

Frequently Asked Questions

5. Are there any negative effects from taking part in the study?

There are no known negative effects from the groups used in this study for any participant. You may become uncomfortable while being asked personal questions, but the interviewers and counselors are trained to recognize this and to provide support if needed.

6. What will I get for taking part in the study?

You will be compensated for the time and effort it takes to participate in the study. The study staff will discuss this with you.

For More Information

For more information about this study, contact your counselor or the research assistant working with your clinic.

For more information on the National Drug Abuse Treatment Clinical Trials Network, visit the NIDA website at www.drugabuse.gov.

For information on other clinical trials, the National Institutes of Health (NIH) has created a website to help patients, family members, and the general public obtain information about government-sponsored clinical trials. You may log on to www.Clinicaltrials.gov to learn about ongoing or new trials for all types of health-related conditions. The descriptions for individual trials include eligibility criteria, purpose of the trial, location, and how to apply if interested. The website is maintained and updated regularly by the National Library of Medicine.

National Institute on Drug Abuse
Center for Clinical Trials Network
6001 Executive Boulevard
Bethesda, Maryland 20892-9557
Telephone; (301) 443-6697
Fax: (301) 443-2317

THIS SPACE PURPOSELY
LEFT BLANK FOR
SITE CONTACT INFORMATION.

03/26/04

CTN-0019

National Drug Abuse Treatment Clinical Trials Network



PROTECTION



**Reducing HIV/STD
Risk Behaviors:
A Research Study for Women
in Drug Abuse Treatment**



RISK REALITY

NIDA NATIONAL INSTITUTE
ON DRUG ABUSE

NATIONAL INSTITUTES OF HEALTH
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

You have taken the first important step to recovery from your drug addiction by coming into treatment. By joining this research study, you may get further help in staying protected from STDs, like HIV, that drug users sometimes get.

Description of the Study

Research shows that being in drug treatment can help people stay safe from infections like, HIV and Hepatitis C that can be spread by needles. Research also shows that taking part in groups that talk about STDs, drug use and safer sex can help people stay healthy. The approaches used in this study were designed to meet this need for women in our clinics. Participants will have a chance to learn more about ways to minimize sexual risk. Some groups will focus in more depth on issues including sexuality, communication, and the connection between sex and drugs.

Who Can Participate

The study will include 480 women in methadone maintenance or outpatient drug-free treatment programs across the country. Participants must be women 18 years or older who are interested in discussing the issues described above.

If You Decide to Join

Your participation in this study is completely voluntary — you may refuse to participate or stop at any time. If you choose not to take part, your relationship with your current treatment provider or your right to health care and other services will not be affected in any way. You are encouraged to ask as many questions as you want to help you decide if you want to join the study. If you do decide that you would like to participate here is what you can expect:

You will be asked to complete a screening interview that will include questions about your drug and alcohol use and your sexual behavior. Before this interview, the purpose of the screening will be fully explained to you and you will be asked for your written consent (agreement) to participate. This interview will determine if you are eligible for the study. If you are eligible, the study will be described to you in more detail and you will be asked to complete a second interview that will also include a urine and breathalyzer test.

1. After being accepted into the study, you will have an equal chance of being assigned to one of two groups focusing on HIV and STD prevention and education. The study groups are in addition to the usual care you receive at your treatment program.
2. During the study you will attend group sessions either 5 times or 1 time, depending on which group you are assigned. The sessions may last up to 90 minutes. There will be 2-7 other women in the group.
3. After the group sessions are completed you will be interviewed 3 more times over the next 9 months. The interviews generally take 2 hours.

Frequently Asked Questions

1. *How long will I be in the study?*

From the time you enroll in the study until the final follow-up interview, you will be in the study for a total of 9 months.

2. *What will I have to do during the study?*

If you want to participate you will:

- * Complete a screening interview.
- * If eligible, complete a second interview, give a urine sample, and take a breathalyzer test.
- * Attend study groups for either 1 or 5 sessions in addition to your regular treatment.
- * Return for three study follow-up visits.

3. *What happens at study follow-up visits?*

Study follow-up visits include questions about your drug and alcohol use, sexual behaviors and also about how you are doing in your life. These questions are similar to the questions that were asked in the other study interviews and will take approximately 2-3 hours to complete.

4. *What are the benefits of being in the study?*

You may or may not benefit personally from participating in this study. You may gain skills to help you reduce your chance of getting and spreading STDs, including HIV. You may also help researchers learn more about the kinds of programs that are most likely to reduce risky sexual behavior. This may provide a powerful benefit to many women.