

Georgia State University School of Public Health
Informed Consent

Title: Understanding Ways to Help Adults Quit Smoking

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Sponsor: The National Cancer Institute

Introduction and Key Information

You are invited to be in a research study. It is up to you to decide if you want to be in the study. The reason for the study is to learn about ways to help people quit smoking.

Your role in the study will last up to 26 hours over about 6 months.

You will be asked to:

- Be in a quit smoking program. You will get nicotine patches, nicotine lozenges, and advice to help you quit. You may also be in an online group with other people, and you may receive text messages about quitting smoking.
- Fill out questionnaires.
- Breathe into a device to see how much carbon monoxide is in your breath. Carbon monoxide is a chemical that is related to smoking.
- Put a saliva swab under your tongue to measure nicotine in the body.

The risks of being in this study are that we will ask you some personal information, like your education, health history, smoking habits, mood, alcohol and drug use. You may feel uncomfortable when answering these questions. You can skip or ignore any questions that you do not want to answer.

This study is created to help you quit smoking. You will receive a quit smoking program and nicotine patches and lozenges for free. This study may also help others quit smoking in the future.

If you do not wish to take part in this study, the alternative is to use nicotine replacement therapy or non-nicotine prescription drugs to help quit smoking.

Purpose

The purpose of this study is to learn about ways to help people quit smoking. You are invited to be in this research study because you are at least 18 years old, smoke cigarettes, and want to quit smoking. There will be about 525 people in this study.

Procedures

All participants will be randomly placed in one of four quit smoking programs. The reason is so that the researchers can find out the best ways to help people quit smoking. No one will get to choose which group they want to be in. Everyone will get nicotine patches, nicotine lozenges, and advice for quitting. After today, you will come to Georgia State University at weeks 8, 12, and 24.

Participants in two of the programs will also meet weekly in an online video-based group. These groups will meet once every week for 2 hours, for a total of 8 weeks (16 hours total). There will also be an online group orientation for people in these groups. All participants are expected to attend the entirety of group sessions unless there are unforeseen circumstances (e.g., emergencies). If you are in these groups, we strongly encourage you to show your video during the session so that you can get to know your group members better. Participants in two of the programs will also get text messages about quitting smoking.

Questionnaires and Short-surveys

You will fill out questionnaires before the start of the program (today), at four times during the program (weeks 1, 3, 5, and 8), and again at 1 month and 4 months after the end of the program (weeks 12 and 24). You will receive links to the week 1, 3, and 5 surveys through email and/or text message. If you prefer to take the surveys by phone, you can talk with a research staff member to answer the questions over the phone. You will come back to GSU in person to take the surveys at weeks 8, 12 and 24.

During your in-person visits at weeks 8 and 12 you will breathe into a device that shows how much carbon monoxide is in your breath. Many people find it helpful to see the amount of carbon monoxide in their breath go down as they quit smoking.

The last study visit (week 24) will be in-person. At that visit you will put a saliva swab under your tongue for 1 to 2 minutes to measure the amount of nicotine in the body. If you cannot come to that visit, you can do this at home and mail it to us at Georgia State University.

From week 2 to week 8 of the study, you will complete short-surveys every other day about your smoking and mood. The short-surveys will come to your phone as text messages and we will also send them to you by email. You can click on a link to do the surveys online.

Taking the surveys will take up to 10 hours over the course of this study. This includes the baseline session (today, 1.5 hours), the surveys at weeks 1, 3, and 5 (30 minutes each), in-person visits at weeks 8 and 12 (1 to 1.5 hours each), the in-person visit at week 24 (1.5 to 2 hours) and the short-surveys (up to 2 hours total).

Nicotine Patches and Lozenges

You will get nicotine patches and nicotine lozenges to help you quit smoking. You will get a total of 8 weeks' worth of nicotine patches and lozenges to take with you today.

How You Will Hear From Us

You will get text messages about the study and your appointments. Normal messaging/data rates may apply. Although you will be paid for doing study assessments, you will not be paid directly for any costs of the text messages. Please do not read or send text messages when driving or at any other time it would be dangerous. Using your cell phone while operating a motor vehicle is against the law in Georgia, even if you are stopped at a traffic light. Text messaging is not a good way to ask for help if you are in crisis. Call 911 if you have an emergency.

We may contact you by mail, telephone, text message, and/or e-mail at any time during the study, to remind you about appointments visits and/or to ask about your smoking and feedback about the program. You will provide the names and contact information for family and/or friends for the study staff to contact, if the study staff has trouble reaching you.

You can borrow a basic study phone if you:

- do not own a cell phone,
- do not own a cell phone that can receive and send phone calls, texts and picture messages,
- prefer to use a study phone, or
- do not have consistent phone service

You can borrow a basic study tablet if you:

- are randomly put in the group that meets online weekly
- do not own a tablet with a working web camera
- do not have consistent Wi-Fi

If you borrow a phone, you must bring it back to GSU at the last study visit (week 24). If you borrow a tablet, you must bring it back to GSU after the final group session (week 8). Before receiving equipment, you will be asked to sign an agreement saying that you will use the device to take part in the study, keep it safe to the best of your ability, and return it to GSU.

The study team will delete all information from your borrowed device so that no one will have access to your personal information. If the phone is lost or stolen, we will replace it one time. If it is lost or stolen again, the phone will not be replaced again. If the tablet is lost or stolen, it will not be replaced. If the tablet is stolen, we will file a police report and remotely lock and reset the device. If the tablet is lost, we will remotely lock and reset the device. If you choose to stop being in the study, a study staff person will reclaim the device from you.

You may be removed from this study if your behavior disrupts others or stops others from receiving and/or benefiting from the treatment.

Depending on which quit smoking program you are in, your group sessions may be audio and video recorded. These recordings will be used to help the research team make sure the study is being done correctly. Also, if a group member is unable to attend a session they may make it up by watching the video recording. They will only be able to do this by making an appointment with study staff to watch the video together.

Future Research

Researchers will remove information that may identify you and may use your data for future research. If we do this, we will not ask for any additional consent for you.

Risks

The most common side effect of nicotine patches is a short feeling of itching or burning, which can be helped by using hydrocortisone cream or other lotions. Other less common side effects are: stomach complaints; dry mouth; joint pain; tenderness or pain in the muscles; abnormal dreams; nervousness; insomnia; or sweating. Side effects of nicotine lozenges can be mouth sores, hiccups, sore throat, headache, stomach complaints, or dizziness.

Stop using the patch and lozenges and tell your doctor right away if you have any serious side effects like severe dizziness, mood changes, numbness or tingling in your hands/feet, or swelling in your hands/ankles/feet. Stop using the patch and lozenges and get medical help right away if you have any very serious side effects like chest pain, confusion, severe headache, fast or irregular heartbeat, slurred speech, or weakness on one side of the body. A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), or trouble breathing.

It is very important that you do not smoke while wearing the patch or using lozenges. If you have serious side effects, tell the research staff immediately and stop using the patch and lozenge.

This study does not give nicotine patches or lozenges to people who are pregnant. The US Centers for Disease Control and Prevention (CDC) encourages pregnant women to try to quit smoking without these medicines because nicotine may have effects on the developing baby. If you do become pregnant during this study, we will not give you patches and lozenges, but you can still use the other study tools to help you quit smoking. If you become pregnant, talk to your doctor about the best treatment for you. It is very important to quit smoking as soon as possible when pregnant.

Mood changes, sleep changes, and trouble concentrating are common when people quit smoking. Less common symptoms while quitting smoking are headache, upset stomach, and increased hunger. These feelings usually only last for around 1-2 weeks after quitting and don't affect health long-term. The nicotine patches may help with some of these symptoms but may not help all of them.

Providing contact information of friends or relatives for the purpose of contacting you may cause them to find out about your participation in this study. If they are not aware of this already, this may cause distress or concern. You do not have to provide this information if you do not want to.

The study surveys will ask you some personal information, like your education, health history, smoking habits, mood, alcohol and drug use. You do not have to answer any questions that make you feel uncomfortable. If you feel uncomfortable providing breath or saliva samples, you do not have to do this testing.

If you have any questions or believe you have been harmed by the study, contact Dr. Claire Spears at 404-413-9335. Referrals for psychological or medical treatment will be provided upon request. Georgia State University, however, has not set aside funds to pay for this care or to compensate you for any harm.

Benefits

This study could help you quit smoking. You will get nicotine patches, lozenges, and advice to help you quit smoking, free of charge. This research may also help others by improving future programs to help people quit smoking.

Alternatives

The alternative to taking part in this study is to not be in the study. Other options are to use other resources to help you quit smoking, such as calling 1-800-QUIT-NOW, and/or using nicotine patches, other nicotine replacement therapy, or medication prescribed by your doctor.

Compensation

You will get either MARTA bus/train vouchers (two-ways for each visit) or parking for each study visit at GSU after today. Please tell the research staff if you prefer MARTA or parking. The research team will give you the exact starting date for the study. We will also tell you the other dates that you will come to GSU.

You can receive up to \$380 total for participating in this study. See the table below.

Here is a breakdown of the payment:

- During the quit smoking program, you will receive \$25 when you do study questionnaires at weeks 1, 3, and 5. If you do your questionnaire within 24 hours of receiving it, you will get a \$5 bonus. You can earn a total of \$30 for each questionnaire.
- You will also be paid for the online short-surveys in between study visits (every other day starting at week 2). The short-surveys will not take more than 5 minutes each. You will be paid \$5 per short-survey. If you do all of the short-surveys, you can earn up to \$120 for all 6 weeks.
- You will receive \$40 for completing questionnaires at week 8. You will come in-person to GSU this week to complete study activities and receive your payment.
- You will receive \$60 for completing questionnaires at week 12. You will come in-person to GSU this week to complete study activities and receive your payment.
- You will receive \$70 for completing questionnaires at week 24. You will come in-person to GSU this week to complete study activities and receive your payment. This is the final study visit.

If you drop out of the study or do not complete the questionnaires, you will be paid for the part(s) that you complete, but you will not be paid for the part(s) that you do not complete.

This table on the next page shows when you will do the surveys and when you will be paid. After you take the surveys on your own, you will be paid by e-gift cards (sent to you by email and/or text message). You will be paid in cash for the surveys that you take at GSU.

Procedure	What	When	Where	Compensation
Week 1	Questionnaires	1 st week of treatment	On your own	\$25 (or \$30 if you take the survey within 24 hours)
Short-Surveys	3 to 4 short-surveys per week (for example: Sunday, Tuesday, Thursday, Saturday)	Every other day starting at week 2 (total of 6 weeks)	On your own (you will be paid together with the next questionnaire)	<ul style="list-style-type: none"> • \$5 per survey • Total for 6 weeks = \$120 if you complete all the short-surveys
Week 3	Questionnaires	3 rd week of treatment	On your own	\$25 (or \$30 if you take the survey within 24 hours)
Week 5	Questionnaires	5 th week of treatment	On your own	\$25 (or \$30 if you take the survey within 24 hours)
Week 8	Questionnaires	8 th and last week of treatment	GSU	\$40
Week 12	Questionnaires	1 month after the end of treatment	GSU	\$60
Week 24	Questionnaires	4 months after the end of treatment (last study visit)	GSU	\$70

Voluntary Participation and Withdrawal

You do not have to be in this study. If you decide to be in the study and change your mind, you have the right to drop out at any time. You may skip questions or stop participating at any time. You may refuse to take part in the study or stop at any time, this will not cause you to lose any benefits that you have otherwise.

Confidentiality

We will keep your records private to the extent allowed by law. The following people and entities will have access to the information you provide:

- Principal Investigator Dr. Claire Spears and her research team at GSU
- GSU Institutional Review Board
- Office for Human Research Protection (OHRP)
- National Cancer Institute

We will use a random ID number instead of your name on study records. All records will be kept in locked files or password-protected computer files. The text messages will have your first name, but your name will be removed from your text message responses. Although the researcher cannot promise that other group members will maintain confidentiality, participants are asked to keep what they hear private. It is also possible that people near you could see your text messages.

When we present or publish the results of this study, we will not use your name or other information that may identify you. A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Contact Information

Contact Dr. Claire Spears at cspears@gsu.edu or 404-413-9335

- If you have questions about the study or your part in it
- If you have questions, concerns, or complaints about the study
- If you think you have been harmed by the study

Contact the GSU Office of Human Research Protections at 404-413-3500 or irb@gsu.edu

- If you have questions about your rights as a research participant
- If you have questions, concerns, or complaints about the research

Consent

We will give you a copy of this consent form to keep. If you are willing to volunteer for this research, please sign below.

Printed Name of Participant

Signature of Participant

Date

Principal Investigator or Researcher Obtaining Consent

Date