

Supervision/Monitoring: All study counseling sessions – both MET and TAU – will be audiotaped and rated by independent experts to ensure that there is a discernable difference between the MET sessions and the TAU sessions. For MET clinicians, audiotapes of both the practice cases and the study cases will be rated by MET supervisors to make sure that you are following the manual and that you have an acceptable level of skill in MET. MET clinicians will also have group supervision twice a month and individual supervision as needed.

If I will have to do extra work, why should I participate as a clinician in a research study?

There are many reasons to participate as a clinician in a clinical trial. First, you will learn techniques and therapies that are not yet commonly used in community treatment settings, but which have been shown to help people stop or reduce their drug and/or alcohol use. These techniques will be helpful in your work with clients for years to come. You may be provided with additional training and supervision that may help you with licensure or certification as well as adding to your skills as a clinician. If you are considering returning to school, experience in a research trial may enhance your application. Additionally, you will be helping to develop the process of transferring research-based treatments into clinical practice. Finally, as a clinician in the Clinical Trials Network, you are in a unique position to contribute to the knowledge of effective drug abuse treatment.

What should I tell clients about the Clinical Trials Network and the study?

Two informational handouts are available for clients interested in participating in clinical trials. You should familiarize yourself with these brochures so that you can answer any questions and refer potential participants to the right sources. *What Are Clinical Trials?* is an excellent source for understanding the benefits of participating in a research study. *Motivational Enhancement Therapy for Pregnant Substance Users – Should I Join?* is a brochure for clients that describes this study in general terms that potential participants can easily understand. More specific information about the study can be found in the Informed Consent form that the research assistant will read with a client who is deciding whether or not to participate. If you become a clinician for the study, you will receive training on how to talk with the clients about the research project. If you ever find yourself unable to answer a question about the research, you should consult your supervisor, the research assistant, or an investigator for more information.

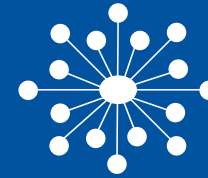
QUESTIONS

For more information on the National Institute on Drug Abuse 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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National Drug Abuse Treatment
Clinical Trials
Network



**Motivational
Enhancement Therapy
to Improve Treatment
Utilization and
Outcomes in Pregnant
Substance Users**





The agency you work for has agreed to participate in a clinical trial to study a behavioral intervention called Motivational Enhancement Therapy (MET). This brochure provides an overview of this intervention and answers to questions you might have about participating as a clinician in this research project.

What is Motivational Enhancement Therapy?

During your career as a clinician you probably have run across clients who report wanting to recover from their drug problems, but who seem insufficiently motivated to make the changes that would help them in their recovery. MET is a brief intervention designed to help clients make changes in their behavior by using proven strategies that are likely to increase their motivation to change. Unlike some interventions regularly used in community treatment programs, MET is a manualized intervention, which means that clinicians who deliver the intervention follow a written set of guidelines (the intervention manual).

What will it be like to provide counseling using MET?

You will be providing a three session intervention that will involve using assessment information collected on a personal feedback form combined with motivational strategies to assist clients in engaging in treatment.

Why is MET being tested?

MET has been shown to be an effective intervention for alcohol use disorders and smoking. While researchers do not necessarily believe that MET alone will give clients with severe drug problems all the tools they need to

change, it is hypothesized that the addition of MET strategies will positively impact the utilization of other clinic services.

If I volunteer to be a study clinician, will I automatically learn MET?

One of the unique things about participating in a research study is that in order to determine if an intervention is beneficial, it must be compared to a standard intervention. In this study, all clinicians who volunteer and are selected to be study clinicians will be assigned at random to provide either Treatment As Usual (TAU), which will consist of three individual treatment sessions in the beginning phase of a client's treatment, or the MET which will be delivered in place of those first three sessions. Those who are assigned to be MET clinicians will receive MET training before the study begins. Those who are assigned to TAU will be offered MET training at the completion of the study.

Why will you randomly assign us?

In order to make sure that the characteristics of the clinicians providing counseling to both groups are balanced, random assignment is necessary. It is possible that more therapists of a certain gender, race, or level of experience would choose to do a certain intervention. In such a situation, when statisticians analyze the research results it would be hard to tell whether differences between the MET and TAU groups were due to the intervention or due the characteristics of the clinicians. Random assignment will help to minimize the chances of an imbalance related to clinician characteristics.

How will participating as a clinician on a research trial differ from my current role and responsibilities?

Because a major goal of the Clinical Trials Network is to move interventions that have been shown to be effective in tightly

controlled research settings into community treatment settings, it is hoped that your activities as clinicians in the CTN trials will be similar to your duties before you joined the study. However, there will be differences such as those listed below:

Paperwork: If you volunteer for this study, you will be asked to fill out some paperwork before the study begins that describes your eligibility for the study and your characteristics as a clinician. Once the study begins, you will need to fill out a checklist for each counseling session in the study, and will fill out a questionnaire regarding therapeutic alliance after each participant's second session.

Training: Regardless of which intervention you are assigned to, you will receive additional training. MET clinicians will receive training in MET. The MET training will consist of three days of a classroom seminar and role play exercises. Next you will complete at least one practice/training case, which will give you an opportunity to practice new skills and reach a level of mastery in MET. Once the study is over, TAU clinicians will be offered the MET training as well.

Treatment Manual Adherence: In many community clinics, therapists tend to use whatever techniques seem to work with their clients. As is typical of clinical therapy trials, the clinicians in this study will need to deliver their counseling sessions according to the therapy condition you are assigned to. For TAU clinicians, your three study sessions will not differ from what you ordinarily do. For MET clinicians, you will use the techniques learned in training and you will follow the guidelines for each session as outlined in the manual.