Official Title: Diet and Hypertension Management in African Americans With Chronic Kidney Disease

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DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
ADULT
Diet and Hypertension in African Americans with Chronic Kidney Disease (Counseling Intervention)

CONCISE SUMMARY

The purpose of this study is to determine whether DASH diet counseling improves the ability of African Americans with chronic kidney disease to follow the DASH diet and to determine if the DASH diet safely lowers blood pressure in African Americans with chronic kidney disease. Participants will undergo screening that includes completion of study questionnaires about medical history, diet, and lifestyle, completion of blood pressure measurements, and collection of blood and urine samples. Once screening is complete, participants will be assigned to either meet with a dietitian by videoconference for a single 30 minute visit or to meet in a group with other study participants once per week for 12 weeks and receive diet counseling by a dietitian. Approximately half of the group meetings will occur in person and half will occur by videoconference. During the study, participants will be asked to complete questionnaires about diet, physical activity, health behavior, and medication use and to complete 24-hour urine collections, 24-hour blood pressure monitoring, collect small samples of their stool and complete blood draws.

The most serious risk of participating in the study is the possibility of developing high blood potassium levels and/or low blood pressure from following the DASH diet. This risk will be monitored by testing your blood chemistry and measuring your blood pressure at predetermined times during the study. People who use insulin or take certain diabetes medications may also be at risk for developing low blood sugars and will be required to get permission from their diabetes provider to participate in the study.

If you are interested in learning more about this study, please continue to read below.

You are being asked to take part in this research study because you are African American and have high blood pressure and kidney disease. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

A grant from the National Institutes of Health (NIH) will sponsor this study. Portions of Dr. Crystal Tyson's and her research team's salaries will be paid by this grant.

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WHO WILL BE MY DOCTOR ON THIS STUDY?

If you decide to participate, Dr. Crystal Tyson will be your doctor for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

WHY IS THIS STUDY BEING DONE?

This study is being done to determine if diet counseling improves the ability of African Americans with chronic kidney disease to follow the DASH diet and to determine whether following the DASH diet is a safe way to improve blood pressure in African Americans with kidney disease. DASH stands for *Dietary Approaches to Stop Hypertension* and is a diet that is high in fruit, vegetables, whole grains, nuts, seeds, beans, and lean meat, and is low in saturated fat and added sugar. The DASH diet is proven to lower blood pressure in people with normal kidney function but its effect in African Americans with kidney disease is not known. African Americans with kidney disease tend to have blood pressure that is higher and more difficult to treat than people with normal kidney function. Additionally, people with kidney disease often have to limit or avoid certain foods that could be harmful when their kidney function becomes poor. Therefore, this study will help determine if the DASH diet is a safe and effective diet to lower blood pressure in African Americans with kidney disease.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 50 people will take part in this study at Duke.

WHAT IS INVOLVED IN THE STUDY?

If you agree to participate in this study, you will be asked to sign and date this consent form. You will then be asked to complete a medical screening. If you pass the medical screening, you will then proceed to the other study phases. There will be three phases to this study: 1) an Assessment Phase, 2) an Intervention Phase, and 3) a Follow-up Phase.

MEDICAL SCREENING

Medical screening will occur during your first visit. It will involve a review of your medical history, medications, and medical records, and include a brief physical exam which includes measures of your height, weight, arm circumference, and blood pressure.

Blood samples will also be collected to measure your kidney function and basic body chemistries to confirm that you meet criteria for the study and that it is safe for you to participate. Approximately 1-5 teaspoons of blood will be collected.

ASSESSMENT PHASE

The assessment phase will occur during your second visit and at week 5 and week 13. You will be asked to complete a series of questions about your food environment, social support system, eating habits, and different attitudes about your health and health habits. These should take approximately one (1) hour to complete. You are free to omit any questions that you do not wish to answer.

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We will measure your weight. You will also be asked to complete a 24-hour food recall during the visit and two additional recalls within one week of the visit by phone interview or using a self-administered questionnaire.

Your blood pressure will be measured in the office and over the next 24-hours. For the 24-hour blood pressure measurements, you will wear a small portable blood pressure cuff and monitor that will automatically inflate at scheduled times during the day and night and measure your blood pressure during your normal activities.

You will be asked to collect urine over a 24-hour period. The full volume of urine will be collected in a container for 24 hours. These samples will be used to collect information about your kidney function and diet.

You will be asked to collect two small sample of your stool in the privacy of your home before you receive diet counseling and at weeks 5 and 13. These samples will be used to determine if the bacteria in your gut is affected by your diet. We will provide stool collection kits for you. Your stool will be frozen and stored until we are able to perform the planned tests.

INTERVENTION PHASE
The intervention phase will last for 13 weeks. You will be randomly assigned (like the flip of a coin) to one of the following two groups:

a) Standard Care – If you are assigned to Standard Care, you will:
- Meet with a dietitian *one time* for 30 minutes by videoconference
  - You will be allowed to invite one health partner to attend the videoconference with you. A health partner is a spouse, relative, or close friend who you believe would help support you in changing your diet.
- Get advice about how to reduce the amount of salt you eat to lower your blood pressure
- Receive handouts and tip sheets to help you follow the dietitian's advice on your own

b) Group Counseling – If you are assigned to Group Counseling, you will
- Meet with a dietitian *one time* for 30 minutes by videoconference
  - You will be allowed to designate one health partner to attend the videoconference with you. A health partner is a spouse, relative, or close friend who you believe would help support you in changing your diet.
- Get advice about how to reduce the amount of salt you eat to lower your blood pressure
- Receive handouts and tip sheets to help you follow the dietitian's advice
- Meet with a dietitian twelve additional times (once per week for 12 weeks) in person and by videoconference as part of a group with other study participants to get advice on how to follow the DASH diet

- You will be allowed to invite the same health partner to attend weekly group meetings with you, the dietitian, other study participants, and their designated health partners. The group size may range from 5-15 people.

- Have your blood drawn at weeks 3 and 9 so that the safety of your diet changes can be monitored. If at any time your body chemistries become abnormal, you will be asked to complete an additional blood test within 3-7 days and the study doctor will meet with you by phone or in person to determine if it is safe for you to remain in the study. You may also be asked to complete 1-2 additional diet recalls and meet one-on-one with the study dietitian to receive personal diet advice.
- Be interviewed for 20-30 minutes by phone or 60 minutes in a group to determine factors that made it easy or difficult to follow the DASH diet and get your opinion about how to improve the counseling program

Regardless of your group assignment, at week 5 you will:
- have your blood drawn to measure your kidney function and basic body chemistries
- have your weight and office blood pressure measured
- report what you eat and drink
- fill out surveys

Regardless of your group assignment, at week 13 you will:
- have your blood drawn to measure your kidney function and basic body chemistries
- have your weight and office blood pressure measured
- report what you eat and drink
- fill out surveys
- measure your blood pressure for 24 hours
- collect your urine for 24 hours
- provide two small sample of your stool

We anticipate that your blood will be drawn a total of four times during the 12-week period. However, if you are assigned to Group Counseling, it may be measured as many as 12 times, if necessary, if you develop abnormal lab results.

FOLLOW-UP PHASE
Twelve weeks after you complete the intervention phase, you will be asked to come back for one follow-up visit. During this visit, we will measure your weight, office blood pressure, and ask you to collect your urine for 24 hours. We will review your medications, ask you to complete a diet recall during the visit and 2 additional recalls within one week of the visit by phone interview or using a self-administered questionnaire, and complete questions about your diet habits and lifestyle.

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HOW LONG WILL I BE IN THIS STUDY?

The medical screening and assessment phase will last 2 weeks. The intervention phase of the study will last 12 weeks (3 months) and you will return for a follow-up phase visit 12 weeks (3 months) later. Therefore, if you complete all phases of the study, you will be in the study for approximately 26 weeks (6 ½ to 7 months). You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to the study doctor first.

WHAT ARE THE RISKS OF THE STUDY?

Risks of Drawing Blood:
Risks associated with drawing blood from your arm include momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting are also possible, although unlikely.

Risks of abnormal blood tests:

- Hyperkalemia (high blood potassium levels): high blood potassium concentrations may cause muscle weakness and loss of muscle function, cardiac conduction abnormalities or cardiac arrhythmias (your heart beats at a rate or in a rhythm that is not normal), metabolic acidosis (too much acid builds up in the body) and death. Mildly elevated blood potassium levels may include tiredness and sensation of a rapid heartbeat.
- Hyperphosphatemia (high blood phosphorus levels): high blood phosphorus levels may cause low blood calcium and result in muscle weakness, loss of muscle function, or calcium-phosphate crystals to deposit into soft tissue. Symptoms of mildly elevated blood phosphorus levels include muscle cramps, numbness or tingling, tiredness, nausea or vomiting, bone and joint pain and difficulty sleeping.
- Hypoglycemia (low blood sugars): Symptoms of low blood sugar may include shakiness, sweating, chills, clamminess, confusion, fast heartbeat, hunger and nausea, sleepiness, weakness, headaches, or being easily irritated, and these symptoms would quickly improve with eating or drinking something that contains sugar. If left untreated, severe low blood sugars can lead to death.

Risks of Food Allergy:
You may be exposed to new foods, creating the possibility of discovering an unknown food allergy that include tingling or itching in the mouth, rash or itching of the skin, swelling of the lips, tongue, throat or other parts of the body, wheezing, nasal congestion or trouble breathing, dizziness, lightheadedness, or fainting. Food allergies can be life-threatening and may result in death. If you develop any of these symptoms, you should go to the emergency department immediately and contact the study doctor after you receive medical care.

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Risk of Food or Lactose Intolerance:
The DASH diet is high in fiber and dairy and may lead to discomfort involving your stomach and intestines. These symptoms may include stomach pain, bloating, increased gas, nausea, constipation, or diarrhea. If you experience these symptoms, you are encouraged to inform the study team.

Drug and Food Interactions:
For your safety, you must tell the study doctor or nurse about all the prescribed medical foods and drugs, herbal products, over-the-counter (OTC) drugs, vitamins, natural remedies, and alcohol that you are taking before you start the study and before starting to take any of these products while you are on the study.

Risk of Loss of Confidentiality:
There is the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

Risk of Low Blood Pressure:
There is a risk of your blood pressure becoming too low by changing your diet. Symptoms of low blood pressure include dizziness, tiredness, loss of balance, falls, and fainting. If you experience these symptoms, you should inform the study team.

Risk of Psychological Stress:
Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop your participation in this study at any time.

Reproductive Risks
Although the study itself does not pose any risks to a developing pregnancy or breastfeeding infant, the dietary needs of women who are planning a pregnancy or breastfeeding are different. Women who are pregnant, planning a pregnancy, or breastfeeding are not allowed to participate in the study.

If you are a woman who could possibly become pregnant (you have not completed menopause, or you have not had a hysterectomy and/or both tubes and/or both ovaries removed) and you have a partner who is able to father children, a urine pregnancy test will be done and it must be negative in order to continue. You and your partner should use an effective method of contraception during the study. Effective methods include (a) partner vasectomy, (b) bilateral tubal ligation, (c) intrauterine devices (IUDs), (d) hormonal methods, or (e) barrier methods (condoms, diaphragms, cervical cap) with spermicide. If you are not using one of these methods, Dr. Tyson will discuss options with you, given your medical condition, your personal preferences, and the level of effectiveness required by this study.

There may be risks, discomforts, drug interactions or side effects that are not yet known.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
If you agree to take part in this study, there may be direct medical benefit to you. A potential benefit is that the study intervention may lower your blood pressure, improve your blood sugars, and improve

your blood cholesterol but this cannot be guaranteed. It is also possible that your blood pressure, blood sugars and cholesterol may stay the same or get worse. We hope that in the future the information learned from this study will benefit other people with your condition.

WHAT ALTERNATIVES ARE THERE TO PARTICIPATION IN THIS STUDY?
Diet modification is only one of many ways to lower blood pressure. Other ways to lower blood pressure include taking medications and making healthy lifestyle choices, such as losing weight and exercising. Please talk to your doctor about these options. The study doctor can also discuss these options with you.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law. For records disclosed outside of DUHS, you will be assigned a unique code number. The key to the code will be stored securely in a computer file on Duke's network. Only study team members will be able to access the file.

If you are assigned to Group Couseling, for your week 13 interview, we may audio record the answers to the questions you are asked about what made it easy or hard to change your diet. Your identifying information including name and date of birth will be removed from the recordings. The audio recordings will be stored electronically on a secure network drive at DUHS.

Some of the blood and urine testing will be performed by labs outside of Duke. When your samples are sent to an outside clinical laboratory, such as LabCorp, for standard clinical testing, we will include your unique study ID number, date of birth and initials.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);
2) you have consented to the disclosure, including for your medical treatment; or
3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

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Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).
You should understand that a Confidentiality Certificate does not prevent you or a member of your family 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. This means that you and your family must also actively protect your own privacy. Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

WHAT ARE THE COSTS TO YOU?
There is no cost to you for participating in this study.

WHAT ABOUT COMPENSATION?
You may be compensated up to $250 for your expenses related to participation, such as travel, lost wages, and time. Compensation will be based on completion of the assessment visits.

Completion of Screening visit	$0
Completion of Baseline visit during assessment phase	$50
Completion of week 5 assessment	$50
Completion of week 13 assessment	$100
Completion of follow up (6 month) assessment	$50
TOTAL	$250

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WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal. All data that have already been collected for study purposes will be retained unless you request otherwise.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Crystal Tyson in writing and let her know that you are withdrawing from the study. Her mailing address is 2727 Erwin Road, Suite 605, Durham, NC 27705. If you chose to withdraw, you will be asked about your experience in the study and reasons for withdrawal.

Dr. Tyson may decide to take you off this study if your condition gets worse, if you have serious side effects, such as abnormal test results, or if she determines that it is no longer in your best interest to continue. The sponsor or regulatory agencies may stop this study at any time without your consent. Reasons why this might occur include: if you develop a condition that suggests your safety is at too high a risk; if you are enrolled and it is later determined that you are not eligible according to test results; and/or if you do not follow the instructions of the study doctor or dietician.

Your urine and stool samples and/or data collected for this study may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed.

We will ask you to provide an additional sample of your blood to use for future research that may involve genetic testing. This collection is optional and will require you to sign a separate consent form.

The use of your data and samples may result in commercial profit. You will not be compensated for the use of your data and samples other than what is described in this consent form.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study. Your doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue. A description of this clinical trial will be available on https://clinicaltrials.gov/ as required by

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U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Crystal Tyson at 919-660-6671 during regular business hours. After business hours, weekends, holidays, please call 919-684-8111 and ask to have Dr. Crystal Tyson paged.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

(Optional) DUKE RESEARCH EQUITY AND DIVERSITY INITIATIVE PROJECT: READI
By agreeing to participate in this research project, you will also have the option to participate in the READI project, which aims to better understand and improve participants' experiences in research studies. If you are willing to share your contact information (name and email address) with the READI project, you may be invited to share information on your research experience through surveys. Sharing your information is completely optional and will not impact your participation in this study. Please indicate your choice by initialing the appropriate statement below:

_____ Yes, I am willing to share my contact information with the READI project.

_____ No, I do not want my contact information shared.

STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Subject	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time