QUESTIONS
(CONTINUED)

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

There are side effects to the medications used in this study. During your participation in this study, you will be watched for known side effects of the medications you will be taking; some side effects may be harmful and some may be unknown. The study medications may conflict with other prescription or over-the-counter medications, or interact with illegal drugs or alcohol to produce side effects. Therefore, you should ask the study staff before taking any medication. You should know the possible side effects of a medication before you decide to take it. Your informed consent form will list the side effects for each of the medications you will take.

Also, much of the information collected during the study is sensitive and there is a risk that others who are not involved in the study will see it. However, this is a relatively small risk since the investigators and their staffs are well-trained in keeping the information condential. Your name will not appear on any of the information you give us. Instead, you will be assigned an ID number that will be used on all forms. In addition, all information collected from study volunteers will be kept in locked areas in the clinic.

FOR MORE INFORMATION

For more information on the National Institute on Drug Abuse Clinical Trials Network, visit the NIDA web site at **www.drugabuse.gov.**

For information on other government-sponsored clinical trials, the National Institutes of Health (NIH) has created a web site to help patients, family members, and the general public. You may log on to **www.clinicaltrials.gov** to learn about ongoing or new trials of 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 web site is maintained and updated regularly by the National Library of Medicine.

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Center for Clinical Trials Network
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NIDA NATIONAL INSTITUTE ON DRUG ABUSE

National Drug Abuse Treatment
Clinical Trials Network

SMOKING CESSATION STUDY

FOR SMOKERS WITH ATTENTION DEFICIT HYPERACTIVITY DISORDER (ADHD)

SHOULD I PARTICIPATE?

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

INTRODUCTION

Adult ADHD is a common disorder, affecting approximately seven to eight million adults in the United States. The symptoms of ADHD include difficulty sustaining attention, distractibility, procrastination, difficulty organizing and completing tasks, misplacing items, restlessness impulsivity and talking out of tum.

Several studies have found that cigarette smoking is twice as common in adults with ADHD as compared to adults without ADHD.

It has been suggested that the increased use of nicotine seen in adult ADHD is related to self medication since nicotine has been found to reduce some of the symptoms of ADHD, such as inability to concentrate and restlessness.

The purpose of this study is to see if a medication effective in treating ADHD, Osmotic Release Methylphenidate (OROS MPH), compared to placebo (sugar pill), helps people with ADHD to quite smoking

This study is open to anyone who is between 18 and 55 years old, has smoked cigarettes for at least the past 3 months and is currently smoking 10 or more cigarettes per day, wants to quit smoking, and has ADHD.

IF YOU DECIDE TO JOIN, WHAT CAN YOU EXPECT TO HAPPEN?

1. You will contact the research clinic and complete a telephone or in- person interview to see if you might be eligible for the study.
2. After this initial interview, you may be scheduled to attend an appointment, at the clinic. At this appointment, the study will be explained to you in detail; you will enter the screening phase during which you will be asked questions about your life history including your cigarette use and medical history.
3. After the screening phase, you will be assigned at random to receive either OROS-MPH or placebo (sugar pill). You will be asked to take the OROS-MPH or placebo for eleven weeks.
4. After 4 weeks in the study you will receive nicotine patches in addition to the OROS-MPH or placebo.
5. You will receive 11 individual smoking cessation counseling sessions. To ensure that your counselor is carrying out the therapy properly, all sessions will be video-recorded and reviewed by supervisors/experts of the research team. Like all your information, the recordings will be kept in a locked, secure location.
6. You will meet with a research assistant weekly during the course of the study and once during follow-up. During these meetings, you will be asked several questions and will be asked to give a breath sample.
7. You will meet regularly with a medical clinician who will check how you are feeling and make sure you are not having any bad reactions to the study medications.
8. All of the information collected in the study will be kept confidential.
9. This study is entirely voluntary and you can withdraw at any time.

QUESTIONS

How long will I be in the study?

You will be in this research study for about 4 months.

How many other people will be in the study?

About 252 adults from across the United States will be in the study.

Will I receive anything for participating?

Yes, you will be given compensation for your time and travel while participating in this study.