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COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT
YALE SCHOOL OF MEDICINE – YALE-NEW HAVEN HOSPITAL

Study Title: Ecological Momentary Assessment and Attentional Retraining for Postpartum Smoking Relapse: A Pilot Study
Principal Investigator: Ariadna Forray, MD
Funding Source: National Institute on Minority Health and Health Disparities

Invitation to Participate and Description of Project

You are invited to participate in a research study designed to look at the social and emotional factors that influence smoking following delivery in women who stopped smoking during pregnancy, and the use of a behavioral task for the treatment of smoking relapse following delivery. This information will help future women prevent relapse after having a baby and may improve treatments for those who resume smoking after pregnancy. You are invited to participate in this study because you are pregnant/near delivery and have a history of smoking. You may or may not be currently using cigarettes, but this study will offer resources and follow up to women who have smoked at some point prior or during pregnancy. Only women who have achieved abstinence defined as no smoking or smoking less than 2 cigarettes per week by 32 weeks' of pregnancy will be eligible to participate in the study. We anticipate that 50 women from this clinic will participate in this study.

In order to decide whether or not you wish to be a part of this research study you should know enough about its risks and benefits to make an informed judgment. This consent form gives you detailed information about the research study, which a member of the research team will discuss with you. This discussion should go over all aspects of this research: its purpose, the procedures that will be performed, any risks of the procedures, possible benefits and possible alternative treatments. Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to sign this form.

Description of Procedures

Screening visit:

- Since you report that you smoked cigarettes at some time in your life, you are now being invited to participate in an interview that will ask you some more detailed questions. This interview will be in person or teleconference using Zoom, and takes about ½ an hour (30 minutes). If you have reached 32 weeks of pregnancy and are currently achieved abstinence defined as no smoking or smoking less than 2 cigarettes per week by 32 weeks' gestation, you will be asked to complete the enrollment visit assessments via a link to an online questionnaire at this time. If you have not reached 32 weeks of pregnancy and have not yet met criteria we will continue to be in touch until that time.

Enrollment Visit (Visit 1):

If you have decreased smoking to less than 2 cigarettes per week by 32 weeks, we will set up a time to ask you to come in for a visit where you will complete additional

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questions. This will be done in conjunction with routine prenatal visits (i.e. we will meet with you at your prenatal visit). This is the only visit you must be seen in person to receive the smartphone and the Covita iCO Smokelyzer. The iCO Smokelyzer is a portable breath carbon monoxide monitor that you plug into the smartphone. When you blow into this device it provides a reading of your exhaled carbon monoxide from home. You will also be asked to provide a breath test (where you breathe into a tube to test for cigarettes in your system) by a research assistant. At this visit your full eligibility for the study will be confirmed.

If you meet all study entrance criteria by 32 weeks, you will be trained in the use of a smartphone and iCO Smokelyzer monitor. You will be given the smartphone for you to carry around with you throughout the day for two weeks. For the two weeks following this visit, the smartphone will beep randomly everyday, three (3) times a day to indicate that you have to answer some questions about your mood, stress level, smoking cravings, and other questions related to your environment. You should answer these questions when you hear the beep by selecting the answers on the smartphone using the appropriate keys on the smartphone keyboard.

You will also be asked to complete a visual probe task. This task consists of looking at two color pictures (or words) side-by-side on the smartphone screen. The pictures will be photographs of smoking-related scenes (e.g., woman holding a cigarette to mouth), paired with a control photograph of another scene lacking any smoking-related cues (e.g., woman applying lipstick). The words will be stress-related words (e.g. panic) paired with a control word (e.g. cloud). The two pictures (or words) disappear after a brief moment and then you will be asked to indicate the location of a dot, which replaces one of the pictures (or word), as quickly as possible by using the keyboard. This procedure will be explained to you in detail by the study personnel.

You will be randomly assigned to a control visual probe task or an intervention visual probe task. The goal of the intervention task is to decrease your attention to smoking cues or stress cues. We believe that decreasing your attention to smoking and stress cues will decrease cravings to smoke. Whether you receive the control or intervention visual probe task does not depend on any of your unique individual characteristics but is done like the flip of a coin. Neither you nor the Investigators will know which task you have been assigned to.

If you are not able to answer the questions or complete the visual probe task when indicated by the smartphone you may delay the time to respond to the questions by 5 minutes. Also, if you know that there will be a time when you will not be able to respond to the smartphone questions and visual probe tasks, you can prevent the smartphone from prompting you for a period of 2 hours. The information collected by the smartphone will be stored on a secure computer system and your personal information will not be linked to your responses. You will only be identified by a number that you will be assigned at the beginning of the study.

Study Visit 2

After the two-week period described above you will be asked to schedule a remote visit by teleconference using Zoom (or come back to our research clinic, if safe to do you so

and you prefer a visit in person) and complete another brief interview (about 15 minutes). Then you will provide a breath test to screen for cigarettes in the body using the iCO Smokelyzer.

Study Visit 3:
Shortly after your baby is born, we will schedule another teleconference visit with Zoom and complete another brief interview (about 15 minutes) and provide breath test to screen for cigarettes in the body using the iCO Smokelyzer. If you continue to qualify for the study, you will be asked to carry the smartphone with you for another two weeks and repeat the procedures described above. This visit can occur in person if it is safe to do so and you prefer this type of visit.

Study Visit 4:
At the end of the two weeks we will again schedule another teleconference visit using Zoom, complete another short interview (about 15 min), and provide another breath test to screen for cigarettes in the body using the iCO Smokelyzer. This visit will mark the end of your participation in our study. This visit can also occur in person if it is safe to do so and you prefer this type of visit.

Post-treatment follow-up Visits 5 (3 months) and 6 (6 months):
A follow-up visit will be scheduled 3 months after treatment phase completion (Visit 5) during which we will ask you to complete another brief interview and a visual probe task, as described above. You will also be asked to a breath test to screen for cigarettes in the body using the iCO Smokelyzer. The same procedure will be repeated 6 months after treatment phase completion (Visit 6). These visits will be done by teleconference using Zoom.

Risks and Inconveniences

There are no physical risks to you or your family for participating in this program. Some of the questions we will ask may seem very personal, but please know that all information will be kept strictly confidential. You have the right to refuse to answer any question you do not want to answer.

Benefits

This study is not designed to guarantee any direct benefit to you; you may respond favorably to education and/or referral, but this cannot be promised. This study is intended to gather valuable information for the effective treatment of cigarette smoking in women. The results of this study may benefit other patients with current or past use of nicotine. By participating in this research study, you will help us to improve our knowledge about the health and recovery issues women face, and help us to improve health care for other women. Whether or not you choose to participate in the study, we will provide you with educational and referral resources.

Economic Considerations

There will be no cost to you for participating in this research protocol. You will be paid $20 for completion of the screening visit and $20 for completion of the enrollment visit (Visit 1). During the study you will receive $2 for each smartphone assessment you complete, plus $8 per week for completing all assessments for the week. This means you may receive up to $200 for completing all 84 smartphone assessments. At the follow-up visit (Visit 2) in pregnancy, after you completed the first two weeks of assessments, you will be given $20 in addition to the compensation for the assessments you completed. At the visit after your baby is born (Visit 3) you will be given $20, and then another $20 at the follow-up visit after you complete another two weeks of assessments after delivery (Visit 4). At Visit 4 you will also receive compensation for the number of assessments you completed on the phone. Participants will be gifted the smartphones as part of their participation in the study once visit 4 is complete. Finally, you will be given $50 at the 3-month follow-up visit (Visit 5) and another $50 at the 6- month follow-up visit (Visit 6). This means the maximum you can earn by participating in this study is $400. You will be able to keep the smartphone once Visit 4 is completed and the iCO Smokalyzer provided at the end of the study. Participants who complete phase 1 and/or 2 will be asked to complete a short feedback survey and will receive $10 compensation for your time. All payments will be in the form of Amazon e-gift cards, which will be texted or emailed to you after each visit. You are responsible for paying state, federal, or other taxes for the payments you receive for being in this study. Taxes are not withheld from your payments

Treatment Alternatives/Alternatives

You do not have to participate in this study to receive counseling or referrals for smoking cessation. You can receive medical education and community referrals from your medical provider and/or from the clinic social worker. We will tell you if we learn any new information that could change your mind about taking part in this study.

Confidentiality

Any identifiable information that is obtained in connection with this study will remain confidential and will be disclosed only with your permission or as required by U.S. or State law. Every effort will be made to ensure your privacy and to maintain complete confidentiality. Access to the information you provide and the data we collect from you for the purposes of this research will be restricted to the Yale Human Investigation Committee and members of the research team.

All of the information you give us will be protected. The information you give us will be identifiable by a code number only, so that you will never be personally identified for reporting purposes. Information will be used by the research study, only for the purposes of researching factors that influence smoking in women following pregnancy. We will protect your confidentiality as much as we are legally able.

If we believe that you or someone else is in danger, we will report that to someone who can help you (for example, if you are suicidal, we will communicate this with other medical professionals, including a hospital ER; if we discover a minor is being abused, we will communicate this with the State of CT Department of Children and Families).

During the course of this study, you will have brief evaluation of your emotional health which may be beneficial to other health care providers. If you wish another health care professional to have the information we obtain during the course of this study, you must sign a written release of medical information. The research team can only give information about you to others for research with your permission. If you decide to take part in this study and sign this permission form, you will not be allowed to look at or copy your study-related information until after the research is completed.

The health-related information that we gather about you in this study is personal. The information about your health that will be collected in this study includes: research records, records about phone calls made as part of this research, records about your study visits, information obtained during this research regarding your physical and mental health, and questionnaires. The health care providers and research staff involved with this study are required by law to protect the privacy of the information known as protected health information or PHI. All reasonable efforts will be made to protect the confidentiality of your PHI, which may be shared with others to aid in your treatment, support this study, and to comply with the law as required. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity unless your specific consent for this activity is obtained. Despite these protections, there is a possibility that information about you could be used or disclosed in a way that it will no longer be protected.

If you decide to be in this study, the researcher will get information that identifies you and your personal health information. This may include information that directly identifies you, such as your name and address, date of birth and telephone numbers. Your study file will be kept for 7 years after the completion of the entire study, but in a de-identified fashion, meaning that we will replace your identifying information with a code that does not directly identify you. After that time, it will be destroyed. The principal investigator does keep a link that identifies you to your coded information, but this link will be kept secure and available only to the PI or selected members of the research team. Any information that can identify you will remain confidential. The research team will only give this coded information to others to carry out this research study.

We may share your information with:

- The U.S. Department of Health and Human Services (DHHS) agencies
- Representatives from Yale University, the Yale Human Research Protection Program and the Institutional Review Board (the committee that reviews, approves, and monitors research on human participants), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.

By signing this form, you give permission for research staff to use and/or disclose the information described above for this study. You have a right to refuse to sign this form. If you do not wish to participate, please do not sign this form. This will not affect your medical treatment or your relationships with health care staff in any way.

This authorization to use and disclose your health information collected during your

participation in this study will never expire.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

You should understand that a Certificate of Confidentiality does not prevent you 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.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of suspected or known sexual, physical, or other abuse of a child or elderly person, or threats of violence to yourself or others.

Voluntary Participation and Withdrawal

Participating in this study is voluntary. You are free to choose not to take part in this study. Refusing to participate will involve no penalty or loss of benefits to which you are otherwise entitled (such as your health care outside the study, the payment for your health care, and your health care benefits). However, you will not be able to enroll in this research study and will not receive study procedures as a study participant if you do not allow use of your information as part of this study.

Withdrawing From the Study

If you do become a subject, you are free to stop and withdraw from this study at any time during its course. If you decide to withdraw from the study, you are expected to inform Dr. Forray immediately and arrange to return to the study site for a final visit, during which you will be asked questions about your experiences in the study, complete follow-up assessment measures, and return the smartphone.

To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want to take part. This will cancel any future appointments, with the exception of a final visit to complete endpoint assessment measures. The researchers may withdraw you from participating in the research if necessary. This might be the case if for some reason you are unable to complete the smartphone assessments.

Withdrawing from the study will involve no penalty or loss of benefits to which you are otherwise entitled. It will not harm your relationship with your own doctors or with Yale-New Haven Hospital.

Withdrawing Your Authorization to Use and Disclose Your Health Information

You may withdraw or take away your permission to use and disclose your health information at any time. You may withdraw your permission by telling the study staff or by writing to: Dr. Ariadna Forray, Yale University School of Medicine, Perinatal Research Program, 40 Temple St, Suite 6B, New Haven, CT 06510.

If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others until the end of the research study, as necessary to insure the integrity of the study and/or study oversight.

Questions

We have used some technical medical terms in this form. Please feel free to ask about anything you do not understand. We are here to clarify any information you find unclear or difficult to understand. Please carefully consider your decision to participate in this research. If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator, Dr. Ariadna Forray at (203) 764-6621. If you have any questions concerning your rights as a research subject, you may contact the Human Investigation Committee at (203) 785-4688.

Authorization

I have read this form and have decided to participate in the project described above. Its general purposes, the particulars of involvement and possible hazards and inconveniences have been explained to my satisfaction. I voluntarily consent to participate in this research study. My signature also indicates that I have received a copy of this consent form.

Name of Subject:_____

Signature:_____

Date:_____

_____ _____
Signature of Principal Investigator Date

or

_____ _____
Signature of Person Obtaining Consent Date

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator Ariadna Forray, MD at (203) 764-6621. If you would like to talk with someone other than the researchers to discuss problems, concerns, and questions you may have concerning this research, or to discuss your rights as a research subject, you may contact the Yale Human Investigation Committee at (203) 785-4688.