

Primary Prevention

Project EXPLORE: A Randomized Clinical Trial of the Efficacy of a Behavioral Intervention to Prevent Acquisition of HIV among Men Who Have Sex with Men

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Project Description: This is a Phase IIb randomized controlled, proof of concept trial, which will assess the efficacy of a behavioral intervention vs. standard risk reduction counseling to prevent HIV infection among men who have sex with men. The behavioral intervention consisted of ten sessions over a four-month period followed by quarterly maintenance sessions. The control condition consisted of semi-annual risk reduction counseling sessions based on the Centers for Disease Control and Prevention (CDC)/Project RESPECT model for HIV pre- and post-test counseling. The trial enrolled 4,295 MSM recruited at sites in Boston, Chicago, Denver, New York, San Francisco and Seattle study sites. The participants were followed for an average of 3.5 years. The seroincidence rate of HIV infection will be compared between the two arms of the study at the end of the three-year period. Data collection concluded in July 2003. Preliminary results will be published in early 2004.

Significance: Data from the HIVNET Vaccine Preparedness Study (VPS) have shown that brief (less than one-hour), didactic, one-session HIV risk reduction counseling in which HIV test results are discussed is not sufficient to change behavior. On the other hand, recent reports from the Project RESPECT I study suggest that two or four individual, participant-centered counseling sessions, such as those to be studied in this trial, can lower HIV and STD infection rates among heterosexual patients being tested and treated for STDs. This study extends these positive findings to a higher risk sample of MSM, and focuses on a number of risk reduction targets, including condom use, sexual behaviors in the context of alcohol or drug use, and sexual behaviors in the context of different types of partners and relationships. It also looks at communication skills, where participants meet their sexual partners, and how thoughts and feelings may influence their risk-taking.

This is the first time that an HIV biological endpoint will be used to test the efficacy of a behavioral intervention in the United States

Project Web Site: www.explorestudy.org or www.hptn.org