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Title: REHAB-HF: A Trial of Rehabilitation Therapy in Older Acute Heart Failure Patients

Date: 2/20/2019

REHAB-HF:
A TRIAL OF REHABILITATION THERAPY IN OLDER ACUTE HEART
FAILURE

Informed Consent Form to Participate in Research
Dalane Kitzman, MD, Principal Investigator

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 are in the hospital with a diagnosis of heart failure. 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 assess the effect of a physical rehabilitation program for people admitted to the hospital with a diagnosis of heart failure.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

360 people at 3 lead research sites (each lead research site may have up to 3 satellite sites) will take part in this study, including up to 200 people at this research site.

WHAT IS INVOLVED IN THE STUDY?**Screening**

If you agree to participate in this study, you will be asked to sign this consent form. You will then have the following tests and procedures to make sure you meet the requirements to participate:

- A physical exam and medical history, including a review of your medical records
- An examination of your ability to walk a short distance (about 13 feet)
- A set of questions about your ability to participate

Baseline Testing

If you meet the requirements to participate in the study and wish to continue, you will be asked to complete the following tests while you are in the hospital:

1. Physical Performance Battery: These are tests that measure your level of physical function. They include testing your hand grip strength, your ability to stand up from a

seated position, your ability to maintain your balance while standing, and your ability to walk a short distance (about 13 feet).

2. Six minute walk test: This is a test to see how far you can normally walk in a six minute period of time.
3. Questionnaires: These questionnaires will ask you about your health, physical symptoms, daily activities, and mood. You will also be asked to complete a short series of mental tasks.
4. Blood draw: About 36 ml (about 2 tablespoons, four 8 ml tubes) of blood will be drawn from a vein in your arm. The blood will be used to measure hormones that affect the heart and to test your levels of energetic capacity (a measure of cell energy). Blood will be drawn at both the baseline and 3-month follow-up visit. There may also be a blood draw for up to 2 rehospitalizations, if these occur during the time you are in the study.
5. Activity Monitor: We will ask you to wear a small activity monitor while you are in the study. The activity monitor will be worn on your non-dominant hand. You will wear the activity monitor at all times during the 6 months of this study, except when showering/bathing. The monitor will collect data corresponding to the frequency, duration, and intensity of any physical activity you participate in, as well as track the quality and quantity of your sleep. The data will not be associated with your name or other personally identifying information; you will be assigned a study identification number.

Randomization

After completing these baseline tests, you will be randomly assigned to one of the 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 into either group.

There are 2 possible groups that you could be randomly assigned to:

1) Rehabilitation Intervention Group

If you are assigned to the rehabilitation intervention (treatment) group, you will participate in a program of rehabilitation activities starting while you are in the hospital. The rehabilitation may include activities such as walking, balance activities such as standing, reaching, and turning, and strengthening activities such as rising from a chair and resistance exercises using weights or resistance bands. These activities will be done with medical supervision and guidance from trained study personnel, and will be based upon your own personal abilities. Each day during your hospital stay you will have a rehabilitation session lasting about 30-45 minutes each. Once you are discharged from the hospital, you will continue the rehabilitation program as soon as possible at an outpatient rehabilitation facility for 3 days per week for 12 weeks. These supervised rehabilitation sessions will last about 45-60 minutes.

In addition to the supervised rehabilitation sessions performed 3 times per week, you will be

instructed to participate in walking exercise and other strengthening exercises at home on 2 of the other days of the week. Within one week after you are discharged from the hospital, a person from the study will visit you at home to customize the home exercise program for you and to evaluate your home environment for safe participation in the home exercises. You will be given a pedometer to help track your home exercise.

2) Attention Control Group

If you are assigned to the attention control group, you will receive the usual care that you would normally receive in the hospital and the usual follow-up care when you are discharged from the hospital as ordered by your personal physician. In addition to the follow-up visits described below, a study staff member will contact you at home by phone 3 times total to ask you questions about your symptoms, medical care, activity level, any physical therapy or other treatments that you may have received, and any hospital visits or medical events that may have occurred. These phone calls will occur approximately 2, 6, and 10 weeks following your discharge from the hospital. You will not receive any specific rehabilitation recommendations or be given specific exercises by study personnel. You may receive any physical or occupational therapy recommended by your non-study physicians or other health care providers.

Regardless of group assignment, you will be asked to wear a monitor on your wrist (like a watch) that will track your movement and sleep patterns.

Follow-Up Visits

Regardless of group assignment, you will be asked to return 2 times for evaluation visits. These visits will take place approximately 1 month and 3 months following your discharge from the hospital. At each of these visits, you will be asked to repeat the physical performance battery, six minute walk test, and questionnaires. You will also be asked to repeat the blood draw once at the 3 month visit. Within the first 2 weeks following your discharge from the hospital, a study staff member will briefly visit with you in-person. When possible, this contact will occur during a regularly scheduled rehabilitation session or a usual care clinic follow-up visit. In addition to these visits, a study staff member will call you at home approximately 2 months following your discharge from the hospital to ask you questions about your symptoms, medical care, activity level, what rehabilitation you may have received, and any hospital visits or medical events that may have occurred. Following your 3 month visit, there will be three similar phone calls about 1 month, 2 months, and 3 months later.

STORAGE OF BIOLOGICAL TISSUE

As mentioned in the testing description, if you agree to participate in this study, we will draw 36 ml of blood (about 2 tablespoons) 2 times from a vein in your arm, once at the baseline and once at the 3-month follow-up visit. There may also be a blood draw for up to 2 rehospitalizations, if these occur during the time you are in the study. The blood will be used to measure hormones that affect the heart and test your energetic capacity. Any leftover blood not used will be stored for future research. This sample will be kept and may be used in future research to learn more about other diseases. The sample will be stored in the CRU and it will be given only to researchers approved by Dr. Kitzman. An Institutional Review Board (IRB) must also approve

any future research study using your blood sample. In order to participate in this study, you must be willing to provide this sample for future research.

Your blood sample will be stored with a unique identifier and will not include any identifiable information about you such as your name, address, telephone number, social security number, medical record number or any of the identifiers outlined in the HIPAA Privacy Rule. 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. Your name, address, social security number, etc., will never be disclosed to future researchers and neither will the code that links your identifiers to the sample.

The research that may be performed with your blood sample is not designed to help you specifically. There is no personal benefit to you from taking part in this aspect of the research study. It might help people who have diseases at some point in the future, but it is not known if this will happen. The results of the research performed with your blood will not be given to you or your doctor. The results will not be put in your medical record. The research using your blood sample will not affect your care.

Your blood sample will be used only for research and will not be sold. The findings from this research may result in the future development of products that are of commercial value. There are no plans to share any of the profits with you which may occur as a result of the research.

In the future, people who do research may need to know more about your health. While the study investigator may give reports about your health, he/she will NOT be given your name, address, phone number, or any other identifying information about who you are, unless you agree to be contacted in the future.

☐ YES you may contact for future research studies
☐ NO I do not want to be contacted regarding future research studies.

HOW LONG WILL I BE IN THE STUDY?

You will be in your assigned study group for about 3 months, ending with the final evaluation visit. After this, there will be three follow-up phone calls about 1 month, 2 months, and 3 months later.

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 may involve some risk to you. You should discuss the risk of being in this study with the study staff. Risks and side effects related to the procedures we are studying include:

Rehabilitation Intervention Program: Rehabilitation activities are generally considered to be safe for patients who have a heart failure diagnosis, but you may feel tired or short of breath during or after the rehabilitation session. You may also develop pain or soreness in your muscles or joints after the rehabilitation session. Other risks and injuries that are possible, such as a fall, an abnormal heart rhythm, a heart attack, a stroke, or even death, are rare. All rehabilitation sessions will be closely supervised by trained personnel, who will instruct you in proper techniques.

Blood Draw: 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.

Six Minute Walk Test: There is a rare chance you could lose your balance, trip, or fall. To minimize this risk, we will make sure you have a clear walking path and that trained staff is always nearby.

Activity Monitor: There are no known risks associated with the use of the activity monitor.

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 side effects 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.

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.

A Data Safety and Monitoring Committee, an independent group of experts, will be reviewing the data from this research throughout the study.

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. The benefits of participating in this study may include improvements in endurance, strength, and balance; fewer symptoms from heart failure; fewer hospitalizations; and reduced risk of death. We also hope the information learned from this study will benefit other people in the future.

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.

WHAT ARE THE COSTS?

There are no costs to you for taking part in this study. All study costs, including any study medications and procedures related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

WILL YOU BE PAID FOR PARTICIPATING?

You will be paid \$75 if you complete the scheduled study visits and final follow-up phone call. If you withdraw for any reason from the study before completion you will be paid \$25 for each of the follow-up study visits and \$25 for the final follow-up phone call.

To receive payment, you must provide your social security number, name and address so that we can comply with IRS (Internal Revenue Service) reporting requirements. When payments are reported to the IRS we do not let them know what the payment is for, only that you have been paid. If you do not wish to provide this information you can still take part in this study but you will not be paid.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by the National Institutes of Health, NIH. 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 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 Dr. Dalane Kitzman [REDACTED] or after hours you may call the hospital operator at [REDACTED] and ask to speak to the Cardiology Fellow on call.

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.

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.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the NIH, which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you 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.

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: contact information, medical history and current health information directly related to study eligibility and participation, and the results of tests and procedures.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study may be placed in your medical record,

and may 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.

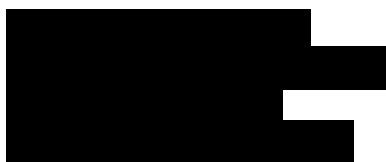
Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; 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. Study investigators and research staff also conducting this research study at other sites may also have access. This includes personnel at Duke University Health System in North Carolina and Thomas Jefferson University Hospital in Pennsylvania.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to the participant's original medical record for verification of clinical trial procedures or data, without violating confidentiality of the participant and to the extent permitted by other applicable laws.

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. 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. Dalane Kitzman 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:



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. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

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.

A North Carolina Baptist Hospital (NCBH) medical record will be created for all study participants. Information about your participation in the study will be placed in the NCBH medical record, along with any routine medical test results that were obtained at NCBH as part of 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, your condition worsened, new information becomes available, 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, contact the study investigator, Dr. Dalane Kitzman at [REDACTED] or after hours you may call the hospital operator at [REDACTED] and ask to speak to the Cardiology Fellow on call.

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].

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