## Reduced HIV risk-taking and low HIV incidence after enrollment and risk-reduction counseling in a sexually transmitted disease prevention trial in Nairobi, Kenya

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## **Abstract:**

There is an urgent need in sub-Saharan Africa to develop more effective methods of HIV prevention, including improved strategies of sexually transmitted infection (STI) prevention or an HIV vaccine. The efficacy of these strategies may be tested through clinical trials within cohorts at high risk for STI and HIV, such as female commercial sex workers. For ethical reasons, standard HIV prevention services, including access to free condoms, risk-reduction counseling, and STI therapy, will generally be offered to all study subjects. Because study subjects would often not otherwise have access to these prevention services, it is possible that enrollment in such clinical trials will itself reduce incidence rates of STI and HIV below expected levels, reducing the power to test the efficacy of the randomized intervention. We show that the provision of standard HIV prevention services as part of a randomized STI/HIV prevention trial is temporally associated with a dramatic reduction in sexual risk-taking, and that this reduction is directly associated with reduced STI incidence. This finding should be considered in the design of clinical trials with an endpoint of HIV incidence, in particular HIV preventive vaccine trials