QUESTIONS

How long will I be in the study?

The study lasts four weeks, with two follow-up visits which are one month and three months after the study ends. In all, then, you will be in the study a total of four months.

How many other people will be in the study?

About 200 pregnant women across the United States will be in the study.

What will I need to do in the study?

- Meet once a week with the research assistant
- Meet three times with a research clinician for counseling
- Fill out questionnaires, answer questions, and give urine and breath samples
- Return for study follow-up visits
- Contact the research assistant if you have any problems between visits

Can I still attend my regular treatment during the study?

Absolutely! During the study you may receive any treatment services you are scheduled for.

Will I receive anything for participating?

Yes. You will be given compensation for your time and travel in the form of vouchers or retail gift certificates.

Will I have any bad effects from taking part in this study?

There are no known negative effects from the counseling used in this study.

FOR MORE INFORMATION

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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NIDA NATIONAL INSTITUTE ON DRUG ABUSE

National Drug Abuse Treatment

Clinical Trials Network

Motivational Enhancement Therapy for Pregnant Substance Users

National Institutes of Health
U.S. Department of Health and Human Services

INTRODUCTION

Pregnant women are more likely to have healthy, full-term babies if they are able to avoid using alcohol, tobacco, and/or illicit drugs. Substance use treatment can help women quit or reduce their substance use and increase their chances of delivering healthy babies. However, some substance-using pregnant women find it hard to consistently participate in the services that are recommended to them. The National Institute on Drug Abuse Clinical Trials Network (CTN) is doing a study called **Motivational Enhancement Therapy to Improve Treatment Utilization and Outcome in Pregnant Substance Users.** This study will examine ways of helping pregnant, substance-using women increase their participation in recommended services.

You are being invited to take part in this study to help find out how clinicians can best assist pregnant, substance using women in using their recommended treatment services more effectively. ***Your participation is entirely voluntary.*** If you choose not to take part, your treatment will not be affected in any way.

STUDY DESCRIPTION

The purpose of this research study is to compare two types of alcohol/drug counseling. One type of counseling is called Motivational Enhancement Therapy (MET). The other type of counseling will be standard care as provided by this clinic. The study will determine if one method works better to keep patients in treatment and help them stop using alcohol and/or drugs.

A research assistant will need to get your written permission to involve you in the study. You will need to review and sign an informed consent form. You are encouraged to ask as many questions as you want to help you decide whether or not to participate. If you are willing to join the study, you will be asked a series of questions about yourself to determine whether or not you are eligible for the study. After completing these questions, you will be assigned at random to receive three sessions of either:

STANDARD TREATMENT

In Standard Treatment, you will receive the treatment normally given in this clinic. It will include at least three individual sessions that will focus on orienting you to the treatment program and helping you with overcoming alcohol and drug use. You may also receive other individual and/or group counseling which is standard to the clinic and not part of this study.

- OR -

MOTIVATIONAL ENHANCEMENT THERAPY (MET)

MET will take place in three individual counseling sessions within a four week period. During MET you will be asked about what you see as problems associated with your substance use. If you express a desire to change, you will be encouraged to develop a plan for changing your behavior. Each of these sessions will require about one hour. In addition to these three counseling sessions, you may also receive other individual and/or group counseling which are standard to the clinic and not part of this study.

IF YOU DECIDE TO JOIN

If you decide to take part in the study, here is what you can expect:

1. You will be assigned at random (for example, by the flip of a coin) to receive either Standard Treatment or MET. That means you cannot choose which one you will get.
2. You will receive three individual sessions of either Standard Treatment or MET within four weeks of enrolling in the study.
3. In order to be sure that the clinicians are carrying out the treatment properly, your three individual sessions will be audiotaped and reviewed by expert members of the research team. Your identity on the tapes will be kept confidential. The tapes will be kept in a locked, secure location and will be erased at the end of the study.
4. You will meet with a research assistant weekly during the course of the study, and twice for follow up. During these meetings, you will be asked several questions and will be asked to give a urine and breath sample. The urine sample will be tested for opiates, cocaine, methamphetamines, benzodiazepines, and marijuana. The breath sample will be tested for alcohol level.
5. All of the information collected in the study, including urine test results, will be kept confidential.