

Questions (Continued)

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

Your teenager may experience side effects due to the medication used in this study. During his/her participation in this study, your teenager will be watched for known side effects of the medication he/she will be taking. Still, some side effects may be harmful and some may be unknown. The study medication may conflict with other prescriptions or over-the-counter medications or interact with illegal drugs or alcohol to produce side effects. 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 because the investigators and their staffs are well trained in keeping the information confidential. Neither yours nor your teenager's name will appear on any of the information you or your teenager give us. All information collected from study volunteers will be kept in locked areas in the clinic.

What are the benefits of CBT?

CBT has been shown to 1) reduce substance abuse & relapses by exploring and tracking patterns of use; 2) improve family relationships; 3) enhance performance at school; 4) advance communication skills; 5) develop anger management skills; and 6) develop job seeking skills. The treatment includes one 60-minute session each week of the study, with three being family sessions.

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 clinical trials, the National Institutes of Health (NIH) has created a Web site 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 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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4/26/06

CTN-0028

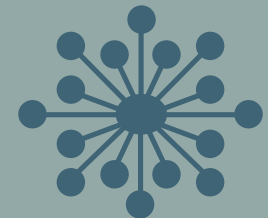
NIDA NATIONAL INSTITUTE
ON DRUG ABUSE

National Drug Abuse Treatment Clinical Trials Network

ADHD in Adolescent Substance Abusers

Parents:

Read About a Treatment Study Designed for Your Teenager



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

INTRODUCTION

Approximately 30-50% of adolescents in the United States who abuse drugs also have ADHD. The symptoms of ADHD include difficulty sustaining attention, distractibility, procrastination, difficulty organizing and completing tasks, misplacing items, restlessness, impulsivity, and talking out of turn.

Research shows that as many as one-half of adolescents in drug treatment programs have ADHD, which is associated with more severe drug use, behavior problems, more drop outs, and treatment failure when compared to adolescents with substance-dependence without ADHD.

One reason for poor treatment outcomes is that the majority of adolescents in community-based treatment programs may not receive medication for their ADHD while in treatment for their drug use.

The purpose of this study is to find out if Osmotic-Release Methylphenidate (OROS-MPH), a medication approved for the treatment of ADHD, compared to placebo (sugar pill), can help adolescents with drug and alcohol problems.

Your teenager will be eligible to participate if he/she is between 13 and 18 years old, has ADHD and is willing to take a medication / placebo, has drug/alcohol problems, and is willing to participate in the study's outpatient Cognitive Behavioral Therapy (CBT) to help his or her drug/alcohol use.

IF YOUR TEENAGER DECIDES TO JOIN, WHAT WILL HAPPEN?

- If under 18, your teenager will contact the research clinic and complete a confidential telephone screening to see if he/she might be eligible for the study.
- If your teenager qualifies for the study, based on a pre-screening questionnaire, he/she will be scheduled for an appointment at the research clinic. At this visit, the study will be explained to you both in detail and then your teenager will be asked more questions (in private) about his/her drug/alcohol use as well as medical history, including ADHD.
- If your teenager qualifies after the initial screening phase, he/she will have the following: a physical exam and vital signs measured; a small amount of blood taken to make sure he/she is healthy (and a test for pregnancy if female), his/her urine tested for drugs of abuse, and an ECG to measure the activity of your child's heart. Your teenager will also answer more questions (in private) about his/her drug use and ADHD.
- If all study criteria are met, your teenager will be assigned at random (for example, with the flip of a coin) to receive either OROS-MPH or placebo and will be asked to take the OROS-MPH or placebo every day for 16 weeks.
- Your teenager will spend about 2 hours at the clinic each week. During that time, he/she will participate in Cognitive Behavioral Therapy (CBT) sessions that last about 1 hour.

- Your teenager will be asked questions about his/her drug use and ADHD and will be asked to give a urine sample. The samples will be tested for drugs of abuse.
- Your teenager will also meet with a medical clinician during those times to check how he/she is feeling and to be sure he/she is not having any bad reactions to the study medications.
- At the end of the 16-week study, your teenager will again have a small amount of blood taken.
- Your teenager will come back for a follow-up visit 1 month after his/her last study visit.
- All of the information collected in the study will be kept confidential.
- This study is entirely voluntary and you and your teenager can withdraw at any time without any penalty to either of you.

Questions

How long will my teenager be in the study?

Your teenager will be in this research study for about 5 months.

How many other people will be in the study?

About 300 adolescents from across the United States will be in the study.

Will my teenager receive anything for participating?

Yes, your teenager will be given compensation for his/her time and for travel while participating in this study.