Participating in research is likely to increase the amount of paperwork needed for clients who enroll, and some information may need to be recorded in a location separate from clinic records. Since much of the information being obtained in this study is research-related but not directly treatment-related, it may have to be handled and filed separately. Research-related data will need to be coded so that patient confidentiality is maintained.

What are the benefits to our clinic from participating in this clinical trial?

There are several possible benefits to participating in a clinical trial. First, taking part in this study will give therapists an opportunity to learn techniques that are not yet commonly used in community substance abuse rehabilitation programs. These techniques will be helpful in work with clients for many years to come, and will put your clinic in a unique position to deliver state-of-the-art smoking cessation treatment. Second, participation in this trial will provide your patients with access to new treatment strategies that may support them in their efforts to stay off drugs. Third, clinic staff will receive training and experience in carrying out clinical trials that may be useful in future research efforts. Finally, your clinic will play an important role in advancing our knowledge of effective treatment strategies for this population.

What should I tell clients about the Clinical Trials Network and the "Stop Smoking Study"?

Clients who smoke should be told that the clinic is participating in a national study of a stop smoking treatment program in community substance abuse rehabilitation programs. Clients who express interest and would like more information should be referred to informational handouts developed by the National Drug Abuse Treatment Clinical Trials Network. As a staff person in a participating clinic, you should familiarize yourself with these brochures so that you can answer 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. *"Should I Join the Stop Smoking Study?"* is a brochure for clients that describes the smoking cessation 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. Since your clinic will be participating in this study, you will receive training in 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 with your supervisor, the research assistant, node coordinator, or an investigator for more information.

For More Information

More information on the National Drug Abuse Treatment Clinical Trials Network can be found at ***www.drugabuse.gov***. Go to ***www.Clinicaltrials.gov*** to learn about other studies sponsored by the government. Information on who can take part and where and why the study is being done are available. Instructions on how to apply for studies are also on this site.

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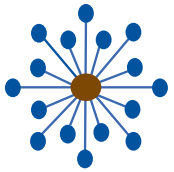
National Drug Abuse Treatment

Clinical Trials Network



STOP SMOKING STUDY INFORMATION

FOR CLINIC STAFF

A research study on the effects of adding treatment for quitting smoking to community substance abuse program

NIDA NATIONAL INSTITUTE ON DRUG ABUSE
NATIONAL INSTITUTES OF HEALTH
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Introduction

Your clinic is going to participate in a clinical trial to study the effects of treatment for quitting smoking in community substance abuse rehabilitation programs. The treatment for quitting smoking will last for 9 weeks and consists of the NicoDerm CQ nicotine skin patch in combination with counseling. The study will assess whether adding this treatment for quitting smoking to existing treatment for substance abuse results in higher rates of abstinence from drugs and/or alcohol. The study will also examine whether the smoking cessation treatment helps people quit smoking, keeps them in substance abuse treatment longer, and works well in a community substance abuse rehabilitation setting.

The study includes 3 follow-up visits, so each participant will be enrolled for 26 weeks. This pamphlet gives an overview of this study. It also answers questions you might have about your involvement with the study. More information about clinical trials in general can be found in the National Drug Abuse Treatment Clinical Trials Network brochure, ***What are Clinical Trials?***

Why is it important to study this question?

Many people who abuse drugs and alcohol also smoke cigarettes. Cigarette smoking is associated with nicotine addiction. Nicotine addiction, like addiction to drugs and alcohol, is difficult to break. Smokers may need medication and/or counseling to help them stop smoking. Quitting smoking is important, because smoking poses significant health risks that add to the risks of substance abuse. Quitting smoking may make it easier for some people to stop using drugs and alcohol. By adding treatment for smoking, patients may stay in substance abuse treatment longer. Unfortunately, there is very little information available to guide practitioners on how best to help substance abusers quit smoking. Even less is known about whether or how to incorporate smoking cessation treatment into existing community substance abuse rehabilitation programs. This study is likely to be an important step towards addressing these questions.

Why is the nicotine patch being tested?

The nicotine patch addresses nicotine addiction by replacing some of the nicotine lost after quitting smoking. The nicotine patch releases a small amount of nicotine into the body through the skin. The amount of nicotine released from the patch is enough to at least reduce smoking withdrawal symptoms, and, in many people, to make quitting easier. The nicotine patch is easy to use, is well tolerated, and can be purchased over the counter.

How will this study affect our current treatment procedures?

All of the participants in this study will take part in the usual substance abuse treatment offered by your clinic. Clients who want to enroll in this study will have to undergo screening to make sure they meet the eligibility criteria for the study. Clients who meet criteria and pass the screening tests will be randomly assigned (like the flip of a coin) to one of the smoking cessation treatment groups. Two-thirds of the participants will get smoking cessation treatment while they are in the study. The other one-third of participants will get smoking cessation treatment after completing the study (about 26 weeks later). Participants will also be assessed at three follow-up visits at weeks 9, 13 and 26 following their target "quit date." The study visits will be separate from the substance abuse treatment appointments and should not interfere with treatment as usual.

Why are participants assigned to treatment groups randomly, and why do some have to wait to get smoking cessation treatment?

Random assignment is the best method for assigning participants to treatments because it helps to balance treatment groups. If participants were allowed to choose, it is possible that most participants of a certain gender, race, or severity of dependence would choose to be in one of the groups. If this happened, it would be hard to know if a difference in treatment outcome was related to the intervention or to one of these other factors. Random assignment will help to reduce the possibility of an imbalance in study groups related to participant characteristics. Comparing patients who receive smoking cessation treatment during drug treatment with those who receive it after enables us to compare groups while still allowing everyone to get active treatment.

How will participating in this study change our current practices?

For the most part, conducting research in the clinic should not have a big impact on how you interact with clients. Clients participating in the study will be screened more extensively than those not participating. Care will have to be taken to ensure that no study data are collected before documentation of informed consent.

Different, and perhaps more strict, rules for maintaining confidentiality and privacy apply in the case of research. For example, the fact that a client is participating in a study may have to be kept confidential from other staff, and definitely should not be discussed in common areas or mentioned to other clients.