Official Title: Text Message Follow-up for Patients Who Have Missed Well-Child Visits: Randomized Controlled Trial
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Wake Forest®
School of Medicine

Department of Pediatrics

TEXT MESSAGE FOLLOW-UP FOR PATIENTS WHO HAVE MISSED WELL-CHILD VISITS
Informed Consent Form to Participate in Research
Katherine Poehling, MD, MPH, Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to assess reasons for missed well child visits and opinions about trauma-informed care at prior pediatric care at Wake Forest Baptist Health. You are invited to be in this study because you are a caregiver for a child ages 0-17 years old who is a patient at one of five Wake Forest Baptist Health Locations (Pediatrics – Downtown Health Plaza, Pediatrics – Winston East, Pediatrics – Clemmons, Family Medicine – Piedmont Plaza, or Family Medicine – Peace Haven), and your child missed a scheduled well-child visit.

Participation in this study will involve a single survey that will take about 10-20 minutes to complete. All research studies involve some risks. A slight risk to this study that you should be aware of is that there will be a breach of confidentiality of your data. You may not benefit from participation in this study.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Dr. Katherine Poehling. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is [redacted], or you can contact study coordinator, Andy Mayfield at amayfiel@wakehealth.edu.

If you have any questions, suggestions or concerns about your 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

You are invited to participate in a research study. Research studies are designed to gain scientific knowledge that may help people in the future. You are invited to be in this study because you are a caregiver for a child ages 0-17 years old who is a patient at one of five Wake Forest Baptist Health Locations (Pediatrics – Downtown Health Plaza, Pediatrics – Winston East, Pediatrics – Clemmons, Family Medicine – Piedmont Plaza, or Family Medicine – Peace Haven), and your child missed a scheduled well-child visit. Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. Please take your time in making your decision as to whether or not you wish to participate. Ask 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 is to assess reasons for missed well child visits and opinions about trauma-informed care at prior pediatric care at Wake Forest Baptist Health.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Up to 1500 people will take part in this study.

WHAT IS INVOLVED IN THE STUDY?

If you agree to participate in this research study, you will be asked to use an electronic device (e.g., smartphone, computer) to access an online questionnaire system to complete a one-time brief questionnaire. It will include questions that will ask you about reasons for missing a well child visit and a series of questions about whether you think the care your child received at prior visits could be considered supportive for people who have experienced trauma. We expect it will take about 10-20 minutes to complete.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study until the end of the survey. You can stop participating at any time. If you decide to stop participating in the survey, there are no health or safety consequences.

WHAT ARE THE RISKS OF THE STUDY?

As part of this study, you will be asked survey questions about reasons for missing a well child appointment and about whether you think the care your child received at prior visits could be considered supportive for people who have experienced trauma. 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.

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. There also may be other risks that we cannot predict.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure

and allowing only authorized people to have access to research records, will be made to keep your information safe.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

You are not expected to receive any direct benefit from taking part in this research study. We hope the information learned from this study will benefit other people in the future.

WHAT OTHER CHOICES ARE THERE?

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

WHAT ARE THE COSTS?

There are no costs associated with this study. Costs for you or your child's regular medical care, which are not related to this study, will be your own responsibility.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

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

Participant information may be provided to Federal and other regulatory agencies as required.

WILL YOU BE PAID FOR PARTICIPATING?

After completing the survey, you will be asked to provide your contact information to receive an electronic gift card worth $15.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by the Center for Healthcare Innovation at Wake Forest Baptist Health. The sponsor is providing money or other support to our team in the Departments of Pediatrics and Family and Community Medicine to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the Twilio platform that was used to send you an invitation(s) to this survey.

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes: reasons for missing a well child visit, whether you think the care your child received at prior visits could be considered supportive for people who have experienced trauma. We will also collect your contact information if you choose to provide it, but this will only be used to contact you about a gift card raffle.

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

Your personal health information and information that identifies you ("your 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, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your 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; and representatives from government agencies such as the Office of Human Research Protections (OHRP), and the Department of Health and Human Services (DHHS).

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study.

You can tell Dr. Katherine Poehling that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Katherine Poehling, M.D., M.P.H.
[redacted]

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

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you 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 you are entitled or to which your child is entitled. The investigators also have the right to stop your participation in the study at any time. This could be because you failed to follow instructions, or because the entire study has been stopped.

You will be given any new information we become aware of that would affect your 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, you can reach the study investigator, Katherine Poehling, at [redacted] or study coordinator, Andy Mayfield at

amayfiel@wakehealth.edu.

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your 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] or the Research Subject Advocate at [redacted].

By clicking continue, I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. I have had a chance to ask questions about being in this study and have those questions answered. By taking part in the study, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.