Motivational Interviewing, IMB	Computer web-based	0.03	1	52	STI clinic	Nursing professionals, Research staff

Appendix E Table 2. Intervention Characteristics: Adults*

Author, year Quality	Int arm	Int name	Brief description	Control	Theoretical or Therapeutic approach	Delivery	Mos	Total number of contacts	Est total min	Setting	Provider
	IG2	NA	One 22 min video + general health questionnaire	Attention control (general health video + general health questionnaire)	Motivational Interviewing, IMB	Computer web-based, Video	0.03	1	52	STI clinic	Nursing professionals Research staff
	IG3	NA	One 22 min video + sexual health questionnaire	Attention control (general health video + general health questionnaire)	Motivational Interviewing, IMB	Computer web-based, Video	0.03	1	52	STI clinic	Nursing professionals, Research staff
Jemmott, 2007 ¹²⁸ Good	IG1	Sister to Sister	One 200-minute group counseling session, skills-based	Attention control (general health promotion)	Social cognitive theory	Group	0.03	1	200	Women's health clinic	Nursing professionals
	IG2	Sister to Sister	One 200-minute group counseling session, information-based	Attention control (general health promotion)	Social cognitive theory	Group	0.03	1	200	Women's health clinic	Nursing professionals
	IG3	Sister to Sister	One 20-minute individual counseling session, skills-based	Attention control (general health promotion)	Social cognitive theory	Individual	0.03	1	20	Women's health clinic	Nursing professionals
	IG4	Sister to Sister	One individual, 20-minute counseling session, information-based	Attention control (general health promotion)	Social cognitive theory	Individual	0.03	1	20	Women's health clinic	Nursing professionals
Marrazzo, 2011 ¹³⁵ Fair	IG1	NA	One 30-minute individual counseling session	Minimal intervention (education session on pap smears with study staff)	Motivational Interviewing	Individual	0.03	1	30	Research clinic	Research staff
Mittal, 2017 ¹⁴² Fair	IG1	Supporting positive and healthy relationships (SUPPORT)	Three 135-minute individual counseling sessions + five 135-minute group counseling sessions	Minimal intervention (eight weekly group-based intervention sessions on abuse and relationships)	IMB, Theory of Gender and Power, and transitional family therapy	Individual Group, Phone,	2	8	1080	Convenient location in the community (details NR)	Facilitator
Neumann, 2011 ¹⁴⁵ Fair	IG1	VOICES/VO CES	One 45-minute group counseling session	Usual care	NR	Group	0.03	1	45	STI clinic	Research staff
O'Cleirigh, 2019 ¹⁶² Fair	IG1	NA	Ten in-person therapy sessions + HIV/STI counseling and testing	Usual care	CBT	Individual	3	10	300	Research clinic	Psychologists
Peragallo Montano, 2019 ¹⁶¹ Fair	IG1	Salud, Educacion, Prevencion y Autocuidado (SEPA)	Three 2.5-hour sessions	Waitlist	Freire's pedagogy and Social Cognitive model	Group	12	3	450	Community-based health clinic	Research staff

Appendix E Table 2. Intervention Characteristics: Adults*

Author, year Quality	Int arm	Int name	Brief description	Control	Theoretical or Therapeutic approach	Delivery	Mos	Total number of contacts	Est total min	Setting	Provider
Petersen, 2007 ¹⁴⁹ Fair	IG1	Women's Reproductive Assessment Program (WRAP)	One individual counseling + followup phone call or visit	Attention control (brief general counseling on prevention health care [e.g., smoking, diet, exercise])	Motivational Interviewing	Individual	2	2	60	Primary care clinic	Health educators
Tzilos Wernette, 2018 ¹⁶⁵ Fair	IG1	NA	One 60-minute computer session + one 15-minute booster session	Attention control	Motivational Interviewing	Computer, web-based	1	2	75	Prenatal or OB-GYN	NA
Warner, 2008 ¹⁵⁶ Good	IG1	Safe in the City	One 23-minute video + educational pamphlets and condoms	Usual care	NR	Print, Video	0.03	1	23	STI clinic	Self-directed

* Four studies did not exclude adolescents, but primarily recruited adults and the mean age in the study populations was above 25 years

Abbreviations: E-SexG = Enhanced Sex, Games, and Videotape intervention; Est = estimated; HIV = human immunodeficiency virus; IG = intervention group; IMB = Information-Motivational Behavioral Skills Model; int = intervention; MI = motivational interviewing; Mos = months; NA = not applicable; NR = not reported; OB-GYN = obstetrician-gynecologist; STI = sexually transmitted infection; VOICES/VOCES = Video Opportunities for Innovative Condom Education and Safer Sex.

Appendix E Table 3. STI Infection Results: Adolescents and Young Adults

Author, year	Outcome	Outcome description	Recall period	Int arm	Group	F/U mos	IG n (%) or Mean (SD), n	CG n (%) or Mean (SD), n	Result (95% CI)	P-value
Berenson, 2012 ¹⁰⁷	Any STI	Number of participants with at least one STI, assessed by self-report and medical record review	NR	IG1	Overall	12	13/384 (3.4)	18/388 (4.6)	OR: 0.72 (0.35 to 1.49)*	NSD
			NR	IG2	Overall	12	12/383 (3.1)	18/388 (4.6)	OR: 0.66 (0.32 to 1.40)*	NSD
Champion, 2012 ¹¹⁶	Chlamydia, gonorrhea	Number of participants with a new infection of chlamydia or gonorrhea	NA	IG1	Overall	0	0/155 (0.0)	11/163 (6.7)	OR: 0.04 (0.00 to 0.73)*	0.001
						6	6/166 (3.6)	13/167 (7.8)	OR: 0.02 (0.00 to 0.39)	0.009
						12	8/166 (4.8)	22/167 (13.2)	OR: 0.04 (0.00 to 0.53)	0.016
					History of sexual abuse	12	19/123 (15.4)	11/118 (9.3)	OR: 1.78 (0.81 to 3.92)*	0.157
					Without history of sexual abuse	12	0/76 (0.0)	9/92 (9.8)	OR: 0.06 (0.00 to 1.00)*	0.017
Crosby, 2009 ¹¹⁸	Any STI	Subsequent diagnosis of an STI	NA	IG1	Overall	6	45/141 (31.9)	63/125 (50.4)	OR: 0.32 (0.12 to 0.86)	0.02
DiClemente, 2004 ¹¹⁹	Trichomonas	Positive test for trichomonas	NA	IG1	Overall	0	33/251 (13.1)	33/271 (12.2)	OR: 1.09 (0.65 to 1.83)*	NSD
						12	./219 (.)	./241 (.)	OR: 0.37 (0.09 to 1.46)	0.16
	Gonorrhea	Positive test for gonorrhea	NA	IG1	Overall	0	14/251 (5.6)	13/271 (4.8)	OR: 1.17 (0.54 to 2.55)*	NSD

Appendix E Table 3. STI Infection Results: Adolescents and Young Adults

Author, year	Outcome	Outcome description	Recall period	Int arm	Group	F/U mos	IG n (%) or Mean (SD), n	CG n (%) or Mean (SD), n	Result (95% CI)	P-value
	Chlamydia	Positive test for chlamydia	NA	IG1	Overall	12	./219 (.)	./241 (.)	OR: 0.14 (0.01 to 3.02)	0.21
						0	48/251 (19.1)	43/271 (15.9)	OR: 1.25 (0.80 to 1.97)*	NSD
	Any STI	Positive for any STI, %	NA	IG1	AA female adolescents w/ hist. of gender-based violence	12	./219 (.)	./241 (.)	OR: 0.17 (0.30 to 0.92)	0.04
						0	20/73 (27.4)	19/73 (26.0)	OR: 1.07 (0.52 to 2.23)*	NSD
						6	11/63 (17.5)	26/65 (40.0)	OR: 0.32 (0.14 to 0.72)*	<0.05
						12	11/61 (18.0)	15/65 (23.1)	OR: 0.47 (0.25 to 0.87)	0.02
Free, 2016 ¹²²	Chlamydia	Cumulative incidence of Chlamydia	NA	IG1	Overall	0	35/99 (35.4)	42/101 (41.6)	OR: 0.77 (0.43 to 1.36)*	NSD
						3	6/82 (7.3)	3/89 (3.4)	OR: 2.26 (0.55 to 9.36)*	0.263
						12	9/99 (9.1)	15/101 (14.9)	OR: 0.57 (0.24 to 1.38)*	0.218
Jemmott, 2005 ¹²⁷	Any STI	% Positive test for gonorrhea, chlamydia, or trichomonas (study reported combined)	NA	IG1	Overall	0	54/235 (23.0)	37/219 (16.9)	OR: 1.47 (0.92 to 2.34)*	NSD
						6	33/203 (16.3)	29/192 (15.1)	OR: 1.09 (0.63 to 1.88)*	0.80
						12	20/193 (10.4)	37/180 (20.6)	OR: 0.45 (0.25 to 0.80)*	0.05
				IG2	Overall	0	59/228 (25.9)	37/219 (16.9)	OR: 1.72 (1.08 to 2.72)*	<0.05
						6	30/200 (15.0)	29/192 (15.1)	OR: 0.99 (0.57 to 1.73)*	0.89
						12	28/187 (15.0)	34/180 (18.9)	OR: 0.76 (0.44 to 1.31)*	NSD
Kershaw, 2009 ¹²⁹	Chlamydia, gonorrhea	Presence of chlamydia or gonorrhea	6 months	IG1	Overall	6	22/318 (6.9)	23/394 (5.8)	OR: 0.95 (0.55 to 1.64)	0.86
						12	28/318 (8.8)	40/394 (10.2)	OR: 0.72 (0.38 to 1.36)	0.32
						35	22/318 (6.9)	28/394 (7.1)	OR: 0.88 (0.53 to 1.47)	0.63
				IG2	Young adults	12	NR (10.5)	NR (7.5)	NR	NR

Appendix E Table 3. STI Infection Results: Adolescents and Young Adults

Author, year	Outcome	Outcome description	Recall period	Int arm	Group	F/U mos	IG n (%) or Mean (SD), n	CG n (%) or Mean (SD), n	Result (95% CI)	P-value	
					Adolescents	12	NR (9.3)	NR (20.3)	OR: 0.37 (0.17 to 0.77)	<0.05	
Metsch, 2013 ¹³⁷	Trichomonas	Positive trichomoniasis result	NA	IG1	Overall	0	126/837 (15.1)	119/842 (14.1)	OR: 1.08 (0.82 to 1.41)*	NSD	
						6	56/724 (7.7)	53/736 (7.2)	OR: 1.08 (0.73 to 1.60)*	NSD	
	Syphilis	Positive syphilis result	NA	IG1	Overall	0	28/2475 (1.1)	35/2495 (1.4)	OR: 0.80 (0.49 to 1.33)*	NSD	
						6	12/2142 (0.6)	6/2142 (0.3)	OR: 2.01 (0.75 to 5.35)*	NSD	
	HSV-2	Positive HSV-2 result	NA	IG1	Overall	0	758/2492 (30.4)	793/2494 (31.8)	OR: 0.94 (0.83 to 1.06)*	NSD	
						6	53/1492 (3.6)	43/1446 (3.0)	OR: 1.20 (0.80 to 1.81)*	NSD	
	HIV	Positive HIV result	NA	IG1	Overall	0	29/2502 (1.2)	24/2504 (1.0)	OR: 1.21 (0.70 to 2.09)*	NSD	
						6	5/2119 (0.2)	9/2122 (0.4)	OR: 0.56 (0.19 to 1.66)*	NSD	
	Gonorrhea	Positive gonorrhea result	NA	IG1	Overall	0	137/2430 (5.6)	145/2431 (6.0)	OR: 0.94 (0.74 to 1.20)*	NSD	
						6	43/2097 (2.1)	40/2097 (1.9)	OR: 1.08 (0.70 to 1.66)*	NSD	
	Chlamydia	Positive chlamydia result	NA	IG1	Overall	0	238/2434 (9.8)	254/2436 (10.4)	OR: 0.93 (0.77 to 1.12)*	NSD	
						6	104/2094 (5.0)	103/2088 (4.9)	OR: 1.01 (0.76 to 1.33)*	NSD	
	Any STI	Positive STI result	NA	IG1	Overall	0	1049/2412 (43.5)	1092/2419 (45.1)	OR: 0.94 (0.83 to 1.05)*	NSD	
						6	250/2039 (12.3)	226/2032 (11.1)	OR: 1.12 (0.92 to 1.35)*	NSD	
						White	6	55/633 (8.7)	46/618 (7.4)	OR: 1.18 (0.79 to 1.78)*	NSD
						Black	6	119/822 (14.5)	113/833 (13.6)	OR: 1.08 (0.82 to 1.42)*	NSD
Hispanic						6	43/304 (14.1)	42/318 (13.2)	OR: 1.08 (0.69 to 1.71)*	NSD	

Appendix E Table 3. STI Infection Results: Adolescents and Young Adults

Author, year	Outcome	Outcome description	Recall period	Int arm	Group	F/U mos	IG n (%) or Mean (SD), n	CG n (%) or Mean (SD), n	Result (95% CI)	P-value
					Other race/ethnicity	6	28/220 (12.7)	21/217 (9.7)	OR: 1.36 (0.75 to 2.48)*	NSD
					MSM	6	99/529 (18.7)	68/545 (12.5)	OR: 1.62 (1.16 to 2.26)*	<0.05
					Heterosexual	6	42/753 (5.6)	49/740 (6.6)	OR: 0.83 (0.54 to 1.27)*	NSD
					Female	6	104/697 (14.9)	105/701 (15.0)	OR: 1.00 (0.74 to 1.34)*	NSD
					Age less than 25 yrs	6	103/638 (16.1)	101/620 (16.3)	OR: 0.99 (0.73 to 1.34)*	NSD
					Age 25 yrs or older	6	142/1341 (10.6)	121/1366 (8.9)	OR: 1.22 (0.94 to 1.57)*	NSD
Peipert, 2008 ¹⁴⁸	Trichomonas	Incident of trichomoniasis	NA	IG1	Overall	24	13/272 (4.8)	9/270 (3.3)	OR: 1.46 (0.61 to 3.46)*	NSD
	Gonorrhea	Incident of gonorrhea	NA	IG1	Overall	24	12/272 (4.4)	13/270 (4.8)	OR: 0.91 (0.41 to 2.04)*	NSD
	Chlamydia	Incident of chlamydia	NA	IG1	Overall	24	27/272 (9.9)	26/270 (9.6)	OR: 1.03 (0.59 to 1.82)*	NSD
	Any STI	Incident of any STI	NA	IG1	Overall	24	43/272 (15.8)	44/270 (16.3)	OR: 0.96 (0.61 to 1.53)*	NSD
Shafii, 2019 ¹⁶⁴	Chlamydia	Incident chlamydia infection	NA	IG1	Overall	0	15/130 (11.5)	17/142 (12.0)	OR: 0.96 (0.46 to 2.01)	NSD
			NA	IG1	Overall	3	13/112 (11.6)	26/130 (20.0)	OR: 0.53 (0.26 to 1.08)	0.10
			NA	IG1	Female	3	NR	NR	IRR: 0.86 (0.34 to 2.13)	0.74
			NA	IG1	Male	3	NR	NR	IRR: 0.31 (0.74 to 1.32)	1.11
Shain, 2004 ¹⁵⁵	Chlamydia, gonorrhea	Incidence of chlamydia, gonorrhea	NA	IG1	Overall	12	48/236 (20.3)	68/254 (26.8)	OR: 0.50 (0.31 to 0.80)	0.004
					Overall	24	80/232 (34.5)	99/249 (39.8)	OR: 0.47 (0.30 to 0.73)	<0.001
				IG2	Overall	12	55/219 (25.1)	68/254 (26.8)	OR: 0.51 (0.31 to 0.83)	0.006

Appendix E Table 3. STI Infection Results: Adolescents and Young Adults

Author, year	Outcome	Outcome description	Recall period	Int arm	Group	F/U mos	IG n (%) or Mean (SD), n	CG n (%) or Mean (SD), n	Result (95% CI)	P-value
						24	78/209 (37.3)	99/249 (39.8)	OR: 0.54 (0.34 to 0.85)	<0.008
Wingood, 2013 ¹⁵⁸	HPV	Incident high-risk HPV	1 year	IG1	Overall	12	36/153 (23.5)	24/61 (39.3)	OR: 0.37 (0.18 to 0.77)	0.008
	Gonorrhea, chlamydia, trichomonas	Any nonviral STI (chlamydia, gonorrhea, trichomonas)	NA	IG1	Overall	0	99/605 (16.4)	45/243 (18.5)	OR: 0.86 (0.58 to 1.27)*	NSD
						6	27/441 (6.1)	19/194 (9.8)	OR: 0.52 (0.26 to 1.04)	NSD
						12	42/452 (9.3)	22/183 (12.0)	OR: 0.62 (0.40 to 0.96)	0.033

* Calculated estimate from reported raw study data. P-values are based on statistical analyses reported in the published study results

Abbreviations: AA = African American; CG = control group; CI = confidence interval; F/U = followup; Hist = history; HIV = human immunodeficiency virus; HPV = human papillomavirus; HSV = herpes simplex virus; IG = intervention group; int = intervention; IRR = incidence rate ratio; MI = motivational interviewing; Mo = month; MSM = men who have sex with men; n = number of participants; NA = not applicable; NR = not reported; NSD = no significant difference; OR = odds ratio; SD = standard deviation; STI = sexually transmitted infection; Yrs = years.

Appendix E Table 4. STI Infection Results: Adults*

Author, year	Outcome	Outcome description	Recall period	Int arm	Group	F/U mos	IG n (%) or Mean (SD), n	CG n (%) or Mean (SD), n	Result (95% CI) [†]	P-value
Bailey, 2016 ¹⁰⁵	Any STI	Number of STI diagnoses	NA	IG1	Overall	12	7/80 (8.8)	9/69 (13.0)	OR: 0.64 (0.22 to 1.82)	0.543
Carey, 2010 ¹¹²	Any STI	STDs, counts of incident infections (urine specimens, Amplified DNA Assays; medical record review)	NA	IG1	Overall	3	101/1115 (9.1)	NR	NR	NR, NSD
						6	94/1093 (8.6)	NR	NR	NR, NSD
						12	46/1013 (4.5)	NR	NR	NR, NSD
Carey, 2015 ¹¹³	Chlamydia, gonorrhea, trichomoniasis, syphilis, HIV	Positive for chlamydia, gonorrhea, trichomoniasis, syphilis, or HIV	1 year	IG1	Overall	6	25/250 (10.0)	28/254 (11.0)	OR: 0.90 (0.51 to 1.59)	NSD
						12	43/250 (17.2)	33/254 (13.0)	OR: 1.39 (0.85 to 2.27)	NSD
				IG2	Overall	6	28/252 (11.1)	28/254 (11.0)	OR: 1.01 (0.58 to 1.76)	NSD
						12	43/252 (17.1)	33/254 (13.0)	OR: 1.38 (0.84 to 2.25)	NSD
				IG3	Overall	6	18/254 (7.1)	28/254 (11.0)	OR: 0.62 (0.33 to 1.14)	NSD
						12	38/254 (15.0)	33/254 (13.0)	OR: 1.18 (0.71 to 1.95)	NSD
Jemmott, 2007 ¹²⁸	Gonorrhea, chlamydia, trichomonas	Tested positive for gonorrhea, chlamydia, or trichomonas	6 months	IG1	Overall	0	24/118 (20.3)	18/81 (22.2)	OR: 0.89 (0.45 to 1.78)	NSD
						6	21/118 (17.8)	12/81 (14.8)	OR: 1.24 (0.57 to 2.70)	NSD
						12	18/118 (15.3)	22/81 (27.2)	OR: 0.48 (0.24 to 0.97)	<0.05
				IG2	Overall	0	26/124 (21.0)	18/81 (22.2)	OR: 0.93 (0.47 to 1.83)	NSD
						6	20/124 (16.1)	12/81 (14.8)	OR: 1.11 (0.51 to 2.41)	NSD
						12	24/124 (19.4)	22/81 (27.2)	OR: 0.64 (0.33 to 1.25)	NSD
				IG3	Overall	0	27/123 (22.0)	18/81 (22.2)	OR: 0.98 (0.50 to 1.93)	NSD
						6	27/123 (22.0)	12/81 (14.8)	OR: 1.62 (0.77 to 3.41)	NSD
						12	17/123 (13.8)	22/81 (27.2)	OR: 0.43 (0.21 to 0.87)	<0.05
				IG4	Overall	0	19/118 (16.1)	18/81 (22.2)	OR: 0.67 (0.33 to 1.38)	NSD
						6	20/118 (16.9)	12/81 (14.8)	OR: 1.17 (0.54 to 2.56)	NSD

Appendix E Table 4. STI Infection Results: Adults*

Author, year	Outcome	Outcome description	Recall period	Int arm	Group	F/U mos	IG n (%) or Mean (SD), n	CG n (%) or Mean (SD), n	Result (95% CI) [†]	P-value
						12	26/118 (22.0)	22/81 (27.2)	OR: 0.76 (0.39 to 1.46)	NSD
Marrazzo, 2011 ¹³⁵	BV	Incidence of BV	NA	IG1	Overall	3	15/45 (33.3)	11/42 (26.2)	OR: 1.41 (0.56 to 3.56)	NSD
						6	19/45 (42.2)	17/42 (40.5)	OR: 1.07 (0.46 to 2.52)	NSD
						9	21/45 (46.7)	18/42 (42.9)	OR: 1.17 (0.50 to 2.72)	NSD
						12	24/45 (53.3)	21/42 (50.0)	OR: 1.14 (0.49 to 2.65)	NSD
Neumann, 2011 ¹⁴⁵	Any STI	Incident STIs, (chancroid, chlamydia, gonorrhea, granuloma inguinale, lymphogranuloma, venereum, non-gonococcal urthritis, mucopurulent cervicitis, syphilis, and HIV in NY site; gonorrhea, chlamydia, new onset herpes, syphilis, and HIV in PR site)	NA	IG1	Overall	17	171/1685 (10.1)	226/1680 (13.5)	OR: 0.73 (0.59 to 0.90)	0.016
					Female	17	64/867 (7.4)	98/867 (11.3)	OR: 0.63 (0.45 to 0.87)	<0.05
					Male	17	107/815 (13.1)	128/816 (15.7)	OR: 0.81 (0.62 to 1.07)	NSD
Petersen, 2007 ¹⁴⁹	Chlamydia, "other"	% STI (chlamydia, "other")	NA	IG1	Overall	12	NR	NR	NR	NSD
Tzilos Wernette, 2018 ¹⁶⁵	Trichomoniasis	Incidence of trichomoniasis	NA	IG1	Overall	0	2/30 (6.7)	0/17 (0.0)	OR: 3.07 (0.14 to 67.75)	NSD
						4	2/23 (8.7)	1/14 (7.1)	OR: 1.24 (0.10 to 15.05)	NSD
Warner, 2008 ¹⁵⁶	Chlamydia, gonorrhea, trichomoniasis, syphilis, HIV	Incident STI (includes gonorrhea, chlamydia, trichomoniasis [females only], syphilis, or HIV)	NA	IG1	Overall	0	3052/19073 (16.0)	2934/19562 (15.0)	OR:† 1.08 (1.02 to 1.14)	NR
						14.8	929/19073 (4.9)	1113/19562 (5.7)	OR:† 0.85 (0.78 to 0.93)	NR
					Confirmed STI at index visit	14.8	349/2982 (11.7)	482/3008 (16.0)	OR:† 0.69 (0.60 to 0.81)	NR
					No STI confirmation at index visit	14.8	580/16091 (3.6)	685/16554 (4.1)	OR:† 0.87 (0.77 to 0.97)	NR

Appendix E Table 4. STI Infection Results: Adults*

Author, year	Outcome	Outcome description	Recall period	Int arm	Group	F/U mos	IG n (%) or Mean (SD), n	CG n (%) or Mean (SD), n	Result (95% CI) [†]	P-value
					Age less than 25 yrs	14.8	359/5987 (6.0)	376/6041 (6.2)	OR: [†] 0.96 (0.83 to 1.12)	NR
					Age 25 yrs or older	14.8	570/13084 (4.4)	737/13521 (5.5)	OR: [†] 0.79 (0.71 to 0.88)	NR
					Female	14.8	267/5819 (4.6)	267/5804 (4.6)	OR: [†] 1.00 (0.84 to 1.19)	NR
					Male	14.8	660/13219 (5.0)	843/13715 (6.1)	OR: [†] 0.80 (0.72 to 0.89)	NR
					Transgender	14.8	2/34 (5.9)	3/43 (7.0)	OR: [†] 0.83 (0.13 to 5.29)	NR
					MSM	14.8	398/4038 (9.9)	507/4318 (11.7)	OR: [†] 0.82 (0.72 to 0.94)	NR
					Hispanic	14.8	216/4838 (4.5)	272/4974 (5.5)	OR: [†] 0.81 (0.67 to 0.97)	NR
					Heterosexual	14.8	256/9071 (2.8)	333/9302 (3.6)	OR: [†] 0.78 (0.66 to 0.92)	NR
					White	14.8	356/8752 (4.1)	399/8957 (4.5)	OR: [†] 0.91 (0.79 to 1.05)	NR
					Black	14.8	277/3488 (7.9)	341/3615 (9.4)	OR: [†] 0.83 (0.70 to 0.98)	NR
					Other race/ethnicity	14.8	80/1995 (4.0)	101/2016 (5.0)	OR: [†] 0.79 (0.59 to 1.07)	NR

* Four studies did not exclude adolescents, but primarily recruited adults and the mean age in the study populations was above 25 years

[†] Calculated estimate from reported raw study data. P-values are based on statistical analyses reported in the published study results

Abbreviations: BL = baseline; BV = bacterial vaginosis; CG = control group; CI = confidence interval; DNA = deoxyribonucleic acid; F/U = followup; HIV = human immunodeficiency virus; HPV = human papillomavirus; HR = hazard ratio; HSV = herpes simplex virus; IG = intervention group; Int = intervention; MI = motivational interviewing; Mo = month; MSM = men who have sex with men; n = number of participants; NA = not applicable; NR = not reported; NSD = no significant difference; NY = New York; OR = odds ratio; PR = primary research; SD = standard deviation; STI = sexually transmitted infection; Yrs = years.

Appendix E Table 5. Condom Use and Unprotected Sexual Activity: Adolescents and Young Adults

Study	Outcome	Outcome description	Recall period	Int arm	Group	F/U mos	IG n (%) or Mean (SD), n	CG n (%) or Mean (SD), n	Result (95% CI)	P-value
Bai, 2018 ¹⁶⁰	UI	Condomless intercourse	6 months	IG1	Overall	0	28/95 (29.5)	33/92 (35.9)	OR: 0.75 (0.40 to 1.38)	NSD
						12	.62 (.)	.56 (.)	OR: 0.75 (. to .)	0.617
Berenson, 2012 ¹⁰⁷	Condom use at last sex	% partner used condom at last sex	1 month	IG1	Overall	3	100/384 (26.0)	82/388 (21.1)	OR: 1.31 (0.94 to 1.83)*	0.08
						6	58/384 (15.1)	51/388 (13.1)	OR: 1.32 (1.03 to 1.70)	0.45
				IG2	Overall	3	75/383 (19.6)	82/388 (21.1)	OR: 0.91 (0.64 to 1.29)*	0.08
						6	46/383 (12.0)	51/388 (13.1)	OR: 1.12 (0.87 to 1.45)	0.45
	Dual method consistent condom use	% dual use of oral contraceptive and condoms correctly and consistently	1 month	IG1	Overall	3	48/384 (12.5)	45/388 (11.6)	OR: 1.09 (0.71 to 1.68)*	0.37
						6	32/384 (8.3)	28/388 (7.2)	OR: 1.14 (0.85 to 1.53)	0.38
				IG2	Overall	3	36/383 (9.4)	45/388 (11.6)	OR: 0.79 (0.50 to 1.26)*	0.37
						6	22/383 (5.7)	28/388 (7.2)	OR: 1.01 (0.75 to 1.37)	0.38
Costa, 2017 ¹¹⁷	Number of times condom used	Number of times condoms used during last 4 sex acts	NA	IG1	Overall	3	2.3 (1.8), 62	2.1 (1.9), 33	MeanDiff: 0.23 (-0.57 to 1.03)*	NSD
						6	3.4 (1.9), 62	2.4 (1.9), 33	MeanDiff: 1.04 (0.25 to 1.83)*	0.048
				IG2	Overall	3	2.5 (1.6), 65	2.1 (1.9), 33	MeanDiff: 0.49 (-0.28 to 1.26)*	NSD
						6	2.9 (1.4), 65	2.4 (1.9), 33	MeanDiff: 0.58 (-0.13 to 1.29)*	0.440
Crosby, 2009 ¹¹⁸	Condom use at last sex	% condom use at last sexual intercourse with female partner	3 months	IG1	Overall	0	74/141 (52.5)	53/125 (42.4)	OR: 1.50 (0.92 to 2.44)*	0.10
						3	76/141 (53.9)	49/125 (39.2)	OR: 2.06 (1.07 to 3.96)	0.03
	UI	Frequency of unprotected penetrative sexual intercourse with a female partner	3 months	IG1	Overall	3	12.3 (25.8), 99	29.4 (79.3), 84	MeanDiff: -11.90 (-31.30 to 7.50)	0.21
DiClemente, 2004 ¹¹⁹	Condom use at last sex	% condom use at last sex	NR	IG1	Overall	0	74/251 (29.5)	79/271 (29.2)	OR: 1.02 (0.70 to 1.48)*	NSD
						6	183/226 (81.0)	131/243 (53.9)	OR: 5.08 (2.83 to 9.14)	<0.001

Appendix E Table 5. Condom Use and Unprotected Sexual Activity: Adolescents and Young Adults

Study	Outcome	Outcome description	Recall period	Int arm	Group	F/U mos	IG n (%) or Mean (SD), n	CG n (%) or Mean (SD), n	Result (95% CI)	P-value					
					AA female adolescents w/ hist. of gender-based violence	12	158/219 (72.1)	130/241 (53.9)	OR: 3.94 (2.58 to 6.03)	<0.001					
						0	36/73 (49.3)	39/73 (53.4)	OR: 0.85 (0.44 to 1.62)*	NSD					
						6	42/63 (66.7)	22/65 (33.8)	OR: 3.91 (1.88 to 8.14)*	<0.05					
					Adolescents with depressive symptomatology	12	39/61 (63.9)	31/65 (47.7)	OR: 3.69 (1.78 to 7.65)	0.0001					
						0	70/126 (55.6)	73/119 (61.3)	OR: 0.79 (0.47 to 1.31)*	NSD					
						6	84/111 (75.7)	51/103 (49.5)	OR: 3.89 (1.83 to 8.26)	0.0004					
						12	82/109 (75.2)	53/104 (51.0)	OR: 3.80 (2.11 to 6.82)	0.0001					
						Consistent condom use	% consistent condom use (every vaginal sex act) in past 30 days	1 month	IG1	Overall	0	60/251 (23.9)	75/271 (27.7)	OR: 0.82 (0.55 to 1.22)*	NSD
											6	170/226 (75.2)	141/243 (58.0)	OR: 1.77 (0.97 to 3.20)	0.06
					12						161/219 (73.5)	136/241 (56.4)	OR: 2.01 (1.28 to 3.17)	0.003	
					AA female adolescents w/ hist. of gender-based violence	0	42/73 (57.5)	41/73 (56.2)	OR: 1.06 (0.55 to 2.04)*	NSD					
						6	39/63 (61.9)	25/65 (38.5)	OR: 2.60 (1.27 to 5.30)*	<0.05					
12	44/61 (72.1)	32/65 (49.2)	OR: 2.71 (1.24 to 5.93)	0.01											
Adolescents with depressive symptomatology	0	79/126 (62.7)	75/119 (63.0)	OR: 0.99 (0.59 to 1.66)*	NSD										
	6	77/111 (69.4)	55/103 (53.4)	OR: 1.49 (0.73 to 3.04)	0.276										
	12	79/109 (72.5)	61/104 (58.7)	OR: 1.78 (1.01 to 3.13)	0.045										
Proportion of sexual episodes condom used	Mean percentage of condom use during vaginal intercourse acts in past 30 days	1 month	IG1	Overall	6	84.9 (30.8), 226	65.1 (44.3), 243	MeanDiff: 18.38 (10.47 to 25.45)	<0.001						
					12	80.0 (36.6), 219	62.8 (45.3), 241	MeanDiff: 21.09 (13.70 to 28.48)	<0.001						
					AA adolescents w/ hist. of gender-based violence	6	74.3 (38.9), 63	53.9 (42.5), 65	MeanDiff: 20.34 (6.23 to 34.45)*	<0.05					
						12	76.7 (40.6), 61	55.0 (47.6), 65	MeanDiff: 17.00 (2.01 to 32.00)	0.03					
						6	79.3 (36.1), 111	60.1 (46.2), 103	MeanDiff: -0.18 (-0.32 to -0.01)	0.013					

Appendix E Table 5. Condom Use and Unprotected Sexual Activity: Adolescents and Young Adults

Study	Outcome	Outcome description	Recall period	Int arm	Group	F/U mos	IG n (%) or Mean (SD), n	CG n (%) or Mean (SD), n	Result (95% CI)	P-value
	Unprotected vaginal sex in the last 30 days	Mean episodes of unprotected vaginal sex in the last 30 days	1 month	IG1	Adolescents w/ depressive symptomatology	12	80.1 (36.0), 109	62.6 (46.4), 104	MeanDiff: 0.22 (0.11 to 0.33)	0.003
					Overall	6	1.0 (3.4), 226	2.0 (4.3), 243	GEE: -1.06 (-1.82 to 0.27)	0.46
						12	1.1 (3.0), 219	2.0 (4.5), 241	MeanDiff: -1.17 (-1.88 to -0.45)	0.001
					AA adolescents w/ hist. of gender-based violence	6	2.2 (5.1), 63	3.3 (5.2), 65	MeanDiff: -1.13 (-2.91 to 0.65)*	
						12	0.9 (2.1), 61	3.0 (5.8), 65	MeanDiff: -1.48 (-3.19 to 0.23)	0.04
					Adolescents w/ depressive symptomatology	6	1.6 (4.5), 111	2.3 (4.7), 103	MeanDiff: 0.58 (-1.21 to 1.61)	0.383
						12	1.2 (3.1), 109	2.0 (4.3), 104	MeanDiff: -1.27 (-2.65 to 0.10)	0.085
Ehrhardt, 2002 ¹⁰²	Female Condom Use	% first time female condom use	3 months	IG1	Overall	6	4/100 (4.0)	7/104 (6.7)	OR: 0.54 (0.15 to 1.92)	NSD
					12	6/110 (5.5)	5/115 (4.3)	OR: 1.30 (0.90 to 4.95)	NSD	
				IG2	Overall	6	6/121 (5.0)	7/104 (6.7)	OR: 0.73 (0.24 to 2.23)	NSD
					12	7/123 (5.7)	5/115 (4.3)	OR: 1.77 (0.51 to 6.17)	NSD	
	UI	Maintaining or improving safer sex (no unprotected occasions or decreased unprotected vaginal and/or anal intercourse)	3 months	IG1	Overall	12	80/110 (72.7)	71/115 (61.7)	OR: 1.65 (0.94 to 2.90)	0.08
					IG2	Overall	12	82/123 (66.7)	71/115 (61.7)	OR: 1.22 (0.72 to 2.08)
Free, 2016 ¹²²	Condom use at last sex	% used condom at last sex	NA	IG1	Overall	0	32/99 (32.3)	35/101 (34.7)	OR: 0.90 (0.50 to 1.62)*	NSD
					12	29/80 (36.3)	23/83 (27.7)	OR: 1.48 (0.76 to 2.88)*	0.247	
Jemmott, 2005 ¹²⁷	UI	Mean number of days of sex without condom use in the past 3 months	3 months	IG1	Overall	3	3.7 (11.3), 225	3.5 (11.2), 208	MeanDiff: 0.25 (-1.87 to 2.37)*	0.95
					6	3.0 (10.3), 221	3.3 (10.0), 206	MeanDiff: -0.28 (-2.21 to 1.65)*	0.66	
					12	2.3 (11.7), 209	5.1 (11.4), 199	MeanDiff: -2.78 (-5.03 to -0.53)*	0.002	

Appendix E Table 5. Condom Use and Unprotected Sexual Activity: Adolescents and Young Adults

Study	Outcome	Outcome description	Recall period	Int arm	Group	F/U mos	IG n (%) or Mean (SD), n	CG n (%) or Mean (SD), n	Result (95% CI)	P-value			
				IG2	Overall	3	3.6 (10.9), 210	3.5 (11.2), 208	MeanDiff: 0.10 (-2.02 to 2.22)*	0.89			
						6	2.6 (9.8), 206	3.3 (10.0), 206	MeanDiff: -0.66 (-2.57 to 1.25)*	0.43			
						12	4.0 (11.2), 196	5.1 (11.4), 199	MeanDiff: -1.01 (-3.24 to 1.22)*	0.32			
				Unprotected sex while high on drugs or alcohol	Mean number of days of having unprotected sex while high on drugs or alcohol in the past 3 months	3 months	IG1	Overall	3	0.4 (2.8), 225	0.3 (2.9), 208	MeanDiff: 0.14 (-0.40 to 0.68)*	0.44
									6	0.2 (1.6), 221	0.2 (1.6), 206	MeanDiff: -0.02 (-0.32 to 0.28)*	0.80
									12	0.1 (2.2), 209	0.5 (2.1), 199	MeanDiff: -0.36 (-0.78 to 0.06)*	0.02
					IG2	Overall	3	0.2 (2.8), 210	0.3 (2.9), 208	MeanDiff: -0.15 (-0.69 to 0.39)*	0.31		
							6	0.1 (1.6), 206	0.2 (1.6), 206	MeanDiff: -0.14 (-0.44 to 0.16)*	0.21		
							12	0.2 (2.1), 196	0.5 (2.1), 199	MeanDiff: -0.24 (-0.66 to 0.18)*	0.27		
	Kershaw, 2009 ¹²⁹	Proportion of sexual episodes condom used	Mean estimated percentage of sex acts used condom in past 6 months	6 months	IG1	Overall	6	51.0 (40.6), 318	40.7 (40.1), 394	MeanDiff: 10.36 (4.39 to 16.33)*	0.007		
							12	49.8 (41.4), 318	44.1 (40.8), 394	MeanDiff: 5.65 (-0.43 to 11.73)*	0.04		
							35	34.7 (39.2), 318	29.0 (39.3), 394	MeanDiff: 5.66 (-0.14 to 11.46)*	0.30		
UI		Number of acts of unprotected sexual intercourse	1 month	IG1	Overall	6	3.8 (6.5), 318	4.7 (7.0), 394	MeanDiff: -0.91 (-1.90 to 0.08)*	0.18			
						12	3.9 (6.5), 318	5.3 (7.8), 394	MeanDiff: -1.37 (-2.42 to -0.32)*	0.04			
						35	4.5 (6.9), 318	4.1 (6.6), 394	MeanDiff: 0.33 (-0.67 to 1.33)*	0.49			
Lewis, 2018 ¹³²	Any condom use	% any condom use during sex with all partners	1 month	IG1	Overall	6	. /134 (.)	. /133 (.)	OR: 0.70 (0.28 to 1.81)	NSD			
				IG2	Overall	6	. /135 (.)	. /133 (.)	OR: 0.65 (0.27 to 1.94)	NSD			
	Condom use count	Times used condoms among those with any condom use	1 month	IG1	Overall	6	. (.), 134	. (.), 133	RRPoisson: 0.93 (0.60 to 1.46)	NSD			
				IG2	Overall	6	. (.), 135	. (.), 133	RRPoisson: 0.69 (0.43 to 1.15)	NSD			
Metsch, 2013 ¹³⁷	Unprotected sex acts	Predicted mean number of unprotected sex acts	6 months	IG1	Overall	6	17.4 (49.8), 2505	18.3 (52.4), 2507	IRRnegbin: 0.98 (0.86 to 1.13)	NSD			

Appendix E Table 5. Condom Use and Unprotected Sexual Activity: Adolescents and Young Adults

Study	Outcome	Outcome description	Recall period	Int arm	Group	F/U mos	IG n (%) or Mean (SD), n	CG n (%) or Mean (SD), n	Result (95% CI)	P-value
Morrison-Beedy, 2013 ¹⁴⁴	Any condom use	% used condom during sexual intercourse	3 months	IG1	Overall	0	144/318 (45.3)	155/299 (51.8)	OR: 0.77 (0.56 to 1.06)*	NSD
						3	147/318 (46.2)	125/299 (41.8)	OR: 1.19 (0.85 to 1.68)	0.32
						6	137/280 (48.9)	129/262 (49.2)	OR: 0.86 (0.61 to 1.21)	0.92
						12	102/245 (41.6)	84/236 (35.6)	OR: 1.30 (0.90 to 1.87)	0.17
	UVI	% of any episodes of unprotected vaginal sex	3 months	IG1	Overall	0	216/324 (66.7)	211/309 (68.3)	OR: 0.93 (0.67 to 1.30)*	NSD
						3	162/278 (58.3)	162/259 (62.5)	OR: 0.84 (0.59 to 1.18)*	NSD
						6	154/284 (54.2)	176/262 (67.2)	OR: 0.58 (0.41 to 0.82)*	<0.05
						12	170/249 (68.3)	171/235 (72.8)	OR: 0.81 (0.54 to 1.19)*	NSD
		Mean number of episodes of unprotected vaginal intercourse	3 months	IG1	Overall	3	4.5 (7.0), 278	5.2 (7.5), 259	Beta coefficient†: 0.20 (-0.16 to 0.57)	NSD
						6	5.1 (8.3), 284	6.1 (8.8), 262	Beta coefficient†: 0.62 (0.26 to 0.99)	<0.001
					12	7.0 (11.1), 249	8.1 (11.0), 235	Beta coefficient†: 0.29 (-0.12 to 0.70)	NSD	
Peipert, 2008 ¹⁴⁸	Consistent condom use	% consistent condom use	2 years	IG1	Overall	24	124/272 (45.6)	124/270 (45.9)	OR: 0.99 (0.70 to 1.38)*	NSD
	Dual method condom use	% any dual protection condom use	2 years	IG1	Overall	24	86/272 (31.6)	71/270 (26.3)	OR: 1.30 (0.89 to 1.88)*	NSD
Proude, 2004 ¹⁵⁰	Condom use at first sex with new partner	% condom use at first sex with new partner	3 months	IG1	Overall	3	8/11 (72.7)	10/13 (76.9)	OR: 0.80 (0.13 to 5.09)*	0.813
Redding, 2014 ¹⁶³	Consistent condom use	Consistent condom use	1 month	IG1	Overall	0	171/424 (40.3)	163/404 (40.3)	OR: 1.00 (0.76 to 1.32)	NSD
						6	139/228 (61.0)	94/206 (45.6)	OR: 1.86 (1.22 to 2.80)	<0.01
						12	136/266 (51.1)	89/228 (39.0)	OR: 1.65 (1.08 to 2.53)	0.02
						18	119/252 (47.2)	95/209 (45.5)	OR: 1.12 (0.72 to 1.72)	0.64

Appendix E Table 5. Condom Use and Unprotected Sexual Activity: Adolescents and Young Adults

Study	Outcome	Outcome description	Recall period	Int arm	Group	F/U mos	IG n (%) or Mean (SD), n	CG n (%) or Mean (SD), n	Result (95% CI)	P-value
Scholes, 2003 ¹⁵⁴	Percentage of time condom used	% condom use with any partner	3 months	IG1	Overall	0	381/536 (71.1)	412/565 (72.9)	OR: 0.91 (0.70 to 1.19)*	NSD
						6	390/536 (72.8)	356/565 (63.0)	OR: 1.86 (1.32 to 2.65)	0.0005
	Consistent condom use	% consistent condom use with all partners	3 months	IG1	Overall	6	52.7 (.), 536	47.9 (.), 565	MeanDiff: 5.20 (0.40 to 10.40)	0.05
						6	197/536 (36.8)	189/565 (33.5)	OR: 1.24 (0.89 to 1.73)	0.21
Shafii, 2019 ¹⁶⁴	UVI	Unprotected vaginal intercourse (no condom used)	2 months	IG1	Overall	3	. (.), 112	. (.), 130	IRR: 0.67 (0.44 to 1.01)	0.06
					Female	3	NR	NR	IRR: 0.50 (0.30 to 0.85)	0.01
					Male	3	NR	NR	IRR: 0.76 (0.41 to 1.42)	0.39
Shain, 2004 ¹⁵⁵	UI	Unprotected sex with untreated or incompletely treated partner	1 year	IG1	Overall	12	24/236 (10.2)	46/254 (18.1)	OR: 0.51 (0.30 to 0.87)*	0.01
					IG2	Overall	12	17/219 (7.8)	46/254 (18.1)	OR: 0.38 (0.21 to 0.69)*
Whiteley, 2018 ¹⁶⁶	UI	Unprotected vaginal and anal sex	3 months	IG1	Overall	0	7/24 (29.2)	9/21 (42.9)	OR: 0.55 (0.16 to 1.89)	0.919
						3	4/24 (16.7)	10/21 (47.6)	OR: 0.22 (0.06 to 0.87)	<0.05
Ybarra, 2017 ¹⁵⁹	Condomless sex acts	Mean number of condomless sex acts	3 months	IG1	Overall	3	2.8 (12.3), 137	2.7 (16.0), 146	IRRnegbin: 1.02 (0.51 to 2.04)	NSD
					Sexually experienced	3	5.5 (16.9), 69	5.3 (22.7), 71	IRRnegbin: 0.95 (0.45 to 2.02)	NSD
					Sexually inexperienced	3	0.2 (0.7), 68	0.3 (1.4), 75	IRRnegbin: 0.62 (0.12 to 3.18)	NSD

* Calculated estimate from reported raw study data. P-values are based on statistical analyses reported in the published study results

† Beta coefficient from logistic regression component of zero-inflated Poisson (ZIP) regression

Abbreviations: AA = African American; Calc = calculated; CG = control group; CI = confidence interval; Diff = difference; F/U = followup; GEE = generalized estimating equation; Hist = history; IG = intervention group; Int = intervention; IRR = incidence rate ratio; IRRnegbin = incidence rate ratio, negative binomial regression; Mos = months; n = number of participants; NA = not applicable; NR = not reported; NSD = no significant difference; OR = odds ratio; RR = risk ratio; RR Poisson = relative risk, Poisson regression; RRnegbin = relative risk, negative binomial regression; SD = standard deviation; UI = unprotected intercourse; UVI = unprotected vaginal intercourse.

Appendix E Table 6. Condom Use and Unprotected Sexual Activity: Adults*

Study	Outcome	Outcome description	Recall period	Int arm	Group	F/U mos	IG n (%) or Mean (SD), n	CG n (%) or Mean (SD), n	Result (95% CI)	P-value		
Berkman, 2007 ¹⁰⁸	Proportion of sexual episodes condom used	Mean percentage sexual acts using condoms	3 months	IG1	Sexually active at BL	8	93.4 (21.3), 53	75.8 (38.1), 53	MeanDiff: 17.60 (5.85 to 29.35) [†]	0.06		
						14	82.9 (36.2), 53	76.5 (39.4), 53	MeanDiff: 6.40 (-8.00 to 20.80) [†]	0.57		
Billings, 2015 ¹¹⁰	Proportion of sexual episodes condom used	Mean percentage of sexual intercourse episodes with 5 most recent sex partners in past 30 days	1 month	IG1	Overall	4	59.5 (40.4), 45	31.7 (34.7), 38	MeanDiff: 27.88 (11.73 to 44.03) [†]	0.027		
	UI	Number of unprotected vaginal/anal sex acts with 5 most recent partners in past 30 days	1 month	IG1	Overall	4	1.0 (0.9), 39	1.6 (0.8), 34	MeanDiff: -0.62 (-1.01 to -0.23) [†]	0.098		
Carey, 2004 ¹¹¹	UVI	Frequency of unprotected vaginal intercourse	3 months	IG1	Overall	6	9.5 (23.1), 123	10.0 (21.1), 110	MeanDiff: -0.50 (-6.18 to 5.18) [†]	NSD		
						9	7.2 (14.5), 123	8.0 (17.9), 110	GEE: -0.27 (-0.47 to -0.07)	0.004		
Carey, 2010 ¹¹²	UI	Mean number of unprotected sex episodes in the past 3 months	3 months	IG1	Overall	3	12.3 (17.0), 166	10.5 (15.1), 199	MeanDiff: 1.80 (-1.53 to 5.13) [†]	NSD		
						6	14.4 (19.2), 178	10.6 (15.2), 184	MeanDiff: 3.80 (0.23 to 7.37) [†]	<0.05		
						12	15.7 (22.1), 166	11.6 (17.9), 172	MeanDiff: 4.10 (-0.20 to 8.40) [†]	NSD		
						IG2	Overall	3	12.1 (16.6), 184	10.5 (15.1), 199	MeanDiff: 1.60 (-1.59 to 4.79) [†]	NSD
								6	11.3 (16.3), 197	10.6 (15.2), 184	MeanDiff: 0.70 (-2.46 to 3.86) [†]	NSD
								12	13.1 (17.8), 176	11.6 (17.9), 172	MeanDiff: 1.50 (-2.25 to 5.25) [†]	NSD
				IG3	Overall	3	10.6 (15.4), 180	10.5 (15.1), 199	MeanDiff: 0.10 (-2.98 to 3.18) [†]	NSD		
						6	14.2 (19.9), 176	10.6 (15.2), 184	MeanDiff: 3.60 (-0.07 to 7.27) [†]	NSD		
						12	14.0 (19.7), 180	11.6 (17.9), 172	MeanDiff: 2.40 (-1.53 to 6.33) [†]	NSD		
				IG4	Overall	3	12.0 (16.6), 179	10.5 (15.1), 199	MeanDiff: 1.50 (-1.71 to 4.71) [†]	NSD		
						6	15.1 (20.3), 186	10.6 (15.2), 184	MeanDiff: 4.50 (0.85 to 8.15) [†]	<0.05		

Appendix E Table 6. Condom Use and Unprotected Sexual Activity: Adults*

Study	Outcome	Outcome description	Recall period	Int arm	Group	F/U mos	IG n (%) or Mean (SD), n	CG n (%) or Mean (SD), n	Result (95% CI)	P-value	
					Overall	12	13.9 (19.6), 172	11.6 (17.9), 172	MeanDiff: 2.30 (-1.67 to 6.27) [†]	NSD	
						IG5	3	12.5 (17.2), 174	10.5 (15.1), 199	MeanDiff: 2.00 (-1.31 to 5.31) [†]	NSD
						6	14.1 (19.8), 180	10.6 (15.2), 184	MeanDiff: 3.50 (-0.13 to 7.13) [†]	NSD	
						12	15.0 (20.8), 178	11.6 (17.9), 172	MeanDiff: 3.40 (-0.66 to 7.46) [†]	NSD	
Carey, 2015 ¹¹³	Unprotected sex with all partners	Total number of unprotected vaginal and anal sex acts with all partners	3 months	IG1	Overall	3	16.3 (23.2), 250	15.7 (25.7), 254	MeanDiff: 0.61 (-3.66 to 4.88) [†]	NSD	
						6	16.6 (26.6), 250	16.4 (25.8), 254	MeanDiff: 0.24 (-4.33 to 4.81) [†]	NSD	
						9	15.1 (22.0), 250	14.3 (22.0), 254	MeanDiff: 0.79 (-3.05 to 4.63) [†]	NSD	
						12	13.9 (21.2), 250	13.5 (21.5), 254	MeanDiff: 0.43 (-3.30 to 4.16) [†]	NSD	
				IG2	Overall	3	13.2 (18.6), 252	15.7 (25.7), 254	MeanDiff: -2.47 (-6.37 to 1.43) [†]	NSD	
						6	14.6 (23.5), 252	16.4 (25.8), 254	MeanDiff: -1.75 (-6.05 to 2.55) [†]	NSD	
						9	12.8 (20.2), 252	14.3 (22.0), 254	MeanDiff: -1.57 (-5.25 to 2.11) [†]	NSD	
						12	13.3 (19.7), 252	13.5 (21.5), 254	MeanDiff: -0.16 (-3.75 to 3.43) [†]	NSD	
				IG3	Overall	3	12.9 (19.3), 254	15.7 (25.7), 254	MeanDiff: -2.81 (-6.76 to 1.14) [†]	NSD	
						6	15.2 (24.9), 254	16.4 (25.8), 254	MeanDiff: -1.14 (-5.55 to 3.27) [†]	NSD	
						9	14.1 (22.9), 254	14.3 (22.0), 254	MeanDiff: -0.25 (-4.16 to 3.66) [†]	NSD	
						12	13.2 (20.6), 254	13.5 (21.5), 254	MeanDiff: -0.26 (-3.92 to 3.40) [†]	NSD	
Jemmott, 2007 ¹²⁸	Condom use at last sex	% used condom at last sex	3 months	IG1	Overall	0	51/118 (43.2)	30/81 (37.0)	OR: 1.29 (0.72 to 2.31) [†]	NSD	
						3	61/118 (51.7)	32/81 (39.5)	OR: 1.64 (0.92 to 2.91) [†]	NSD	
						6	71/118 (60.2)	41/81 (50.6)	OR: 1.47 (0.83 to 2.61) [†]	NSD	
						12	70/118 (59.3)	32/81 (39.5)	OR: 2.23 (1.25 to 3.98) [†]	<0.05	
				IG2	Overall	0	42/124 (33.9)	30/81 (37.0)	OR: 0.87 (0.49 to 1.56) [†]	NSD	

Appendix E Table 6. Condom Use and Unprotected Sexual Activity: Adults*

Study	Outcome	Outcome description	Recall period	Int arm	Group	F/U mos	IG n (%) or Mean (SD), n	CG n (%) or Mean (SD), n	Result (95% CI)	P-value		
						3	63/124 (50.8)	32/81 (39.5)	OR: 1.58 (0.90 to 2.79) [†]	NSD		
						6	57/124 (46.0)	41/81 (50.6)	OR: 0.83 (0.47 to 1.45) [†]	NSD		
						12	45/124 (36.3)	32/81 (39.5)	OR: 0.87 (0.49 to 1.55) [†]	NSD		
						IG3	Overall	0	47/123 (38.2)	30/81 (37.0)	OR: 1.05 (0.59 to 1.88) [†]	NSD
								3	64/123 (52.0)	32/81 (39.5)	OR: 1.66 (0.94 to 2.93) [†]	NSD
								6	57/123 (46.3)	41/81 (50.6)	OR: 0.84 (0.48 to 1.48) [†]	NSD
								12	68/123 (55.3)	32/81 (39.5)	OR: 1.89 (1.07 to 3.35) [†]	<0.05
						IG4	Overall	0	48/118 (40.7)	30/81 (37.0)	OR: 1.17 (0.65 to 2.09) [†]	NSD
								3	60/118 (50.8)	32/81 (39.5)	OR: 1.58 (0.89 to 2.81) [†]	NSD
				6	70/118 (59.3)			41/81 (50.6)	OR: 1.42 (0.80 to 2.52) [†]	NSD		
				12	61/118 (51.7)			32/81 (39.5)	OR: 1.64 (0.92 to 2.91) [†]	NSD		
				IG1	Overall			3	0.8 (0.2), 118	0.7 (0.2), 81	MeanDiff: 0.07 (0.01 to 0.13) [†]	<0.05
						6	0.7 (0.2), 118	0.7 (0.2), 81	MeanDiff: 0.01 (-0.05 to 0.07) [†]			
						12	0.8 (0.2), 118	0.6 (0.3), 81	MeanDiff: 0.17 (0.10 to 0.24) [†]	<0.05		
						IG2	Overall	3	0.7 (0.2), 124	0.7 (0.2), 81	MeanDiff: 0.01 (-0.05 to 0.07) [†]	
								6	0.7 (0.2), 124	0.7 (0.2), 81	MeanDiff: -0.04 (-0.10 to 0.02) [†]	
	12	0.7 (0.2), 124	0.6 (0.3), 81					MeanDiff: 0.07 (0.00 to 0.14) [†]				
	IG3	Overall	3			0.7 (0.2), 123	0.7 (0.2), 81	MeanDiff: 0.06 (0.00 to 0.12) [†]				
			6	0.7 (0.2), 123	0.7 (0.2), 81	MeanDiff: -0.02 (-0.08 to 0.04) [†]						
			12	0.7 (0.2), 123	0.6 (0.3), 81	MeanDiff: 0.08 (0.01 to 0.15) [†]	<0.05					
IG4	Overall	3	0.7 (0.2), 118	0.7 (0.2), 81	MeanDiff: -0.01 (-0.07 to 0.05) [†]							
Proportion of sexual episodes condom used	Mean proportion of days of sex used condom	3 months	IG1	Overall	3	0.8 (0.2), 118	0.7 (0.2), 81	MeanDiff: 0.07 (0.01 to 0.13) [†]	<0.05			
					6	0.7 (0.2), 118	0.7 (0.2), 81	MeanDiff: 0.01 (-0.05 to 0.07) [†]				
					12	0.8 (0.2), 118	0.6 (0.3), 81	MeanDiff: 0.17 (0.10 to 0.24) [†]	<0.05			
					IG2	Overall	3	0.7 (0.2), 124	0.7 (0.2), 81	MeanDiff: 0.01 (-0.05 to 0.07) [†]		
							6	0.7 (0.2), 124	0.7 (0.2), 81	MeanDiff: -0.04 (-0.10 to 0.02) [†]		
							12	0.7 (0.2), 124	0.6 (0.3), 81	MeanDiff: 0.07 (0.00 to 0.14) [†]		
					IG3	Overall	3	0.7 (0.2), 123	0.7 (0.2), 81	MeanDiff: 0.06 (0.00 to 0.12) [†]		
6	0.7 (0.2), 123	0.7 (0.2), 81	MeanDiff: -0.02 (-0.08 to 0.04) [†]									
12	0.7 (0.2), 123	0.6 (0.3), 81	MeanDiff: 0.08 (0.01 to 0.15) [†]	<0.05								
IG4	Overall	3	0.7 (0.2), 118	0.7 (0.2), 81	MeanDiff: -0.01 (-0.07 to 0.05) [†]							

Appendix E Table 6. Condom Use and Unprotected Sexual Activity: Adults*

Study	Outcome	Outcome description	Recall period	Int arm	Group	F/U mos	IG n (%) or Mean (SD), n	CG n (%) or Mean (SD), n	Result (95% CI)	P-value		
	UI	Mean number of days of unprotected sexual intercourse	3 months	IG1	Overall	6	0.7 (0.2), 118	0.7 (0.2), 81	MeanDiff: -0.05 (-0.11 to 0.01) [†]			
						12	0.7 (0.2), 118	0.6 (0.3), 81	MeanDiff: 0.07 (0.00 to 0.14) [†]			
						3	4.5 (7.9), 118	8.2 (14.6), 81	MeanDiff: -3.71 (-7.19 to -0.23) [†]	<0.05		
						6	4.9 (7.9), 118	6.9 (13.2), 81	MeanDiff: -1.97 (-5.19 to 1.25) [†]	NSD		
						12	5.1 (9.7), 118	8.3 (17.1), 81	MeanDiff: -3.20 (-7.31 to 0.91) [†]			
						IG2	Overall	3	5.3 (6.0), 124	8.2 (14.6), 81	MeanDiff: -2.88 (-6.23 to 0.47) [†]	
								6	3.8 (3.8), 124	6.9 (13.2), 81	MeanDiff: -3.13 (-6.09 to -0.17) [†]	<0.05
								12	5.9 (6.9), 124	8.3 (17.1), 81	MeanDiff: -2.40 (-6.32 to 1.52) [†]	NSD
						IG3	Overall	3	3.1 (5.1), 123	8.2 (14.6), 81	MeanDiff: -5.12 (-8.42 to -1.82) [†]	<0.05
								6	3.4 (5.7), 123	6.9 (13.2), 81	MeanDiff: -3.52 (-6.57 to -0.47) [†]	<0.05
								12	3.6 (7.1), 123	8.3 (17.1), 81	MeanDiff: -4.74 (-8.67 to -0.81) [†]	<0.05
						IG4	Overall	3	5.4 (4.6), 118	8.2 (14.6), 81	MeanDiff: -2.80 (-6.08 to 0.48) [†]	
								6	5.6 (3.7), 118	6.9 (13.2), 81	MeanDiff: -1.32 (-4.28 to 1.64) [†]	NSD
								12	5.1 (2.6), 118	8.3 (17.1), 81	MeanDiff: -3.22 (-6.97 to 0.53) [†]	
						Mittal, 2017 ¹⁴²	Episodes of unprotected sex w/ other partners	Episodes of unprotected sex with other partners	3 months	IG1	Overall	3
Episodes of unprotected sex w/ steady partner	Episodes of unprotected sex with steady partner	3 months	IG1	Overall	3		. (.), 19	. (.), 21	RRPoisson: 1.09 (0.57 to 2.11)	0.79		
Unprotected sex with all partners	Episodes of unprotected sex with all partners	3 months	IG1	Overall	3		. (.), 19	. (.), 21	RRnegbin: 0.74 (0.34 to 1.62)	0.45		

Appendix E Table 6. Condom Use and Unprotected Sexual Activity: Adults*

Study	Outcome	Outcome description	Recall period	Int arm	Group	F/U mos	IG n (%) or Mean (SD), n	CG n (%) or Mean (SD), n	Result (95% CI)	P-value
O'Cleirigh, 2019 ¹⁶²	UAI	Unprotected anal intercourse	3 months	IG1	Overall	0	15/17 (88.2)	16/19 (84.2)	OR: 1.41 (0.21 to 9.62)	NSD
						3	1.0 (4.3), 19	5.1 (9.2), 19	CalcMeanDiff: -4.10 (-8.68 to 0.48)	p<0.001
						3	2/19 (10.5)	12/19 (63.2)	OR: 0.59 (0.37 to 0.96)	0.03
						6	1/18 (5.6)	10/19 (52.6)	OR: 0.05 (0.01 to 0.48)	<0.05
						6	0.9 (4.3), 18	3.0 (6.2), 19	CalcMeanDiff: -2.04 (-5.43 to 1.35)	NSD
						9	2/17 (11.8)	12/18 (66.7)	OR: 0.68 (0.59 to 0.81)	<0.001
						9	1.2 (3.9), 17	4.3 (8.4), 18	CalcMeanDiff: -3.09 (-7.39 to 1.21)	0.04
Peragallo Montano, 2019 ¹⁶¹	Condomless sex acts	Number of condomless sex acts	1 month	IG1	Overall	6	7.3 (7.8), 128	5.9 (8.3), 131	CalcMeanDiff: 1.42 (-0.54 to 3.38)	NSD
						12	5.9 (6.4), 131	6.3 (9.1), 128	CalcMeanDiff: -0.37 (-2.29 to 1.55)	NSD
	Any condom use	Any condom use	1 month	IG1	Overall	0	56/160 (35.0)	64/160 (40.0)	OR: 0.81 (0.51 to 1.27)	NSD
						6	57/128 (44.5)	64/131 (48.9)	OR: 0.84 (0.52 to 1.37)	NSD
						12	61/128 (47.7)	71/131 (54.2)	OR: 0.77 (0.47 to 1.25)	NSD
	Sexual acts with condom	% of sex events where condoms were used	1 month	IG1	Overall	6	31.8 (41.5), 128	40.2 (44.8), 131	CalcMeanDiff: -8.42 (-18.94 to 2.10)	NSD
						12	38.3 (44.6), 128	42.7 (44.4), 131	CalcMeanDiff: -4.38 (-15.22 to 6.46)	NSD
Petersen, 2007 ¹⁴⁹	Consistent condom use	% consistent condom use	1 month	IG1	Overall	12	NR	NR	NR	NSD
Tzilos Wernette, 2018 ¹⁶⁵	UVI	Condomless vaginal sex	4 months	IG1	Overall	0	30/31 (96.8)	19/19 (100.0)	OR: 0.52 (0.02 to 13.46)	NSD
						4	22/30 (73.3)	18/19 (94.7)	OR: 5.50 (0.59 to 51.21)	0.13

* Four studies did not exclude adolescents, but primarily recruited adults and the mean age in the study populations was above 25 years

† Calculated estimate from reported raw study data. P-values are based on statistical analyses reported in the published study results

Abbreviations: BL = baseline; Calc = calculated; CG = control group; Diff = difference; F/U = followup; GEE = generalized estimating equation; IG = intervention group; Int = intervention; Mo = months; n = number of participants; NR = not reported; NSD = no significant difference; OR = odds ratio; SD = standard deviation; VEE = vaginal equivalent episodes.

Appendix E Table 7. Other Sexual Behaviors: Adolescents and Young Adults

Study	Outcome	Outcome description	Recall period	Int arm	Group	F/U mos	IG n (%) or Mean (SD), n	CG n (%) or Mean (SD), n	Result (95%CI)	P-value
Berenson, 2012 ¹⁰⁷	BC	Correct and consistent use of birth control pills	1 month	IG1	Overall	3	224/384 (58.3)	214/388 (55.2)	OR: 1.14 (0.86 to 1.51)*	0.06
						6	151/384 (39.3)	145/388 (37.4)	OR: 1.09 (0.86 to 1.40)	NSD
				IG2	Overall	3	191/383 (49.9)	214/388 (55.2)	OR: 0.81 (0.61 to 1.07)*	0.06
						6	122/383 (31.9)	145/388 (37.4)	OR: 0.80 (0.63 to 1.03)	0.08
Crosby, 2009 ¹¹⁸	Sex partners	Number of female partners	3 months	IG1	Overall	3	2 (1.6), 105	4.2 (5.6), 91	MeanDiff: -1.87 (-2.96 to -0.79)	0.001
DiClemente, 2004 ¹¹⁹	New sex partners	New vaginal sex partner in the past 30 days	1 month	IG1	Overall	0	11/251 (4.4)	20/271 (7.4)	OR: 0.58 (0.27 to 1.23)	NSD
						6	6/226 (2.7)	18/243 (7.4)	OR: 0.29 (0.11 to 0.77)	0.01
						12	8/219 (3.7)	13/241 (5.4)	OR: 0.40 (0.19 to 0.82)	0.01
				AA female adolescents w/ hist. of gender-based violence	Overall	0	5/73 (6.8)	9/73 (12.3)	OR: 0.52 (0.17 to 1.64)*	NSD
						6	2/63 (3.2)	7/65 (10.8)	OR: 0.27 (0.05 to 1.36)*	NSD
						12	3/61 (4.9)	4/65 (6.2)	OR: 0.31 (0.09 to 1.08)	0.07
Free, 2016 ¹²²	Sex partners	More than 1 sexual partner	1 year	IG1	Overall	0	93/99 (93.9)	92/101 (91.1)	OR: 1.52 (0.52 to 4.43)*	NSD
						12	39/77 (50.6)	39/80 (48.8)	OR: 1.08 (0.58 to 2.02)*	0.812
Guilamo-Ramos, 2011 ¹²⁵	Frequency of sexual intercourse	Frequency of sexual intercourse in the past 30 days	1 month	IG1	Overall	9	1.1 (.), 133	1.5 (.), 131	NR	<0.05
	Oral sex	Engaged in oral sex with a member of the opposite sex	9 months	IG1	Overall	0	4/133 (3.0)	4/131 (3.1)	OR: 0.98 (0.24 to 4.02)*	NSD
						9	5/124 (4.0)	13/126 (10.3)	OR: 0.37 (0.13 to 1.06)*	<0.054
	Vaginal intercourse	Percent engaged in vaginal sexual intercourse	9 months	IG1	Overall	0	9/133 (6.8)	8/131 (6.1)	OR: 1.12 (0.42 to 2.99)*	NSD
						9	8/124 (6.5)	28/126 (22.2)	OR: 0.24 (0.11 to 0.55)*	<0.05

Appendix E Table 7. Other Sexual Behaviors: Adolescents and Young Adults

Study	Outcome	Outcome description	Recall period	Int arm	Group	F/U mos	IG n (%) or Mean (SD), n	CG n (%) or Mean (SD), n	Result (95%CI)	P-value
Jemmott, 2005 ¹²⁷	Sex while high on drugs or alcohol [†]	Mean number of days of sex while high on drugs or alcohol in the past 3 months	3 months	IG1	Overall	6	0 (1.4), 221	.4 (1.4), 206	MeanDiff: -0.24 (-0.52 to 0.04)*	0.005
						12	.4 (3.6), 209	.6 (3.6), 199	MeanDiff: -0.24 (-0.93 to 0.45)*	0.37
				IG2	Overall	6	.2 (1.4), 206	.4 (1.4), 206	MeanDiff: -0.16 (-0.44 to 0.12)*	0.10
						12	.6 (3.6), 196	.6 (3.6), 199	MeanDiff: -0.13 (-0.82 to 0.56)*	0.65
	Multiple partners [†]	Percent reporting 2 or more partners in the past 3 months	3 months	IG1	Overall	0	29/235 (12.3)	36/219 (16.4)	OR: 0.72 (0.42 to 1.21)*	NSD
						6	21/221 (9.5)	29/206 (14.1)	OR: 0.64 (0.35 to 1.16)*	0.12
						12	14/209 (6.7)	33/199 (16.6)	OR: 0.36 (0.19 to 0.70)*	0.002
				IG2	Overall	0	43/228 (18.9)	36/219 (16.4)	OR: 1.18 (0.73 to 1.92)*	NSD
						6	26/206 (12.6)	29/206 (14.1)	OR: 0.88 (0.50 to 1.56)*	0.54
						12	21/196 (10.7)	29/199 (14.6)	OR: 0.70 (0.39 to 1.28)*	0.09
	Sex partners [†]	Mean number of sex partners in the past 3 months	3 months	IG1	Overall	6	1 (.8), 221	1 (.8), 206	MeanDiff: -0.08 (-0.25 to 0.09)	0.22
						12	1 (.8), 209	1 (.8), 199	MeanDiff: -0.13 (-0.27 to 0.01)	0.04
				IG2	Overall	6	1 (.8), 206	1 (.8), 206	MeanDiff: -0.02 (-0.19 to 0.15)	0.56
						12	1 (.6), 196	1 (.8), 199	MeanDiff: -0.04 (-0.18 to 0.10)	0.51
Lewis, 2018 ¹³²	Casual sex partners	Percent of ppt reporting any non-zero count of casual sexual partners	1 month	IG1	Overall	6	./134 (.)	./133 (.)	OR: 0.60 (0.23 to 1.55)	NSD
				IG2	Overall	6	./135 (.)	./133 (.)	OR: 0.31 (0.12 to 0.79)	<0.05
	Non-zero mean count of casual sexual partners	1 month	IG1	Overall	6	. (.), 134	. (.), 133	RRPoisson: 0.88 (0.49 to 1.52)	NSD	
			IG2	Overall	6	. (.), 135	. (.), 133	RRPoisson: 1.08 (0.62 to 1.94)	NSD	
	Drinking prior to sex	Percent of ppt reporting any	1 month	IG1	Overall	6	./134 (.)	./133 (.)	OR: 1.42 (0.66 to 3.10)	NSD

Appendix E Table 7. Other Sexual Behaviors: Adolescents and Young Adults

Study	Outcome	Outcome description	Recall period	Int arm	Group	F/U mos	IG n (%) or Mean (SD), n	CG n (%) or Mean (SD), n	Result (95%CI)	P-value
	non-zero count of drinking prior to sex	non-zero count of drinking prior to sex		IG2	Overall	6	. /135 (.)	./133 (.)	OR: 1.37 (0.61 to 2.93)	NSD
		Non-zero mean count of drinking prior to sex	1 month	IG1	Overall	6	. (.), 134	. (.), 133	RRPoisson: 0.81 (0.56 to 1.15)	NSD
				IG2	Overall	6	. (.), 135	. (.), 133	RRPoisson: 0.74 (0.51 to 1.06)	NSD
	Drinks per week	Percent of ppt reporting any non-zero count of typical drinks per week	1 month	IG1	Overall	6	./134 (.)	./133 (.)	OR: 1.01 (0.16 to 5.83)	NSD
				IG2	Overall	6	./135 (.)	./133 (.)	OR: 0.49 (0.09 to 2.52)	NSD
		Non-zero mean count of typical drinks per week	1 month	IG1	Overall	6	. (.), 134	. (.), 133	RRPoisson: 0.88 (0.73 to 1.06)	NSD
				IG2	Overall	6	. (.), 135	. (.), 133	RRPoisson: 0.87 (0.73 to 1.04)	NSD
	Alcohol-related sexual consequences	Percent of ppt reporting any non-zero count of alcohol-related sexual consequences	1 month	IG1	Overall	6	./134 (.)	./133 (.)	OR: 0.80 (0.36 to 1.73)	NSD
				IG2	Overall	6	./135 (.)	./133 (.)	OR: 1.16 (0.57 to 2.50)	NSD
		Non-zero mean count of alcohol-related sexual consequences	1 month	IG1	Overall	6	. (.), 134	. (.), 133	RRPoisson: 1.10 (0.69 to 1.44)	NSD
				IG2	Overall	6	. (.), 135	. (.), 133	RRPoisson: 0.76 (0.52 to 1.06)	NSD
	Metsch, 2013 ¹³⁷	Sex acts	Predicted mean number of sex acts	6 months	IG1	Overall	6	28.6 (56.2), 2505	29.2 (57.4), 2507	IRRnegbin: 0.99 (0.90 to 1.09)
Sex partners		Predicted mean number of sex partners	6 months	IG1	Overall	6	2.8 (3.8), 2505	3 (5.2), 2507	IRRnegbin: 0.88 (0.82 to 0.94)	<0.05
Unprotected partners		Predicted mean number of unprotected sexual partners	6 months	IG1	Overall	6	1.2 (2.6), 2505	1.2 (1.2), 2507	IRRnegbin: 0.97 (0.90 to 1.05)	NSD

Appendix E Table 7. Other Sexual Behaviors: Adolescents and Young Adults

Study	Outcome	Outcome description	Recall period	Int arm	Group	F/U mos	IG n (%) or Mean (SD), n	CG n (%) or Mean (SD), n	Result (95%CI)	P-value
Morrison-Beedy, 2013 ¹⁴⁴	Vaginal sex acts [†]	Percent reporting any episode of protected or unprotected vaginal sex	3 months	IG1	Overall	0	292/324 (90.1)	283/309 (91.6)	OR: 0.84 (0.49 to 1.44)*	NSD
						6	219/284 (77.1)	229/262 (87.4)	OR: 0.49 (0.31 to 0.77)*	<0.05
						12	206/249 (82.7)	198/235 (84.3)	OR: 0.90 (0.55 to 1.45)*	NSD
		Mean number of episodes of protected or unprotected vaginal sex	3 months	IG1	Overall	6	10.8 (13.6), 284	13.6 (15.6), 262	Beta coefficient [†] : 0.79 (0.31 to 1.26)	<0.01
						12	14.6 (17.8), 249	16 (18.4), 235	Beta coefficient [†] : 0.12 (-0.37 to 0.62)	NSD
	Multiple partners [†]	Two or more sexual partners	3 months	IG1	Overall	0	93/325 (28.6)	98/309 (31.7)	OR: 0.55 (0.27 to 1.12)	NSD
						6	43/284 (15.1)	56/262 (21.4)	OR: 0.37 (0.19 to 0.71)	<0.01
						12	45/249 (18.1)	49/236 (20.8)	OR: 0.71 (0.36 to 1.42)	NSD
	Avoided drinking or drug use before sex [†]	Avoided drinking or drug use before sex (as a risk reduction strategy)	3 months	IG1	Overall	0	81/318 (25.5)	77/299 (25.8)	OR: 0.99 (0.69 to 1.41)*	NSD
						6	102/280 (36.4)	105/262 (40.1)	OR: 0.85 (0.61 to 1.21)	0.43
						12	86/245 (35.1)	86/236 (36.4)	OR: 0.94 (0.65 to 1.40)	0.76
	Avoided sex when drunk or high [†]	Avoided sex when drunk or high (as risk reduction strategy)	3 months	IG1	Overall	0	72/318 (22.6)	70/299 (23.4)	OR: 0.96 (0.66 to 1.39)*	NSD
						6	107/280 (38.2)	92/262 (35.1)	OR: 1.14 (0.81 to 1.62)	0.45
						12	87/245 (35.5)	88/236 (37.3)	OR: 0.92 (0.64 to 1.32)	0.69
Sexual abstinence [†]	Abstained from all sex (as risk reduction strategy)	3 months	IG1	Overall	0	20/318 (6.3)	23/299 (7.7)	OR: 0.81 (0.43 to 1.50)*	NSD	
					6	41/280 (14.6)	31/262 (11.8)	OR: 1.28 (0.78 to 2.11)	0.08	
					12	34/245 (13.9)	31/236 (13.1)	OR: 1.06 (0.62 to 1.80)	0.62	
Proude, 2004 ¹⁵⁰	New sex partners	New sex partner	3 months	IG1	Overall	3	11/103 (10.7)	13/108 (12.0)	OR: 0.87 (0.37 to 2.05)*	NSD
Sanci, 2015 ¹⁵³	Pregnancy risk [†]	Risk of pregnancy, no further specification	3 months	IG1	Overall	0	53/377 (14.1)	61/524 (11.6)	OR: 1.24 (0.84 to 1.84)*	NSD
						12	25/377 (6.6)	53/524 (10.1)	OR: 0.53 (0.30 to 0.94)	0.03

Appendix E Table 7. Other Sexual Behaviors: Adolescents and Young Adults

Study	Outcome	Outcome description	Recall period	Int arm	Group	F/U mos	IG n (%) or Mean (SD), n	CG n (%) or Mean (SD), n	Result (95%CI)	P-value
	STI risk†	Risk of STI, no further specification	3 months	IG1	Overall	0	70/377 (18.6)	92/524 (17.6)	OR: 1.07 (0.76 to 1.51)*	NSD
					Overall	12	39/377 (10.3)	66/524 (12.6)	OR: 0.79 (0.51 to 1.24)	0.31
Shafii, 2019 ¹⁶⁴	Sex partners	Number of sexual partners	2 months	IG1	Overall	3	. (.), 112	. (.), 130	IRRnegbin: 0.80 (0.61 to 1.05)	0.11
					Female	3	NR	NR	IRRnegbin: 0.71 (0.50 to 1.00)	0.05
					Male	3	NR	NR	IRRnegbin: 1.08 (0.77 to 1.52)	0.65
Shain, 2004 ¹⁵⁵	Multiple partners	>1 sexual partner	1 year	IG1	Overall	12	86/199 (43.2)	110/199 (55.3)	OR: 0.62 (0.41 to 0.91)*	0.01
					Overall	24	72/199 (36.2)	101/199 (50.8)	OR: 0.55 (0.37 to 0.82)*	<0.002
				IG2	Overall	12	79/186 (42.5)	110/199 (55.3)	OR: 0.60 (0.40 to 0.89)*	0.001
					Overall	24	70/186 (37.6)	101/199 (50.8)	OR: 0.59 (0.39 to 0.88)*	<0.005
Wingood, 2013	Multiple partners	Multiple nonoverlapping partners in the past 6 months	6 months	IG1	Overall	0	215/602 (35.5)	97/243 (39.9)	OR: 40.21 (25.65 to 63.05)*	<0.05
					Overall	12	111/452 (24.6)	52/183 (28.4)	OR: 0.73 (0.54 to 0.99)	0.045
		Concurrent partner in the past 6 months	6 months	IG1	Overall	0	30/605 (5.0)	89/243 (36.6)	OR: 0.09 (0.06 to 0.14)*	0.51
					Overall	12	68/452 (15.0)	32/183 (17.5)	OR: 0.55 (0.37 to 0.83)	0.005
Ybarra, 2017 ¹⁵⁹	Sexual abstinence	Abstinence in that last 90 days	3 months	IG1	Overall	0	68/137 (49.6)	75/146 (51.4)	OR: 0.93 (0.59 to 1.49)*	0.49
					Overall	3	80/137 (58.4)	94/146 (64.4)	OR: 0.63 (0.36 to 1.12)	NSD
					Sexually experienced	3	23/69 (33.3)	33/71 (46.5)	OR: 0.48 (0.23 to 1.00)	<0.05
					Sexually inexperienced	3	57/68 (83.8)	61/75 (81.3)	OR: 0.98 (0.38 to 2.53)	NSD

* Calculated estimate from reported raw study data. P-values are based on statistical analyses reported in the published study results

† 3-month differences are available in publication

Abbreviations: BC = birth control; BL = baseline; Calc = calculated; CG = control group; Diff = difference; F/U = followup; IG = intervention group; Int = intervention; IRRnegbin = incidence rate ratio, negative binomial regression; mos = months; n = number of participants; NR = not reported; NSD = no significant

Appendix E Table 7. Other Sexual Behaviors: Adolescents and Young Adults

difference; OR = odds ratio; RR Poisson = relative risk, Poisson regression; SD = standard deviation; STI = sexually transmitted infection; VEE = vaginal equivalent episodes.

Appendix E Table 8. Other Sexual Behaviors: Adults*

Study	Outcome	Outcome description	Recall period	Int arm	Group	F/U mos	IG n (%) or Mean (SD), n	CG n (%) or Mean (SD), n	Result (95%CI)	P-value
Berkman, 2007 ¹⁰⁸	Vaginal sex acts	Percent of sexual acts which were vaginal	3 months	IG1	Sexually active at BL	8	100 (0), 53	89 (30.0), 53	MeanDiff: 10.90 (2.82 to 18.98) [†]	0.10
						14	100 (0), 53	78.4 (37.6), 53	MeanDiff: 21.70 (11.58 to 31.82) [†]	0.01
Carey, 2004 ¹¹¹	Sex partners	Number of sexual partners	3 months	IG1	Overall	6	1 (.8), 123	1.2 (1.2), 110	MeanDiff: -0.19 (-0.45 to 0.07) [†]	0.037
						9	1 (.8), 123	1 (1.4), 110	GEE: -0.15 (-0.32 to 0.01)	
Carey, 2010 ¹¹²	Sex partners [‡]	Number of sexual partners in the past 3 months, mean (SD)	3 months	IG1	Overall	6	2 (1.8), 178	2 (1.8), 184	MeanDiff: -0.10 (-0.47 to 0.27) [†]	
						12	2 (1.4), 166	1.8 (1.6), 172	MeanDiff: 0.10 (-0.21 to 0.41) [†]	
				IG2	Overall	6	2 (2), 197	2 (1.8), 184	MeanDiff: 0.00 (-0.38 to 0.38) [†]	
						12	2 (1.8), 176	1.8 (1.6), 172	MeanDiff: 0.10 (-0.24 to 0.44) [†]	
				IG3	Overall	6	2 (2), 176	2 (1.8), 184	MeanDiff: 0.00 (-0.39 to 0.39) [†]	
						12	1.8 (1.6), 180	1.8 (1.6), 172	MeanDiff: 0.00 (-0.31 to 0.31) [†]	
				IG4	Overall	6	1.8 (1.8), 186	2 (1.8), 184	MeanDiff: -0.20 (-0.56 to 0.16) [†]	
						12	1.8 (1.2), 172	1.8 (1.6), 172	MeanDiff: -0.20 (-0.50 to 0.10) [†]	
				IG5	Overall	6	2 (2.2), 180	2 (1.8), 184	MeanDiff: 0.00 (-0.41 to 0.41) [†]	
						12	1.8 (1.6), 178	1.8 (1.6), 172	MeanDiff: 0.00 (-0.32 to 0.32) [†]	
Carey, 2015 ¹¹³	Sex partners	Number of sexual partners	3 months	IG1	Overall	6	2 (2), 250	2 (2), 254	MeanDiff: 0.17 (-0.19 to 0.53) [†]	
						12	1.8 (1.6), 250	1.8 (1.6), 254	MeanDiff: 0.06 (-0.22 to 0.34) [†]	
				IG2	Overall	6	2.2 (1.8), 252	2 (2), 254	MeanDiff: 0.26 (-0.07 to 0.59) [†]	
						12	1.8 (1.4), 252	1.8 (1.6), 254	MeanDiff: -0.05 (-0.31 to 0.21) [†]	
				IG3	Overall	6	2.2 (2), 254	2 (2), 254	MeanDiff: 0.26 (-0.10 to 0.62) [†]	
						12	1.8 (1.4), 254	1.8 (1.6), 254	MeanDiff: -0.06 (-0.32 to 0.20) [†]	

Appendix E Table 8. Other Sexual Behaviors: Adults*

Study	Outcome	Outcome description	Recall period	Int arm	Group	F/U mos	IG n (%) or Mean (SD), n	CG n (%) or Mean (SD), n	Result (95%CI)	P-value
Petersen, 2007 ¹⁴⁹	Consistent contraceptive use	Percent consistent use of contraception	1 month	IG1	Overall	0	215/365 (58.9)	216/372 (58.1)	OR: 1.04 (0.77 to 1.39) [†]	NSD
						8	167/265 (63.0)	231/372 (62.1)	OR: 1.04 (0.75 to 1.44) [†]	NSD
						12	234/365 (64.1)	223/372 (59.9)	OR: 1.19 (0.89 to 1.61) [†]	NSD
					Black	12	16/27 (59.3)	15/28 (53.6)	OR: 1.26 (0.43 to 3.67) [†]	NSD

* Four studies did not exclude adolescents, but primarily recruited adults and the mean age in the study populations was above 25 years

[†] Calculated estimate from reported raw study data. P-values are based on statistical analyses reported in the published study results

[‡] Other time points reported in the publication

Abbreviations: BL = baseline; Calc = calculated; CI = confidence interval; CG = control group; Diff = difference; F/U = followup; GEE = generalized estimating equation; IG = intervention group; Int = intervention; Mo = months; n = number of participants; NR = not reported; NSD = no significant difference; OR = odds ratio; SD = standard deviation; VEE = vaginal equivalent episodes.

Appendix E Table 9. Detailed Intervention Descriptions

Author, year	Int arm	Intervention name	Brief description	Detailed description	Control
Bai, 2018 ¹⁶⁰	IG1	Healthy Teens	Ten 60-minute in-person sessions	The intervention aimed to target risk and protective factors for the development of health risk behaviors. (HRBs) For participants who were engaging in fewer HRBs, intervention sessions emphasized prevention, potential triggers, and pressures that the participants might confront, and reinforced healthy choices. For participants presenting with multiple HRBs, the intervention targeted the behaviors and promoted competing healthier behaviors. The intervention took place over 10, 60 min weekly sessions. In the first session an initial intervention plan was developed with the care manager and the primary care physician was contacted to review and finalize the plan. Two-session long modules covered each of the 4 HRBs: smoking, alcohol/drug use, unsafe sexual practices, and obesity/diet/exercise. The order of modules was based on patient priorities and goals identified during the initial session. The final session focused on reviewing and reinforcing change, and developing a plan for continued progress. Overall, the intervention focused on: 1) strengthening motivation to engage in health behavior by increasing awareness of negative consequences of HRBs, encouraging youth to consider their goals and values, and disrupting the automaticity of HRB sequences; 2) increasing awareness of affective, thought, and situational/environmental triggers; 3) introducing & practicing competing cognitive and behavioral responses to these triggers; and 4) modeling and coaching behaviors that support a healthy lifestyle.	Usual care
Bailey, 2016 ¹⁰⁵	IG1	Men's Safer Sex	One 10-minute website visit	Computer-based interaction with Men's Safer Sex website while in the clinic waiting room; and website included setting goals to change behavior. Participants were able to access the website after leaving the clinic for a duration of 12 months. Tailored information based on individual responses regarding barriers to condom use will be presented most prominently on the homepage when return to website. Monthly e-mails were sent as reminders about their set goals and to visit the website.	Usual care
Berenson, 2012 ¹⁰⁷	IG1	NA	One 45 minute, individual, clinic-based counseling session + >6 phone calls	One-on-one, clinic-based counseling for 45 minutes delivered by a research assistant. Counselors used education and behavioral techniques based on the health belief model, geared toward lower health literacy. Components included (1) handouts with instructions for birth control pills and condom use, (2) verbally reviewing instructions using visual aids, (3) developing a cue to assist with adherence to oral contraceptives, (4) discussing pregnancy risk, (5) discussing non-contraceptive beliefs of birth control pills, (6) discussing side effects, (7) discussing STIs and need for condom use, (8) practicing condom application and discussion condom negotiation skills. In addition, participants were contacted weekly until they began their OC and then monthly for 6 months by a contraceptive counselor to review correct use, missed doses, side effects, and importance of condom use, average 8 calls total.	Usual care

Appendix E Table 9. Detailed Intervention Descriptions

Author, year	Int arm	Intervention name	Brief description	Detailed description	Control
	IG2	NA	One 45 minute, individual, clinic-based counseling session	One-on-one, clinic-based counseling for 45 minutes delivered by research assistant. Counselor used education and behavioral techniques based on health belief model and geared toward lower health literacy. Components included (1) handouts with instructions for birth control pills and condom use, (2) verbally reviewing instructions using visual aids, (3) developing a cue to assist with adherence to oral contraceptives, (4) discussing pregnancy risk, (5) discussing noncontraceptive beliefs of birth control pills, (6) discussing side effects, (7) discussing STIs and need for condom use, (8) practicing condom application and discussion condom negotiation skills.	Usual care
Berkman, 2007 ¹⁰⁸	IG1	Enhanced SexG (E-SexG)	Thirteen 60-minute, group counseling sessions	E-SexG intervention aimed to decrease episodes of high-risk sex through increased condom use. The intervention was designed specifically for mentally ill men, incorporating lessons from clinical experience, ethnographic research, and the feedback of those participating in the original SEXG intervention (Susser & Gonzalez, 1992; Susser et al., 1993). Decision-making skills and strategies to overcome obstacles to condom use were presented in relevant and socially appropriate contexts. Participants related exercises to their own past and current sexual experiences and rehearsed safer sexual behaviors both within and outside the group session. E-SexG consisted of ten one-hour sessions. The first eight were held twice a week for four weeks followed by a 4-week break, after which the last two sessions were held. Session 1: building group cohesion and comfort; Session 2: discuss personal stories, condom use role playing, negotiation skills; Session 3: increase intent to use condoms; Session 4: identify/solve barriers to condom use; Session 5: better response to condom use request by partner; Session 6: increase awareness of UVI/UAI; Session 7: confidence and ability to have safe sex; Session 8: develop goals; Session 9: reviewing goals and problem solving skills; Session 10: increase goals, commitment, problem solving skills. Booster sessions at 3, 6, and 9 months after intervention completion to reduce behavioral decay; participants recalled past 3-month sexual history, brainstormed solutions to risk sex behaviors. Manualized curriculum.	Attention control (one HIV presentation that emphasized condom use [time NR] + 13 money management sessions)

Appendix E Table 9. Detailed Intervention Descriptions

Author, year	Int arm	Intervention name	Brief description	Detailed description	Control
Billings, 2015 ¹¹⁰	IG1	Safe Sistah	1 computer-based educational session	Computer-based intervention that was fully audio-narrated with a wide range of multimedia elements including video, interactive exercises, and quizzes; participants were given personalized log-in information, a new set of ear buds, and a list of free internet sites; they had 1 month to view Safe Sistah. Women were provided their personalized risk reduction plan and received training based on their risk profile. The principal aim of the intervention was to teach women HIV prevention skills adapted to the specific challenges they face in their daily lives. Condom negotiation, particularly in steady relationships, was a key focus. Additionally, the intervention aimed to teach women how to refuse sex in a way that minimizes the potential for intimate partner violence, as well as, the negative influence of alcohol & other drugs on effective communication and condom use was emphasized along with alternative strategies to manage those situations. There was also messages of gender empowerment and positive racial identity delivered through the program.	Waitlist
Carey, 2004 ¹¹¹	IG1	NA	Ten group counseling sessions	Patients attended a twice weekly HIV prevention group for 5 weeks. Sessions sought to enhance patient's knowledge, motivation and behavioral skills about risky sexual behavior. Sessions included information (e.g., sexual HIV transmission basics, assessing partner risks, value of HIV testing and counseling); motivational exercises to increase risk awareness and sensitization, encourage identification of pros/cons of risk reduction strategies and identify behavior change options; discuss social norms regarding risk and safer sex and encourage mutual social support for risk reduction; and exercises to develop safer sex, self-management, condom negotiation and sexual assertiveness skills; prepare patients to obtain, store and use condoms correctly (IMB model); develop coping strategies and self-efficacy for dealing with high-risk situations. Included homework and interactive role playing. Used a motivational interviewing approach, including elements of the FRAMES (Feedback for personal risk, emphasized personal Responsibility for change, provide clear Advice to change, provided a Menu of change options, demonstrated Empathy, and encouraged participants' Self-efficacy and optimism for change).	Usual care

Appendix E Table 9. Detailed Intervention Descriptions

Author, year	Int arm	Intervention name	Brief description	Detailed description	Control
Carey, 2010 ¹¹²	IG1	NA	One 15-minute individual counseling session + 4 hour intensive motivational, behavioral, skills workshop	Based on Transtheoretical Model, tailored to each patient. Open-ended questions used to understand patient's life circumstances, sexual risk behaviors, and stage-of-change for risk reduction' counseling appropriate to the patient's stage was delivered; condom use and attendance at intensive intervention emphasized. Participants also invited to workshop; they were called until reached to encourage attendance. Workshop included three components: information, motivation and behavioral skills. Information: HIV transmission and prevention information. Motivation: received local HIV/STD rates; watched a video of infected HIV individuals and discussed what it would be like; placed cards with sexual behaviors along a risk continuum, discussed basis for each appraisal, and reflected on own sexual behaviors. Behavior skills: engaged in interactive exercises to learn personal triggers for risky sex, strategies for managing triggers, talk with partner about condom use and safer sexual behaviors, apply condom; role-playing allowed practice of skills. Workshop concluded with goal setting and a review.	Minimal intervention (one 15-minute education intervention with clinic nurse)
	IG2	NA	One 15-minute individual counseling session + 4-hour intensive informational workshop	Based on Transtheoretical Model, tailored to each patient. Open-ended questions used to understand patient's life circumstances, sexual risk behaviors, and stage-of-change for risk reduction' counseling appropriate to the patient's stage was delivered; condom use and attendance at intensive intervention emphasized. Participants also invited to workshop; they were called until reached to encourage attendance. Intensive informational workshop included information about HIV/STD transmission, prevention, testing and treatment. Facilitators distributed cards about HIV/STD. Participants took turns reading statements aloud, and then discussed statements. Participants placed cards labelled with different sexual activities along a risk continuum. Workshop concluded with a Q&A gameshow covering workshop content.	Minimal intervention (one 15-minute education intervention with clinic nurse)
	IG3	NA	One 15-minute individual counseling session	Based on Transtheoretical Model, tailored to each patient. Open-ended questions used to understand patient's life circumstances, sexual risk behaviors, and stage-of-change for risk reduction' counseling appropriate to the patient's stage was delivered; condom use and attendance at intensive intervention emphasized.	Minimal intervention (one 15-minute education intervention with clinic nurse)

Appendix E Table 9. Detailed Intervention Descriptions

Author, year	Int arm	Intervention name	Brief description	Detailed description	Control
	IG4	NA	One 15-minute informational video + 4-hour intensive informational workshop	Brief-information intervention delivered via DVD in a private room. DVD content adapted from a validated intervention and included information about HIV and STI, testing, sexual risk reduction options presented in an engaging and culturally appropriate style. DVD also stated attending educational and safer sex workshops could help people stay healthy. Nurse met briefly with patients and asked a series of close-ended questions to assess sexual risk behavior and stage-of-change for risk reduction. Participants also invited to workshop; they were called until reached to encourage attendance. Intensive informational workshop included information about HIV/STI transmission, prevention, testing and treatment. Facilitators distributed cards about HIV/STI. Participants took turns reading statements aloud, and then discussed statements. Participants placed cards labelled with different sexual activities along a risk continuum. Workshop concluded with a Q&A gameshow covering workshop content.	Minimal intervention (one 15-minute education intervention with clinic nurse)
	IG5	NA	One 15-minute informational video + 4 hour intensive motivational, behavioral, skills workshop	Brief-information intervention delivered via DVD in a private room. DVD content adapted from a validated intervention and included information about HIV and STD, testing, sexual risk reduction options presented in an engaging and culturally appropriate style. DVD also stated attending educational and safer sex workshops could help people stay healthy. Nurse met briefly with patients and asked a series of close-ended questions to assess sexual risk behavior and stage-of-change for risk reduction. Participants also invited to workshop; they were called until reached to encourage attendance. Workshop included three components: information, motivation and behavioral skills. Information: HIV transmission and prevention information. Motivation: received local HIV/STD rates; watched a video of infected HIV individuals and discussed what it would be like; placed cards with sexual behaviors along a risk continuum, discussed basis for each appraisal, and reflected on own sexual behaviors. Behavior skills: engaged in interactive exercises to learn personal triggers for risky sex, strategies for managing triggers, talk with partner about condom use and safer sexual behaviors, apply condom; role-playing allowed practice of skills. Workshop concluded with goal setting and a review.	Minimal intervention (one 15-minute education intervention with clinic nurse)

Appendix E Table 9. Detailed Intervention Descriptions

Author, year	Int arm	Intervention name	Brief description	Detailed description	Control
Carey, 2015 ¹³	IG1	NA	One 22 min video + sexual health questionnaire	Participants viewed a sexual health-focused video which lasted 22 min. The video included didactic segments, one-on-one interviews, and dramatic segments which contained risk reduction messages. Actors, images, and music were selected to appeal to an urban and youthful sensibility. To promote condom use and reduce the number of partners, the intervention targeted IMB constructs. Informational components included data regarding HIV and STI rates, and facts about HIV transmission and prevention. Motivational elements were addressed through vignettes based on formative research. Characters identified barriers to condom use (e.g., condoms reduce pleasure and imply a lack of trust) and to partner reduction (e.g., a man's nature is to have multiple partners), and also provided suggestions for overcoming these barriers. Skills elements were addressed through a demonstration of the correct way to use male and female condoms and a dramatic segment demonstrating how to discuss condom use with a partner. Although the intervention portrayed heterosexual couples, the risk reduction strategies were appropriate to men and women, regardless of age or sexual orientation. Additionally, participants responded to items assessing sexual history, as well as constructs identified by the IMB model of health behavior change, including informational, motivational, and behavioral skills measures. Lastly, they had a physical examination, STI/HIV testing, and medical treatment (if indicated).	Attention control (general health video + general health questionnaire)
	IG2	NA	One 22 min video + general health questionnaire	Participants viewed a sexual health-focused video which lasted 22 min. The video included didactic segments, one-on-one interviews, and dramatic segments which contained risk reduction messages. Actors, images, and music were selected to appeal to an urban and youthful sensibility. To promote condom use and reduce the number of partners, the intervention targeted IMB constructs. Informational components included data regarding HIV and STI rates, and facts about HIV transmission and prevention. Motivational elements were addressed through vignettes based on formative research. Characters identified barriers to condom use (e.g., condoms reduce pleasure and imply a lack of trust) and to partner reduction (e.g., a man's nature is to have multiple partners), and also provided suggestions for overcoming these barriers. Skills elements were addressed through a demonstration of the correct way to use male and female condoms and a dramatic segment demonstrating how to discuss condom use with a partner. Although the intervention portrayed heterosexual couples, the risk reduction strategies were appropriate to men and women, regardless of age or sexual orientation. Additionally, participants responded to items assessing detailed diet, physical activity, sleep, alcohol use, drug use, smoking, social support, and neighborhood disorder and violence. Lastly, they had a physical examination, STI/HIV testing, and medical treatment (if indicated).	Attention control (general health video + general health questionnaire)

Appendix E Table 9. Detailed Intervention Descriptions

Author, year	Int arm	Intervention name	Brief description	Detailed description	Control
	IG3	NA	One 22 min video + sexual health questionnaire	Participants viewed a general health video which lasted 22 min. The content was focused on physical activity, healthy eating, smoking, alcohol use, managing stress, and (very briefly) safer sex. The video included didactic segments, one-on-one interviews, and dramatic segments which contained risk reduction messages. Actors, images, and music were selected to appeal to an urban and youthful sensibility. Additionally, participants responded to items assessing sexual history, as well as constructs identified by the IMB model of health behavior change, including informational, motivational, and behavioral skills measures. Lastly, they had a physical examination, STI/HIV testing, and medical treatment (if indicated).	Attention control (general health video + general health questionnaire)
Champion, 2012 ¹⁶	IG1	Project SAFE	Two 3-4-hour group counseling sessions, 2 or more individual counseling sessions, 3-5 optional support group sessions	All participants received enhanced clinical counseling which included asking participants if they took all their medicine, if they had sex before completing treatment, if their partner was treated, and if they had sex with him either before or during treatment. Physical exam and semi-structured one-to-one interview at entry, 6- and 12-month followup (1.5-2-hour duration), two workshop sessions initiated 1-3 weeks after entry (4-8 participants, 3-4 hours in duration, one per week), conducted in round table format using motivational interviewing principles. Session 1 (awareness and perception of risk): raise awareness of personal risk, illustrate risks, discuss general STI and transmission routes, discuss selection of sex partners, discuss unintended pregnancy. Session 2 (commitment to change, strategies to reduce risk behavior): discuss how STI and unintended pregnancy can be prevented, discussion with sexual partner, importance of completing STI treatment, reflect on romantic relationships, share sexual decision-making skills, empathize how bx can change patient life, discuss how to find support, reflect on knowledge and goals. Problem solving followup visits as needed. Weekly (3-5) support group sessions started 1 week after completion of both workshops. Two or more individual counseling sessions as initiated by participant to focus on expressed needs.	Minimal intervention (one session of clinical counseling surrounding STI treatment [time NR] with nurse practitioner)

Appendix E Table 9. Detailed Intervention Descriptions

Author, year	Int arm	Intervention name	Brief description	Detailed description	Control
Costa, 2017 ¹¹⁷	IG1	NA	Six 120-minute group counseling sessions	Six small group sessions (7-10 women; 2 hours/session) presented over 2 months. During first four sessions, videos (20-25 min per session) were watched to expose higher levels of confrontation with a man in relation to sexual and romantic affairs; and to facilitate engagement and to reduce attrition. Then, participants practiced what they saw; and practiced negotiation techniques using mental and behavioral rehearsal. Negotiation components of sessions 1 to 4 included (1) requesting sex with condom; (2) explaining rationale to partner; (3) anticipating likely response from partner and one's own reaction; (4) pursue goal with firmness, not aggressive; (5) understand partner's goals; (6) expressing concern for the goals and needs of the partner, and (7) finding compromise to meet the partner's needs without compromising safe sex. In addition, women learned how specifically defuse escalating conflict with negotiation techniques and avoidance of bodily harm. In sessions 5 and 6, participants were asked to present difficult past situations and the group leader used mental rehearsal of successful performance and behavioral rehearsal to practice the learned negotiation skills.	Waitlist
	IG2	NA	Two 15-minute individual counseling sessions, informational	Two informational one-on-one sessions over one month. Focused on enhancing knowledge about safe sex and STI risk, including a discussion on the myths, etiology, and epidemiology of HIV. Sessions included reviewing a list of risk factors, stressing behaviors that can endanger like (1) multiple partners, (2) nonuse of condoms, (3) partner-associated risk signals (e.g., drug use, dating other women, etc.), and (4) unsafe sexual behaviors. Two HIV prevention brochures given during the first session. Female facilitator encouraged participants to meet their goals but without engaging them in interactive counseling.	Waitlist

Appendix E Table 9. Detailed Intervention Descriptions

Author, year	Int arm	Intervention name	Brief description	Detailed description	Control
Crosby, 2009 ¹¹⁸	IG1	Focus on the Future	One 45-50-minute individual counseling session, variety of condoms and water-based lubricant	Predicated on the information, motivation, and behavioral skills model. Men learned about variety of condoms, water-based lubricant better than oil-based (showed how oil-based can deteriorate condom); encouraged to feel good about using condoms, that they are compatible with sexual pleasure, and that they protect them from acquiring STDs. Men allowed to respond to HIV/AIDS burden posters in which advisor responded to questions, problems and concerns regarding safer sex with female partners. Men prompted to think about ways to initiate condom use and skill acquisition (demonstration of correct condom use and lubricant application). Men encouraged to use condoms that fit well and provided a sense of security. Men provided with water-based lubricants and 12+ condoms of any brand and size. Also received nurse delivered messages regarding condom use per CDC guidelines (few minutes) informing them that condoms effective at preventing STDs and additional 12+ condoms of one particular size and brand. The intervention was delivered by a "lay advisor" who was a young African American male who had grown up & resided in the main catchment area served by the clinic, selected based on his ability to discuss sex & condom use in a nonjudgmental manner.	Minimal intervention ("few minutes" of messaging based on CDC guidelines with nurse + 12 free condoms)
DiClemente, 2004 ¹¹⁹	IG1	HORIZONS	Four 4-hour group counseling sessions	Four 4-hour interactive group sessions implemented on consecutive Saturdays at a family medicine clinic; 10-12 participants per group. Implemented by a trained African American female health educator and 2 African American female peer educators. Content based on social cognitive theory and theory of gender and power. Session 1: ethnic and gender pride; session 2: enhanced awareness of HIV risk reduction strategies (e.g., abstinence, consistent condom use, fewer sexual partners); session 3: role-play and cognitive rehearsal to enhance confidence in initiating safer-sex conversations, negotiating safer sex, refusing unsafe sex, modeling condom use; session 4: importance of healthy relationships.	Attention control (four 4-hour health promotion group sessions)
Ehrhardt, 2002 ¹⁰²	IG1	NA	Eight 2-hour group counseling sessions	Eight session gender-specific HIV/STD risk reduction strategy based on the AIDS Risk Reduction Model and designed to decrease unsafe sexual practices among women. Each group session lasted 2 hours; one topic was covered per session. Topics included caring about getting HIV/STDs, avoiding partners who don't care, best ways to protect self, resource to find out if infected, ways to ask and influence partner to use protection, ways to refuse sex/unprotected sex, and ways to continue protecting self and others. Group activities included: role-playing, problem solving, letter writing, attitude confrontation, storytelling, and modeling. A two-hour booster session was provided 9 months after baseline to review progress, take pride in achievements, receive assistance, help other group members and be renewed by the group's support (From Miller 2000). Female condoms were provided and discussed in a session and made available to participants in future sessions if desired (From Hoffman 2003).	None

Appendix E Table 9. Detailed Intervention Descriptions

Author, year	Int arm	Intervention name	Brief description	Detailed description	Control
	IG2	NA	Four 2-hour group counseling sessions	Four session gender-specific HIV/STD risk reduction strategy based on the AIDS Risk Reduction Model and designed to decrease unsafe sexual practices among women. Each group session lasted 2 hours; two topics were covered per session. Topics included caring about getting HIV/STDs, avoiding partners who don't care, best ways to protect self, resource to find out if infected, ways to ask and influence partner to use protection, ways to refuse sex/unprotected sex, and ways to continue protecting self and others. To make this version of the intervention as similar as possible to the 8-session intervention, the same topic areas were covered and less time was spent on group exercises. Group activities included: role-playing, problem solving, letter writing, attitude confrontation, storytelling, and modeling. Female condoms were provided and discussed in a session and made available to participants in future sessions if desired (From Hoffman 2003).	None
Free, 2016 ¹²²	IG1	NA	49 to 63 text messages tailored to participant characteristics (gender, STI)	Over a 1-year period, 49 to 63 text messages employing specific intervention functions and behavior change techniques were tailored according to gender and infection status (no infection, chlamydia, gonorrhea, or non-specific urethritis) at time of enrollment. The messages were delivered automatically, directly to participants' mobile phone. Additional tailoring enabled participants to choose a daily time period when they did not want messages delivered. The messages were delivered at different frequencies and spacing for those diagnosed with STI vs those with no infection. The message sets for those diagnosed with STI were similar to each other, except that the information provided was specific to the STI diagnosed. For the first two weeks, text messages to those with STI focused on engaging with the study, getting treatment, taking treatment, providing information and telling partner(s) about an infection. The messages then provided links to services that could inform partners and links to support for anyone concerned about violence in their relationship after telling a partner about an infection. After day 14 the messages targeted condom use and testing for STIs before having unprotected sex with a new partner, employing the same messages as for those who were not diagnosed with an infection: how to prevent infections and how to assess risk according to how well know someone or by their appearance; instructions on how to use condoms; emphasis on positive aspects of condom use; and tips on preventing condom problems. Participants were prompted to think about risks that they had taken and what they could do differently in the future and also to consider how they had carried out safer sexual behaviors in the past. Text messages included advice regarding getting tested before unprotected sex with a new partner. Participants were also sent links to further web-based information regarding contraception, alcohol and sexual risk, how to use a condom and general communication about sex. Women were sent messages covering how other women had negotiated condom use. The messages were designed to provide social support for safer sexual behaviors.	Attention control (13 text messages spaced 30 days apart)

Appendix E Table 9. Detailed Intervention Descriptions

Author, year	Int arm	Intervention name	Brief description	Detailed description	Control
Guilamo-Ramos, 2011 ¹²⁵	IG1	Families Talking Together (FTT)	Mother received one 30-minute individual counseling session + program manual + 2 phone calls	After completing baseline questionnaire, mothers met with a social worker for 30 minutes and were provided with a packet containing reference materials and family activities to take home and use with child (homework assignments). Packet was a written manual that taught parents effective communication and parenting strategies for reducing adolescent sexual risk behavior. It included nine modules addressing adolescent development and self-esteem, parental self-efficacy to communicate, general parenting strategies, ways to improve the parent-adolescent relationship and communication, adolescent assertiveness skills and techniques for dealing with peer pressure, adolescent sexual behavior, health consequences of sexual risk taking, and birth control and protection. Also included two communication aids. After child completed physician exam, mother met with physician to discuss exam and physician provided a brief endorsement of the Family Talking Together program. Mothers received two booster calls 1 month and 5 months after intervention to determine whether the mother had reviewed the intervention materials and implemented the materials and activities with their adolescent child. Social work interventionist answered any questions the mother had regarding the materials and encouraged the mother to work with the materials.	Usual care
Jemmott, 2005 ¹²⁷	IG1	Be Proud! Be Responsible!	One 250 minutes group counseling session, skills-based	Based on cognitive behavioral theories and previous research with individuals from the study population. Designed to be culturally and developmentally appropriate for inner-city African American and Latino adolescent girls. The intervention involved 250 minutes of group discussions, videotapes, games, and experimental exercises implemented in a single session with 2-10 participants. The information addressed the elevated risk of HIV and STD among inner-city African American and Latino young women, personal vulnerability to HIV and STD, HIV transmission, messages about sex, responsibility for risk reduction in relationships, the importance of using condoms, and the belief that condoms interfere with sexual enjoyment. In addition, participants practiced the skills needed to use condoms by handling condoms, practicing correct use of condoms with anatomical models, and role-playing to increase skill in negotiating the use of condoms.	Attention control (one 4-hour group health promotion session)

Appendix E Table 9. Detailed Intervention Descriptions

Author, year	Int arm	Intervention name	Brief description	Detailed description	Control
	IG2	Be Proud! Be Responsible!	One 250-minute group counseling session, information-based	Based on cognitive behavioral theories and previous research with individuals from the study population. Designed to be culturally and developmentally appropriate for inner-city African American and Latino adolescent girls. The intervention involved 250 minutes of group discussions, videotapes, games, and experimental exercises implemented in a single session with 2-10 participants. The information in this intervention group addressed the elevated risk of HIV and STD among inner-city African American and Latino young women, personal vulnerability to HIV and STD, HIV transmission, messages about sex, responsibility for risk reduction in relationships, the importance of using condoms, and the belief that condoms interfere with sexual enjoyment. HIV educational videotapes showed correct condom use.	Attention control (one 4-hour group health promotion session)
Jemmott, 2007 ¹²⁸	IG1	Sister to Sister	One 200-minute group counseling session, skills-based	Based on social cognitive theory. 200-minute session with 3 to 5 participants. Designed to increase skills regarding condom use, to allay participants concerns about the adverse effects of condom use on sexual enjoyment, group discussions, brainstorming, videos, interactive exercises, games, condom demonstrations, practice and role playing to increase self-efficacy and skills related to correct use of condoms and negotiation of condom use with sexual partners.	Attention control (general health promotion)
	IG2	Sister to Sister	One 200-minute group counseling session, information-based	Based on social cognitive theory, 200-minute session with 3 to 5 participants. Designed to increase perception of vulnerability to HIV/STDs, increase knowledge about transmission and prevention of HIV/STD. Involved group discussions, brainstorming, videos, interactive exercises and games. Did not provide behavioral skills demonstrations, practice or address participants beliefs about adverse effect of condom use on sexual enjoyment.	Attention control (general health promotion)
	IG3	Sister to Sister	One 20-minute individual counseling session, skills-based	Based on social cognitive theory 20-minute session tailored to the specific needs of each participant. Designed to increase skills regarding condom use; review of HIV/STD brochure, video clips, condom demonstration, practice, and role playing to increase self-efficacy and skill related to correct condom use and negotiation of condom use with partner.	Attention control (general health promotion)
	IG4	Sister to Sister	One individual, 20-minute counseling session, information-based	Based on social cognitive theory 20-minute session tailored to the specific needs of each participant. Designed to increase knowledge about HIV/STD transmission, prevention and personal vulnerability; reviewed HIV/STD prevention brochure and discussion of basic HIV/STD risk reduction information. No behavioral skill demonstrations or practice.	Attention control (general health promotion)

Appendix E Table 9. Detailed Intervention Descriptions

Author, year	Int arm	Intervention name	Brief description	Detailed description	Control
Kershaw, 2009 ¹²⁹	IG1	Centering Pregnancy Plus	Ten 120-minute group counseling sessions	Prenatal care within a group setting, curriculum provided by a trained practitioner. 10 sessions (2 hours each) during pregnancy cover self-care activities such as weight and blood pressure assessment, group discussion to address issues in prenatal care, childbirth preparation, and postpartum care. Included three sessions (sessions 4, 5, and 7) where 40 minutes were devoted to HIV prevention skills; based on social cognitive theory and the ecological model. Session 4, participants watched testimonials of HIV adolescents, discussed barriers and benefits to condom use, personalized HIV/STI risk, set safe sex behavior goals. Session 5, developed sexual partner communication skills through role-playing and modeling. Session 7, reinforced communication skills through role play and modeling, evaluated goals and set new goals for safe sexual behavior after pregnancy.	Usual care
Lewis, 2018 ¹³²	IG1	NA	One 5-minute computer web-based personalized feedback session	The intervention consisted of the same feedback components (i.e., norms, expectancies, alcohol myopia, protective behavioral strategies), but information on alcohol was not integrated into the feedback on sexual behavior and vice versa. Components were presented without the discussion of the influence of alcohol on risky sexual behavior.	Attention control (feedback on health-related behaviors [e.g., nutrition, exercise])

Appendix E Table 9. Detailed Intervention Descriptions

Author, year	Int arm	Intervention name	Brief description	Detailed description	Control
	IG2	NA	One 5-minute computer web-based integrated personalized feedback session	<p>Upon completion of the baseline survey, participants were sent a link that routed them to their feedback. Participants were also sent an email inviting them to view their feedback at any time. The feedback synthesized alcohol use components specific to sexual behavior (e.g., normative comparisons for the number of drinks consumed prior to sex) and risky sexual behavior (RSB) components related to alcohol (e.g., condom-related protective behavioral strategies when drinking), which were drawn from previously efficacious web-based interventions, by presenting feedback highlighting how these behaviors relate. Descriptive normative comparison components consisted of alcohol-related RSB normative comparisons and highlighted discrepancies between the participant's own alcohol related RSB and alcohol-related RSB normative perceptions as compared to the normative referent's (i.e., typical person your age and biological sex) actual alcohol-related sexual behavior. Feedback was presented about positive alcohol outcome expectancies (i.e., effects attributed to drinking that the participant sees as positive and likely to happen after consumption of alcohol) specific to sexual behavior to highlight discrepancies between participants' expectations regarding alcohol-related RSB and the actual outcomes associated with alcohol use and sexual behavior. Feedback included corrective information about commonly held positive expectancies related to alcohol and its role in sexual behavior (e.g., alcohol's role in sexual functioning and pleasure) and in particular addressed the positive expectancies that the participant endorsed. Feedback included information on alcohol myopia by addressing alcohol use in sexual contexts that emphasized the important role of intoxication as a barrier to risk reduction in sexual situations. Feedback highlighted how the use of protective behavioral strategies may increase the ability to avoid self-defined "bad" things that may result from drinking or engaging in alcohol-related RSB in a high-risk scenario and in general. Participants were asked to read a scenario involving the potential for them to use alcohol and to engage in risky sex. Participants received a summary of their self-reported likelihood to engage in risk behaviors as well as skill training tips in order to avoid these risk behaviors in response to the risk-conducive situation in the alcohol and risky sex scenario.</p>	Attention control (feedback on health-related behaviors [e.g., nutrition, exercise])

Appendix E Table 9. Detailed Intervention Descriptions

Author, year	Int arm	Intervention name	Brief description	Detailed description	Control
Marrazzo, 2011 ¹³⁵	IG1	NA	One 30-minute individual counseling session	<p>Using a motivational interviewing approach and the Health Belief Model as a framework, patients were instructed on how to employ behaviors aimed at reducing the likelihood of transferring vaginal fluid to female partners during sex and providing safe sex kits (male condoms, nitrile gloves, water-based lubrication). Behaviors targeted included use of gloves during digital-vaginal sex, use of a condom if insertive toys were shared and use of lubricant provided or another water-based lubricant. Participants were treated with vaginal metronidazole.</p> <p>The intervention addressed the 4 factors that the HBM postulates to account for variation in health behavior as follows. To address perceived susceptibility to BV, participants were educated about the relatively high prevalence of BV among women reporting sex with other women and the high degree of concordance of BV within monogamous female sexual partnerships. Perceived severity was addressed by educating participants on the symptoms of BV and its consequences. To address perceived benefits, the interventionists emphasized the benefits of treating and preventing BV, including the possibility of the reduced likelihood of BV transmission to female sex partners. Finally, perceived barriers to implementing the behavioral intervention were explored with participants, including ways to incorporate cleaning sex toys or using male condoms on sex toys into participants' sexual routines.</p>	Minimal intervention (education session on pap smears with study staff)
Metsch, 2013 ¹³⁷	IG1	RESPECT-2	One 30-minute individual counseling session + HIV testing	<p>Participants in the RESPECT-2 intervention group received a rapid HIV test and individual patient-centered risk-reduction counseling. The counseling included a discussion of the patient's specific HIV/STI risk behaviors and negotiation of achievable risk-reduction steps. Discussions may have included but were not limited to unprotected sex with multiple partners, increased sexual risk taking due to heavy substance use, and lack of discussion of HIV status with sexual partners. After a plan for risk reduction was developed, the OraQuick Advance Rapid HIV-1/2 Antibody test was performed on finger-stick blood. Results were presented after completion. When disclosing reactive test results, counselors provided posttest counseling about the meaning of the test results and the need to avoid behaviors that pose a risk for transmission to others. Blood was drawn for a confirmatory test and follow-up arranged to provide the results. Patients with confirmed positive results were linked to HIV primary care. The intervention provided referrals, lubricant, condoms to participants with negative results.</p>	Minimal intervention (HIV testing, brief information about HIV according to CDC)

Appendix E Table 9. Detailed Intervention Descriptions

Author, year	Int arm	Intervention name	Brief description	Detailed description	Control
Mittal, 2017 ¹⁴²	IG1	Supporting positive and healthy relationships (SUPPORT)	Three 135-minute individual counseling sessions + five 135-minute group counseling sessions	The three individual sessions (sessions 1, 3, and 4) were focused on developing a 3- to 5-generation genogram with the participants. These sessions highlighted: (1) intergenerational transmission of unresolved trauma, loss, and grief; (2) family strengths and resilience; (3) sources of personal support and triggers; (4) psycho-education on the family life cycle; and (5) a recovery message for positive change and hope for future generations. The purpose of this set of exercises was to help empower the participants to take charge of change in their lives and in the lives of subsequent generations by understanding the link between intergenerational trauma and the here-and-now. The five group sessions included psycho-education and activities focused on STDs and HIV-infection, IPV, safety and self-protection, and choosing a healthy lifestyle. The goals of the group sessions were to (1) increase HIV-related knowledge, motivation, and skills to practice safer sex; (2) deconstruct healthy and unhealthy relationships; (3) understand the impact of psychological trauma and violence on the participant and her relationships; (4) develop a safety plan; (5) understand the interconnection between IPV and STD/HIV infection; (6) analyze protective versus self-destructive decision-making; and (7) develop a grieving ritual to enable the participant and her family to move on from the past. The group facilitator emphasized the importance of confidentiality during the sessions and asked the participants about any new experiences of violence victimization every week. At the end of each session, participants were given a homework assignment to be completed prior to the next session. The facilitator called participants midweek to check on them and the progress of the homework. They brainstormed ideas for overcoming difficulties with the homework assignments, if any were presented.	Minimal intervention (eight weekly group-based intervention sessions on abuse and relationships)
Morrison-Beedy, 2013 ¹⁴⁴	IG1	HIPTeens	Four 120-minute information-motivation-behavioral group counseling sessions + two 90-minute group counseling sessions	Four, weekly, 120-minute sessions and two 90-minute booster sessions at 3- and 6-months post-intervention; groups comprised of 6-9 participants who received \$15 for each session attended. Guided by the Information-Motivation-Behavioral Skills Model, the intervention provided HIV information; increased readiness to reduce risk behaviors (motivation) and instructed, modeled, and allowed participants to practice interpersonal and self-management skills facilitating sexual-risk reduction (SRR) and condom use. The intervention addressed concerns of participants, such as how to persuade a partner to use a condom, obtaining condoms and how fertility could be jeopardized by risky sexual behavior. The structure and content of the intervention included developmentally appropriate strategies such as games, interactive group activities, and skits. As sessions progressed, scenarios became more challenging and drew upon participants' experiences. Booster sessions provided additional reinforcement of intervention components.	Attention control (Four, weekly, 120-minute sessions and two 90-minute booster sessions at 3- and 6-months post-intervention)

Appendix E Table 9. Detailed Intervention Descriptions

Author, year	Int arm	Intervention name	Brief description	Detailed description	Control
Neumann, 2011 ¹⁴⁵	IG1	VOICES/VOCES	One 45-minute group counseling session	Video Opportunities for Innovative Condom Education and Safer Sex (VOICES/VOCES) intervention, 45-minute intervention intended to increase STD knowledge, proper condom use and condom negotiation skills. A facilitator delivered the intervention in a private room with 4 to 8 participants. Information on STD/HIV risk behaviors and condom use was delivered with culturally specific videos, group discussion, posters of various condom brands' features; role playing of condom negotiation was modeled in videos and participants were provided with free condom samples. Participants received an incentive worth approximately \$7. Sexual anatomy added to session content in Puerto Rico to improve participants' understanding of sexual health.	Usual care
O'Cleirigh, 2019 ¹⁶²	IG1	NA	HIV/STI counseling and testing plus 10 in-person therapy sessions	Participants received HIV/STI voluntary counseling and testing. Individual pretest counseling involved discussion of various points from a checklist following Massachusetts State Department guidelines. Following the delivery of the HIV test results participants discussed their result with the counselor and how the result related to their plans for their sexual health going forward. In addition, participants received 10 individual therapy sessions. Sessions 1 and 2 focused on sexual risk reduction counseling, which included identifying motivated targets for sexual risk behavior change, articulating one's sexual risk limits, recognizing barriers to staying within these limits and strategies for overcoming these barriers. Sessions 3 through 8 were comprised of the integration of cognitive therapy strategies, behavioral techniques, and sexual risk reduction counseling. Session 3 also involved psychoeducation about the effects of trauma, normalizing symptoms of post-traumatic stress, and a review of existing adaptive coping strategies. Sessions 4 and 5 included identifying problematic cognitions about self/world related to specific childhood sexual abuse events, describing thoughts and feelings related to the abuse, and generating an impact statement--a written account of the most significant sexual abuse incident. Sessions 5 through 7 involved learning how to identify cognitive distortions (e.g., self-blame, guilt), and strategies for challenging and changing these unrealistic beliefs. During sessions 8 through 10 participants were assigned behavioral experiments as homework. Behavioral experiments were enacted in sexual (or social) situations in which negative post-traumatic thoughts about self were likely to emerge and interfere with sexual risk reduction goals. The final 3 sessions also focused on consolidating the cognitive therapy skills and discussed areas that have most been disrupted by childhood sexual abuse. Every session allocated 10 minutes specifically relating the participants' current sexual behavior to post-traumatic responding and integrating the cognitive therapy skill set into the participants' specific sexual risk reduction plan.	Usual care

Appendix E Table 9. Detailed Intervention Descriptions

Author, year	Int arm	Intervention name	Brief description	Detailed description	Control
Peipert, 2008 ¹⁴⁸	IG1	NA	Three 30-minute individually tailored computer web-based sessions	The computer-based intervention utilized a model that conceptualizes a progression through stages of change towards consistent dual condom and contraceptive use through precontemplation, contemplation, preparation, action, and maintenance. a Multimedia expert system administered questions on-screen text and by voice, including pictures and music. Responses were used by the expert system for treatment feedback based on patient's readiness to change behavior. The feedback was written at a 6th grade level to ensure comprehension. There were three sessions: one at baseline, one at 1 month and one at 2 months. Content was divided into (1) current stage of change, (2) current pros/cons of condom and other contraceptive use, (3) help with at-risk situations and appropriate coping responses to increase efficacy for condom and other contraceptive behavior, (4) information about over-use and under-use of those processes appropriate for that individual's stage of change; and (5) more tip and strategies to facilitate progress.	Minimal intervention
Peragallo Montano, 2019 ¹⁶¹	IG1	Salud, Educacion, Prevencion y Autocuidado (SEPA)	Three 2.5-hour sessions	Three 2.5-hour sessions per week conducted with small groups of 6-8 participants. Participants chose whether groups were conducted in English or Spanish according to their preference. The sessions consisted of group discussions, role playing, negotiation skills, partner communication, and skill building.	Waitlist
Petersen, 2007 ¹⁴⁹	IG1	Women's Reproductive Assessment Program (WRAP)	One individual counseling + followup phone call or visit	Intervention was adapted from motivational interviewing; emphasized three elements: exploring discrepancies between pregnancy intention and contraceptive use; between STD risk and condom use; sharing information with participants and promoting behaviors to reduce risk. Initial session encouraged women to adopt consistent, effective contraceptive use and condom use to prevent STD. Counseling individualized on current contraceptive use and risk reduction. Obtainment or referral for any type of contraception available. In-person or telephone booster session focused on progress on risk reduction steps 2 months after initial session.	Attention control (brief general counseling on prevention health care [e.g., smoking, diet, exercise])
Proude, 2004 ¹⁵⁰	IG1	NA	One 15-minute physician counseling session + informational resource pamphlets, 2 condoms, lubricant	Physician started intervention by inquiring about sexual risk. According to the patient's response, the physician offered brief behavioral advice and gave the patient a discreetly packaged set of complementary resources. These resources included condoms, lubricant, educational pamphlets, a postcard of information about alcohol/drug information services, and a pamphlet about condoms which included written suggestions about how to discuss their use with a partner.	Attention control (tobacco screening and counseling)

Appendix E Table 9. Detailed Intervention Descriptions

Author, year	Int arm	Intervention name	Brief description	Detailed description	Control
Redding, 2014 ¹⁶³	IG1	Step by Step	Four 25-minute computer sessions followed by individual counseling	Participants received multimedia interactive computer feedback, which incorporated culturally targeted pictures, background music, brief movies, and voice feedback. TTM-tailored feedback, which integrated both theoretical and empirical decision rules for feedback on stages of condom use and either smoking cessation or smoking acquisition was used. Sessions were client-centered, personalized, and integrated MI techniques. Each section of expert system feedback was tailored to the participant's own stage of readiness to use condoms consistently or stage of change for smoking behaviors. The intervention was designed to accelerate stage progress among those in early stages of change or to prevent relapse among those further along. Feedback was presented in 5 sections: stage of change, pros and cons, situational self-efficacy or temptations, information about the over-use or under-use of key processes of change appropriate for that person's stage of change, and finally supportive tips and strategies to facilitate progress. Programs took 20-30 min to complete and were completed at 3, 6, and 9 months post BL. Counselors with family planning counseling experience provided stage-targeted counseling to participants. A counseling protocol was provided to each counselor that provided stage-matched counseling activities for both condom use and smoking cessation. Counseling provided an open, responsive environment, where those factors most influential for the teen's motivations to change could be reflected and enhanced. Following counseling, standard family planning medical care was provided.	Minimal intervention (information and advice to use condoms or avoid smoking)
Sanci, 2015 ¹⁵³	IG1	NA	Clinicians received 9 hours of training + 2 practice visits	Participating clinicians participated in 9 hours of experiential workshops focused on implementing the best practice guidelines recommending that clinicians screen and counsel young people across multiple psychosocial risk factors. Workshops covered 3 topics of 3 hours each: youth-friendly care; screening for and discussing health risks using HEADSS framework; and providing a response to detected risky behaviors with a brief intervention based on motivational interviewing principles, including health promotion advice. Adolescent actors allowed clinicians to practice new skills by role play and provided feedback and coaching in youth-friendly communication skills. 2-3 hours of training in youth-friendly care was also provided to practice support staff. During workshops, clinicians were introduced to the study screening tool designed to prompt them to raise and discuss health risk behaviors and also protective factors and strengths with their patients. After the workshops two practice visits were conducted two weeks apart. Using the plan-do-study-act cycle of continuous quality improvement, practices were assisted with integrating screening into office and clinical procedures. Clinics were also provided posters and pamphlets addressing youth-friendly care and health risk behaviors.	Minimal intervention (3-hour seminar on youth-friendly care)

Appendix E Table 9. Detailed Intervention Descriptions

Author, year	Int arm	Intervention name	Brief description	Detailed description	Control
Scholes, 2003 ¹⁵⁴	IG1	NA	2 tailored print mailings	Participants received two rounds of individually tailored materials. They received a tailored 12-page self-help magazine style booklet (called Insights); a safe sex kit containing male and female condoms, a condom carrying case, and instructions on condom use. After 3 months, they received a tailored booster feedback newsletter (called Extra Insights) and a condom packet. Tailored sections of the booklets incorporated messages specific to each participant using responses to selected survey tailoring items. Constructs used in tailoring included stage off readiness to adopt condom use, beliefs and norms regarding condom use, intentions and efficacy to use condoms, perceived barriers/facilitators to condom use, perceived STI risk, and type of partner.	Usual care
Shafii, 2019 ¹⁶⁴	IG1	<i>e-KISS (electronic-KIOSK Intervention for Safer Sex)</i>	One computer-based tailored feedback session	Participants received an interactive computer-based intervention. They were provided three options for interacting with the computer: using a static male physician avatar, a female physician avatar, or no avatar (text only). They then received personalized feedback about their protective and risky sexual behaviors from the avatar or via text only. The computer program identified all risky and protective behaviors as reported in the participant's sexual history and the avatar presented results to them. After the feedback was provided participants were asked to choose what they wanted to discuss further: STI/HIV and male condom use, or birth control use and unintended pregnancy. Participants were offered video modules targeting sexual health knowledge and skills, including demonstrations of how to use condoms and birth control; a vignette of a teenage couple dispelling pregnancy prevention myths; and a vignette of a young adult couple negotiating condom use with each other. At the end of the intervention each participant was asked to identify a sexual risk behavior they planned to change and to make a personal goal to adopt that change before the study followup visit.	None

Appendix E Table 9. Detailed Intervention Descriptions

Author, year	Int arm	Intervention name	Brief description	Detailed description	Control
Shain, 2004 ¹⁵⁵	IG1	NA	One individual counseling session + three 3-hour group counseling sessions + option to attend five 90-minute group counseling sessions	The intervention consisted of interactive STI counseling (individual session) and a standard behavioral-cognitive intervention (group sessions). Upon enrollment, participants received individual, interactive counseling lasting 15-20 minutes. Research staff emphasized full treatment for the participant and their partners, avoidance of sexual intercourse until treatment was completed, mutual monogamy, taking time between partners to be selective, consistent and correct condom usage, avoidance of douching, and seeking care whenever they suspected infection. There were three weekly small group sessions lasting approximately 3 hours; separate sessions were held for each ethnic group with ethnically-matched female facilitators. Interventionists adapted the AIDS Risk Reduction Model for the target populations. Overall goals were to have women recognize STD risk, commit to behavior change, acquire necessary skills to effect change, and be vigilant in promptly seeking care for possible infection. Five optional enhanced support group sessions were offered, which included the discussion of changing behavior, abuse (e.g., emotional, physical, sexual), social/sexual roles, love, trust and intimacy lasting 90 minutes.	Minimal intervention (one 10-to15-minute standardized STI presentation + STI test and referral to treatment)
	IG2	NA	One individual counseling session + three 3-hour group counseling sessions	The intervention consisted of interactive STI counseling (individual session) and a standard behavioral-cognitive intervention (group sessions). Upon enrollment, participants received individual, interactive counseling lasting 15-20 minutes. Research staff emphasized full treatment for the participant and their partners, avoidance of sexual intercourse until treatment was completed, mutual monogamy, taking time between partners to be selective, consistent and correct condom usage, avoidance of douching, and seeking care whenever they suspected infection. There were three weekly small group sessions lasting approximately 3 hours; separate sessions were held for each ethnic group with ethnically-matched female facilitators. Interventionists adapted the AIDS Risk Reduction Model for the target populations. Overall goals were to have women recognize STD risk, commit to behavior change, acquire necessary skills to effect change, and be vigilant in promptly seeking care for possible infection.	Minimal intervention (one 10-to15-minute standardized STI presentation + STI test and referral to treatment)

Appendix E Table 9. Detailed Intervention Descriptions

Author, year	Int arm	Intervention name	Brief description	Detailed description	Control
Tzilos Wernette, 2018 ¹⁶⁵	IG1	NA	One 60-minute computer session + one 15-minute booster session	Participants interacted with the computer and were guided by an animated narrator, which engaged in a MI-consistent style, had the ability to use emotionally expressive statements and empathetic reflection. The intervention was self-administered with the assistance of research staff and included a behavioral skills component where models for male and female condom use was reviewed using video instruction guided by the computer. The intervention presented information and education regarding health risks and included testimonial videos of women who were HIV positive and pictures of STIs. All participants were given the option to create a personalized safety plan that was tailored and designed to increase awareness of the interconnected risk factors for STI/HIV and alcohol/drug use in the woman's life. At the booster session, the narrator reviewed the components of the intervention session and participants reviewed their personalized plan and identified any barriers to increasing safety behaviors. Participants received brochures specifically designed to facilitate health risk behaviors during pregnancy.	Attention control (TV shows + brochures to facilitate health risk behaviors during pregnancy)
Warner, 2008 ¹⁵⁶	IG1	Safe in the City	One 23-minute video + educational pamphlets and condoms	Based on integrated theoretical approach to achieving health behavior change. Safe in the City video (23 minutes) incorporated key prevention messages aimed at increasing knowledge and perception of STD/HIV risk, promoting positive attitudes toward condom use, and building self-efficacy and skills to facilitate partner treatment, safer sex, and the acquisition, negotiation, and use of condoms. Video contained vignettes that modeled young couples of various race/ethnicities and sexual orientations negotiating safer sex. Animated segments demonstrated proper condom use and variety of available condoms. Posters in waiting and exam room directed attention to the video and reinforced key messages. Condoms and educational pamphlets on STD prevention available to all patients.	Usual care
Whiteley, 2018 ¹⁶⁶	IG1	NA	Eight emails containing 19 links to internet content	The intervention included links to interactive websites, some with games and quizzes, and YouTube videos. Topics included puberty, basic anatomy, HIV/STI information, contraception, pre- and post-exposure prophylaxis, personal risk assessment, influence of peer norms, HIV's impact on minority communities, benefits of abstinence and protected sex, condom skills, communication skills, and dangers of substance use. Researchers organized website selections into topic areas of 1) relevant information, 2) personal motivation to stay safe, and 3) the confidence and skills needed for safer sex. Participants received 19 links (from 9 different websites and 4 YouTube videos) via 8 emails over the course of 4 weeks (2 emails each with 2-3 links per week).	Waitlist

Appendix E Table 9. Detailed Intervention Descriptions

Author, year	Int arm	Intervention name	Brief description	Detailed description	Control
Wingood, 2013 ¹⁵⁸	IG1	SISTA	Two 4-hour group counseling sessions	Intervention informed by CDC HIV interventions and social cognitive theory informed content by seeking to enhance participants' attitudes and skills in abstaining from sexual intercourse, practicing low-risk sexual behaviors, avoiding untreated STIs, using condoms consistently, and refraining from having multiple and concurrent sexual partners. Content emphasized valuing one's body, perceiving one's body as a temple (culturally appropriate), information on risk of STI/HIV when engaging in concurrency, and discussing partner selection strategies that encouraged monogamy. Also informed by Theory of Gender and Power to enhance women's awareness of power imbalances and increasing self-sufficiency, educating participants about gender-related HIV prevention strategies (e.g. refraining from douching & enhancing sexual communication), and educating women about biological influences that could reduce HIV risk (e.g., encouraging participants to have their male sexual partners seek STI testing and treatment if necessary).. Consisted of 2, 4-hour group sessions facilitated by 2 trained African American female health educators.	Attention control (nutrition health promotion)

Appendix E Table 9. Detailed Intervention Descriptions

Author, year	Int arm	Intervention name	Brief description	Detailed description	Control
Ybarra, 2017 ¹⁵⁹	IG1	Guy2Guy Intervention Group	Text messages 5-10 times/day five consecutive weeks + text messages for one week	Content included HIV information (e.g., what it is, how to prevent it), motivation (e.g., reasons why AGBM choose condoms), and behavioral skills (e.g., correct condom use). Additional topics covered the importance of HIV testing, healthy and unhealthy relationships, coming out, and bullying. Although the same concepts were discussed for sexually experienced and inexperienced youth, the content was tailored by experience (e.g., “When you’re in a healthy relationship and start having sex...” versus “When you have sex...”). The intervention integrated 2 game-like features: At the end of each program week, intervention participants had the opportunity to “level up” by answering a question about the week’s content. Intervention participants could earn “badges,” meant to help engagement in HIV preventive behavior in a concrete, stepwise fashion. Both sexually experienced and inexperienced intervention youth were encouraged to first buy condoms (Badge 1) and carry condoms with them (Badge 2). Youth who were sexually experienced at baseline were then encouraged to use condoms if they were currently having sex (Badge 3). They also were encouraged to get tested for HIV (Badge 4). Participants were given up to three chances to earn a badge. At the outset, participants were not notified of the total number of badges or the activities that would earn badges. However, as the program progressed, they received text messages asking whether they had achieved a particular badge activity. Additionally, G2Genie was an on-demand feature that provided scripted “answers” to common questions that intervention youth could query (e.g., how to break up with a boyfriend). Intervention participants were also paired to a text buddy. The goal was for paired intervention participants to practice program skills and provide mutual social support. Text buddies were matched on sexual experience, time zone (i.e., within 1 zone), and distance (at least 500 miles apart to prevent meeting each other), when possible.	Attention control (general health text messages)

Abbreviations: AIDS = acquired immunodeficiency syndrome; AGBM = adolescent gay and bisexual men; BV = bacterial vaginosis; CDC = Centers for Disease Control and Prevention; DVD = digital video disc; E-SexG = Enhanced Sex, Games, and Videotape intervention; HIV = human immunodeficiency virus; IG = intervention group; Int = intervention; IMB = Information-Motivation-Behavioral; IPV = intimate partner violence; MI = motivational interviewing; Min = minutes; NR = not reported; OC = oral contraception; Q&A = question & answer; RESPECT = Recovery, Empowerment, Social Services, Prenatal care, Education, Community, and Treatment; RSB = risky sexual behavior; SRR = sexual risk reduction; STD = sexually transmitted disease; STI = sexually transmitted infection; UVI/UAI = unprotected vaginal intercourse/unprotected anal intercourse; VOICES/VOCES = Video Opportunities for Innovative Condom Education and Safer Sex.

Appendix E Table 10. Overview of Intervention Components

Author, year	Target pop	Int arm	Low contact (<30 min)	Mod contact (≥30 to ≤120 min)	High contact (>120 min)	Single contact	Multiple contacts	Health professional delivered	Clinic setting	Community Setting	Motivational Interviewing concepts or practices	Cognitive Behavioral Therapy	Theory based	In-person	Individual Counseling	Group Counseling	Tech-based (computer, internet, text)	Telephone (voice)	Passive (eg, pamphlet, video)
Bai, 2018 ¹⁶⁰	Adol	IG1			X		X	X	X		X	X		X	X				
Bailey, 2016 ¹⁰⁵	Adol-YA-Adult [M]	IG1	X			X			X								X		
Berenson, 2012 ¹⁰⁷	Adol-YA [F]	IG1			X	X			X			X	X	X	X			X	
		IG2		X		X			X				X	X	X				
Berkman, 2007 ¹⁰⁸	YA-Adult [M]	IG1			X		X	X						X		X			
Billings, 2015 ¹¹⁰	YA-Adult [F]	IG1		X		X											X		
Carey, 2004 ¹¹¹	YA-Adult	IG1			X		X				X			X		X			
Carey, 2010 ¹¹²	YA-Adult	IG1			X		X	X	X		X		X*	X	X	X			X
		IG2			X		X	X	X				X	X	X	X			
		IG3	X			X		X	X		X		X	X	X				
		IG4			X		X	X	X					X		X			X
		IG5			X		X	X	X		X		X	X	X	X			X
Carey, 2015 ¹¹³	Adol-YA-Adult	IG1		X		X		X	X		X		X				X		
		IG2		X		X		X	X		X		X				X		X
		IG3		X		X		X	X		X		X				X		X
Champion, 2012 ¹¹⁶	Adol [F]	IG1			X		X	X		X		X	X	X	X				
Costa, 2017 ¹¹⁷	Adol-YA [F]	IG1			X		X	X	X			X		X		X			
		IG2		X			X		X					X	X				X
Crosby, 2009 ¹¹⁸	YA-Adult [M]	IG1		X		X			X					X	X				
DiClemente, 2004 ¹¹⁹	Adol [F]	IG1			X		X		X				X	X		X			
Ehrhardt, 2002 ¹⁰²	YA [F]	IG1			X		X		X					X		X			
		IG2			X		X		X					X		X			
Free, 2016 ¹²²	Adol-YA	IG1		X			X										X		
Guilamo-Ramos, 2011 ¹²⁵	Adol	IG1		X			X	X	X			X†		X	X			X	X

Appendix E Table 10. Overview of Intervention Components

Author, year	Target pop	Int arm	Low contact (<30 min)	Mod contact (≥30 to ≤120 min)	High contact (>120 min)	Single contact	Multiple contacts	Health professional delivered	Clinic setting	Community Setting	Motivational Interviewing concepts or practices	Cognitive Behavioral Therapy	Theory based	In-person	Individual Counseling	Group Counseling	Tech-based (computer, internet, text)	Telephone (voice)	Passive (eg, pamphlet, video)
Jemmott, 2005 ¹²⁷	Adol [F]	IG1			X	X			X			X		X		X	X		
		IG2			X	X			X			X		X		X	X		
Jemmott, 2007 ¹²⁸	YA-Adult [F]	IG1			X	X		X	X				X	X		X			
		IG2			X	X		X	X				X	X		X			
		IG3	X			X			X	X				X	X	X			
		IG4	X			X			X	X				X	X	X			
Kershaw, 2009 ¹²⁹	Adol-YA-Adult [F]	IG1			X		X	X					X	X		X			
Lewis, 2018 ¹³²	YA	IG1	X			X											X		
		IG2	X			X											X		
Marrazzo, 2011 ¹³⁵	YA-Adult [F]	IG1		X		X					X			X	X				
Metsch, 2013 ¹³⁷	YA	IG1		X		X			X					X	X				
Mittal, 2017 ¹⁴²	YA-Adult [F]	IG1			X		X			X [†]			X	X	X	X		X	
Morrison-Beedy, 2013 ¹⁴⁴	Adol [F]	IG1			X		X		X				X	X		X			
Neumann, 2011 ¹⁴⁵	YA-Adult	IG1		X		X			X					X		X			
O'Cleirigh, 2019 ¹⁶²	Adult [M]	IG1			X		X	X				X		X	X				
Peipert, 2008 ¹⁴⁸	Adol-YA-Adult [F]	IG1		X			X						X				X		
Peragallo Montano, 2019 ¹⁶¹	Adult [F]	IG1			X		X		X				X	X		X			
Petersen, 2007 ¹⁴⁹	Adol-YA-Adult [F]	IG1		X			X		X		X			X	X				
Proude, 2004 ¹⁵⁰	YA	IG1	X			X		X	X					X	X				
Redding, 2014 ¹⁶³	Adol [F]	IG1			X		X		X		X			X	X		X		
Sanci, 2015 ¹⁵³	Adol-YA	IG1			X		X		X		X			X	X	X			

Appendix E Table 10. Overview of Intervention Components

Author, year	Target pop	Int arm	Low contact (<30 min)	Mod contact (≥30 to ≤120 min)	High contact (>120 min)	Single contact	Multiple contacts	Health professional delivered	Clinic setting	Community Setting	Motivational Interviewing concepts or practices	Cognitive Behavioral Therapy	Theory based	In-person	Individual Counseling	Group Counseling	Tech-based (computer, internet, text)	Telephone (voice)	Passive (eg, pamphlet, video)
Scholes, 2003 ¹⁵⁴	YA [F]	IG1	X				X												X
Shafii, 2019 ¹⁶⁴	Adol-YA	IG1	X			X			X		X						X		
Shain, 2004 ¹⁵⁵	Adol-YA-Adult [F]	IG1			X		X		X			X	X	X	X	X			
		IG2			X		X		X			X	X	X	X	X			
Tzilios Wernette, 2018	Adol [F]	IG1		X			X		X		X						X		
Warner, 2008 ¹⁵⁶	Adol-YA-Adult	IG1	X			X			X										X
Whiteley, 2018 ¹⁶⁶	Adol-YA	IG1	X				X						X				X		
Wingood, 2013 ¹⁵⁸	YA-Adult [F]	IG1			X		X		X			X		X		X			
Ybarra, 2017 ¹⁵⁹	Adol [M]	IG1			X		X						X				X [§]		

* Family therapy

† Included IMB and transtheoretical theories

‡ Convenient location in the community (details NR)

§ Text messages, no email

Abbreviations: Adol = adolescent; F = female; IG = intervention group; Int = intervention; KQ = key question; M = male; Min = minute; Mod = moderate; OR = odds ratio; Pop = population; Tech = technology; YA = young adult.

Appendix F Table 1. Behavioral Intervention Implementation Table: Summary and Examples of Included Interventions

Primary Population	Individuals at increased risk for STI based on infection history, sexual risk behaviors, or high STI prevalence subpopulation		
Primary Outcomes	STI infection, condom use, unprotected intercourse, number of sexual partners		
Study Findings	Behavioral counseling interventions were generally consistent in reducing incident STI across a range of study populations, most at increased risk due to their STI history or attendance at STI clinics, sexual behaviors, or having sociodemographic characteristics associated with higher STI prevalence (E.g., adolescents, young adults, racial and ethnic minorities in low-resource communities). Increased condom use and reduced unprotected sex were also associated with behavioral interventions to prevent STI.		
Behavior change goals and techniques	A variety of therapeutic approaches (i.e., Cognitive Behavioral Therapy, Motivational Interviewing, family therapy) and theoretical models of behavior change (e.g., Social Cognitive Theory, AIDS Risk Reduction Model, Information-Behavior-Motivation Model, Theory of Gender and Power) were used in the included interventions. Interventions often provided information, addressed condom use and negotiation skills, evaluated and aimed to change risk perceptions, stage of change, and motivations, including some that were tailored to the individual.		
Interventions contact time and duration	The most effective interventions required over 2 hours of participant time. A few studies involving low (<30 minutes) or moderate (30-120 minutes) contact times reported benefits, but evidence was more limited. Interventions commonly involved multiple contacts (over a few weeks or an entire year), and a few involving a single encounter of low, moderate or high contact time were also effective.		
Settings of Studies	Many studies took place in primary care settings, including women’s health and family planning clinics. Several were conducted in STI clinics.		
To Whom is Intervention Targeted?	Most of the effective interventions were targeted to populations at increased STI risk, including some at especially high risk based on recent STI or STI clinic visits. Much of the available evidence is for interventions to prevent STI among adolescent girls and women. Fewer of the effectiveness studies from the past 20 years that were included in this review focused just on men or on mixed gender populations, and evidence of a benefit among those was less commonly found.		
	Intervention Mode*		
INTERVENTION PARTICIPANTS AT RISK FOR STI	Group counseling (group only or group + individual)	Individual counseling	Media-based (e.g., computer, video, text message)
Mode and intensity of delivery	<p>Group counseling interventions were conducted in-person with trained facilitators. Additional individual counseling sessions were also sometimes included.</p> <p>Most interventions with group counseling involved total contact times of more than 120 minutes and multiple sessions over 1-12 months.</p> <p>Group counseling interventions often focused on specific demographic groups defined by age range and/or race/ethnicity.</p>	<p>In person, individual counseling sessions were with a mental health professional, counselor, or trained layperson.</p> <p>Most involved > 30 minutes of total contact time and were often provided in a single session.</p>	<p>Media-based interventions did not include in-person counseling. Several involved one or more interactive computer sessions; others involved viewing a video or receiving emails or mobile phone text messages.</p> <p>Approximately half of media-only interventions involved total contact times of 30-90 minutes; others involved < 30 minutes. Interventions involving video or computer interaction entailed fewer sessions than those involving repeated text or emails over many months.</p>
Interventions included in meta-analysis of STI prevention efficacy	Champion†, DiClemente†, Jemmott 2005†, Jemmott 2007†,‡, Kershaw, Wingood†, Shain†,Neumann†	Berenson, Marazzo, Crosby†, Metsch, Jemmott 2007†,‡	Free, Peipert, Carey 2015, Bailey, Warner† , Shafii, Tzilos Wernette
Examples intervention materials§	<p>https://effectiveinterventions.cdc.gov/home/interventions-previously-supported-by-cdc/sista</p> <p>https://www.etr.org/ebi/programs/be-proud-be-responsible/</p> <p>https://www.cdc.gov/hiv/pdf/research/interventionresearch/compendium/rr/cdc-hiv-horizons-best-rr.pdf</p> <p>https://www.cdc.gov/hiv/pdf/research/interventionresearch/compendium/cdc-hiv-VOICES_VOICES_BEST_RR.pdf</p>	<p>https://www.cdc.gov/hiv/pdf/research/interventionresearch/compendium/rr/cdc-hiv-focus_on_the_future_best_rr.pdf</p> <p>https://www.cdc.gov/hiv/pdf/research/interventionresearch/compendium/rr/cdc-hiv-Sister_to_Sister_BEST_RR.pdf</p>	<p>https://www.cdc.gov/std/safe-in-the-city/default.htm</p>

Appendix F Table 1. Behavioral Intervention Implementation Table: Summary and Examples of Included Interventions

Evidence of effect modification	There is evidence that interventions with group counseling and with higher contact times had larger preventive effects for STI outcomes, but these intervention features were correlated and unclear what accounts for the effect.
Comparison group	Attention control and minimal intervention (to address other health risk behaviors such as nutrition) most common. Usual care, waitlist, and no intervention also used.
Interventionist and Training Required	Trained clinical health professionals such as nurses, physicians, or psychologists conducted nearly one-third of the interventions evaluated, the remainder were with research staff, peer educators, or health educators, often matched to race/ethnicity, age and other characteristics of target population.
Reported Intervention Adherence	Relatively high adherence with most studies reporting more than three-quarters of the intervention participants completing the full intervention. Participation rates tended to be slightly lower for less intensive interventions.

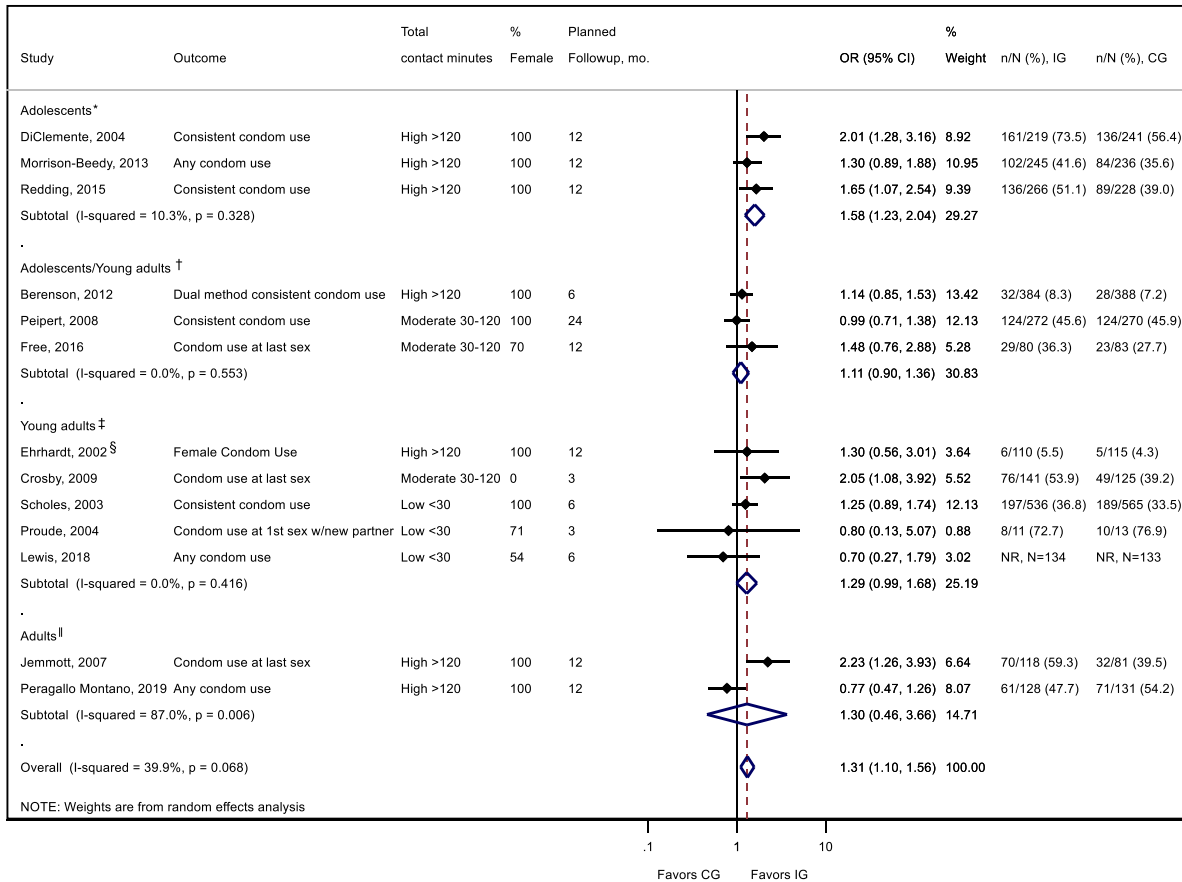
* Most intensive intervention component if multiple modes used (e.g., group counseling + video).

† Intervention tested in the study was associated with a statistically significant reduction in STI incidence.

‡ Two different intervention modalities were associated with reduced STI incidence in this study.

§ Materials for practice were identified by examining published studies and public resources (e.g., Centers for Disease Control and Prevention. An extensive catalogue of behavioral interventions for different at-risk populations are available online at <https://www.cdc.gov/hiv/research/interventionresearch/compendium/rr/characteristics.html>)

Appendix G Figure 1. Condom Use: Pooled Results



Confidence intervals for the pooled estimates in this forest plot were calculated with the Dersimonian and Laird method, thus subgroup effects based on few studies may overestimate precision

* Study participants ranged in age from 12 to 19 years

† Study participants ranged in age from 12 to 25 or study included adolescents and adults with population mean age < 25 years

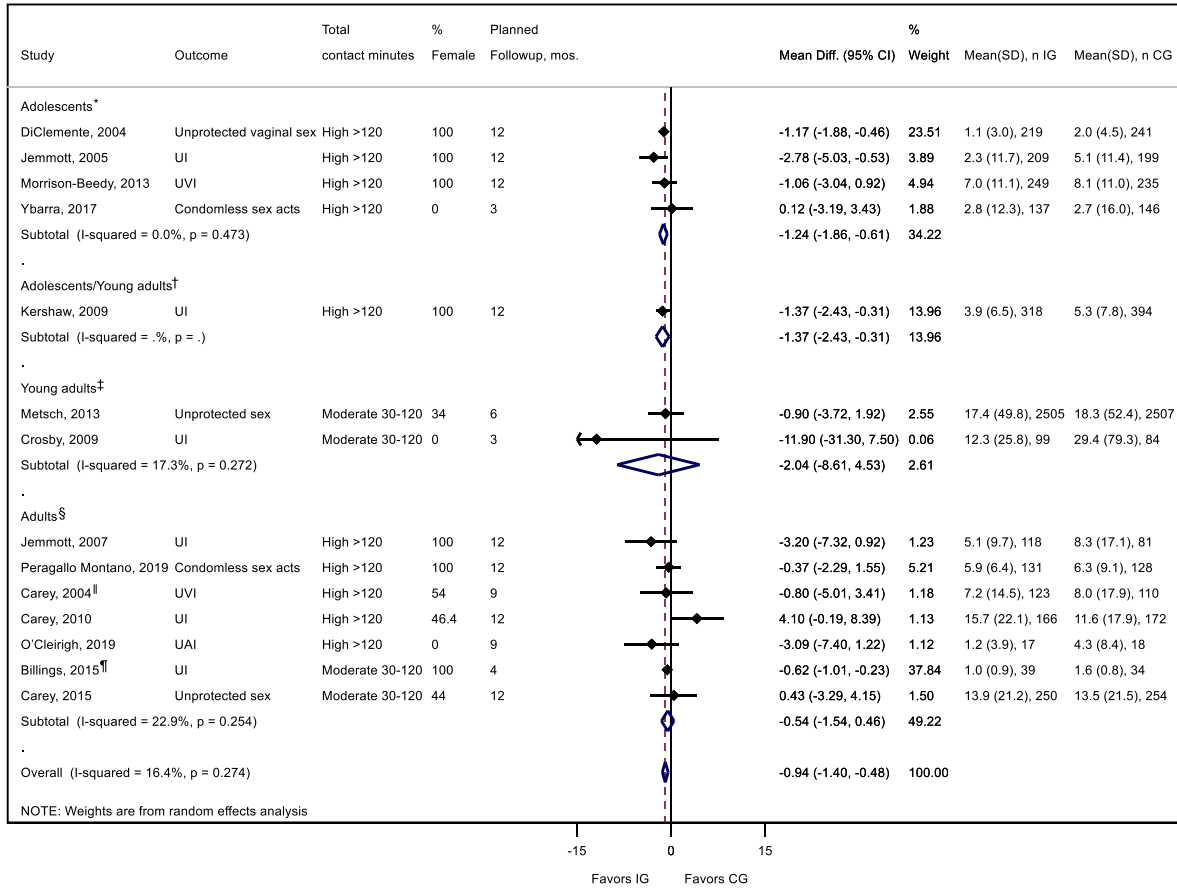
‡ Study participants ranged in age from 18 to 25 only or study enrolled adults of all ages with population mean age <25 years

§ Only trial reported female condom use; trial reported "borderline statistical significance (all women: p=0.06; at-risk women: p=0.10)

|| Study participants ages 18 and older or enrolled broad age range population with mean age ≥25 years

Abbreviations: CG = control group; CI = confidence interval; IG = intervention group; Mo = month; n = number of observations; NR = not reported; OR = odds ratio.

Appendix G Figure 2. Unprotected Intercourse: Pooled Results



Confidence intervals for the pooled estimates in this forest plot were calculated with the Dersimonian and Laird method, thus subgroup effects based on few studies may overestimate precision

* Adolescents: Study participants ranged in age from 12 to 19 years

† Adolescents/Young adults: Study participants ranged in age from 12 to 25 or study included adolescents and adults with population mean age < 25 years

‡ Young adults: Study participants ranged in age from 18 to 25 only or study enrolled adults of all ages with population mean age <25 years

§ Adults: Study participants ages 18 and older or enrolled broad age range population with mean age ≥25 years

¶ Trial reported GEE with group x time interaction for non-normal outcome, p=0.004; effect size from mean differences are plotted

¶¶ Trial reported a trend of unprotected intercourse decreasing, p=0.098; forest plot with mean difference is presented as significant

Abbreviations: CG = control group; CI = confidence interval; Diff. = difference; IG = intervention group; Mo = month; n = number of observations; NR = not reported; OR = odds ratio; SD = standard deviation; UAI = unprotected anal intercourse UI = unprotected intercourse; UVI = unprotected vaginal intercourse.

Appendix H. Ongoing Studies

Trial identifier	Study name	Location	Participants n	Intervention	Relevant outcome measures	Status 2019
NCT03826342	Technology-Based Intervention for Reducing Sexually Transmitted Infections and Substance Use During Pregnancy	U.S.	NA	Health Check-up for Expectant Moms (HCEM), a computer-delivered screening and brief intervention (SBI)	Number of unprotected sexual occasions	Not yet recruiting
NCT03736876	About Us: A Healthy Relationships Program for Vulnerable Youth	U.S.	NA	10 lessons (2 that are between 30-45 minutes long 8 that are 50 minutes long) that blend group-based activities with online activities implemented in a small group format	Rates of vaginal or anal sex without condoms	Recruiting
NCT02965014	Young Women-Focused HIV Prevention: Seek & Test in North Carolina (NC) Clinics	U.S.	700	HIV counseling, testing, a two-session face-to-face intervention. The face-to-face sessions include information addressing the intersection of substance use, sexual risk, and violence through skill building, role-play, and rehearsal.	Condomless sex, number of sex partners, frequency of substance use	Recruiting
NCT03408743	Engineering an Online STI Prevention Program: CSE2	U.S.	22337	Online intervention	Unprotected sex behavior at most recent sex	Active, not recruiting
NCT03666247	Mobile Messaging Intervention to Present New HIV Prevention Options for MSM	U.S.	1,206	Personalized mobile messaging platform; free condoms, lube, and HIV/STI testing kits	Change in condom use compliance, change in condom use, change in STI testing	Recruiting

Appendix H. Ongoing Studies

Trial identifier	Study name	Location	Participants n	Intervention	Relevant outcome measures	Status 2019
NCT03167606	A Pragmatic Clinical Trial of MyPEEPS Mobile to Improve HIV Prevention Behaviors in Diverse Adolescent MSM	U.S.	700	Mobile technology to deliver HIV prevention information specifically developed for at-risk YMSM	Change in male-male sexual risk (total number of sex partners and condomless anal sex partners, frequencies of condomless sex acts (anal or oral), sex (anal or oral) with or without condoms under the influence of drugs/alcohol, unprotected anal intercourse under the influence of alcohol/drugs)	Recruiting
NCT02993185	An Integrated Group-Individual Curriculum to Prevent Teen Pregnancy	U.S.	2,100	Your Move (YM), an interactive sex education intervention. Seven 75-minute sessions, and each session contains 60 minutes of facilitator-led discussion, video clips, activities, and games as well as 15 minutes of "personal reflection" time during which girls practice the decision-making skills they have learned.	Number of sexual partners for vaginal, oral, or anal sex intercourse; Number of incidents of unprotected vaginal, oral, or anal sex; Condom errors or failure	Recruiting

Appendix H. Ongoing Studies

Trial identifier	Study name	Location	Participants n	Intervention	Relevant outcome measures	Status 2019
NCT03284541	A New Approach to Integrating Primary and Secondary HIV Prevention in Young Male Couples	U.S.	400	2GETHER is an HIV prevention and relationship education program designed for young male couples. 2GETHER consists of 4 sessions (2 group sessions, 2 individualized couple session) administered over the course of 1 month (1 session per week). Group sessions focus on developing skills related to sexual health and relationship functioning, including HIV prevention in couples, communication skills, coping skills, problem-solving and acceptance. Individualized couple sessions focus on implementation of skills specific to the needs of each couple.	Condomless anal sex, occurrence of STIs	Active, not yet recruiting
NCT03765255	Personal Responsibility Education Program Innovative Strategies: Digital Initiative for Youth	U.S.	1360	6 hours of in-person sexual health and adolescent development education with an app that includes a resource locator, text message reminders (for one month), goal setting, and other resources.	Condom/contraceptive use or no sex in the last 3 months; number of sexual partners in the past 3 months	Recruiting
NCT03465852	HIV Prevention Among Latina Transgender Women Who Have Sex with Men: Evaluation of a Locally Developed Intervention	U.S.	140	Two 4-hour group sessions over a period of two weeks to groups of about 10 participants	Consistent condom use	Active, not yet recruiting

Appendix H. Ongoing Studies

Trial identifier	Study name	Location	Participants n	Intervention	Relevant outcome measures	Status 2019
NCT02513225	Randomized Controlled Trial of an Adapted STD Screening and Risk Reduction Intervention	U.S.	350	Project EMPWR; comprised of 2 sessions delivered approximately 7-10 days apart by a trained Apache paraprofessional interventionist. Curriculum will include information regarding personal risk factors for STDs and developing an achievable personalized risk-reduction plan that emphasizes individual and community-based strengths and resources. STD testing will be offered.	Condom use	Recruiting
HYPERLINK "https://clinicaltrials.gov/show/NCT03009539" \o "Current version of study NCT03009539 on ClinicalTrials.gov" NCT03009539	Evaluating the Effectiveness of an eHealth EBI for Latino Youth in Primary Care	U.S.	456	eHealth Familias Unidas (an adaptation of the face-to-face version); aims to prevent drug use, sexual risk behaviors, and STIs by improving family functioning; a multi-level intervention that targets risk and protective factors at the multiple systems affecting the youth and youths' family. Consists of 12 sessions: eight (12 - 15 minute) "mock" parent sessions in Spanish and four (30 - 45 minute) online family sessions delivered in either Spanish and/or English.	Unprotected sexual behavior; STI incidence	Recruiting