NCT#: NCT05458960

Title: Evaluating the Impact of Basic needs Assessment and Support to Improve Colposcopy Show rate: The BASICS Trial

Date: 10/24/2024

Hello, may I speak with _____?

My name is _____from Washington University in St. Louis-School of Medicine. I am calling you because you had an appointment at our colposcopy clinic for follow up for your abnormal cervical cancer screen that was missed or rescheduled. I am calling you about a research study.

Would you be interested in learning more about the study? Please feel free to ask questions at any time.

[If the individual states, "no"]
Thank you for your time and consideration. **[End the call]**

-OR-

[If the individual states, "yes"]

We invite you to participate in a research study being conducted by investigators from Washington University in St. Louis.

This research study examines whether helping patients reduce their unmet social needs will make it easier for them to get to their follow up appointments for cervical cancer screening. You should carefully consider the information in this consent document and discuss it with the research team. You should understand why you might want to participate, or why you might not want to participate. If you don't participate, you will still get your normal health care.

If you agree and give verbal consent, you will be volunteering to participate in the research study. As a voluntary participant, you will be asked to complete questionnaires today and 4 months from now. You will also be asked to take part in an interview portion of the study which may take about 45 minutes. You will be randomized to either a social needs navigator program or enhanced usual care. Your total participation is expected to last 4 months. During that time you will complete questionnaires that should take 7-10 minutes to complete, and have information collected from your medical record. The main risks to you if you participate are your confidential information being disclosed and feeling uncomfortable with some of the questions asked.

You may or may not benefit from being in this study by being referred to additional services, but it will help us understand barriers and unmet social needs that prevent women from attending follow ups for cervical cancer screening, and how we can better provide care for those patients. By volunteering you may help someone else in the future. There is no cost to you and you be paid up to $100 in gift cards for being a volunteer participant.

Does this sound like something you are interested in participating in?

[If the individual states, "no"]
Thank you for your time and consideration. **[End the call]**

-OR-

[If the individual states, "yes"]
Great! I will read through the consent to provide you with further information. Please feel free to ask questions at any time. Also, if during the survey you wish to take a break or need more time to think about your participation in this study, just let me know. I can always call you back another time.

The purpose of the study is to learn more about barriers and unmet social needs that keep women from attending follow ups for cervical cancer screening. We hope to learn more about these needs and ways to address them to help in the prevention of cervical cancer. The National Institutes of Health (NIH) is funding this research study.

If you agree to participate, we will have you complete a questionnaire about unmet needs and distress you may be experiencing. We will also ask you some questions about your demographics and contact preferences. This should take about 10 minutes to complete. You are free to skip any questions that you prefer not to answer.

After you have completed this assessment, you will be randomly assigned to either social needs navigator program or enhanced usual care. You will have a 50/50 chance of receiving any one of the study treatments.

If you are randomized to the navigator program, you will be paired with a community health worker who will provide support to address unmet social needs over a 4 month period.

If you are randomized to the enhanced usual care you will be offered a verbal referral to a federally funded, free, 24-hr assistance hotline. This hotline is called United Way 2-1-1, and will connect you with community services to help address unmet social needs.

In 4 months, we will contact you again to complete the questionnaire about unmet needs and distress. This should take about 7-10 minutes. Again, you are free to skip any questions that you prefer not to answer.

We will collect information from your medical record during the trial. This will include demographics, medical history, information about your colposcopy follow up, pap test history and results, and HPV vaccination status.

The interview portion of this study will be recorded. Recordings will be available to members of the research team for analysis and transcribing by a professional medical transcription service. Recordings will be destroyed when the study has been completed.

While all video and audio recordings are stored in a confidential manner, please be aware that the recordings will likely contain information that would identify you.

We would like to use the data we are obtaining in this study for studies going on right now as well as studies that are conducted in the future. These studies may provide additional information that will be helpful in understanding cervical cancer prevention and barriers women face, or other diseases or conditions, including research to develop investigational tests, treatments, drugs or devices that are not yet approved by the U.S. Food and Drug Administration. It is unlikely that what we learn from these studies will have a direct benefit to you. There are no plans to provide financial compensation to you should this occur. By allowing us to use your data you give up any property rights you may have in the data.

We will share your data with other researchers. They may be doing research in areas similar to this research or in other unrelated areas. These researchers may be at Washington University, at other research centers and institutions, or industry sponsors of research. We may also share your research data with large data repositories (a repository is a database of information) for broad sharing with the research community. If your individual research data is placed in one of these repositories only qualified researchers, who have received prior approval from individuals that monitor the use of the data, will be able to look at your information.

If you change your mind and do not want us to store and use your data for future research you should contact the research team member identified at the top of this document. The data will no longer be used for research purposes. However, if some research with your data has already been completed, the information from that research may still be used. Also, if the data has been shared with other researchers it might not be possible to withdraw the data to the extent it has been shared.

Approximately 72 people will take part in this study at Washington University.

There is a small risk of your confidential information being accidentally disclosed.

You will not have any costs for being in this research study.

You will be paid for being in this research study.

You will be asked to provide your social security number (SSN) in order for us to pay you. You will need to provide your address so a giftcard can be mailed to you. You will receive a $25 gift card at enrollment, a $25 gift card for completing surveys at 4 month, and an additional $50 gift card should you choose to complete the interview. The maximum compensation you may receive is $100. You will only be compensated for those parts of the study you complete.

We will keep the information you provide confidential by using an ID code on the surveys you answer so that your name is not directly attached to your answers. We will have a master list that is password protected that links the ID code to your name. Only the principal investigator of the study and members of the research team will have access to the master list. Any paper documents will be kept in a locked drawer in a locked office of a member of the research team. Electronic work will be done on WU computers which are secure and password protected. The service used to transcribe the audio recordings is HIPAA compliant. Data will be stored in a WU-approved, HIPAA-compliant database called REDCap.

Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

Federal regulatory agencies and Washington University, including the Washington University Institutional Review Board (a committee that reviews and approves research studies) and the Human Research Protection Office may inspect and copy records pertaining to this research.

We will disclose to the proper authorities information shared with us or activities we observe concerning abuse, neglect or harm to others or yourself.

To further protect your privacy, this research is covered by a Certificate of Confidentiality from the federal government. This means that the researchers can refuse to disclose information that may identify you in any legal or court proceeding or to anyone who is not connected with the research except if:

- there is a law that requires disclosure, such as to report child abuse and neglect, or harm to self or others;
- you give permission to disclose your information, including as described in this consent form; or
- it is used for other scientific research allowed by federal law.

This Certificate may not be effective for information held in foreign countries.

You have the right to share your information or involvement in this study with anyone at any time. You may also give the research team permission to disclose your information to a third party or any other person not connected with the research.

If information about you or your involvement in this research is placed in your medical record the information may no longer be protected under the Certificate. However, information in your medical records is protected in other ways.

I would like to tell you about what we will be doing with the information you give us.

This research will create Protected Health Information (PHI) that identifies you. Your health information is protected by law under HIPAA (the Health Insurance Portability and Accountability Act). Because of this law, you will need to give the research team permission to use and share your protected health information collected for this research.

When possible, the research team will make sure information cannot be linked to you. Once information doesn't identify you, it may be used and shared for other purposes not discussed in this document.

The information collected during the study may be seen by people making sure the research is being done right. This may be people at Washington University, people from the federal Office for Human Research Protections, the Food and Drug Administration, the NIH, the data and safety monitoring board and the transcription service.

- If you agree, you are giving permission for us to use of your PHI for this research, and your permission will not expire.

- If you do not agree to allow us to use your PHI it will not affect your treatment or the care given by your health provider, insurance payments or enrollment in any health plans, or any benefits to which you are entitled. However, it will not be possible for you to take part in this study.

- Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

- If you change your mind and do not want the research team use or share your information, you will need to provide a written letter to the research team cancelling your permission. Please contact the Human Research Protection Office for more information on how to revoke your authorization or contact the research team to request the withdrawal letter. If you do this, the research team may only use and share information already collected for the study. You will not be allowed to continue to participate in the study.

- If you have questions or concerns about your privacy and the use of your protected health information, please contact the University's Privacy Officer at 866-747-4975.

- You will not be able to see the research information, but you may be given access to your health care records by contacting your health care provider.

Your participation in this study is completely voluntary. You may choose not to take part at all. If you decide to participate in the study you may stop participating at any time. Any data that was collected as part of this study will remain as part of the study records and cannot be

removed. If you decide not to take part in the study or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

If you do not wish to participate in this study or want to end your participation in the study, you can let the research team know.

We encourage you to ask questions. If you have any questions about the research study itself or feel you have been harmed, please contact: Dr. Kuroki, 314-362-1740. If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office at 1-(800)-438-0445 or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

Thank you very much for your consideration of this research study.