The female condom and STDs: design of a community intervention trial.

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OBJECTIVES:
The main purpose of this study is to compare sexually transmitted disease (STD) prevalence in cohorts of women with and without access to female condoms.

METHODS:
Six matched pairs of communities were identified from Kenya tea, coffee and flower plantations. One community within each pair was randomly selected to receive the female condom intervention. Approximately 160 eligible women were enrolled at each site. Female condom communities underwent an education program on use of female and male condoms and STDs, comprising group meetings, puppetry and other folk media, and training of clinic service providers and community outreach workers. Control communities received similar information on use of male condoms (freely available at all sites). At baseline, participants were tested for cervical gonorrhea and chlamydia and vaginal trichomoniasis, to be repeated at 6 and 12 months. The study has 80% power to detect a 10% prevalence difference, assuming an aggregate STD prevalence of 20% with 25% loss to follow-up and intracluster correlation of 0.03.

RESULTS:
Among 1929 women at baseline, the mean age was 33.1 years; 78% had never used a male condom. The prevalences of gonorrhea, chlamydia and vaginal trichomoniasis were 2.6%, 3.2% and 20.4%, respectively (23.9% overall). The intracluster correlation based on these data was near zero.

CONCLUSIONS:
Comparable pairs of study sites have been selected. STD prevalence is sufficiently high, and the variation between sites is acceptably low. The study is feasible as designed.

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