FINDINGS OF THE REVIEW: Unprotected sex leads to many unintended pregnancies and sexually transmitted infections (STIs). Hence, condom use for dual protection is important and women need counselling on the correct and consistent use of condoms. This review aimed to evaluate comparative studies of behavioural interventions to improve effectiveness of condom use as measured with biological assessments (clinically determined pregnancy or STI). Seven randomized controlled trials were included: six cluster randomized trials (2157â€“15614 participants) and one individual randomized trial (764 participants). Overall, studies were of moderate-to-low quality, conducted in Africa, USA, and UK. The study participants were mostly adolescents or young adult women. A meta-analysis was not performed owing to the varied interventions. Results from most cluster trials could not been analysed due to insufficient information to calculate the effect of sample size and were presented in the review as reported in the studies. No significant differences in pregnancy rates and or HIV infection were seen between intervention and control groups. Two studies reported a lower incidence of herpes virus type 2 in the intervention group. One study found lower incidence of syphilis and gonorrhoea in the intervention group, although another study reported that controls had lower prevalence of gonorrhoea than the intervention group. No adverse events were reported.

IMPLEMENTATION: Available data on behavioural interventions to make condom use more effective for dual protection show little, if any, clinically beneficial effects for relevant outcomes. Better behavioural interventions studied through sound research are needed.

COCHRANE REVIEW


ABSTRACT
Unprotected sex is a major risk factor for disease, disability, and mortality in many areas of the world due to the prevalence and incidence of sexually transmitted infections (STI) including HIV. The male condom is one of the oldest contraceptive methods and the earliest method for preventing the spread of HIV. When used correctly and consistently, condoms can provide dual protection, i.e., against both pregnancy and HIV/STI.

We examined comparative studies of behavioral interventions for improving condom use. We were interested in identifying interventions associated with effective condom use as measured with biological assessments, which can provide objective evidence of protection.

Through September 2013, we searched computerized databases for comparative studies of behavioral interventions for improving condom use: MEDLINE, POPLINE, CENTRAL, EMBASE, LILACS, OpenGrey, COPAC, ClinicalTrials.gov, and ICTRP. We wrote to investigators for missing data.

Studies could be either randomized or nonrandomized. They examined a behavioral intervention for improving condom use. The comparison could be another behavioral intervention, usual care, or no intervention. The experimental intervention had an educational or counseling component to encourage or improve condom use. It addressed preventing pregnancy as well as the transmission of HIV/STI. The focus could be on male or female condoms and targeted to individuals, couples, or communities. Potential participants included heterosexual women and heterosexual men.

Studies had to provide data from test results or records on a biological outcome: pregnancy, HIV/STI, or presence of semen as assessed with a biological marker, e.g., prostate-specific antigen. We did not include self-reported data on protected or unprotected sex, due to the limitations of recall and social desirability bias. Outcomes were measured at least three months after the behavioral intervention started.

Two authors evaluated abstracts for eligibility and extracted data from included studies. For the dichotomous outcomes, the Mantel-Haenszel odds ratio (OR) with 95% CI was calculated using a fixed-effect model. Cluster randomized trials used various methods of accounting for the clustering, such as multilevel modeling. Most reports did not provide information to calculate the effective sample size. Therefore, we presented the results as reported by the investigators. No meta-analysis was conducted due to differences in interventions and outcome measures.

Seven studies met our eligibility criteria. All were randomized controlled trials; six assigned clusters and one randomized individuals. Sample sizes for the cluster-randomized trials ranged from 2157 to 15,614; the number of clusters ranged from 18 to 70. Four trials took place in African countries, two in the USA, and one in England. Three were based mainly in schools, two were in community settings, one took place during military training, and one was clinic-based.

Five studies provided data on pregnancy, either from pregnancy tests or national records of abortions and live births. Four trials assessed the incidence or prevalence of HIV and HSV-2. Three trials examined other STI. The trials showed or reported no significant difference between study groups for pregnancy or HIV, but favorable effects were evident for some STI. Two showed a lower incidence of HSV-2 for the behavioral-intervention group compared to the usual-care group, with reported adjusted rate ratios (ARR) of 0.65 (95% CI 0.43 to 0.97) and 0.67 (95% CI 0.47 to 0.97), while HIV did not differ significantly. One also reported lower syphilis incidence and gonorrhea prevalence for the behavioral intervention plus STI management compared to the usual-care group. The reported ARR were 0.58 (95% CI 0.35 to 0.96) and 0.28 (95% CI 0.11 to 0.70), respectively. Another study reported a negative effect on gonorrhea for young women in the intervention group versus the control group (ARR 1.93; 95% CI 1.01 to 3.71). The difference occurred among those with only one year of the intervention.
We found few studies and little clinical evidence of effectiveness for interventions promoting condom use for dual protection. We did not find favorable results for pregnancy or HIV, and only found some for other STI. The overall quality of evidence was moderate to low; losses to follow up were high. Effective interventions for improving condom use are needed to prevent pregnancy and HIV/STI transmission. Interventions should be feasible for resource-limited settings and tested using valid and reliable outcome measures.

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