Official Title: Interagency Collaboration To Improve Home Care of Children With Medical Complexity
NCT03978468
IRB-Approved Date: 3/14/22

Wake Forest®
School of Medicine

Department of *Pediatrics*

INTERAGENCY **COLLAB**ORATION TO IMPROVE HOME CARE OF CHILDREN WITH MEDICAL COMPLEXITY

Informed Consent Form to Participate in Research

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SUMMARY

Your child is invited to participate in a research study. The purpose of this research is to test whether collaboration between home health nurses, primary-care doctors, and the complex care team (a special team at Brenner Children's Hospital that provides care for children with complex chronic medical conditions (CCMC)) can improve the health of these children. CCMC are many different conditions that are chronic (i.e. last 12 months or longer) and need care from multiple doctors and other providers. Your child is invited to be in this study because he/ she has a CCMC, is currently admitted to the hospital, and receives/ will be receiving home health nursing care after discharge from the hospital. Your child's participation in this research will last about 7 months.

Participation in this study will involve:1) getting information about your child's health, diagnosis, and hospital stays and Emergency Room (ER) visits from his/her medical records; 2) getting information from you about your child's health, the names of your child's home health nurses and primary-care physicians, the difficulties you face in coordinating the care of your child, and your experiences with home health nursing services. In addition, if your child is assigned to the intervention group, the nurse and physician of the complex care team will share health information about your child with his/ her home health nurse and primary-care physician to help them provide care for your child at home.

All research studies involve some risks. A risk to this study that your child should be aware of is identification of your child's personal information. There is the possibility that your child may benefit from participation in this study.

Your child's participation in this study is voluntary. Your child does not have to participate in this study if your child does not want to. Your child will not lose any services, benefits, or rights your child would normally have if your child chooses not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. Your child can ask any questions if your child needs help deciding whether to join the study. The person in charge of this study is Dr. Savithri Nageswaran. If your child has questions, suggestions, or concerns regarding this study or your child wants to withdraw from the study her contact information is: [redacted].

If your child has any questions, suggestions or concerns about your child's rights as a volunteer

in this research, contact the Institutional Review Board at [redacted] or the Research Subject Advocate at Wake Forest at [redacted].

INTRODUCTION

Your child is invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. Your child is being asked to take part in this study because your child has a complex chronic medical condition (CCMC), is admitted to the hospital, and receives/ will be receiving home health nursing care. Your child's participation is voluntary. Please take your time in making your decision as to whether or not your child wishes to participate. Ask your child's study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to test whether a new model of care for children with CCMC improves their health. The new model of care, called **ICollab**, involves collaboration between home health nurses, primary-care physicians and the Pediatric Enhanced Care Program. The Pediatric Enhanced Care Program is a special team at Brenner Children's Hospital that provides care coordination for children with CCMC.

In this study, **ICollab** in addition to usual care will be compared to usual care only. Usual care is the care that all children with CCMC discharged from Brenner Children's Hospital receive.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Approximately 440 people will participate in this study. Approximately 110 children with CCMC and 110 caregivers at this research site will be enrolled. In order to identify the 110 children needed, we may need to screen as many as 150 children because some people will not qualify to be included in the study. For the children in the **ICollab group**, their home health nurses, approximately 3 nurses per child (so 165 nurses) and 1 primary-care physician per child (so 55 primary-care physicians) will be enrolled.

WHAT IS INVOLVED IN THE STUDY?

Your child will be randomized into one of the study groups described below. Randomization means that your child is put into a group by chance. It is like flipping a coin. Your child will have an equal chance of being placed in one of the following 2 groups:

1. Usual Care group: When a child with CCMC is discharged from Brenner Children's Hospital, doctors, nurses, care coordinators, or staff of the Pediatric Enhanced Care Program assist parents/caregivers of children with CCMC with follow-up appointments, and communicate with home health nurses and primary-care doctors. After discharge, the staff of the Pediatric Enhanced Care Program assist parents/caregivers of children with CCMC by coordinating appointments, addressing practical needs (e.g. transportation), and communicating with doctors and providers on an as needed basis.

2. ICollab Group: In addition to usual care above, children in the ICollab group (about 55 children) will receive the following care from the ICollab team (consisting of a doctor and a

nurse of the Pediatric Enhanced Care Program) for about 6 months of "home care" after discharge from the hospital. Home care is the time your child is receiving care at home and not in the hospital.

(A) The nurse of the ICollab team will share with your child's home health nurse, health information about your child (from doctors' visits, ER visits etc.) to help the home health nurse provide care for your child at home. (B) The ICollab team will discuss with your child's home health nurse about once a month about your child's health condition in a collaborative meeting. (C) The physician of the ICollab team will share health information about your child with his/her primary-care physician to help the primary-care physician provide care for your child at home.

If your child takes part in this study, your child will experience the following as part of the study:

1. Baseline Survey: Before discharge from the hospital, we will ask you to complete a survey that asks information about your child's: demographics (age, sex, race/ ethnicity, insurance type, household income, education level of caregivers), home health nursing services , names of your child's home health nurses, health condition (difficulty with function, hospital stays and visits), and your perspective on collaboration between your child's healthcare providers, satisfaction with home health care, and how the care of your child with CCMC affects you and your family. This survey will take approximately 40 minutes of your time.

2. Monthly Surveys: After enrollment in the study and approximately after every month of home care, we will ask you to complete a survey asking details about your child's home health nursing services, doctor visits, ER visits, and hospital admissions. These surveys will take about 20 minutes of your time.

3. Final Survey: After enrollment in the study and about 6 months of home care, we will ask you to complete a final survey asking you about your child's health condition, your experience and satisfaction with home health nursing services, and your perspective on how the care of your child with CCMC affects you and your family. This survey will take approximately 40 minutes of your time.

4. Medical records: We will get details about your child including date of birth, sex, insurance, diagnosis, health condition, provider and agency names, and information about hospitalizations and ER visits.

5. If your child is assigned to the **ICollab group**, he/ she will receive the ICollab model of care as described above.

6. If your child is assigned to the **ICollab group**, after enrollment in the study, we will survey your child's home health nurses and primary-care doctor about their perspectives on caring for children with CCMC, and how the ICollab team can help them care for your child. About 3 and 6 months after enrollment, we will ask your child's primary-care doctor and home health nurses

for their feedback on the ICollab model.

How Long Will I Be in the Study?

Your child will be in the study for about 7 months. . However, depending on how long your child is at home, he/ she may be in the study for about 10 months. Your child can stop participating at any time.

What Are the Risks of the Study?

Being in this study involves some risk to your child. The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests. You should discuss the risk of being in this study with the study staff. Because researchers do not know which study arm will experience better outcomes there is a chance that your child may be assigned to the group that performs either better or worse than the other group."

Taking part in this research study may involve providing information that your child considers confidential or private. There is a slight risk of a breach of confidentiality. We will do our best (e.g. coding research records, keeping research records secure and allowing only authorized people to have access to research records) to protect your child's confidential information.

Are There Benefits to Taking Part in the Study?

If your child agrees to take part in this study, there may or may not be direct benefit to your child. We hope the information learned from this study will benefit other people in the future. The benefits of participating in this study may be improved home health nursing care at home.

What Other Choices Are There?

This is not a treatment study. Your child's alternative is to not participate in this study.

What Are the Costs?

All study costs will be paid for by the study. Costs for your child's regular medical care, which are not related to this study, will be your own responsibility.

Will Your child's Research Records be Confidential?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your child's identity and/or your child's personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of your child or others. There is always some risk that even de-identified information might be re-identified.

Will You Be Paid for Participating?

You will be paid with a $20 gift card if you complete the baseline caregiver survey, a $20 gift card

if you complete the first monthly survey and a $10 gift card each if you complete the remaining monthly survey (4 times), and a $20 gift card if you complete the final survey. You will receive a total of $100 in gift cards if you complete all the surveys. If your child withdraws for any reason from the study before completion you will be paid for each completed survey. Home health nurses of children assigned to the ICollab group will receive a $20 gift card for each meeting (about 6 meetings in 6-9 months) with the ICollab team that they participate.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by the Health Resources & Services Administration. The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor.

What About Your Child's Health Information?

In this research study, any new information we collect from you about your child and any information we get from your child's medical records about your child's health is considered Protected Health Information. The information we will collect for this research study includes**:**

Your child's demographic information (date of birth, sex, race/ethnicity, insurance type, household income, education level of caregivers), home health nursing services (hours, type, names of your child's home health nurses), name of your child's primary-care doctor, child's health condition (diagnosis, difficulty with function, doctor visits, ER visits, and hospital admissions), and your perspective on collaboration between your child's healthcare providers, satisfaction with home health care, and how the care of your child with CCMC affects you and your family.

We will make every effort to keep your child's Protected Health Information private. We will store records of your child's Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your child's personal health information and information that identifies your child ("your child's health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, and to provide required reports.

Some of the people, agencies and businesses that may receive and use your child's health information are the research sponsor; representatives of the sponsor assisting with the research; the Institutional Review Board; representatives of Wake Forest University Health Sciences and

North Carolina Baptist Hospital; representatives from government agencies such as the Office of Human Research Protections (OHRP), or the Department of Health and Human Services (DHHS).

Some of these people, agencies and businesses may further disclose your child's health

information. If disclosed by them, your child's health information may no longer be covered by federal or state privacy regulations. Your child's health information may be disclosed if required by law. Your child's health information may be used to create information that does not directly identify your child. This information may be used by other researchers. Your child will not be directly identified in any publication or presentation that may result from this study.

If required by law or court order, we might also have to share your child's Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your child's Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from your child in this study that is maintained in the research records will be kept for at least six years after the study is finished. At that time any research information not already in your child's medical record will either be destroyed or it will be de-identified. Any research information entered into your child's medical record will be kept for as long as your child's medical record is kept by the Medical Center. You will not be able to obtain a copy of your child's Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Dr. Savithri Nageswaran (study doctor) that you want to take away your child's permission to use and share your child's Protected Health Information at any time by sending a letter to this address:

Savithri Nageswaran
[redacted]

However, if you take away permission to use your child's Protected Health Information your child will not be able to be in the study any longer. We will stop collecting any more information about your child, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your child's Protected Health Information for this study.

If your child chooses to participate in this study, your child's medical record at Wake Forest University Baptist Medical Center will indicate that your child is enrolled in a clinical trial.

Information about the research may also be included in your child's medical record. This part of the medical record will only be available to people who have authorized access to your child's medical record.

A description of this clinical trial, NCT 03978468, will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify your child. At most, the website will include a summary of the results. You can search this Web site at any time.

Relevant medical reports created as a result of your child's participation in the research study may be entered into the computer systems of Wake Forest University Health Sciences and North Carolina Baptist Hospital. These will be kept secure, with access to this information limited to individuals with proper authority, but who may not be directly involved with this research study.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. Your child may choose not to take part or your child may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which your child are entitled. The investigators also have the right to stop your child's participation in the study at any time. This could be because new information becomes available, or because the entire study has been stopped. Information that identifies your child may be removed from the data that are collected as part of this study and could be used for future research or shared with others without additional consent.

You will be given any new information we become aware of that would affect your child's willingness to continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, *Savithri Nageswaran* at [redacted].

The Institutional Review Board (IRB) is a group of people who review the research to protect your child's rights. If you have a question about your child's rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, You should contact the Chairman of the IRB at ([redacted]).

You will be given a copy of this signed consent form.

What does my signature on this consent form mean?

Your signature on this form means that:

- You understand the information given to you in this form
- You have been able to ask the researcher questions and state any concerns
- The researcher has responded to your questions and concerns
- You believe you understand the research study and the potential benefits and risks that are involved for your child.
- You understand that even if you give your permission, your child may choose not to take part in the study.

Statement of Consent

I give my voluntary permission for my child to take part in this study. I will be given a copy of this consent document for my records.

Printed Name of Minor:_____

Signature of Parent/Guardian_____Date:_____Time:_____am pm

Printed Name of Parent/Guardian:_____

Relationship of Parent/Guardian to the Minor:_____

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Statement of Person Obtaining Informed Consent

I have carefully explained to the parent of the child being asked to take part in the study what will happen to their child.

I certify that when this person signs this form, to the best of my knowledge, he or she understands the purpose, procedures, potential benefits, and potential risks of his or her child's participation.

I also certify that he or she:

- Speaks the language used to explain this research
- Reads well enough to understand this form or, if not, this person is able to hear and understand when the form is read to him or her
- Does not have any problems that could make it hard to understand what it means for his or her child to take part in this research.

Signature of Person Obtaining Consent:_____Date:_____Time:_____am pm

Printed Name of Person Obtaining Consent:_____