

*National Drug Abuse Treatment
Clinical Trials
Network*



STOP
SMOKING
STUDY

*Should
I Join?*



NIDA NATIONAL INSTITUTE
ON DRUG ABUSE

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

Introduction

Many people who abuse drugs and alcohol also smoke cigarettes. Cigarette smoking can cause problems with your health and energy. Smoking increases your risk of having heart problems, lung cancer and stroke. Smoking cigarettes can also add to the health risks of substance abuse, and may make it harder to stop using drugs and alcohol. Most people do not realize that cigarette smoking is the most common cause of death among substance abusers.



Quitting smoking can improve your health and make it easier to stop using drugs and alcohol. It can be very difficult to stop smoking, because most smokers are addicted to nicotine. Addiction to nicotine, like addiction to drugs and alcohol, can be very difficult to break. Smokers may need medications and/or counseling to help them quit. Most substance abuse treatment programs do not offer treatment for quitting smoking. This is unfortunate, because studies show that it is easier for some people to stop using drugs and alcohol if they stop smoking at the same time.

The National Drug Abuse Treatment Clinical Trials Network is doing a study to see if adding a stop smoking program to substance abuse treatment will help people quit smoking and stay off of drugs and alcohol better than substance abuse treatment alone. The treatment for quitting smoking consists of group counseling in combination with the nicotine skin patch (NicoDerm CQ). Using the nicotine patch often makes quitting smoking easier. NicoDerm CQ is an approved medication that is available over the counter. The patch will be provided for free to people who participate in the study.

Who is eligible to participate in this study?

You may qualify to join this study if you smoke, you want to quit, and you are enrolled in substance abuse treatment at this clinic. If you qualify to join the study, you may be offered treatment for stopping smoking in addition to the treatment you receive for substance abuse. You could get stop smoking treatment as part of or after you finish the study. Because this is research, you will not get to choose whether you will get the smoking treatment as part of or after the study, that will be decided by chance (like the flip of a coin). You must be willing to accept your treatment assignment. Two out of three people who join the study will receive the smoking treatment during the study. One out of three who join the study are eligible to receive quit smoking treatment after completing the study. If you choose not to take part in the research study, your substance abuse treatment at this clinic will not change and you will not lose any of your treatment benefits.

What can I expect if I decide to participate?

1. You will have to give your written permission if you want to be in the study.
2. You will be asked to sign a consent form that describes all parts of the study, including risks and benefits.
3. Before signing the form, you will have a chance to ask questions and to talk it over with friends and family.
4. If you decide to provide consent, you will undergo a screening process to see if you qualify for the study. The screening procedures include:
 - * A check of your vital signs (heart rate, blood pressure, temperature, weight and breathing)
 - * Urine and breath tests to measure drug and alcohol use and smoking
 - * Questions about your drug use and cigarette smoking
 - * Questions about your drug or alcohol treatment

- * Questions about your health and mood
- * A urine pregnancy test for women

What happens if I qualify?

If you qualify for the study, you will be assigned to a group at random (for example, by the flip of a coin; you will not get to choose). Group 1 is standard drug treatment plus treatment to stop smoking and Group 2 is standard drug treatment alone.

If you are in Group 1, you will attend the standard substance abuse treatment program as usual. In addition, you will participate in a 9-week stop smoking program. The first week of the stop smoking program will help you prepare for your quit smoking date. The second week, you will stop smoking. On the day you stop smoking, you will begin using the NicoDerm CQ patch. You will use a 21 mg/day dose patch each day for 6 weeks, and then a 14 mg/day dose each day for 2 weeks.

You will also have counseling sessions 2 times a week for the first 2 weeks, and once per week after that.

If you are in Group 2, you will attend the standard substance abuse treatment program as usual. If you show up for most of the study visits, you may be eligible to get free stop smoking counseling and nicotine patches at the end of the study. You may also look into other ways to help you stop smoking at any time.

The study lasts about 26 weeks. You will visit the clinic every week for the first 9 weeks. You will meet often with the study staff. Your study doctor or nurse will watch you closely during the study. You will be asked each week how you are feeling and your vital signs will be checked.

How long does the study last?

The study lasts about 26 weeks. You will visit the clinic every week for the first 9 weeks. You will meet often with the study staff. The research assistant will ask you questions and help you fill out questionnaires. They will collect urine and breath samples to test for drug, alcohol, and tobacco use.

They will also help answer any questions you might have.

After that, you will return to the clinic for 3 follow-up visits at weeks 9, 13 and 26. The visits are for interviews, for a check of your vital signs and for tests of your urine and breath samples. Each of these visits should take about 45 minutes to complete.

All the information you provide will be kept confidential. The research assistant will explain how the information will be protected, and who will be allowed to see it.

Other Commonly Asked Questions About the Study

These are the answers to some common questions about the study. They may help you decide if you would like to take part.

1. How many people will be taking part in the study?

About 864 people across the United States will take part in the study.

2. What will I have to do during the study?

There are only a few things you will need to do for the study.

- * Continue with your substance abuse treatment program throughout the study
- * Fill out questionnaires and give breath and urine samples
- * Use the NicoDerm CQ patch if you are in Group 1
- * Attend stop smoking counseling sessions if you are in Group 1
- * Return for study visits
- * Report any side effects and smoking, medication and drug use
- * Contact the clinic if you have any health problems between visits

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3. Can women who are able to have children join the study?

Yes, but women should not get pregnant while using NicoDerm CQ because it can harm an unborn baby. If you are a woman who is able to get pregnant, you will need to use birth control while taking NicoDerm CQ. The study doctor will discuss this with you in detail, and will do a pregnancy test during the study. Call your doctor right away if you think you are pregnant and are using the nicotine patch.

If you become pregnant, your study doctor will talk with you about your choices. Your doctor will want to follow your pregnancy and to know when your baby is born.

4. What happens at study follow-up visits?

The follow-up visits will include:

- * Check of your vital signs
- * Urine and breath samples for drug, alcohol and tobacco use
- * Questions about all drugs or medications you are taking
- * Questions about how you have been feeling
- * Questions about how you are doing in different areas of your life (for example, family/friends, legal, job areas)
- * Questions about your smoking

5. What will I get for taking part in the study?

Taking part in the study may help you to stay off drugs. You will get more monitoring of your symptoms during the study than in a regular treatment program. You may also get more counseling. If you are in Group 1, the nicotine patch and counseling may help you to quit smoking. You will be given \$20 for your time and travel expenses after you have completed all screening tests and procedures and told whether you quali-

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fy for the study. If you qualify, you will be given \$10 for showing up as directed, assigned to a treatment group, and completed all related tasks. Once the stop smoking treatment begins, you will receive money for your time and travel for each study visit (\$10) and each follow-up visit (\$20). There is also a bonus payment of \$20 for finishing the whole study. You could earn up to \$200 if you complete the study. Your method of payment (whether cash, gift certificate, or script) will depend on your program policies.

6. Will I have any bad effects from taking part in the study?

The NicoDerm CQ nicotine patch can have side effects. Most of these side effects are minor, but some may be harmful. Some side effects of the nicotine patch include skin irritation, increased blood pressure, rapid heartbeat, irregular heart beat, and difficulty sleeping. Symptoms of too much nicotine, such as nausea, vomiting, dizziness, and weakness can also occur, and these effects may be made worse if you continue to smoke. Your informed consent paper will list the side effects for the nicotine patch. We will monitor any side effects during the study, and if necessary, may lower the dose of nicotine. The nicotine patch may not react well with other medications you are taking. Ask your doctor before taking any medication.

When you quit smoking, you may still have symptoms of nicotine withdrawal even if you use the patch. You may have anxiety, fatigue, trouble concentrating, impatience, irritability, trouble sleeping, and increased eating. You may also want cigarettes. These symptoms may be unpleasant but are not harmful.

You may be upset about not getting into the group that you wanted. Remember, you will have a chance to get stop smoking treatment when the study is over. A possible risk is

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continued smoking if your program does not work. Since we want to help you and others with similar problems, we are conducting this study.

Another possible risk is that people not involved in the study will see your information. This is a very small risk. The study staff is trained to keep your information private. Your name will not be on any information that leaves this clinic. Certain institutions are allowed to look at your information, including the National Institute on Drug Abuse, the Department of Health and Human Services, and research review committees working with your clinic and study staff. Individuals at these institutions will not reveal your name or private information to anyone outside the study staff.

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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