

# *Clinical Trials Network*

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## WOMEN'S TREATMENT FOR TRAUMA AND SUBSTANCE USE DISORDERS

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A research study  
for women dealing with  
trauma and substance abuse

**Should I  
sign up?**



**NIDA** NATIONAL INSTITUTE  
ON DRUG ABUSE

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

**Y**ou have taken the first important step to recovery of your drug addiction by coming into treatment, and you want to make the most of it. By joining this research study, you may be able to further benefit from your current treatment and could also help counselors find out how to best help other women like yourself.

## **Description of the Study**

As many as 80% of women seeking treatment for drug abuse have experienced either sexual or physical assault. These experiences often lead to nightmares, an inability to stop thinking about the event, feeling numb, being easily frightened and jumpy, or feeling depressed, worried, or hopeless. These are just a few signs of a condition known as posttraumatic stress disorder (PTSD).


This study will compare two different interventions designed specifically for women: *Seeking Safety* and *Women's Health Education*. These interventions will be in addition to the usual treatment provided at your treatment program. We are studying these groups to see how well they help women 1) reduce their substance use, stress, and other emotional problems and 2) increase their treatment attendance. This study is being conducted at several sites across the United States. About 480 women will be enrolled nationwide, including about 60 volunteers at your treatment program.

## If You Decide To Join

Your participation in this study is completely voluntary — you may refuse to participate or stop participating any time. If you choose not to take part, your relationship with your current treatment provider will not be affected in any way nor will your right to health care and other services. 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 to participate, this is what you can expect:

You will be asked to complete a screening interview that will include questions about your mental health, physical health, and drug use. 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 be used to 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.

1. After being accepted into the study you will have an equal chance of being assigned to one of the two women's groups. The study groups are in addition to the usual care you receive at your treatment program.
2. Once you begin treatment, you will attend the intervention two times each week for six weeks (a total of 12 groups). Each group session will last for 90 minutes. There will be 2-7 other women in the group, some of whom may have backgrounds and experiences similar to yours.

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3. Each week, you will be asked to complete some forms about your experiences in the group as well as your mental health and substance use. You will also be asked for a urine and a saliva sample (for drug and alcohol screening) at this visit.
  4. At the end of the 6 weeks, you will be interviewed for approximately 2 hours. You will be contacted to complete this interview again 3, 6 and 12 months after the study group ends, whether or not you are still enrolled in the treatment program.
  5. All of the information that you give us, including urine test results, will be kept confidential. The staff will explain the details of confidentiality to you.

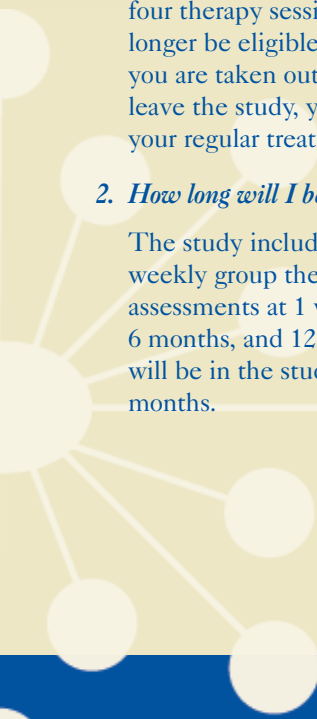
## Frequently Asked Questions

### *1. What happens if I miss a session?*

If you are hospitalized or miss more than four therapy sessions in a row, you may no longer be eligible for the study. However, if you are taken out of the study or choose to leave the study, you can still continue in your regular treatment program.

### *2. How long will I be in the study?*

The study includes 6 weeks of twice weekly group therapy and follow-up assessments at 1 week, 3 months, 6 months, and 12 months. Therefore, you will be in the study for approximately 14 months.



## Frequently Asked Questions

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

If you do want to participate, you will:

- \* Complete a screening interview.
- \* If eligible, complete a second interview.
- \* Attend study treatment sessions for approximately 6 weeks in addition to your regular treatment.
- \* Fill out questionnaires and give saliva and urine samples.
- \* Return for four study follow-up visits.

### 4. *What happens at study follow-up visits?*

Study visits include questions about:

- \* Your health and how you are feeling.
- \* Drugs you are taking.
- \* How you are doing in your life (family/social, legal, employment, etc.).

### 5. *What are the benefits of being in the study?*

You may or may not benefit personally from participating in this study.

Investigators may find out which, if any, of the groups are most useful for treating other women who have histories of trauma and abuse substances. This may provide a powerful benefit to many women like you.

### 6. *Are there any negative effects from taking part in the study?*

Psychotherapy, interviews, assessments, and urine collection pose limited risks. You may become uncomfortable while being asked personal questions, but the interviewers and counselors are trained to recognize this and to provide support.

## For more information

For more information on the National Drug Abuse Treatment Clinical Trials Network, visit the NIDA website at [www.drugabuse.gov](http://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](http://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  
Room 4234, MSC 9557  
Bethesda, Maryland 20892-9557  
Telephone: (301) 443-6697  
Fax: (301) 443-2317