Consent Cover Page

Official Title of the Study: Project Q Pilot: Smoking Cessation for Light Smokers

NCT Number: NCT03416621

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DUKE UNIVERSITY HEALTH SYSTEM

Project Q Pilot

CONCISE SUMMARY

This is a research study to test whether people who smoke less than 10 cigarettes per day find a new program helpful as they attempt to quit smoking. A possible benefit from being in this study is quitting smoking.

Participants have a 1 in 2 chance of receiving the more intensive counseling. One group will receive support through text messages to stop smoking and counseling. The second group will receive text messaging support, counseling and studies in the lab to examine what cues trigger smoking. Depending on the group, participants will be asked to come to Duke up to 6 times and also use their phones to text the study staff. Participants will be in the study for about 4-6 weeks total.

If you are interested in learning more about this study, please continue reading below.

You are being asked to take part in this research study because you smoke between one to ten cigarettes every day. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell study staff if you are taking part in another research study.

Dr. Kathryn Pollak will conduct the study and it is funded by Duke Cancer Institute. Portions of Dr. Kathryn Pollak's research team's salaries will be paid by this grant.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to test whether people find a new program helpful as they attempt to quit smoking. The study includes counseling and texting about your smoking and cravings to smoke.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 30 people will complete this study at Duke.

WHAT IS INVOLVED IN THE STUDY?

If you agree to be in this study, you will be asked to sign and date this consent form. To make sure the study is right for you, you will be asked to answer

- Questions on the following: how often you smoke, use of other tobacco products, depression, anxiety, drug and alcohol use, willingness to attend all study visits.

Depending on the results of the questions, you may not be eligible for the study.

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Enrollment and randomization: If you sign the consent and pass screening criteria, you may be in the study. If you are in the study, we will assign you (like flipping a coin) to one of two groups.

We will ask you to pick a smoking quit date that is about one week after your first study visit (today). Also, we will ask you to attend up to six study visits (including today's visit), each lasting about 1 to 1.5 hours.

- **Study Visit 1** will occur after you sign this consent form. We will ask you to answer questions and give us a sample of your breath to test for a chemical called carbon monoxide, which comes from smoking cigarettes. We also will ask you to talk to our study staff about your smoking and make plans to try to quit. We will provide instructions on how to send us text messages to help us learn about your smoking. We will ask you to pick a quit date that is within 1-2 weeks.
- **Real time smoking data collection**. (Second group only) After Study Visit 1, we will ask that you text us every time you smoke for 4 days. We will ask you a few questions about what is going on for you when you are smoking. We will also ask you to take a picture of where you are each time you smoke for those 4 days.
- **Study Visit 2** will occur approximately 1 week after Visit 1. We will ask you to answer a few questions about your smoking and provide another breath sample. We will ask you to meet with someone to talk about your smoking and how your attempt to quit smoking is going.
    - If you are assigned to the second group, we will go over the summary of the information you texted about your smoking.
    - If you are assigned to the second group, we will show you a mix of your photos and photos we have related to smoking, as well as other items that may remind you of smoking (such as cigarettes, a lighter, etc.). You will not be able to smoke while viewing the photos or holding these objects. We will ask you to answer questions about your desire to smoke afterwards.
- **Between Visit 2 and Visit 3:** We will send you one or two text messages a day to help you not smoke. We will also ask you to text the study when you are craving a cigarette or if you smoke and the study will text you to help you not smoke at that time and to ask you questions about craving and stress level.
- **Study Visit 3** will occur approximately 1 week after Visit 2. Study Visit 3 is exactly like Study Visit 2. We will ask you to answer a few questions about your smoking and provide another breath sample. We will ask you to meet with someone to talk about your smoking and how your attempt to quit smoking is going.
    - If you are assigned to the second group, we will show you a mix of your photos and photos we have related to smoking, as well as, other physical items that may remind you of smoking (i.e. cigarettes, a lighter, etc.). You will not be able to smoke while viewing the photos or holding these objects. We will ask you to answer questions about your desire to smoke afterwards.
- **Between Visit 3 and Visit 4.** We will send you one or two text messages a day to help you not smoke. If you are assigned to the second group, you will be asked to text the study when you are craving a cigarette or if you smoke and the study will text you to help you not smoke at that time and to ask you questions about craving and stress level.
- **Study Visit 4** will occur approximately1 week after Visit 3. We will ask you to answer a few questions about your smoking and provide another breath sample.

- If you are assigned to the first group, this will be your last visit. In addition to the items listed above, you will also be asked to provide a saliva sample.
- If you are assigned to the second group, we will ask you to meet with someone to talk about your smoking and how your attempt to quit smoking is going. We will also show you a mix of your photos and photos we have related to smoking, as well as, other physical items that may remind you of smoking (i.e. cigarettes, a lighter, etc.). You will not be able to smoke while viewing the photos or holding these objects. We will ask you to answer questions about your desire to smoke afterwards.

- **Between Visit 4 and Visit 5** (Second group only)**.** We will send you one or two text messages a day to help you not smoke. If you are assigned to the second group, you will be asked to text the study when you are craving a cigarette or if you smoke and the study will text you to help you not smoke at that time and to ask you questions about craving and stress level.
- **Study Visit 5** will occur approximately1 week after Visit 4. Only those in the second group will attend Study Visit 4. We will ask you to answer a few questions about your smoking and provide another breath sample. We will ask you to meet with someone to talk about your smoking and how your attempt to quit smoking is going.
  - If you are assigned to the second group, we will show you a mix of your photos and photos we have related to smoking, as well as, other physical items that may remind you of smoking (i.e. cigarettes, a lighter, etc.). You will not be able to smoke while viewing the photos or holding these objects. We will ask you to answer questions about your desire to smoke afterwards.
- **Between Visit 5 and Visit 6** (Second group only). We will send you one or two text messages a day to help you not smoke. If you are assigned to the second group, you will be asked to text the study when you are craving a cigarette or if you smoke and the study will text you to help you not smoke at that time and to ask you questions about craving and stress level.
- **Visit 6** will occur approximately1 week after Visit 5 for those in the second group. We will ask you to answer a few questions about your smoking, provide another breath sample and provide a saliva sample. We will ask you if we can contact you to ask you for feedback on the study. If you agree, we will call you or meet you in-person to hear about your experience in the study.

We may call or text you between visits to remind you of visits. However, please call us immediately if you have any questions or concerns.

We may audio record some of your answers to the surveys and your counseling sessions. We will seek verbal permission from you to audio record your answers at the time of the surveys. The audio recordings will be stored electronically on a password protected, encrypted computer that will be kept in a locked office at Duke University. The recordings will not be shared with anyone outside of the research team. Once the study is complete, the audio recordings will be destroyed. You have the right to refuse to be audio-recorded, and it will not impact your ability to participate in this study.

HOW LONG WILL I BE IN THIS STUDY?
Your entire study participation, including follow-up, will last approximately 7 weeks.

WHAT ARE THE RISKS OF THE STUDY?

There is the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop your participation in this study at any time.

As a result of your participation in this study, you are at risk for the side effects described below. You should discuss these side effects with the study doctor or physician assistant, as well as your regular health care provider if you choose.

Smoking Withdrawal:

When quitting smoking you may experience some, all or none of the withdrawal symptoms: headache, nausea, constipation or diarrhea, decrease in heart rate and blood pressure, fatigue, drowsiness, and insomnia, irritability, difficulty concentrating, anxiety, depression, tobacco cravings, increased desire for the taste of sweets, and/or increased hunger and caloric intake leading to weight gain.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may be direct medical benefit to you. A possible benefit from participation in this study is quitting smoking. We hope that in the future the information learned from this study will benefit people that smoke in the future.

WHAT ALTERNATIVES ARE THERE TO PARTICIPATION IN THIS STUDY?

If you do not wish to participate in this study, there are other alternatives to treat tobacco use. You can talk with your doctor about prescription medicines that may help you quit (including Varenicline or Bupropion), or nicotine-replacement products offered outside of this study, both over-the-counter and by prescription. Information about these resources is available through the North Carolina Tobacco Use Quit line at http://www.quitnownc.org or by calling (800) 784-8669.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Participation in research can involve some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information to conduct the research. Your personal information may also be given out if required by law.

The texting gateway system used for delivering the text messages to and from your cell phone will store the phone number you use for sending and receiving messages, along with the content of the text messages you will receive or send. These messages will only be about your smoking. The texting system will be managed by People Designs in Durham, NC. Once the study is over, we will destroy all text messages.

In addition, your records may be reviewed to meet federal or state regulations. Reviewers may include the Duke Cancer Institute, the Duke University Health System Institutional Review Board, and others as appropriate. If any of these groups review your research record, they may also need to review your entire medical record.

If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by the federal privacy regulations.

Results of tests and studies done solely for this research study and not as part of your regular care will not be included in your medical record. Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

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.

WHAT ARE THE COSTS TO YOU?

There will be no additional costs to you as a result of being in this study. However, routine medical care you would have received whether or not you were in this study will be charged to you or your insurance company. You may wish to contact your insurance company to discuss this further. We will monitor your DUHS patient care charges to make sure that costs are directed appropriately. If you have any questions or concerns about appropriate billing, contact your study team coordinator so that he/she can help find a resolution. These tests and studies are not a part of routine care, and people who are not part of the study do not usually have them performed. Please ask Dr. Pollak or the study staff if you would like to know more about which tests and studies are being done solely for research purposes.

WHAT ABOUT COMPENSATION?

You will be reimbursed up to $150 for your expenses related to your participation (parking, gas, and time). You will receive $50 for completing Visit 1. You will be compensated $100 at your final visit (either Visit 4 or Visit 6 depending on which group you are in).

WHAT ABOUT RESEARCH RELATED INJURIES?

Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by

Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. Kathryn Pollak at (919) 681-4757 or the study coordinator, Shayna Clancy at (919) 681-4558 during regular business hours and Dr. Pollak at (919) 602-2485 after hours and on weekends and holidays. You can reach Dr. James Davis, the study doctor, 24-hours a day at (608) 217-9405.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

Being in this trial is voluntary. If you do not sign this consent form, you will continue to receive care, but not as part of this study. You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. However, if you decide to stop participating in the study, we encourage you to talk to study staff first. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Pollak in writing and let her know that you are withdrawing from the study. Her mailing address is 2424 Erwin Road, Suite 602, Durham, NC 27705.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Your doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue. The sponsor or regulatory agencies may stop this study at any time without your consent. Reasons why this might occur include difficulty in study recruitment or retention that will significantly impact the ability to evaluate the study endpoints or any new information becomes available during the study that necessitates stopping the study. If this occurs, you will be notified and your study doctor will discuss other options with you.

Your samples and/or data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your samples or data, we will no longer be able to identify and destroy them.

The use of your samples may result in commercial profit. You will not be compensated for the use of your samples other than what is described in this consent form.
A description of this clinical trial will be available on https://clinicaltrials.gov/ as required by U.S. Law (ClinicalTrials.gov Identifier: NCT03416621). 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.

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WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Kathryn Pollak at (919) 681-4757 during regular business hours and Dr. Pollak at (919) 602-2485 after hours and on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.**STATEMENT OF CONSENT**

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

Signature of Subject	Date	Time
Signature of Person Obtaining Consent	Date	Time