Behavioral Sexual Risk-Reduction Counseling in Primary Care to Prevent Sexually Transmitted Infections: A Systematic Review for the U.S. Preventive Services Task Force

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Background: Sexually transmitted infections (STIs) are common and preventable.

Purpose: To update a previous systematic review about the benefits and harms of sexual risk-reduction counseling to prevent STIs for the U.S. Preventive Services Task Force.

Data Sources: Selected databases from January 2007 through October 2013, manual searches of references lists and gray literature, and studies from the previous review.

Study Selection: English-language fair- or good-quality trials conducted in adolescents or adults.

Data Extraction: One investigator abstracted data and a second checked the abstraction. Study quality was dual-reviewed.

Data Synthesis: 31 trials were included: 16 (n = 56 110) were newly published and 15 (n = 14 214) were from the previous review. Most trials targeted persons at increased risk for STIs based on sociodemographic characteristics, risky sexual behavior, or history of an STI. High-intensity (>2 hours) interventions reduced STI incidence in adolescents (odds ratio, 0.38 [95% CI, 0.24 to 0.60]) and adults (odds ratio, 0.70 [CI, 0.56 to 0.87]). Lower-intensity interventions were generally not effective in adults, but some approaches were promising. Although moderate-intensity interventions may be effective in adolescents, data were very sparse. Reported behavioral outcomes were heterogeneous and most likely to show a benefit with high-intensity interventions at 6 months or less. No consistent evidence was found that sexual risk-reduction counseling was harmful.

Limitations: Low-risk populations and male adolescents were underrepresented. Reliability of self-reported behavioral outcomes was unknown.

Conclusion: High-intensity counseling on sexual risk reduction can reduce STIs in primary care and related settings, especially in sexually active adolescents and in adults at increased risk for STIs.

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The Centers for Disease Control and Prevention estimates that approximately 20 million new cases of sexually transmitted infections (STIs) occur each year in the United States, half of which are among persons aged 15 to 24 years (1). In 2003 and 2004, 38% of sexually active female adolescents aged 14 to 19 years had an STI (2). In 2010, the inflation-adjusted annual direct medical costs of STIs were estimated to be $16.9 billion in the United States (3).

In 2008, the U.S. Preventive Services Task Force (USPSTF) recommended high-intensity behavioral counseling interventions for sexually active adolescents and in adults at increased risk for STIs (B recommendation). The evidence was insufficient, however, to assess the balance of benefits and harms of behavioral counseling to prevent STIs in nonsexually active adolescents and in adults not at increased risk for STIs (I statement). This systematic review updates the previous review that formed the basis of the 2008 recommendation. We developed an analytic framework (**Appendix Figure 1**, available at www.annals.org) with 4 key questions (**Appendix Table 1**, available at www.annals.org) that address counseling's effects on patient health outcomes (key question 1), behavioral outcomes (key question 2), other positive outcomes (key question 3), and harms of counseling (key question 4).

See also:

Related articles 884, 894, 902

Web-Only
Supplements

Methods

The full report describes our methods in detail (4).

Data Sources and Searches

To identify the cumulative body of literature, we examined all studies included in the previous USPSTF review and searched MEDLINE, PubMed, Cochrane Central Register of Controlled Trials, and CINAHL from 1 January 2007 through 4 November 2013 to identify relevant articles published since the previous review (5). We also searched the bibliographies of relevant reviews and Web sites of governmental agencies and professional organizations, and we consulted with outside experts. Between 4 November 2013 and this publication, we actively monitored published literature for potentially important new

trials directly relevant to the key questions in this systematic review; none were located.

Study Selection

Two investigators independently reviewed abstracts and relevant full-text articles against prespecified inclusion criteria. We included trials evaluating counseling interventions targeting risky sexual behaviors to prevent STIs in adults and adolescents. We excluded studies limited to persons with HIV (or populations with very high prevalence of HIV [>10% in the study sample]), inmates and parolees, and persons in inpatient or residential settings because results limited to these groups may not be applicable to general primary care populations.

We required that included interventions be conducted in, or participants be recruited from, primary care or other outpatient clinical settings, including reproductive health clinics, STI clinics, and mental health clinics. We included English-language trials conducted in "very high" human development countries according to the World Health Organization (6). We accepted the following comparators as control groups: usual care, attention control, minimal intervention (<15 minutes of intervention contact), wait list, or no intervention. We included trials reporting 1 or more of the following at 3 months or later after baseline: patient health outcomes (STI incidence and morbidity or mortality related to STIs), sexual behavioral outcomes (for example, condom use or number of sexual partners), and harms of the intervention (for example, care avoidance).

Data Extraction and Quality Assessment

Two investigators independently assessed the methodological quality of each study using USPSTF criteria (7). Studies were rated as good, fair, or poor quality. Good-quality studies had adequate randomization procedures, allocation concealment, blinding of outcome assessors, reliable outcome measures (for example, at least standard laboratory procedures or efforts to minimize demand characteristics for self-reported outcomes), similar groups at baseline and follow-up, low attrition, acceptable statistical methods, and adequate adherence to the intervention. Fair-quality trials met some but not all of these criteria. Poor-quality studies had a serious flaw (for example, attrition >40%, differential attrition >20% between groups, or substantial baseline differences between groups) or multiple important limitations that would invalidate the study findings. We excluded all poor-quality studies. We resolved disagreements through discussion and, if necessary, consultation with a third investigator. One investigator abstracted data from all included studies into a standard evidence table. A second investigator checked the data for accuracy.

Data Synthesis and Analysis

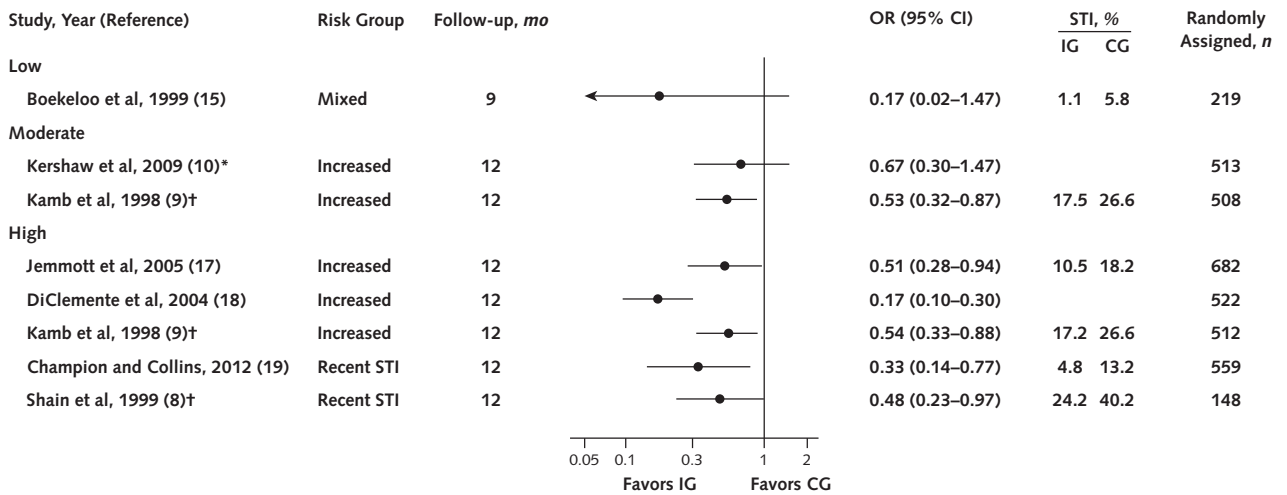
We created summary tables for each key question that included trial characteristics and summaries of results and qualitatively examined the range of results and potential associations with effect size. We stratified our analyses on the basis of age (adolescents vs. adults, including age-based subgroup analyses when reported [8–10]) and estimated intervention intensity: high (>2 hours of intervention contact), moderate (0.5 to 2 hours of intervention contact), and low (brief single session or <0.5 hour of intervention contact). These cut points were selected to correspond with a typical, single brief session that would be feasible in a primary care office (low intensity); a longer single session or 2 to 3 brief sessions that may be feasible in selected primary care settings (medium intensity); and what would probably require multiple nonbrief sessions, usually necessitating specialized and trained staff that could be referred from primary care (high intensity). We categorized populations on the basis of STI "risk." "Low/mix" referred to a mix of sexually active and pre–sexually active participants (for adolescents only). "General" referred to sexually active adults with no further risk factors and not in a setting with increased risk (for adults only). "Increased" referred to participants with increased risk based on sociodemographics (sexually active teenagers, low-income inner-city residents, racial/ethnic subgroups with higher STI prevalence, men who have sex with men [MSM], and mentally ill or disabled persons), sexual history (for example, persons reporting high-risk behaviors), or setting (for example, STI clinics). The "prior STI" category was limited to persons with a current or recent STI at baseline. Additional potential moderators or mediators that we examined in exploratory qualitative analysis include characteristics of the interventions (degree of cultural tailoring, group vs. individual format, condom negotiation or other communication training as an intervention component, counselor characteristics, setting, type of control group, or number of sessions) and population (sex, sexual orientation, socioeconomic status, mental health issues, or history of abuse).

We did random-effects meta-analyses for STI incidence using the DerSimonian–Laird method (11). We analyzed odds ratios (ORs) because they were the most commonly reported outcome, which allowed us to include the largest number of studies in the meta-analysis. We ran sensitivity analyses using the profile likelihood method because some of our pooled estimates were derived from a small number of trials (12). Results were very similar, and all statistically significant results remained statistically significant with the profile likelihood method. Results shown on forest plots are from the DerSimonian–Laird analyses. Statistical heterogeneity was assessed using the I^2 statistic (13). We used Stata, version 11.2 (StataCorp), for all meta-analyses.

Role of Funding Source

The Agency for Healthcare Research and Quality (AHRQ) funded this review under a contract to support the work of the USPSTF. Members of the USPSTF and an AHRQ medical officer assisted in defining this review's scope. The AHRQ staff provided oversight for the project and assisted in the external review of the companion draft evidence synthesis. Although approval from AHRQ was

Figure 1. **STI incidence in included trials targeting adolescents.**



CG = control group; IG = intervention group; OR = odds ratio; STI = sexually transmitted infection.
* Pregnant adolescent subgroup.
† Adolescent subgroup.

required before submission of the manuscript, the authors are solely responsible for its content and the decision to submit it for publication.

RESULTS

Thirty-one trials (8–10, 14–41), reported in 57 publications (8–10, 14–67), were selected from our review of 3241 abstracts and 218 full-text articles (**Appendix Figure 2**, available at www.annals.org). Of the 31 included trials (n = 70 324), 16 were newly published and not included in the previous review (n = 56 110). Most evidence comes from trials in women and nonwhite or minority populations. Most trials targeted high-risk groups based on demographic characteristics, high-risk behaviors, or presence of a recent STI. Study details (including target populations) are presented in **Appendix Tables 2** and **3** (available at www.annals.org) for adolescents and adults, respectively, and **Supplements 1** and **2** (available at www.annals.org).

Although the interventions were very heterogeneous, there were some shared components. All interventions sought to minimize high-risk sexual behaviors (for example, unprotected sexual intercourse or multiple partners) and maximize protective behaviors (for example, condom use). Interventions provided basic information about STIs and commonly included risk assessment, hands-on skill training in condom use, problem solving, decision making, goal-setting, and communication surrounding condom use and safe sex. The depth with which topics were covered varied. Some interventions included additional components, such as HIV testing and contraceptive counseling. Many interventions were culturally tailored to a target group, usually based on age, gender, and ethnicity.

The interventions included 1 to 13 sessions, which ranged from mail-, computer-, or video-only interventions to up to 17 hours of face-to-face contact. We categorized 16 of the intervention groups as high intensity, 10 as moderate intensity, and 9 as low intensity. Most of the high-intensity interventions involved group sessions with extensive educational and behavior change components. Most moderate-intensity interventions involved 1 or 2 individual meetings for a total of 45 to 60 minutes of contact, although several involved group meetings. Most low-intensity interventions involved brief individual meetings with a counselor or primary care provider or were limited to print, computer-based, or video-based materials. Almost all (k = 28) trials were done in the United States. The most common settings were primary care (k = 15) (10, 14–18, 20, 22, 25–27, 29, 34, 36, 40) and STI clinics (k = 8) (9, 23, 28, 30, 35, 38, 39, 41).

Benefits of Sexual Risk-Reduction Counseling

Twenty-three of the included trials reported at least 1 STI outcome (n = 66 902) (8–10, 15, 17–24, 28–30, 33–36, 38–41). Twenty of these could be included in quantitative analysis (**Figures 1** and **2**) (8–10, 15, 17–19, 21–23, 28–30, 33, 34, 36, 38–41). Twenty-six of the trials reported a behavioral outcome, which was usually condom use or unprotected sex occasions (8–10, 14–18, 20–23, 25–27, 29, 31–39, 41).

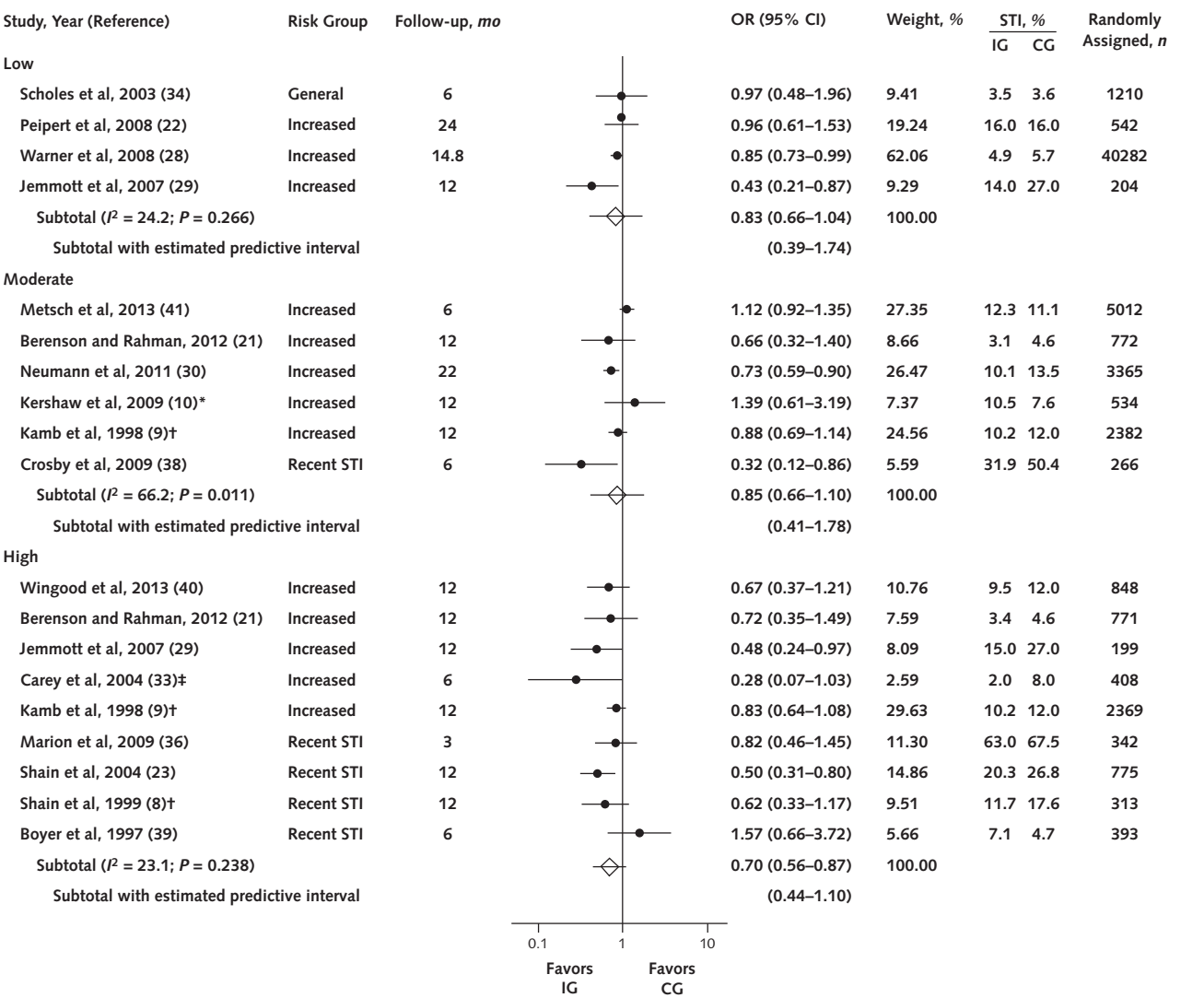
The STI results were generally based on laboratory tests for bacterial infections, most commonly gonorrhea and chlamydia. Because studies provided treatment of baseline infections, bacterial infections at follow-up were considered new infections. For studies that included viral infection outcomes, only infections after baseline assess-

ment were counted in the results. Most trials collected their own samples at follow-up assessment, and many supplemented their testing with patient medical records to identify STIs that occurred between assessments. A few relied on only medical records or patient self-report for STI results.

Adolescents

Incidence of STIs was reduced in all 8 comparisons targeting adolescents ($n = 3407$) (**Figure 1**), although results were not statistically significant in 2 trials (10, 15). Pooled results showed a 62% reduction in the odds of contracting an STI with high-intensity counseling after 12 months (DerSimonian–Laird OR, 0.38 [95% CI, 0.24 to 0.60]; $I^2 = 65\%$; profile likelihood OR, 0.38 [CI, 0.23 to 0.62]; $I^2 = 55\%$; $k = 5$). The CIs suggest that a reduction of 40% or more in the odds of incident STIs with these interventions is likely. When reported, STI rates at follow-up ranged from 13% to 40% in the control groups of trials with high-intensity interventions compared with 5% to 24% in the intervention groups. The 2 moderate-intensity intervention groups resulted in reductions of 33% to 47% in the odds of having an STI, only 1 of which was statistically significant. The only low-intensity intervention trial ($n = 219$) involved a single brief contact with the primary care provider plus a video and print materials for

Figure 2. **STI incidence in included trials targeting adults.**



CG = control group; IG = intervention group; OR = odds ratio; STI = sexually transmitted infection.
* Pregnant adult subgroup.
† Adult subgroup.
‡ Psychiatric patients.

persons aged 12 to 15 years, most of whom were reportedly not sexually active. The young age of the participants and the reliance of the trial on self-report of STI symptoms rather than biological confirmation may have contributed to the low number of STIs at follow-up and statistically nonsignificant group differences (15).

Six trials ($n = 3030$) reported sexual behavior outcomes, and most found beneficial effects for some behavioral outcomes (8, 14–18). Measures of behavior change were very heterogeneous. Measures of condom use or unprotected sex were the most commonly reported behavioral outcomes.

Most trials were limited to sexually active African American and Latina girls; only 1 trial included sexually active male and female teenagers (9). Only 1 of the trials in adolescents was rated as good quality. Several had attrition greater than 15% (up to 34% in 1 trial), and many did not describe their allocation concealment procedures. Four were conducted in, or adolescents were recruited from, primary care settings. Although all 4 of these trials reported reductions in the odds of contracting an STI of 33% or more, not all effects were statistically significant (10, 15, 17, 18).

Heterogeneity was high ($I^2 = 65\%$) in the analysis of high-intensity interventions because of the very large effect size for the outcome of chlamydia infection incidence in 1 study (18). However, I^2 was reduced to 0% in sensitivity analyses when infections of gonorrhea and trichomonas, instead of chlamydia, were analyzed, with only minor attenuation of pooled effect size (OR changed from 0.38 to 0.48). This study did not report a composite outcome of any STI, and we chose, a priori, chlamydia infection as our primary outcome because it has the highest prevalence of the 3 STIs examined.

Adults

Nineteen trials ($n = 61\,909$) reported STI outcomes in adult populations, and 7 of these were conducted in, or participants were recruited from, primary care (10, 20, 22, 29, 34, 36, 40). All trials were included in the meta-analysis except 3 that did not provide necessary data on any of the commonly reported STIs (20, 24, 35).

High-intensity interventions resulted in a 30% reduction in the odds of contracting an STI (DerSimonian–Laird OR, 0.70 [CI, 0.56 to 0.87]; $I^2 = 23\%$; profile likelihood OR, 0.71 [CI, 0.55 to 0.86]; $I^2 = 6\%$; $k = 9$) (**Figure 2**). Upper CIs indicate high probability of at least a 13% to 14% reduction in STIs with high-intensity interventions. The proportion of persons with an STI at follow-up in the high-intensity intervention groups ranged from 2% to 63% compared with 5% to 68% in the control groups. Three of the high-intensity trials were done in primary care settings with ORs ranging from 0.48 (CI, 0.24 to 0.97) to 0.82 (CI, 0.46 to 1.45) (29, 36, 40).

The pooled effects for low- and moderate-intensity trials did not show a reduction in the odds of contracting an STI (**Figure 2**), and most trials did not report group differences, including the 3 trials that could not be included in the meta-analysis. Some of the low- and moderate-intensity trials were effective, however.

Most (9 of 12) of the high-intensity interventions with behavioral outcomes reported beneficial results for at least 1 behavioral outcome. All 4 of the high-intensity trials reporting ORs found increases of 24% to 42% in the odds of condom use (**Appendix Figure 3**, available at www.annals.org). The moderate-intensity interventions had mixed findings, with ORs for condom use and unprotected sex outcomes ranging from 0.98 to 2.2 and CIs crossing 1.0 for the smaller ORs. Most of the low-intensity interventions showed no group differences in behavioral outcomes; although some ORs were large (up to 5.2), CIs were generally very wide and all crossed 1.0. Specific measures of sexual behavior were reported inconsistently, and some trials reported many interrelated behavioral outcomes, which raised concern about opportunistic reporting and elevated type II error rates.

Many of the adult trials were limited to African American and Latina women; however, several studies included men and women and 1 focused on African American men. A few studies included very narrow subpopulations (for example, psychiatric patients or women with genital warts). Only 6 of the adult trials were rated as good quality. Along with concerns about selective reporting of behavioral outcomes, common concerns in the fair-quality trials included high attrition (15% to 40%) and lack of information about randomization and allocation concealment.

Characteristics Influencing the Effectiveness of the Interventions

Population Characteristics

Most of the included trials were done in fairly narrow populations known to have high STI prevalence. Many of the trials targeting African American and/or Latina women were effective in reducing STI incidence. Some trials analyzed subgroups to examine whether their intervention was effective in particular subpopulations, such as smaller age groups, men and women separately, MSM separately from exclusively heterosexual men, persons with and without a history of STIs, and persons with and without a history of substance abuse. Age group was the most common subpopulation difference tested. All 3 trials that reported results separately for adolescents and adults found group differences for adolescents but not adults in at least 1 active intervention group (8–10). Other than the greater likelihood of benefit in adolescents, no clear evidence suggested that interventions were more or less likely to be effective for any important subpopulation. Some subpopulations, however, were poorly represented, such as MSM and American Indian and Alaska Native persons. Subgroup results were usually consistent with overall study results.

Intervention Characteristics

Intervention intensity was the only characteristic that clearly influenced outcomes in these trials. On the basis of qualitative synthesis, we found no clear relationship between the effect size and degree of cultural tailoring, group versus individual format, condom negotiation training, other communication training, counselor characteristics, setting, type of control group, or number of sessions. We could not isolate effects of these features, however, because they were not evenly distributed across the spectrum of intervention intensity or population risk.

Harms of Sexual Risk-Reduction Counseling

Three trials explicitly reported on adverse events (n = 6837) and found no harms related to the counseling interventions (35, 36, 41). We found no statistically significant paradoxical increase in the overall incidence of STIs among any of the studies. A subgroup analysis in 1 trial, however, showed a statistically significant deleterious effect on STI incidence in MSM, with 12.5% of control and 18.7% of intervention participants having an STI at follow-up (adjusted relative risk, 1.41 [98.3% CI, 1.05 to 1.90]) (41). The intervention involved a 25-minute session in an STI clinic before taking a rapid HIV test and a brief follow-up intervention after receiving the results. One other trial testing the brief video-based intervention in STI clinics provided subgroup results for MSM and did not see a deleterious effect (28).

No consistent evidence was found that interventions increased sexual activity in adolescents. Although 1 trial reported a short-term increase in the proportion of youth who were sexually active in the previous 3 months (15), another reported a decrease in this proportion (14). Other trials found no differences in frequency or number of partners (8, 17, 68).

Discussion

Consistent with the evidence considered in 2008, we found that high-intensity (>2 hours) interventions were likely to reduce the rate of STIs in both adults and sexually active adolescents. Condom use also increased with high-intensity interventions, particularly in the short term. Some moderate- and low-intensity interventions were beneficial but less likely to show improvement over usual care. A summary of the evidence is shown in the **Table**. Although a few more trials included men than in the previous review, most still targeted adolescent and young adult African American and Latina women and generalizability to other populations is unclear.

Although we could not identify specific components that were associated with treatment benefit, interventions that were successful generally provided most or all of the following: information about STIs, such as prevalence, transmission, and details on how to reduce the risk for transmission; help in identifying personal risk for STIs; training in common behavior change processes, such as problem solving, decision making, and goal-setting; training in communication surrounding condom use and safe sex; and hands-on practice with condoms. Many successful interventions were also specifically tailored to the gender and race/ethnicity of the participants. These types of interventions are generally not feasible in a typical primary care visit, but they could be feasible in an integrated care setting that included a behavior specialist who was trained to provide sexual risk-reduction counseling. Materials for many of the included interventions are freely available from the authors or online.

We found no consistent evidence suggesting that sexual risk-reduction counseling is harmful for adults or adolescents. The 2 trials in young, mostly pre–sexually active adolescents that reported the proportion of participants engaging in any sexual activity had contradictory results, and sparse reporting precludes us from drawing conclusions. A review of community-based, comprehensive interventions for sexual risk reduction, however, found that similar interventions reduced sexual activity (69).

On the basis of pooled results, 11 high-risk adolescents (95% CI, 9 to 18) would have to receive high-intensity interventions to prevent 1 STI, which assumes a baseline cumulative incidence of 15% over 1 year. Trial data, however, were limited primarily to sexually active urban African American and Latina girls, and generalizability to other sexually active adolescents is unknown. In high-risk adult populations, 25 adults (CI, 17 to 59) would need high-intensity counseling to prevent 1 STI in a setting with an annual cumulative STI incidence of 15%, again based largely on African American and Latina women. This would prevent 41 cases of STIs per 1000 adults. Based on real-world estimates of STI prevalence and patient volume (70), approximately 1300 STIs could potentially be prevented in a large county health department with widespread adoption of high-intensity counseling.

The effects of primary care–based counseling on sexual risk reduction may also potentiate the effects of other types of community-level interventions. For example, the likelihood of benefit from condom distribution programs is enhanced with additional individual, small-group, or community interventions on STI prevention (71). Thus, STI prevention may be enhanced if people hear risk-reduction messages from multiple sources, multiple times. Even relatively modest effects may contribute to clinically important effects in communities in which messages from other sources are also frequently encountered.

One of the main limitations of this report is that it includes relatively little information on populations other than high-risk African American and Latina women. Although this is an important population, the effects in men (particularly MSM and adolescent men) and women of other races or ethnicities are not as well-understood, yet they still experience substantial health burden from STIs. The body of literature on STI and HIV prevention for MSM in community settings is large, however. The Cen-

Table. **Summary of Evidence**

Population	Trials and Observations, *n*	Study Design	Quality; Major Limitations	Consistency	Applicability	Summary of Findings
Key question 1: health outcomes						
Adolescents	Trials: 7 Comparisons: 8 Observations: 3407	RCTs (k = 5); subgroup analyses from RCTs (k = 3)	Fair; minimal data for low- and moderate-intensity interventions; little evidence on effects of counseling in boys, race/ethnicity groups other than African Americans and Latinos, and pre–sexually active adolescents	Consistent	Primarily to African American and Latina girls, particularly in low-income urban settings	Sexual risk-reduction counseling generally reduced the odds of STIs in sexually active adolescents in high-intensity interventions (OR, 0.38 [95% CI, 0.24–0.60]; k = 5; I^2 = 65%); data limited for moderate- and low-intensity interventions; insufficient data on pre–sexually active teenagers (k = 1 in young adolescents; few events)
Adults	Trials: 19 Comparisons: 23 Observations: 61 909	RCTs (k = 19); subgroup analyses from RCTs (k = 4)	Fair; minimal evidence on MSM, few data on general or low-risk primary care settings, and no information on adults aged ≥50 y	Moderately inconsistent	Primarily to younger adults at increased risk for STIs	High-intensity interventions reduced odds of STIs by an average of 30% (OR, 0.70 [95% CI, 0.56–0.87]; k = 9, I^2 =23%); most low- and moderate-intensity interventions were not effective, and pooled estimates did not show a benefit of risk-reduction counseling, although some promising approaches were identified
Key question 2: behavioral outcomes						
Adolescents	Trials: 6 Observations: 3030	RCTs (k = 5); subgroup analyses from RCTs (k = 1)	Fair; relies on potentially unreliable self-reported outcomes; inconsistency in outcomes reported; some outcomes very sparsely reported; same applicability limitations as key question 1	Inconsistent	Primarily to African American and Latina girls, particularly in low-income urban settings	3 of 5 trials reporting outcomes related to condom use found group differences on ≥1 outcome at ≥1 follow-up assessments; other sexual outcomes were sparsely reported, but 4 trials found improvements on other sexual outcomes
Adults	Trials: 21 Comparisons: 25 Observations: 19 288	RCTs (k = 21); subgroup analyses from RCTs (k = 3)	Fair; relies on potentially unreliable self-reported outcomes; inconsistency in outcomes reported; some outcomes very sparsely reported; same applicability limitations as key question 1	Inconsistent	Primarily to younger adults at increased risk for STIs	Most high-intensity trials reported improvements in some behavioral outcomes at some time point; pooled analysis showed a 29% increase in percentage reporting use of condoms in 4 trials (OR, 1.29 [95% CI, 1.13–1.48]; I^2 = 0%); results in moderate-intensity interventions were mixed; 6 low-intensity trials suggested little to no benefit on behavioral outcomes
Key question 3: other positive outcomes						
Adolescents	Trials: 3 Observations: 1936	RCTs	Fair; very sparse data for any single outcome and risk of reporting bias	Inconsistent	Very limited	3 trials reported pregnancy or birth control use; 1 found a short-term (6 mo) reduction in pregnancy, but group differences did not persist at 12 mo
Adults	Trials: 6 Observations: 4062	RCTs	Fair; very sparse data for any single outcome and risk of reporting bias	Pregnancy outcome consistent; NA for other outcomes	Sexually active women	4 trials reported no differences in pregnancy, but 1 of these increased use of a dual contraceptive method (condom plus other) in the intervention group; single trials each reported greater reduction in depression in intervention participants and no differences in intimate partner violence
Key question 4: harms*						
Adults	Trials: 3 Observations: 6792	RCTs	Fair; rarely reported and methods of ascertainment not reported	Consistent	Very limited	2 trials found no harms of counseling; 1 trial found more nonserious harms (e.g., pain at finger-stick site) related to HIV testing among intervention group than control; 2 trials showed statistically nonsignificant increases in STI but with few events overall

MSM = men who have sex with men; NA = not applicable; OR = odds ratio; RCT = randomized, controlled trial; STI = sexually transmitted infection.
* No consistent evidence was found that interventions increased sexual activity in adolescents.

ters for Disease Control and Prevention Community Guide found community-based individual, group, and community-level interventions to be effective in reducing the risk for STIs in MSM (72).

Another limitation of our review is that intervention intensity was difficult to ascertain. We estimated the intervention time, but trials did not always provide details of contact time, and the chosen cut points of 30 minutes and 2 hours were somewhat arbitrary. Although greater contact time improved the likelihood of reducing STIs, the minimum time necessary for benefit was not clear. Further, the quality and intensity of counseling provided in usual care influence trial results; when usual care is extremely minimal, a relatively brief intervention might improve it enough to show a benefit.

We also excluded studies with high HIV prevalence, which we defined as more than 10% of the sample. Some STI clinics may have HIV prevalence in this range and serve populations similar to those in some included studies. Nevertheless, most of the studies we excluded for this reason were limited to only persons with HIV or their partners, which clearly represents a distinct subpopulation. In contrast, one of the studies in our review specifically described their patient population as having high HIV seroprevalence but was included because HIV prevalence in the study sample was lower than 10% (31).

We also did not consider important strategies of STI risk reduction that cannot be implemented in health care settings or that go beyond risk-reduction counseling (for example, STI or HIV testing, partner notification, school-based programs, and condom distribution programs). Other USPSTF reviews address STI testing (73), and the Centers for Disease Control and Prevention maintains a regularly updated compendium of evidence-based individual, group, and community-level interventions on risk reduction and associated dissemination materials, which target a wide range of populations and risk-reduction strategies (74).

More data are needed in mixed-sex populations and broadly applicable interventions that could be implemented in primary care. In addition, the effective low- and moderate-intensity interventions in adults should be replicated (28–30, 38). Uses of interactive mobile, Web-based, or other automated expert systems have been only minimally assessed for STI risk reduction in primary care.

High-intensity interventions conducted in primary care or similar health care settings can reduce sexually transmitted infections and risky sexual behavior in adolescents and in adults who are at high risk for STIs, and they are unlikely to be harmful.

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Disclaimer: The views expressed in this manuscript do not represent and should not be construed to represent a determination or policy of the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services.

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Request for Single Reprints: Reprints are available from the AHRQ Web site (www.ahrq.gov).

Current author addresses and author contributions are available at www.annals.org.

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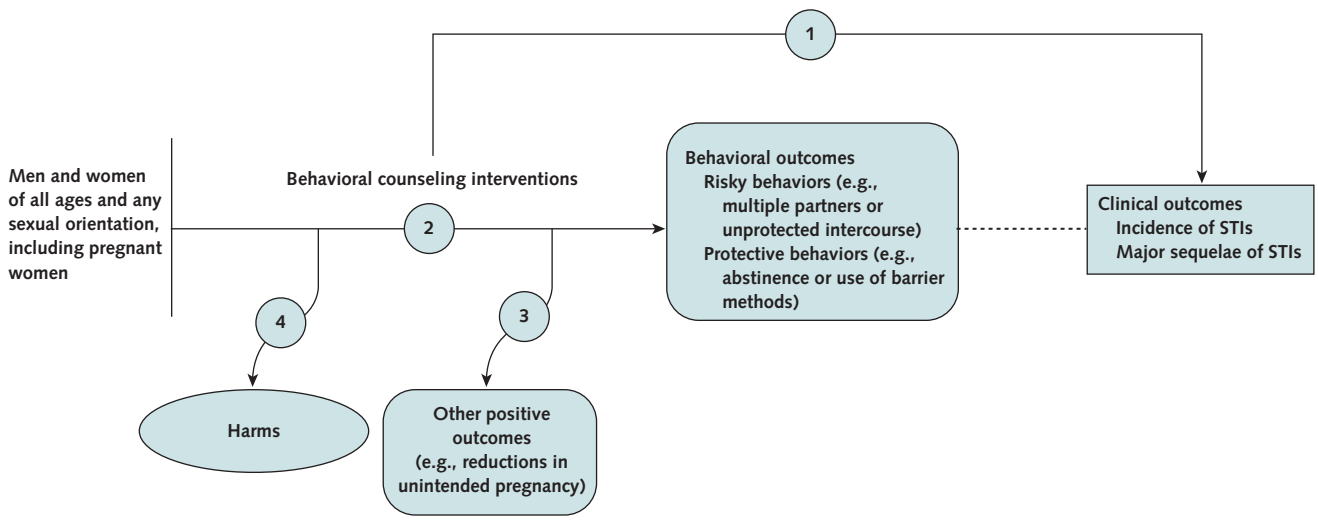
Appendix Table 1. **Key Questions**

KQ 1. Is there direct evidence that behavioral counseling interventions to reduce risky sexual behaviors and increase protective sexual behaviors reduce STI and/or related morbidity and mortality?
  a. Are there population or intervention characteristics that influence the effectiveness of the interventions?
KQ 2. Do behavioral counseling interventions to prevent STIs reduce risky sexual behaviors or increase protective sexual behaviors?
  a. Are there population or intervention characteristics that influence the effectiveness of the interventions?
KQ 3. Are there other positive outcomes besides STI incidence and changes in risky or protective sexual behaviors from behavioral counseling interventions to prevent STIs?
KQ 4. What adverse effects are associated with primary care behavioral counseling interventions to prevent STIs?

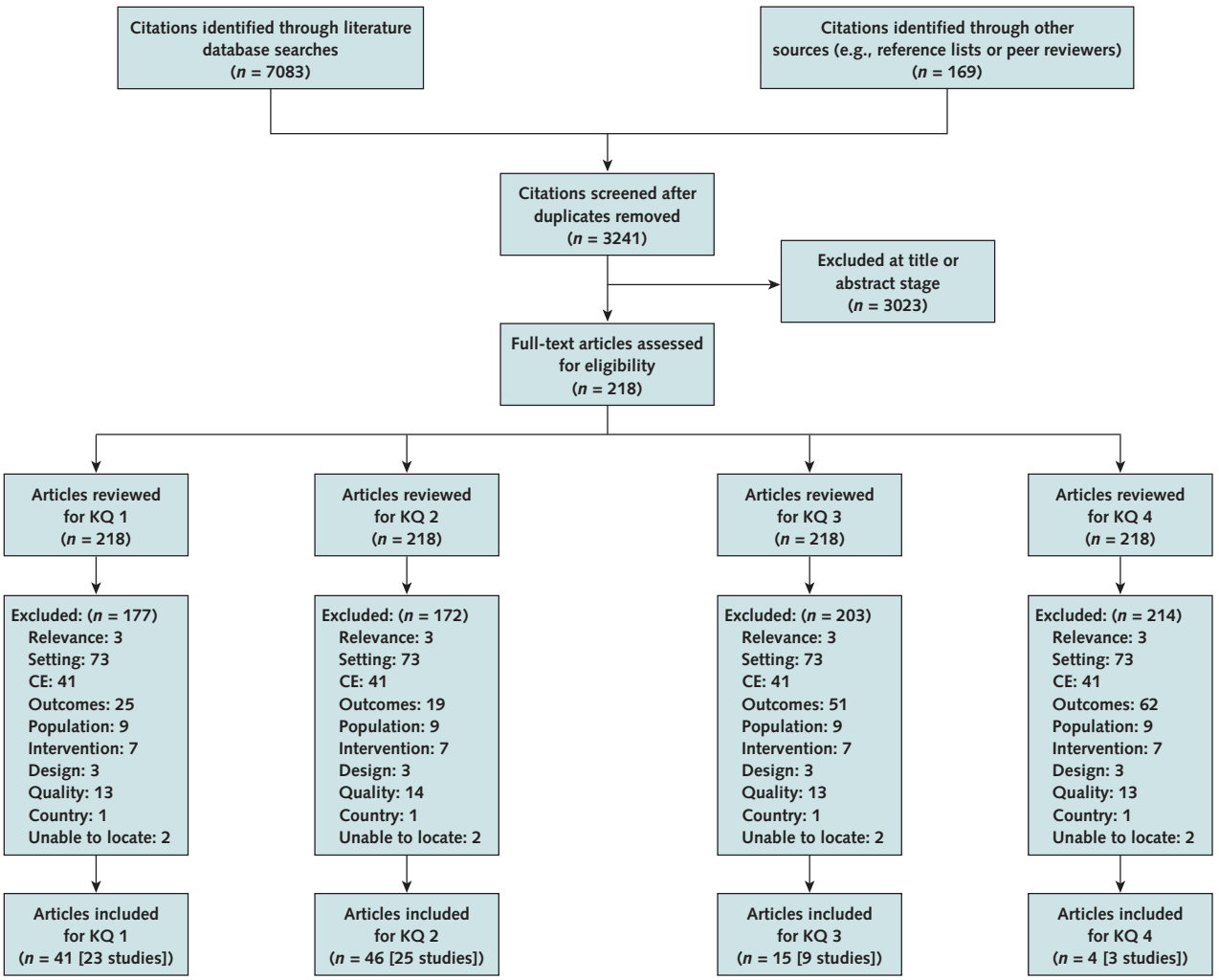
KQ = key question; STI = sexually transmitted infection.

Appendix Figure 1. **Analytic framework.**



STI = sexually transmitted infection.

Appendix Figure 2. **Summary of evidence search and selection.**



CE = comparative effectiveness; KQ = key question.

Appendix Table 2. Summary of Included Studies: Adolescents

Risk	Study, Year (Reference)	Quality	Location	Setting	Patients Randomly Assigned, *n*	Population	STI History	Follow-up Time Points, *mo*	STI Outcomes*	Unprotected Intercourse and Condom Use*	Other Sexual Behavior Outcomes*	Other Positive Outcomes*
Low-intensity interventions (<30 min)												
Low/mix	Boekeloo et al, 1999 (15), and Akers, 2008 (42)	Fair	Washington, DC	Primary care	219	12–15 y	Treated for STI: 5.9%	3, 9	−†	±	±	−
Moderate-intensity interventions (30–120 min)												
Low/mix	Guilamo-Ramos et al, 2011 (14)	Fair	New York City	Primary care	264	African Americans and Latinos aged 11–14 y	NR	9			+	
Low/mix	Danielson et al, 1990 (16)	Fair	Portland, Oregon, and Vancouver, Washington	HMO	1195	Boys aged 15–18 y	NR	12		−		+
Increased	Kershaw et al, 2009 (10)	Fair	Atlanta, Georgia, and New Haven, Connecticut	Primary care	513 (subgroup)	Pregnant adolescents aged <20 y	Lifetime STI: "more than half"	Third trimester, 6, 12	−			
Increased	Kamb et al, 1998 (9); Bolu et al, 2004 (44); Gottlieb et al, 2004 (49); Rhodes et al, 2007 (63); and Semaan et al, 2010 (65)	Fair	5 U.S. cities	STI clinic	508 (subgroup)	Sexually active adolescents aged 14–19 y	Baseline STI: 32%‡	3, 6, 9, 12	+			
High-intensity interventions (>120 min)												
Increased	Jemmott et al, 2005 (17)	Good	Philadelphia, Pennsylvania	Primary care	682	Sexually active African American or Latino adolescent girls aged 12–19 y	Baseline STI: 21.6%	3, 6, 12	±	±	±	
Increased	DiClemente et al, 2004 (18); Benner, 2008 (43); Lang et al, 2009 (53); Milhausen et al, 2008 (57); Kirby, 2008 (58); Sales et al, 2010 (64); and Wingood et al, 2006 (67)	Good	Birmingham, Alabama	Primary care	522	Sexually active African American adolescent girls aged 14–18 y	Baseline STI: Gonorrhea: 5.2% Chlamydia: 17.4% Trichomonas: 12.6%	6, 12	±	+	−	±
Increased	Kamb et al, 1998 (9); Bolu et al, 2004 (44); Gottlieb et al, 2004 (49); Rhodes et al, 2007 (63); and Semaan et al, 2010 (65)	Fair	5 U.S. cities	STI clinic	512 (subgroup)	Sexually active adolescents aged 14–19 y	Baseline STI: 32%‡	3, 6, 9, 12	+			
Prior STI	Champion and Collins, 2012 (19)	Fair	Southwestern United States	Research clinic	559	Ethnic minority adolescent girls with STI or abuse	Lifetime STI: 100% (of analyzed sample)	6, 12	+			
Prior STI	Shain et al, 1999 (8)	Fair	San Antonio, Texas	Research clinic	148 (subgroup)	Mexican American and African American adolescent girls aged 14–18 y with a nonviral STI	Baseline STI: 100%	6, 12	+	−	±	

NR = not reported; STI = sexually transmitted infection.

* Plus (+) sign denotes results that consistently showed a benefit of treatment. Minus (−) sign denotes results that consistently showed no differences between groups. Plus/minus (±) sign denotes results that were mixed, with benefit seen for some outcomes or follow-ups but not all.

† Self-reported (only or in part) STI outcome.

‡ Data for entire study population, which included adults and adolescents.

Appendix Table 3. Summary of Included Studies: Adults

Risk	Study, Year (Reference)	Quality	Location	Setting	Patients Randomly Assigned, *n*	Population	STI History	Follow-up Time Points, *mo*	STI Outcomes*	Unprotected Intercourse and Condom Use*	Other Sexual Behavior Outcomes*	Other Positive Outcomes*	Other Harms*
Low-intensity interventions (<30 min)													
General	Proude et al, 2004 (26)	Fair	Australia	Primary care	312	Aged 18–25 y	NR	3		−			
General	Scholes et al, 2003 (34)	Fair	Washington and North Carolina	Primary care	1210	Sexually active nonmonogamous women aged 18–24 y	Lifetime STI: 27%	6	−†	±			
Increased	Carey et al, 2010 (35) and 2008 (45), and Mittal et al, 2011 (60)	Fair	Syracuse, New York	STI clinic	496	Aged ≥18 y with high-risk behavior in past 3 mo	Baseline STI: 18.1%	3, 6, 12	−	−	−		−
Increased	Peipert et al, 2008 (22) and 2007 (62)	Fair	Providence, Rhode Island	Primary care and Planned Parenthood	542	Women aged 13–35 y at high risk for STI or unplanned pregnancy because of age, behavior, history of STI, or pregnancy	Lifetime STI: 47%	24	−	−		−	
Increased	Warner et al, 2008 (28)	Good	Denver, Colorado, and Long Beach and San Francisco, California	STI clinic	40 282	All patients	Baseline STI: 15.5%	14.8	+				
Increased	Jemmott et al, 2007 (29), and O'Leary et al, 2008 (61)	Good	Newark, New Jersey	Primary care	322	African American women aged 18–45 y	Baseline STI: 20.3%	6, 12	±‡	±‡			
Prior STI	Marrazzo et al, 2011 (24), 2008 (54), and 2010 (55)	Fair	Seattle, Washington	Research clinic	89	Women aged 16–30 y with bacterial vaginosis who have sex with women	Current bacterial vaginosis: 100%	3, 6, 9, 12	−				
Prior STI	Cortes-Bordoy et al, 2010 (37)	Fair	Spain	Gynecology clinic	211	Women aged ≥18 y with vulvoperineal warts	Lifetime STI: 100%	3, 6, 9, 12		−	+	−	
Moderate-intensity interventions (30–120 min)													
General	Petersen et al, 2007 (20)	Fair	Chapel Hill, North Carolina	Primary care	764	Women aged 16–44 y at risk for unintended pregnancy (no IUD or sterilization)	NR	12	−	−		−	
General	Wenger et al, 1992 (27)	Fair	Los Angeles, California	Primary care	435	University students aged ≥18 y	Lifetime STI: 23%	6		−	−		
Increased	Metsch et al, 2013 (41)	Good	7 states and Washington, DC	STI clinics	5012	Aged ≥18 y; seeking services at an STI clinic	Baseline STI: 43.3%	6	−	−	±		−
Increased	Berenson and Rahman, 2012 (21)	Fair	Southeast Texas	Reproductive health clinic	771	Sexually active women aged 16–24 y	Lifetime STI: 26.1%	3, 6	−†	−		−	
Increased	Neumann et al, 2011 (30)	Fair	Harlem, New York, and Puerto Rico	STI clinics	3365	Aged ≥18 y; 99% racial/ethnic minority	Baseline STI: 22.2%	22	+				
Increased	Kershaw et al, 2009 (10)	Fair	Atlanta, Georgia, and New Haven, Connecticut	Primary care	1047	Pregnant women aged <25 y	Lifetime STI: "more than half"	Third trimester, 6, 12	−	±		±	
Increased	Kamb et al, 1998 (9); Bolu et al, 2004 (44); Gottlieb et al, 2004 (49); Rhodes et al, 2007 (63); and Semaan et al, 2010 (65)	Fair	5 U.S. cities	STI clinic	4320	Adults and adolescents aged ≥14 y	Baseline STI: 32%	3, 6, 9, 12	−§	±	±		
Prior STI	Crosby et al, 2009 (38)	Fair	Southern United States	STI clinic	266	African American men aged 18–29 y with newly diagnosed STI and recent experience with condoms	Baseline STI: 100%	3, 6	+	+	+		

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Appendix Table 3—**Continued**

Risk	Study, Year (Reference)	Quality	Location	Setting	Patients Randomly Assigned, *n*	Population	STI History	Follow-up Time Points, *mo*	STI Outcomes*	Unprotected Intercourse and Condom Use*	Other Sexual Behavior Outcomes*	Other Positive Outcomes*	Other Harms*
High-intensity interventions (>120 min)													
Increased	Wingood et al, 2013 (40)	Good	Atlanta, Georgia	HMO	848	Sexually active African American women aged 18–29 y	Baseline STI: 17%	6, 12	+				
Increased	Berenson and Rahman, 2012 (21)	Fair	Southeast Texas	Reproductive health clinic	772	Sexually active women aged 16–24 y	Lifetime STI: 26.1%	3, 6	−†	+		−	
Increased	Cianelli et al, 2012 (25)	Fair	Chile	Primary care	496	Chilean women aged 18–49 y	NR	3		−		+	
Increased	Carey et al, 2010 and 2008, and Mittal, et al, 2011 (35, 45, 60)	Fair	Syracuse, New York	STI clinic	1235	≥18 y with high-risk behavior in past 3 mo	Baseline STI: 18.1%	3, 6, 12	−	−	−		−
Increased	Berkman et al, 2007 (32)	Good	New York	Psychiatric clinic	149	Adult males aged 18–59 y with severe mental illness	NR	6, 12		−	−		
Increased	Jemmott et al, 2007 (29), and O'Leary et al, 2008 (61)	Fair	Newark, New Jersey	Primary care	323	African American women aged 18–45 y	Baseline STI: 20.3%	6, 12	±‡	±‡			
Increased	Carey et al, 2004 (33)	Fair	Syracuse, New York	Psychiatric clinic	408	Aged ≥18 y with a mood or thought disorder and alcohol or drug use in the past year	Lifetime STI: 38%	3, 6	+†	+	±		
Increased	Ehrhardt et al, 2002 (31); Dworkin et al, 2007 (47); Enrhardt et al, 2002 (48); Hoffman et al, 2003 (50); Melendez et al, 2003 (56); and Miller et al, 2000 (59)	Good	Brooklyn, New York	Planned Parenthood	360	Women aged 18–30 y	STI in the past 3 mo: 16.9%	6, 12		±	±	−	
Increased	Kamb et al, 1998 (9); Bolu et al, 2004 (44); Gottlieb et al, 2004 (49); Rhodes et al, 2007 (63); and Semaan et al, 2010 (65)	Fair	5 U.S. cities	STI clinic	4311	Adults and adolescents aged ≥14 y	Baseline STI: 32%	3, 6, 9, 12	−§	±	±		
Prior STI	Marion et al, 2009 (36)	Fair	Chicago, Illinois	Primary care	342	Low-income African American women aged ≥18 y with ≥2 STIs in the past year	Baseline STI: 75%	3	−		+		−
Prior STI	Shain et al, 2004 (23), and Champion et al, 2007 (46)	Fair	San Antonio, Texas	STI clinic	775	Mexican American and African American women aged 15–45 y with 1 of 4 STIs	Baseline STI: 100%	12, 24	+	+	+		
Prior STI	Shain et al, 1999 (8); Holden et al, 2008 (51); Korte et al, 2004 (52); and Thurman et al, 2008 (66)	Fair	San Antonio, Texas	Research clinic	617	Mexican American and African American women aged 14–45 with nonviral STI	Baseline STI: 100%	6, 12	−	+	±		
Prior STI	Boyer et al, 1997 (39)	Fair	San Francisco, California	STI clinic	393	Heterosexuals aged 18–35 y with a previous STI, STI symptoms, or known exposure to an STI	Lifetime STI: 61.8%	3, 5, 6	−	±			

IUD = intrauterine device; NR = not reported; STI = sexually transmitted infection.

* Plus (+) sign denotes results that consistently showed a benefit of treatment. Minus (−) sign denotes results that consistently showed no differences between groups. Plus/minus (±) sign denotes results that were mixed, with benefit seen for some outcomes or follow-ups but not all.

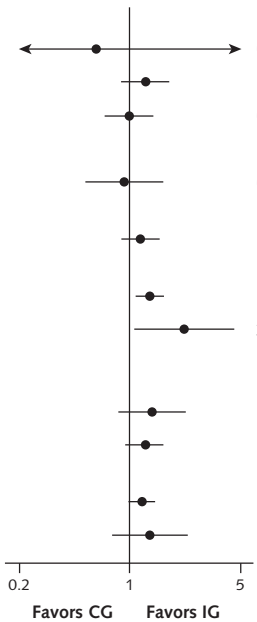
† Self-reported (only or in part) STI outcome.

‡ Data not reported separately for high- and low-intensity interventions. Instead, data were reported for skills-based approach (intervention groups 1 and 3) vs. control, skills-based (intervention groups 1 and 3) vs. information-based approach (intervention groups 2 and 4), and high (intervention group 1) vs. low (intervention group 3) intensity among skills-based interventions. (Intervention group 1: skills-based, high intensity; intervention group 2: information-based, high intensity; intervention group 3: skills-based, low intensity; intervention group 4: information-based, low intensity.)

§ STI results among adult subgroup only and not entire study population, which includes adults and adolescents.

Appendix Figure 3. **Condom use in included trials targeting adults.**

Study, Year (Reference)	Condom Use Measure	Risk Group	Follow-up, *mo*	OR (95% CI)	Condom Use, %		Randomly Assigned, *n*
					IG	CG	
Low							
Proude et al, 2004 (26)	Other	Low/mix	3	0.80 (0.13–5.09)	73	77	312
Scholes et al, 2003 (34)	Consistent use	Low/mix	6	1.24 (0.89–1.73)	36.8	33.5	1210
Peipert et al, 2008 (22)	Consistent use	Increased	24	0.99 (0.70–1.38)	46	46	542
Moderate							
Wenger et al, 1992 (27)	Used during last sexual intercourse	Low/mix	6	0.91 (0.53–1.58)	37	39	435
Berenson and Rahman, 2012 (21)	Used during last sexual intercourse	Increased	6	1.12 (0.87–1.45)	12	13.1	1155
Kamb et al, 1998 (9)	Consistent use	Increased	6	1.24 (1.04–1.49)	39	34	5758
Crosby et al, 2009 (38)	Used during last sexual intercourse	Recent STI	6	2.20 (1.08–4.48)	72.4	53.9	266
High							
Cianelli et al, 2012 (25)	Any use	Increased	3	1.46 (0.91–2.34)	28.8	21.8	496
Berenson and Rahman, 2012 (21)	Used during last sexual intercourse	Increased	6	1.32 (1.03–1.70)	15.1	13.1	1155
Kamb et al, 1998 (9)	Consistent use	Increased	6	1.24 (1.04–1.49)	39	34	5758
Boyer et al, 1997 (39)	Consistent use	Recent STI	5	1.42 (0.83–2.44)	39.1	30.7	393



CG = control group; IG = intervention group; OR = odds ratio; STI = sexually transmitted infection.