Official Title: Development and Pilot Testing of an Equity-focused and Trauma-informed Communication Intervention During Family-centered Rounds

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Duke University Health System

Consent to Participate in a Research Study

Equity Focused and Trauma Informed Communication Intervention
Pro00111356
Version 2.0 Date: 11/14/2024

CONCISE SUMMARY

The purpose of this research study is to test an intervention to improve communication between medical teams and caregivers (parents, guardians, and family members) of children in the hospital. To provide the medical team feedback on their communication with caregivers and to study how the intervention affects communication we will perform audio-recordings of the visit between the team and caregivers. From a subset of caregivers we will collect a sample of saliva before and after the meeting to measure the impact of the intervention on caregiver health and stress. We will also ask caregivers to complete a 15 minute survey by iPad immediately after rounds. Your participation will be done once you complete the post-rounds survey.

There is a risk of loss of confidentiality. There are no direct benefits to patients but we hope the information learned from this study will benefit caregivers and their children in the hospital in the future. Caregivers will be compensated $50 for complete participation in this study.

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

You and your child are being asked to take part in this research study because your child is hospitalized at Duke Children's Hospital. 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 your study doctor or 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 the study doctor or 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. Parente's and her research team's salaries will be paid by this grant.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to test the effect of a communication intervention on the experience and health of caregivers of children in the hospital. We hope that improving communication will make the hospital more safe, more fair, less stressful, and with more partnership between doctors and caregivers.

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HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 105 caregivers and 10 doctors from Duke Children's Hospital will participate in this study.

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. You will then participate in a meeting with your child's doctors, and this meeting will be audio recorded so that the study team can review the discussion. This study includes you:

- Allowing the meeting with your child's doctors to be recorded
- Providing a saliva sample before the meeting with your child's doctors
- Providing a saliva sample 20-30 minutes after the meeting with your child's doctors
- Completing a 15-minute survey immediately following the meeting with your child's doctors
- Allow researchers to collect information from your child's medical record, including information about your child's diagnosis and course of treatment

Half of the medical teams enrolled in this study have received the intervention and half have not. You have a 1 in 2 chance of having a medical team that has already received the intervention.

Your participation in this study is voluntary. Your survey responses will not be shared with your child's doctors. You may refuse to answer any question you are not comfortable answering.

WHAT ARE THE ALTERNATIVES TO PARTICIPATING IN THIS STUDY?

This is not a study to treat your child's condition. If you do not wish to have your meeting audio recorded, provide the saliva samples, or complete the survey, please do not sign this consent form.

Study participation is voluntary and if you do not sign this consent form, your child will continue to receive care at Duke. 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?

You and your child can choose to stop participating at any time without penalty or loss of any benefits to which your child is entitled. However, if you and your child decide to stop participating in the study, we encourage you to talk to your child's doctor first.

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If you agree to participate in this study, you will be in the current study until you complete the survey after rounds. Clinically relevant results of this research will be communicated with you in one year, approximately 7/1/2025, via Duke MyChart.

WHAT ARE THE RISKS OF THE STUDY?
There are no physical risks to you or your child with being in this study. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential. However, this cannot be guaranteed. If your meeting with your child's doctors is audio recorded, with your permission, the 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. 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. Saliva samples will be labeled with a study identification number that cannot be traced back to you. Only members of this research team will have access to your personal information that matches your study identification number.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
If you agree to take part in this study, there is no direct medical benefit to your child. We hope the information learned from this study will improve the experience for caregivers of hospitalized children in the future through better communication with medical teams.

WILL MY CHILD'S INFORMATION BE KEPT CONFIDENTIAL?
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. 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.

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:

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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.

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.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. 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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WHAT ARE THE COSTS TO YOU?
There is no cost to you for participating in this study.

WHAT ABOUT COMPENSATION?
You will be reimbursed up to $50 for your expenses related to your participation (ie- time).

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 Victoria Parente*** at ***919-613-8809*** during regular business hours and at ***(919)-970-2135*** after hours and on weekends and holidays.

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. All data that have already been collected for study purposes will be sent to the study sponsor.

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 or your child's access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Parente by email or in writing and let her know that you are withdrawing from the study. Her email is Victoria.parente@duke.edu and 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 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 data and samples may result in commercial profit. You will not be compensated for the use of your data and samples other than what is described in this consent form.

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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 complaints, concerns or suggestions about the research, contact Dr. Parente at 919-613-8809 during regular business hours and at (919) 970-2135 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 my child and 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 for my child to be in this study, with the understanding that I may withdraw my child at any time. We have discussed the study with my child, if he/she is over 6 years old, who agrees to be in the study. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Child (if 12 years or older)	Date	Time
_____	_____	_____
Signature of Parent/Guardian	Date	Time
_____		
Name of Parent/Guardian		
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time