Community Intervention to Reduce Tobacco Use Among Alaska Native Pregnant Women

NCT02083081

March 1, 2017

YUKON-KUSKOKWIM HEALTH CORPORATION
Written Summary of the Research Study:
Healthy Pregnancy Study

Intervention Group
(Phase II)

To be read to all people who want to be part of this study. You can read this yourself or if **you would like, the study staff or a translator (in language you know) can read this to you.**

This tells you about the study and you can choose if **you do or do not want to be in the study. Please ask questions about the study.** If **you want to be in the study, you will need to sign this form.**

TITLE: Tobacco Cessation Treatment for Pregnant Alaska Natives

PRINCIPAL INVESTIGATOR: Christi Patten, Ph.D., Mayo Clinic

APPROVED BY YKHC HUMAN STUDIES COMMITTEE AND YKHC BOARD: 4-27- 2016
APPROVED BY MAYO CLINIC IRB: 1-11-2017
APPROVED BY AK AREA IRB: 3-1-2017

What is the goal of this study?
This study is being done by the Yukon-Kuskokwim Health Corporation (YKHC) and Mayo Clinic (Rochester, Minnesota). The goal of the study is to learn ways pregnant Alaska Native women in the Y-K Delta can have healthier pregnancies. The study is comparing the effect of using usual care (care that all women in the YK Delta receive from their YKHC provider) or an individual-based and community level program that is given by a Native Sister (female Elder from each village). What we learn in this study will help make a program for Alaska Natives in the Y-K Delta to have healthier pregnancies.

What goes on in this study?
In this study we will enroll 352 pregnant Alaska Native women from 16 different villages (about 22 from each village) to learn if using an intervention helps women in the YK Delta have healthier pregnancies. The group you are put in is determined by which village you live in. The 16 villages were randomly assigned (like the flip of a coin) to one of the two study groups. All women who would like to learn about the study will meet with a study coordinator who will explain the study and answer any questions. This meeting can be done in-person (in Bethel at YKHC) or over the phone. You will read through this informed consent form and have any questions answered (in- person or over the phone). This is likely to take about 15 minutes but may take longer. If you want to be in being in the study, you will sign two copies of this consent form; one of these copies will be given to you to keep for your records. If you are not signing this consent form in-person with the coordinator, you will date and sign this consent form and mail it back in the pre-addressed postage-

paid envelope that was mailed to you with this form. The coordinator will mail you a copy of this consent form with your signature and hers.

After you have signed this consent form and it has been received by the coordinator (in-person or via mail), you will take part in a baseline assessment either in-person (in Bethel at YKHC) or over the phone. This assessment will take about one hour. The coordinator will be asking you questions about your self including your age, education, prenatal care, stress, depression, social support, if you use tobacco and your use of cultural activities. We will also ask you about your cultural beliefs about tobacco use, how often you are around other tobacco users and if you are around second-hand smoke. The coordinator will also have you give a saliva sample for cotinine testing (This test tells us how much nicotine is in your body. This is done by briefly chewing on a special cotton swab that the coordinator will give you you.). You will receive a $25.00 gift card for doing this assessment. You will meet with the coordinator up to four more times for assessments during the study. These assessments can be done in-person (in Bethel at YKHC) or over the phone if needed. Depending on when you are enrolled in the study you will meet with the coordinator 12 weeks after you sign this consent form, and when you are about 36 weeks pregnant. You will also meet with the coordinator 8 weeks after you deliver and 26 weeks after you deliver. Each of these assessments is similar to the baseline assessment and will take about one hour. You will get a $25 gift card for each of assessments you complete for a total of $125.00.

During the study you will get campaign materials (a digital stories DVD and brochures about healthy pregnancies) from the study coordinator. You will also have six phone calls (three when you are pregnant and three after you deliver) with a Native Sister to learn about how to have a healthy pregnancy. The Native Sister will also talk about how family, friends, people in the community and Elders can help you make choices that can help you have a healthy pregnancy. If needed, these meetings can be done in-person instead of over the phone. If the meeting is done in- person it would take place at your village clinic in a private room. These meetings will be audio taped when they are done in-person. Only the study team will hear what is shared during these meetings. The audio files will be kept in a locked file box that the Native Sister has and then in a locked drawer at YKHC.

You CAN be in this study if **you are....**

1) Pregnant Alaska Native
2) 36 weeks pregnant or less
3) Have a working phone that you can use
4) Sign this consent form

You CANNOT be in this study if **you....**

1) Are not pregnant
2) Are 37 weeks pregnant or more
3) Are not an Alaska Native
4) Are under the age of 18
5) Do not have a working phone that you can use
6) Do not want to sign this consent form

What are the risks and benefits of the study?
The risks of being in this study are small like the inconvenience of the assessments with the coordinator and/or the sessions with the Native Sister. You will also be asked to give a saliva sample for a cotinine test at baseline (This tests how much nicotine is in your body), the 36 week gestation assessment and the assessment at 26 weeks after you deliver. The Native Sister will learn whether or not you use tobacco if you are in the study. There are no other risks to being in this study. You may benefit by learning ways to have a healthier pregnancy as well as you may want to stop using tobacco (if you use). There are no other benefits to you from being in the study, but, what we learn from this study may help people in the future have healthier pregnancies.

Can I choose to not be in the study?
This study is being done to learn ways women can have healthier pregnancies. You do not have to be in this study. You can agree to be in the study and change your mind later.

Do I have to pay to be in this study?
You do not pay any money to be in this study. You can get a taxi voucher if you need one to get to YKHC for an assessment. You will not receive money for any other travel costs. You will receive a $25 gift card for each assessment you complete (up to $125 total). The gift cards are a thank you for your time in the study.

Do I have rights if I am in this study?
You do not have to be in this study, but if you do take part, you can change your mind <u>at any time.</u> This will not change your current or future medical care at YKHC, ANMC or Mayo Clinic. You do not give up any of your rights if you are in this study.

Can I be taken out of the study?
The study staff may take you out of the study if:

- The study staff feels it is what is best for you
- You do not follow the study rules
- The study stops

Are things about me kept private?
YKHC and Mayo Clinic pledge to protect your privacy in this study. Data from this study may be printed in a journal for doctors or health care providers. Only summaries of group data will be reported in any publications or presentations, with no identification of individuals or villages. Study results that are printed will never name any person in the study or share any private data. All study results are read and approved by YKHC Human Subjects Committee before they are printed in a journal.

Privacy is kept safe by giving people in the study a study code with no private data in it (for example: no name, birthdate, address or phone number). All records with your data and any recordings from your meeting with the Native Sister are destroyed seven years after the study ends.

All study data are kept in locked files and computers with passwords at YKHC. All study data that the Native Sisters collects is stored in a locked file box that only she is able to open or on a computer that only she is able to use. Only study staff is able to see these files or use these computers. No data about you, like name, birthdate, address or how to contact you will be shared with anyone that is not part of the study team.

Your saliva sample will be shipped to Mayo Clinic to test for cotinine. Your saliva sample will be labeled with a study ID number only. Once your saliva sample has been tested and results finalized, the sample will be destroyed immediately.

What happens after the study is finished:
Study results will be reviewed and approved by YKHC Human Studies Committee and Board. After approval, study results will be shared in the study villages, Tundra Drums and at community events. Native Sisters will help with sharing results in the study villages. All materials used in the Intervention villages will be shared with the Control villages (brochures, posters and digital stories DVD). The results will also be shared with partners at ANTHC by creating a DVD sharing what was learned. This DVD will be shown at prenatal clinics in Y-K Delta and at the 15 health care regions that ANTHC serves. Study staff will share the results at scientific meetings and peer- reviewed journals.

Using and sharing Protected Health Information:
By signing this form, you allow YKHC, Mayo Clinic and the study team to use and share what they learn in this study.

These data may be shared only with study staff that is named above. Staff of the National Institutes of Health (who pay for this study) may have data shared with them. The data may also be shared with the Yukon-Kuskokwim Health Corporation Human Subject Committee, Alaska Area IRB, Mayo Clinic IRB, or other groups who protect people in studies.

If these data are given out to any person other than study staff at YKHC and Mayo Clinic, the data may no longer be safe by federal privacy rules and may be given out by the person or group that gets the data. YKHC and Mayo Clinic will make sure other parties know they need to keep these data private.

This consent lasts until the end of the study. This part of the study (Phase 11) will last about three years. It may take some time to look at all the data and report what we find out in the study. All your personal data will be on file at YKHC (locked file and password protected computer) this entire time.

What if I change my mind and do not want to be in the study?
You can change your mind at any time and choose to not be in this study. You can ask YKHC to destroy all data you gave us. If YKHC and Mayo Clinic need the data you already gave us to make sure they have full and honest study results they may still to use your data even after you have told us to stop but, we will not get any new data from you. The only way you can tell YKHC and Mayo Clinic to stop using your data is by writing to:

Dr. Joseph Klejka
Yukon-Kuskokwim Health Corporation
P.O. Box 528
Bethel, Alaska 99559

Voluntary consent to be in the study:

I agree to be in this study and know that my being in this study is up to me. You should take part in this study only if you have read this form (or it has been read to you) and you know and what it says. If you have any questions about the study or your rights in the study, please call:

- Dr. Joseph Klejka, Medical Director ofYKHC (907) 543-6028 or 1-800-588-6440
- Terry Powell, Administrator, Alaska Area Institutional Review Board, 1-907-729-3924
- Dr. Shanda Lohse, Chair, Alaska Area Institutional Review Board, 1-907-729-3924
- Dr. Christi Patten (Principal Investigator) of Mayo Clinic at (507) 538-7370 or 1-800-957-2950

You may also call the YKHC Legal Department at (907) 543-6032 or 543-6915 if you have questions about your rights in the study.

If you do not want to be in the study or if you want to quit the study, it will not change your health care with your own doctors or with YKHC, ANTHC or Mayo Clinic.

By being in this study, I agree to let YKHC and Mayo Clinic use my answers to the focus group questions and use the recordings of the focus group for this study.

I have had my questions answered. I have been given a copy of this form. I agree to be in this study.

(Date) (Printed Name of Person taking part in the study)

(Signed Name of Person taking part in the study)

(Date) (Printed Name of Study Staff Obtaining Consent)

(Signed Name of Study Staff Obtaining Consent)

Signature of Witness (if needed) Date Printed Name

Signature of Translator (if needed) Date Printed Name