Official Title: Randomized Controlled Trial of the Wake Forest Post-ICU Telehealth (WFIT) Program
NCT04576065
IRB-Approved Date: 9.26.2022

Wake Forest®
School of Medicine

Department of Internal Medicine
Section of Pulmonary, Critical Care Medicine, Allergy and Immunologic Diseases

WAKE FOREST School of Medicine

A RANDOMIZED CONTROLLED TRIAL OF THE WAKE FOREST POST-ICU TELEHEALTH PROGRAM (WFIT)

Informed Consent Form to Participate in Research
Rita Bakhru, MD, MS, Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to determine the cost-effectiveness of the Wake Forest Post-ICU Telehealth Program. You are invited to be in this study because you were critically ill. Your participation in this research will last six months.

Participation in this study will involve either usual care or enrollment in the Wake Forest post-ICU Telehealth program. All research studies involve some risks. A risk to this study that you should be aware of is increased contact and appointments from our team in the intervention arm and a slight risk of breach of confidentiality. There is the possibility that you may 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. There may be other choices available to you. Some other choices may include not participating or being seen in our Wake Forest ICU Recovery Clinic. 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. Rita Bakhru. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is: [redacted] or (after hours) [redacted].

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 be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you have recently been in the intensive care unit with septic shock (a severe infection state) or respiratory failure (you required oxygen and/or breathing assistance with a machine). Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your 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 compare the costs of the Wake Forest post-ICU Telehealth (WFIT) program to costs of usual care for six months after hospitalization. The WFIT program will provide care via phone, video visits, and face to face visits (if needed). Through this program, we hope to prevent urgent care visits, ER visits, and re-hospitalizations by providing more access to providers familiar with problems post-critical illness. Those participants in the usual care arm will receive usual care after discharge from the hospital (as dictated by their clinical team, usually by their Primary Care Provider +/- specialists).

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

400 people at one research site will take part in this study.

WHAT IS INVOLVED IN THE STUDY?

You will be randomized into one of two study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. You will have an equal chance of being placed in each group.

For participants in the usual care group:
This group will follow-up with their primary care provider and/or any specialists as recommended by their inpatient clinical team. Participants in this group will seek any other medical care as they deem necessary. The study team will call participants in this group monthly to determine their healthcare utilization, quality of life, and satisfaction with their care. These calls will each last 15-30 minutes.

For participants in the WFIT program:
This group will meet with our nurse practitioner while in the hospital. We will also arrange telehealth (either phone or video visits) with each participant at 1 week and 2 weeks post-discharge, and as needed up to 6 months post-discharge. If necessary, these participants can be seen in-person in clinic, but we will try to minimize these visits. We will communicate our findings with your primary care physician. The WFIT program participants will also receive monthly phone calls to determine their healthcare utilization, quality of life, and satisfaction with care.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for six months after hospital discharge. You can stop participating at any time. If you decide to stop participating in the study, we encourage you to talk to the investigators or

study staff first to learn about any potential health or safety consequences.

WHAT ARE THE RISKS OF THE STUDY?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. If you are in this study, you will have more contact with the study team than if you were not. If you are randomized to the intervention arm (WFIT program), you will have another care provider. We do not think these will increase your risk of anything other than increased healthcare contacts.

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. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks.

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.

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.

As part of this study, you will be asked questions about depression, which may include thoughts about potentially harming yourself. If we learn that you or someone else is in danger of harm, the study team is required to report that information to the proper authorities.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will benefit other people in the future. The benefits of participating in this study may be increased access to healthcare. Because individuals recover differently after critical illness, no one can know in advance if participation in this study will be helpful in your particular case.

WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study to receive treatment. You should talk to your doctor about all the choices you have. Instead of being in this study, you have these options:

- Usual care by your primary care provider and specialists as determined by your inpatient clinical team.
- You may qualify for the ICU Recovery Clinic, where patients are seen in-person following critical illness.

WHAT ARE THE COSTS?

Study costs, including telehealth visits (phone or video visits) will be paid for by the study. In-person

visits, medications, tests, procedures, referrals to other providers or the emergency room, and other costs from your medical care, etc. which may be recommended to you through the study, will be billed to you and/or your insurance company. Costs for your 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. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive no payment or other compensation for taking part in this study.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by The Duke Endowment and Wake Forest University Health Sciences. 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 or the product being studied.

WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. To the extent research insurance coverage is available under this policy the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. Wake Forest University Baptist Medical Center holds the insurance policy for this coverage. It provides a maximum of $25,000 coverage for each claim and is limited to a total of $250,000 for all claims in any one year. The Wake Forest University School of Medicine, and the North Carolina Baptist Hospitals, Incorporated do not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk and Insurance Management, at [redacted]

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

You do not give up any legal rights as a research participant by signing this consent form. For more

information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call Rita Bakhru, MD, MS at [redacted] or (after hours) [redacted].

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you and/or information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:**
Demographics: Age, Sex, Race, Height, Weight, etc.
Hospital and ICU Information: Admission information, diagnoses, medications, procedures, etc.
Information about your discharge: medications prescribed, discharge location, etc.
Information about your care after discharge: nursing visits, rehabilitation, etc.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study will be placed in your medical record, and will be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

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; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

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 unless there are photographs or recorded media which are identifiable.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your 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 you 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 medical record will either be destroyed or it will be de-identified. Any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Rita Bakhru, MD, MS 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:

Rita Bakhru, MD, MS
[redacted]

However, if you take away permission to use your Protected Health Information 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.

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

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record.

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

Laboratory test results and other clinically relevant medical reports created as a result of your 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. 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. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because of non-adherence to the study protocols or because we are unable to contact you after multiple attempts. Information that identifies you may be removed from the data or specimens 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 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, Rita Bakhru, MD, MS at [redacted] or (after hours) [redacted].

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]

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

SIGNATURES

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. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm

Legally Authorized Representative Name (Print):_____

The above named Legally Authorized Representative has legal authority to act for the research subject based upon (specify health care power of attorney, spouse, parent, etc.)

Relationship to the Subject:_____

Legal Representative Signature: _____ Date:_____ Time:_____ am pm

CONSENT OF THE SUBJECT TO CONTINUE TO BE IN THE STUDY

Your legal representative gave his/her consent for you to be in this research study. This is because you were not able to make your own decision due to your illness. Your condition has now improved. You are being asked to decide whether to continue to be in this study. Your decision is voluntary. This means your decision is up to you.

Subject Statement: I have read the information in this form. Or, someone has explained to me what study procedures will be continuing. My questions have been answered to my liking. I believe that I understand all of the information about this study. I have decided to continue taking part in this study.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm