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Title: Fluid Intake App for Management of Volume Intake in Patients Receiving Chronic Hemodialysis Therapy, Full Scale Trial
Date: 11/11/2020

Wake Forest®
School of Medicine

Department of Internal Medicine/Section on Nephrology

FLUID INTAKE APP FOR MANAGEMENT OF FLUID INTAKE

Full Scale Informed Consent Form to Participate in Research
Michael V. Rocco, 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 have end stage renal disease and receive hemodialysis for treatment of your kidney disease. 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 determine if a phone app that is designed to track your fluid intake can help to minimize your fluid weight gain between hemodialysis sessions.

The app is designed to help you track your intake of fluid throughout the day. You will set a goal with your physician for your fluid intake each day. By entering data into the app it will keep track of how much fluid you had had so far that day.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About 55 people at the Wake Forest Outpatient Dialysis clinics will take part in this study.

WHAT IS INVOLVED IN THE STUDY?

The study will last for 8 months.

You will be required to use a smartphone to participate in this study. The study will not provide a smartphone to you.

You will start the study by having a brief training session to show you how to use the app.

We would like for you to enter data into the app each day to track your fluid intake. We will compare the data that you enter into the app with your weight gains recorded at your dialysis sessions.

You will have the opportunity to meet with the study staff in the dialysis unit as often as needed if you need any help using the app.

We will ask you to meet with the study staff in the dialysis unit on weeks 1, 2, 4, 6 and 8 after the start of the study to review your data which we will ask you to provide to the study coordinator. This will be followed by a 6 month passive phase when you can meet with the study

coordinator as needed and also at the end of this 6 month period. We will continue to collect information about your dialysis treatments and any information you record on the app.

You will also be asked to complete a 20-minute survey at the dialysis unit prior to the conclusion of the 2 month active phase in order to find out your opinions about the usefulness of the app and any suggestions you might have to improve the app.

No additional blood work will be obtained for this study. No additional procedures will be obtained for this study.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for about 8 months.

You can stop participating in the study at any time. You may end your participation in this study at any time, simply by notifying your study doctor or the study staff. You are still free to withdraw at any time and without giving any reason. This decision will not affect the standard of care you receive.

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. Risks and side effects related to the application we are studying include:

- If the application does not work as planned, you may consume fluid in excess of what you usually consume. If this occurs, this could result in the need for additional removal of fluid during your dialysis session.

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.

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 the ability to decrease the amount of fluid that you drink each day, which should help to decrease the amount of fluid that is removed during your hemodialysis treatments. Because individuals respond differently to phone apps, no one can know in advance if it 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. Whether or not you are in the study you have these options:

- Work with your dietitian to help decrease the amount of fluid that you consume**.** If the dietitian is not successful in decreasing your fluid intake, it could result in excess fluid gain between dialysis sessions.

WHAT ARE THE COSTS?

The study phone app will be provided to you free of charge. Note that the study will not pay for any cell phone charges associated with the use of this phone app. 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. We will do our best to protect your confidential information.

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.

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 FUNDING THIS STUDY?

This study is being sponsored by Wake Forest University Health Sciences and funded by Danone Research. The funder 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 funder 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 sponsor 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 sponsor 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.

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. Michael Rocco at [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**:**

- Information from your dialysis treatments, including your weight before and after each hemodialysis treatment, length of the dialysis treatments, blood pressure and pulse during treatment. This data will be obtained during the study as well as a 2 month period prior to study enrollment.
- Information obtained from the app including when the app is used and the timing and quantity of fluid intake

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

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the funder 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), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

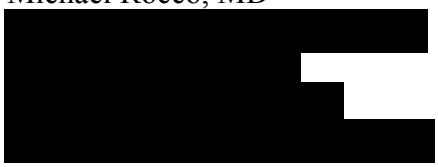
Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used 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] and 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 the study investigator, Dr. Michael Rocco, 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:

Michael Rocco, MD



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.

We can send copies of your test results to your personal physician. Even if you do not wish to have any of your medical information sent to your physician, you can still participate in this research study.

Do you request that we send important medical findings from your study tests/exams to your personal physician?

[ ] Yes [ ] No _____ Initials

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 medical 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, Michael Rocco, MD at [redacted] (24 hour number).

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