Brief Title

Baby Steps III: Testing a Clinician and Patient Intervention to Promote Smoking Cessation Among Pregnant Women

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Duke University Health System

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CONCISE SUMMARY

The purpose of this research study is to test a program to help pregnant women quit smoking by teaching OB clinicians how to talk to patients about their smoking. Additionally, text messages will be sent to women to support their efforts to quit smoking If this study is right for you, you will be asked to audio record your first OB visit and complete surveys before and after the visit. After the visit, we will ask you to enroll in a text message program to receive quit smoking support messages through pregnancy. Total study duration is between four and 12 months depending on how far along you are in your pregnancy.

There is a risk of loss of confidentiality. There is a possible medical benefit to you and/or your baby because you might reduce or quit smoking.

You are being asked to take part in this research study because you are pregnant and you have reported that you smoke cigarettes. 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 them 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.

A grant from the National Institutes of Health (NIH) will sponsor this study. Portions of Dr. Kathryn Pollak's and her research team's salaries will be paid by this grant. This research is also being conducted at the University of Pittsburgh where portions of the research team's salaries will also be funded by this grant.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to test a program that seeks to help pregnant women quit smoking both through receiving text messages about quitting smoking and also by teaching OB clinicians the best ways to talk to their patients about smoking.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 60 clinicians and 540 patients across Duke University Health System and the University of Pittsburgh Medical Center.

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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. This study includes completing two surveys (before and at the end of your first OB visit), potentially audio recording your first OB visit as well as two more surveys at the end of your pregnancy, and 6-weeks post-partum.

You will be asked to complete a survey with questions about you and your health right after signing this consent form. Some of the questions may make you feel uncomfortable. You do not have to answer any questions that you do not want to answer. When you enter the exam room, we may ask you to begin audio recording when your doctor enters the room. At the end of your visit, if we did ask you to audio record, we will ask you to turn off the recorder. We will then ask you to answer some questions on the tablet about how your visit went. If you do not have time to complete this survey after the visit, we will email or mail the survey to you and ask you to complete it.

Your survey responses will not be shared with your clinician. We will also ask that you allow for us to access your medical records to obtain information on: your medical history and birth outcomes.

After your first OB visit, you will be enrolled in a text message program to receive smoking cessation support throughout your pregnancy. You will be required to provide a cell phone number to which you can receive text messages. You will receive text messages each day for the first 7 weeks. After those 7 weeks, you will receive messages on approximately three days per week, through the 35th week of your pregnancy. You do not have to respond to these messages.

A urine sample will be obtained if you report 7-day abstinence at the end of pregnancy and post-partum. Study staff will ask you to provide a urine sample at the end of your visit should you report not smoking. Results of these urine tests will not be shared with your clinician nor be put in or linked to your medical records.

Lastly, study staff will access your and your baby's medical records at the time of delivery to get information about the baby's birth, such as your baby's gender, gestational age, birth weight, and any medical complications associated with your baby's birth. You may be asked to sign a separate form to permit your information to be sent from the hospital where you delivered your baby to us.

Study participation is voluntary and if you do not sign this consent form, you will continue to receive care. If you choose not to participate, it 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.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to participate, you will be in the study until approximately 3 months after your baby is born.

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Depending on when you enroll in the study, this is a total of approximately four to nine months**.** . You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled.

WHAT ARE THE RISKS OF THE STUDY?

Quitting smoking may cause nicotine withdrawal that may lead to headaches, irritability, weight gain, difficulty concentrating, poor sleep, increased appetite, anxious or depressed mood, and craving for cigarettes. The text messages we send you are is designed to help you deal with many of these issues.

There is the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential. However, this cannot be guaranteed. We will email you a copy of this consent form; however, email is not a secure method of communication. By signing this consent form and providing your email, you agree that we may email you a copy of this consent form. If your encounters are audio recorded with your permission, the recordings will be stored electronically on a secure platform. The recordings will not be shared with anyone outside of the research team. 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 these questions and you may take a break at any time during the study. You may stop your participation in this study at any time.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to participate in this study, there may be a direct medical benefit to you and/or your baby because you might cut down or quit smoking. What we learn from you and the other women in the study will help us develop programs that will be useful for other women and their families in the future.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?

All records pertaining to your involvement in this research study will be stored in locked file cabinets, on password-protected computer files, or secure research servers and cloud platforms in the Department of Obstetrics, Gynecology and Reproductive Sciences at the University of Pittsburgh or the Department of Population Health Sciences at Duke University. A case number will indicate your identity on these records.

In addition to the investigators listed and their research staff, the following individuals may have access to your information related to your participation in this research study:

- Authorized representatives of the study sponsor, federal regulatory agencies, monitoring staff at the Department of Population Health Sciences for purposes of monitoring the conduct of this research study.
- If investigators learn that you, or someone with whom you are involved is in serious danger or potential harm, they will need to inform the appropriate agencies, as required by Pennsylvania law.
- Information collected from this study may be shared with other investigators; however, this information will be shared in a de-identified manner (i.e., without identifiers).

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Participation in research involves 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 funding, and regulating the study, and those currently collaborating on the study and those who will possibly be collaborating on the study in the future. Collaborating individuals at the University of Pittsburgh may review your audio recordings and de-identified survey responses in order to analyze the data. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law. Additionally, there is a chance that we would life to share these recordings in the future with researchers at other institutions for which we have data use agreements.

We will send urine samples labeled with your name and date of birth to the study team at the University of Pittsburgh for processing. The urine sample will be processed for the presence of cotinine, which is associated with tobacco smoke exposure, by Dr. Robert Power's lab at the University of Pittsburgh.

Because the urine sample is for study purposes only, the results of laboratory urine tests will not automatically be given to you or be sent to your health care provider to include in your medical record.

By agreeing to participate in this research, you authorize DUHS and the study team at the University of Pittsburgh to use your urine samples for the purposes described in this consent form. You will not have access to the urine sample once it is obtained. These samples are unavailable for clinical (diagnostic) purposes.

Once the urine sample has been processed, the study team at the University of Pittsburgh will destroy the sample.

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.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);
2) you have consented to the disclosure, including for your medical treatment; or

3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project.

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

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. The audio records of the visits may be given to secondary investigators not listed on this current research study and be utilized in future studies. Any additional or future analyses involving these audio records will not include any names or other identifying information.

This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations.

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.

WHAT ARE THE COSTS TO YOU?

There is no cost to you for participating in this study.

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WHAT ABOUT COMPENSATION?

You will be compensated $30 for the baseline survey. Upon completion of the end-of- pregnancy survey you will receive $30 and then $20 after completing the 6 weeks postpartum survey.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE 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. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal.

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 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.

A description of this clinical trial will be available on https://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.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, or if you have complaints, concerns or suggestions about the research, contact Dr. Pollak at 919-681-4757 during regular business hours and 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.

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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