

Training. After completing the 3-day centralized training, counselors are requested to get as much experience with the intervention as possible before conducting a training case. The training case will entail leading four group sessions with at least 3 group members. When you reach an acceptable level of competence in a training case, you will be permitted to start running study groups.

Treatment Manual Adherence. In many community clinics, therapists tend to use whatever techniques seem to work best with their patients. As is typical of clinical therapy trials, in this study, you will need to deliver your therapy sessions according to the manual for the therapy you are assigned. You will use the techniques you learned in training and you will follow guidelines for each session as outlined in the manuals.

Supervision/Monitoring. During the study, you will receive weekly supervision that will include review of randomly selected videotaped sessions. Supervisors will rate the sessions and then meet with you to address clinical issues and plan activities for the upcoming week.

What should I tell clients about the Clinical Trials Network and the “Women and Trauma Study?”

You should also familiarize yourself with the following materials so that you can answer questions and refer potential participants to the right sources:

- ❖ The Clinical Trials Network has produced brochures for potential participants that describe this study and explain what they can expect.
- ❖ More specific information about the study can be found in the *Informed Consent Form* that the research assistant will read with clients as they decide whether or not to participate.
- ❖ The *What are Clinical Trials?* brochure is an excellent summary of the benefits of participating in a research study.

If you ever find yourself unable to answer a question about the research, consult your supervisor, research assistant, Node Coordinator, or an investigator for more information.

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.

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CTN-0015

Clinical Trials Network

WOMEN'S TREATMENT FOR TRAUMA AND SUBSTANCE USE DISORDERS

A research study for women dealing with trauma and substance abuse

For Clinicians



NIDA NATIONAL INSTITUTE ON DRUG ABUSE

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

The agency you work for has agreed to participate in a clinical trial to study behavioral interventions for women experiencing Substance Abuse and Posttraumatic Stress Disorder (PTSD). This pamphlet describes the interventions being studied and answers questions you may have about participating as a therapist in this research project. More information about clinical trials can be found in the National Drug Abuse Treatment Clinical Trials Network (CTN) brochure, *What Are Clinical Trials?*

What interventions are used in the study?

Seeking Safety. The Seeking Safety treatment applies cognitive-behavioral strategies to help patients reduce their substance use and the negative impact of trauma exposure. Each session of Seeking Safety is a sequence of four steps: 1) a check in, 2) a session quotation/ inspiration, 3) relating the topic to the patients' lives and rehearsal of the material and skills, and 4) a check out, where the patient is asked to commit to practicing specific skills in between sessions.

Women's Health Education. Women's Health Education is a short-term psychoeducational group that focuses on topics such as understanding the female body, human sexual behavior, pregnancy and childbirth, STDs, HIV, and AIDS. All sessions have a common seven-step format: 1) introduction of topic; 2) touching base about between-session goals; 3) mini-lecture, video, story-telling and/or text readings; 4) discussion; 5) summary of discussion; 6) goal setting; and 7) processing of reactions to session.

Usual Treatment. All study participants will also participate in usual care in their substance abuse programs. Each subject must attend the standard treatment offered during the six weeks of psychosocial intervention.

Why are these interventions being tested?

Estimates suggest that as many as 80% of women seeking treatment for drug abuse report a history of sexual and/or physical assault. Posttraumatic Stress Disorder (PTSD) can develop as a result of these types of assaults, and is quite common among drug users, particularly among women. Those who suffer from PTSD and substance abuse struggle more with both conditions and have a more difficult time meeting their treatment goals. Thus it is especially important that we find effective treatments for this population.

This study compares the impact of two women's groups, when added to standard substance abuse treatment, on substance use and the severity of PTSD. Researchers will also look at the results in relation to demographic and individual characteristics of study participants. The results of the study will be used to help design maximally effective treatments for women with PTSD and Substance Abuse Disorders.

How are study therapists chosen?

Therapists for the two study groups will be identified by the community treatment programs, the study's lead investigator, and program supervisors. You will be asked to conduct an individual practice session to begin the certification process. If you are chosen to participate in the clinical trial, you will be randomized to one of the two interventions and be asked to attend a 3-day training.

Why are therapists randomly assigned?

Therapists are randomly assigned to each intervention to make sure that the characteristics of the therapists providing therapy to both groups are balanced. For example, it is possible that more therapists of a certain gender, race, or level of experience would choose to do a certain intervention. Random assignment will help to minimize the chances of these potential inequities.

Why should I participate in this research study?

There are many reasons to participate in a clinical trial. First, you will learn techniques and therapies that are not yet commonly used in community treatment settings, but that have been shown in previous studies to help people stop or reduce their substance use. These techniques will be helpful in your work with clients for many years to come—and will add to your skills as a therapist.

The training and supervision you receive may also help you with licensure, certification or continuing education credits. If you are considering returning to school, experience in a research trial can enhance your application.

Additionally, you will be helping in the process of transferring research-based treatments into clinical practice. Finally, as a therapist in the Clinical Trials Network, you are in a unique position to contribute your wisdom and experience to research in drug abuse treatment.

How will participating in this research differ from my current responsibilities?

Because a major goal of the Clinical Trials Network is to apply interventions that have been shown to be effective in tightly controlled research settings to community treatment settings, it is the hope of the researchers that your activities as therapists in the CTN trials will be similar to your typical duties. However, there will probably be differences in the following areas:

Paperwork. Paperwork will be kept to a minimum and will include basic progress notes at the end of every session and a brief questionnaire at the second and sixth week of treatment.