Official Title: Anticipating Decline and Providing Therapy (ADAPT): Post-ICU Cognitive Screening Pilot and Feasibility Randomized Controlled Trial

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Wake Forest University
School of Medicine

Informed Consent Form

Department/Section of Internal Medicine-Pulmonary

ANTICIPATING DECLINE AND PROVIDING THERAPY (ADAPT): POST-ICU COGNITIVE SCREENING PILOT AND FEASIBILITY TRIAL

Informed Consent Form to Participate in Research
Jessica Palakshappa, MD MS, Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to understand how best to support older adults and their families as they recover from a serious or critical illness. Specifically, this study will help us to understand how to better support memory or thinking in the recovery period. You are invited to be in this study because you meet eligibility criteria including admission to an intensive care (ICU). Your participation in this research will involve telephone follow-up and may involve telephone evaluation of your memory and thinking.

Your clinical care will not be changed if you choose not to participate in this study. Your alternative to being in the study is to not be in the study. Your participation is voluntary. There is no penalty if you choose not to join the research study. No one will be upset with your decision.

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. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study please contact the Principal Investigator at [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 Wake Forest University Health Sciences Research Subject Advocate at [redacted].

INTRODUCTION

You are invited to participate in a research study. Research studies help scientists learn new information that may help other people in the future. You are being asked to be in this study because you were in the ICU and met other eligibility criteria. Your participation is voluntary. You do not have to be a part of this study if you do not want to. Please take your time in making your decision to join. 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 goal of this study is to improve our understanding of the recovery process and follow-up care that patients and their families receive after an ICU stay. We are interested in understanding brain health in particular so we can better design interventions and support programs for patients and their families after an intensive care unit stay. This study will test two different ways of supporting patients following an ICU stay. One way is follow-up with your current doctor(s). This is how we typically care for patients now. The other way involves a telephone call to complete memory and thinking tests with a possible referral to a memory specialist if needed. Everyone in the study will be randomized (similar to a coin flip) by a computer to one of these two groups.

Baseline Index Hospitalization	During your hospital stay, we will review your medical chart and collect contact and basic information about you. We may ask if you are willing to have a blood sample drawn.
6 Weeks	Phone call with our study team (this will take about 10 minutes). If you are randomized to the group with additional screening, you will also have a phone call with a memory and thinking test. This will take 30 to 40 minutes.
Caregiver-6 week	Phone call with our study team (this will take about 5 minutes or less) 1 brief questionnaire will be administered.
6 weeks to 6 months	You may be eligible for an in-person visit or video visit with a member of our memory care team to receive a care plan that addresses memory issues. You may also have a second blood sample drawn at approximately 3 months following discharge.
6 months post-discharge	Phone call with study team and possibly memory and thinking test.
Caregiver -7 months post-discharge	Phone call with our study team (this will take about 5 minutes or less) 1 brief questionnaire will be administered.
12 months post-discharge	Medical history review by providers. We will review your medical chart to update your medical history.

A cognitive test may be administered if you have been randomized into this group, the test will be completed by phone with a trained study team member. The phone call will last 30 to 40 minutes, and it will be audio recorded to allow us to review it for accuracy if needed. We may also reach out to the care partner you have identified if needed. The results will be reviewed by our team and communicated to your primary care provider. We may also refer you to our memory center for more information and resources if your primary care provider agrees.

You may also be eligible to have a blood drawn during your hospital stay and around 3 months after you are discharged from the hospital. This is an additional part of the research study and

having your blood drawn is not a requirement in overall participation.

You will have approximately 3 teaspoons of blood draw from a vein on up to two occasions. The total amount of blood drawn during the study will be approximately 6 teaspoons.

If you agree to participate in this study, some of the samples will be kept and may be used in future research to learn more about other diseases. The samples will be stored and given only to researchers approved by Dr. Jessica Palakshappa. Stored samples will not be used in future genetic or genomic research. An Institutional Review Board (IRB) must also approve any future research study using your blood samples.

The research that may be performed with your blood samples is not designed to help you specifically. There is no personal benefit to you from taking part in this aspect of the research study. The results of the research performed with your blood samples will not be given to you or your doctor. The results will not be put in your medical record. The research using your blood samples will not affect your care.

Your blood samples will be used only for research and will not be sold.

With a study ID	Your *blood/tissue* samples will be stored with a unique identifier and will not include any identifiable information about you such as your name, address, telephone number, or social security number. The unique identifier will be a randomly assigned number and only the principal investigator will have access to the code that links the unique identifier to you.

How Many People Will Take Part in the Study?

Approximately 120 patients will take part in this study. We also ask that a family member, caregiver, or friend join the interview with the patient if possible.

What Is Involved in the Study?

As part of this study, you may be in the group to have hospital follow-up as usual care with your doctors. You will be called to ask some questions about your recovery at 6 weeks and 6 months after your discharge. Your care partner or a friend or family member will be asked a short survey as well. If you are in the group for additional screening, you will be asked to complete questionnaires about your memory or thinking at telephone calls at 6 weeks and 6 months after hospital discharged. You may also be referred to see a specialist at our memory center. Your care partner or friend or family member will also be contacted for a short survey at two time points. You will be followed in this study for one year after your hospital discharge. All research studies involve some risks. There may be risk of discomfort or stress in completing the calls and memory tests; this is no more than would be expected from a routine medical visit. The other risk of participation in this study is a breach of confidentiality. You may or may not benefit from participation in this study.

Participation in this study will involve an initial visit during index hospitalization, 2 phone calls with our study team, possibly up to two phone calls with our team to complete memory or thinking questionnaires, possibly an in-person visit with a medical provider, and a medical chart review by medical providers. Some participants may also be asked if they would like to participate in an interview to provide feedback about the care they receive as part of this study. If you are asked to participate in the interview portion, you will be audiotaped. This is being done to be able to accurately analyze the data after the original interview is conducted. You may request the recording be stopped at any time. You can also withdraw your consent to use and disclose the recording before it is used. You will not be able to inspect, review, or approve the audiotapes or other media (including articles containing such) before they are used in this study. We will be reviewing and collecting information from participants' medical records as part of this study. We will delete audiotapes after the completion of the study

How Long Will I Be in the Study?

You will be in the study for about 12 months.

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.

What Are the Risks of the Study?

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.

If you are a participant in the blood draw part of the research study, you may experience discomfort, bruising and/or bleeding where the needle is inserted. Occasionally some people become dizzy, lightheaded or feel faint. Infection may occur on rare occasions. Frequent donation of blood can result in low iron in your blood (iron deficient anemia).

Are There Benefits to Taking Part in the Study?

You may benefit from study participation if you receive cognitive screening and support. Your family member may receive resources and support. We hope the information learned from this study will benefit care providers, patients, or families/friends 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?

All study costs related directly to the study will be paid for by the study. If you are referred to our memory center, this will be handled like a routine medical visit that would normally occur outside of a research study. 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. Participants do not have to use their real name during discussions and can instead opt to use a fictitious name.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Will You Be Paid for Participating?

You will be eligible to receive up to $60 in compensation for participating in this study. You will be paid $30 after completing the 6-week call(s) with our study team and will receive the second $30 after completing the 6-month call.
If you choose to participate in the blood draw part of the research study, you will be eligible to receive up to $150 in compensation. You will receive $50 for the first blood draw, and additional $100 for completing the 3-month blood draw.

The findings from this research may result in the future development of products that are of commercial value. There are no plans to provide you with financial compensation or for you to share in any profits if this should occur.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by the National Institute on Aging. The sponsor is providing money or other support to the researchers to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

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: your medical history prior to the ICU stay, your medications during the hospital stay and after discharge, details about your critical illness (reason for admission to the ICU, laboratory studies, and vital signs during the hospital stay), your appointments and contacts with the healthcare system after discharge. 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.

This research is covered by a Certificate of Confidentiality from the National Institutes of

Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects. Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for an indeterminate period of time. This authorization does not expire. 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 Dr. Jessica Palakshappa 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:

Dr. Jessica Palakshappa
[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.

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 it is in your best medical interest, new information becomes available, you failed to follow instructions, or because the entire study has been stopped. 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, Dr. Jessica Palakshappa at [redacted] She can also be reached at [redacted]. The Institutional Review Board (IRB) is a group of people who review 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].

SIGNATURES

I give permission to Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities and representatives (including third-party agents if applicable) to contact me by text message at the number I provided to send information, reminders, and to communicate with me about the research study. I understand that I am responsible for the standard text message rate of my carrier. I also understand that text messaging is not a secure form of communication and I accept the risk that individuals not involved in the research study may be able to access the text messages. I also understand that texting is not to be used for emergency situations.

By providing my email address, I give permission for Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities and representatives (including third-party agents if applicable) to send me information, reminders, and messages about the research study by email. I understand that these email messages may not be encrypted, and I understand and accept the risks that individuals not involved in the research study may be able to access unencrypted email messages. I also understand that email is not to be used for emergency situations.

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.

I consent to have a blood sample drawn as part of this study:

_____ YES

_____ NO

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

CONTINUING CONSENT

Due to the nature of my illness, my legally authorized representative gave consent allowing me to take part in this research. I am now able to understand the purposes, procedures and risks of this research study. I have had a chance to ask questions and volunteer to continue with participation in this study.

Subject Name (Printed):_____

Subject Signature: _____Date:_____ Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent Signature:_____ Date: _____Time:_____ am pm