MOVE: MOtiVational Strategies to Empower African Americans to Improve Dialysis Adherence

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NCT05003115
Informed Consent Document: 5/20/2022

VUMC Institutional Review Board
Informed Consent Document for Research

Name of participant: _____ Age: _____

The following information is provided to inform you about the research project and your participation in it. Please read this form carefully and feel free to ask any questions you may have about this study and the information given below. You will be given an opportunity to ask questions, and your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:

The purpose of the study is to improve adherence to coming to dialysis and completing dialysis treatments. You are being asked to take part in this research study because you are an African American patient who receives chronic hemodialysis. With this study, we hope to improve how doctors and nurses talk to you about your attendance to dialysis and completion of dialysis treatments. We would like to enroll about 30 African American patients on chronic dialysis in this study at Vanderbilt.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

Procedures to be followed and approximate duration of the study:

You will be asked to fill out a form with questions about your age, background, insurance, and income. You will be asked to complete a few survey packets to get information about your experience and perspectives about coming to dialysis. You will complete these surveys at 3 different time points during the study: baseline, 8-9 weeks, and 12 weeks. It will take you no more than 30 minutes to complete these surveys at each time point. You may complete these before, during or after your dialysis clinic visit. You may also complete these questions over the phone. You will be asked about your general mood and perceptions related to coming to dialysis and completing treatments. You do not have to answer any question that you do not want to answer.

In addition to completing these surveys, you may be randomized to participate in special conversations about challenges associated with keeping to your dialysis schedule. These special sessions will be done

weekly for the 1st month, and repeated during week 6 and week 8. These sessions will either be done in person or virtually and they will be audio-recorded. The initial session will last about 30 to 45 minutes. Subsequent sessions will likely last less than 30 minutes. You also may be asked to participate in a brief exit interview about your special conversations.

We will also look at your medical records for information about your kidney disease and your attendance to dialysis. Your name will not be on the surveys or other information we collect. You will be given a study number which will not be linked to any Protected Health Information (PHI). Once you complete the surveys at the 3 different time points and the special sessions (if selected) at the 6 different time points, you are done with the study. All of the tasks in this study are for research only. The tasks are not part of your usual clinical care.

Expected costs:

There is no cost to you for taking part in this study. If you agree to take part in this research study, you and/or your insurance will not have to pay for the tests and treatments that are being done only for research.

However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

Description of the discomforts, inconveniences, and/or risks that can be reasonably expected as a result of participation in this study:

There are no side effects and no more than minimal risks if you take part in this study. The primary minimal risk is loss of privacy of your health information or survey responses. Study protocols and procedures are used to make all possible efforts to not have a loss of privacy in this study. Completion of the surveys (and participating in the special sessions if applicable) may be time consuming and you may feel uncomfortable answering some of the questions or discussing your adherence to dialysis.

Unforeseeable risks:

There may be risks that we do not know about at this time.

Compensation in case of study-related injury:

If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you can get reasonable, immediate, and necessary medical care for your injury at Vanderbilt University Medical Center. You and/or your insurance will not have to pay for the cost of medical care provided **at Vanderbilt** to treat the injury.

There are no plans for Vanderbilt to pay for any injury caused by the usual care you would normally receive for treating your illness. There are no plans for Vanderbilt to pay for the costs of any additional care, or to give you money for the injury.

Good effects that might result from this study:

a) **The benefits to science and humankind that <u>might</u> result from this study.** We may learn more about how to better talk with African American patients with kidney disease and possibly other diseases. We may also learn more about how to improve adherence to dialysis for African American patients with kidney failure, and possibly other patients with kidney failure.

b) **The benefits you might get from being in this study.** Taking part in this study may not personally help you. However, you may help us learn more about how to better communicate with African American patients with kidney failure regarding adherence to dialysis. You may also become better adherent to dialysis.

Study Results:

As part of the study, Dr. Umeukeje and her study team may share the results of your study and/or non-study linked demographic, survey results or recording results, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections and the Vanderbilt University Institutional Review Board, and third party contracted health coaches and consultants. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

Alternative treatments available:

Taking part in this study is voluntary. You are free to leave the study at any time. If you choose not to take part in the study, you will continue to receive dialysis-care from your physician and the dialysis clinics.

Compensation for participation:

A $25 gift card will be provided to you each time you complete the surveys (total of $75 if you complete the survey at the 3 different time points). Patients who are randomized to participate in the special sessions on dialysis adherence, will receive a $25 gift card each time they participate in these sessions (total of $150 if they participate in the conversations at the 6 different time points). Patients who complete the exit interview will also receive a $25 gift card.

Circumstances under which the Principal Investigator may withdraw you from study participation:

The Principal Investigator may withdraw you from participation if you cannot complete the surveys (and special sessions if applicable). The Principal Investigator may remove you from participation if you leave the dialysis clinics participating in the study or stop receiving dialysis-care visits.

What happens if you choose to withdraw from study participation?

If you decide to withdraw from the study, no additional information will be collected from you. This will have no impact on the care that you receive from your doctor. You are allowing us to use your information from this study for as long as we want. If you decide to withdraw permission, all you need is to let Dr. Umeukeje know. A decision to not participate in this research will not affect your treatment.

Contact Information:

If you should have any questions about this research study or possibly injury, please feel free to contact **DR. EBELE UMEUKEJE** at **(615) 936-3283** or coordinator, [redacted]. If you cannot reach the research staff, please page the study doctor Dr. Ebele M. Umeukeje at (615) 936-3283.

For additional information about giving consent or your rights as a participant in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to contact the Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Confidentiality:

All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. All data will be labeled with a study number. A password protected computer will be used for all research activities. Paper case report forms and other pertinent paper documentation will be kept in a locked office and only study personnel will have access. Data will be entered into the secure online REDCap database. Recordings of the special sessions will be in a digital format and will be de-identified prior to transcription by study personnel or a professional transcriptionist (non-study personnel). They will be stored on a secure network within the VUMC box and/or the Center for Health Services Research. Only approved study personnel will have access this data. The computer network specialists will work with Dr. Umeukeje to make all possible efforts to keep this information secure.

Vanderbilt may share your information without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr. Umeukeje, and her staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

This study may have some support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Privacy:

All efforts, within reason, will be made to keep your protected health information (PHI) private.

PHI is your health information that is, or has been gathered or kept by Vanderbilt as a result of your healthcare. This includes data gathered for research studies that can be traced back to you. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below.

The study results will be kept in your research record for at least ten years after the study is finished. At that time, the research data that has not been put in your medical record will be kept for an unknown length of time. Any research data that has been put into your medical record will also be kept for an unknown length of time.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. Umeukeje and let her know that you withdraw your consent. Her mailing address is: Ebele Umeukeje MD, MPH; Vanderbilt University Medical Center, [redacted]. At that time, we will stop getting any more data about you. But, the health data we stored before you withdrew your consent may still be used for reporting and research quality.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY

I have read this informed consent document and the material contained in it has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to participate.

Date	Signature of patient/volunteer

Consent obtained by:

Date	Signature
	Printed Name and Title