Brief Title: Case Managers for CVD Risk Reduction in HIV Clinic

Official Title: A Clinic-Based Case Manager Administered Telephone Intervention to Reduce Cardiovascular Disease Risk in Persons Living With HIV

NCT03839394

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DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
A Clinic-Based Case Manager Administered Telephone Intervention to Reduce Cardiovascular Disease Risk in Persons Living with HIV
Consent Version: 13 APR 2020

CONCISE SUMMARY

This is a research study to assess the impact of a telephone-based social worker administered intervention in improving cardiovascular health among HIV-infected clinic patients.

If you decide to participate in this study, you will be asked to come to your HIV clinic for research visits every 6 months for a total of 4 visits. You will be randomly assigned (like flipping a coin) to one of two groups- the case manager intervention group or the education control group.

If you are assigned to the case manager intervention group, a social worker will contact you by phone every 2 weeks for 24 weeks. During these calls you will have the chance to pick an education topic from a list that will help improve your cardiovascular health.

If you are assigned to the education control group, you will receive educational pamphlets on topics such as diet, medication adherence, physical activity, smoking cessation, stress management, and weight management.

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

You are being asked to take part in this research study because you are a person living with HIV who also has high blood pressure or high cholesterol. 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.

Dr. Nwora Lance Okeke will conduct the study and it is funded by National Heart, Lung and Blood Institute (NLHBI).

WHO WILL BE MY DOCTOR ON THIS STUDY?
If you decide to participate, Dr. Lance Okeke 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?

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The purpose of this study is to test the effectiveness of a social worker led, telephone-based intervention on decreasing blood pressure and/or cholesterol levels among patients living with HIV.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 50 people will take part in this study at Duke University Health System.

WHAT IS INVOLVED IN THE STUDY?
If you agree to be in this study, you will be asked to sign and date this consent form.

This study is a randomized controlled trial, which means you will be randomly assigned (like the flip of a coin) to receive either the telephone-based social worker intervention or the education control arm.

If you are in the education control arm, you will receive general prevention education in the form of pamphlets including medication management, cardiovascular disease (CVD) risk, diet, stress management, smoking cessation, physical activity and weight management.

If you are in the intervention arm, you will receive a 24-week telephone based intervention. You will be contacted every 2 weeks for a total of 12 calls in the 24-week period by the study social worker. During each call, you will have the chance to select a module from 6 modules in a rotating fashion on topics relevant to cardiovascular disease risk. These topics include medication management, CVD risk, diet, stress management, smoking cessation, physical activity and weight management. Each telephone session will involve the study social worker providing education on the selected module to promote improved cardiovascular health.

Once the 24 week follow up period has been completed, you will be asked to come in for visit 3 (6 months after the intervention) and visit 4 (12 months after the intervention) to test how well the study is doing.

All participants in the control and intervention arm will complete the following assessments at each in-person visit:

1) In-office Blood Pressure obtained by trained research staff
2) Lipid panel (lab tests to measure your cholesterol levels)
3) 10-year ASCVD risk score (a 10-year score that determines your risk for atherosclerotic cardiovascular disease, i.e. a heart attack, or a stroke)
4) Provider trust and communication survey

Participation in research is voluntary and refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled.

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HOW LONG WILL I BE IN THIS STUDY?

You will be participating in this study for 72 weeks (approximately a year and a half). 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 your doctor first.

WHAT ARE THE RISKS OF THE STUDY?

As a result of your participation in this study, you are at risk for the following side effects. You should discuss these with the study doctor and your regular health care provider if you choose.

Loss of confidentiality
The risks associated with potential loss of confidentiality are low. The staff obtaining data will be properly trained and supervised. Participant data will be stored in files on the Duke Division of Infectious Diseases private server, managed by the Duke Office of Information Technology.

Detection of clinically significant problems
Although not caused by study participation, it is possible that clinically significant problems will be detected by study staff during the course of the study. For example, dangerously high blood pressures will be reported to your doctor.

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.

Physical activity
During the course of the study, social workers may encourage you to increase your physical activity, increasing the possibility of injury. Risks from increased physical activity will be minimized by encouraging moderate rather than vigorous activity.

Smoking
Smoking participants will be encouraged to quit smoking, increasing the possibility of withdrawal symptoms from nicotine dependence.

Psychological risks
For the purpose of the study assessments, participants will be asked about personal characteristics such as race/ethnicity, and socioeconomic status that may be uncomfortable to answer. Only questions that are important to inform the study outcomes will be asked during the course of the trial. You may refuse to answer any questions, and continue to participate in the study. It is also possible that you may be uncomfortable talking to the social workers about some topics that will be discussed as part of the intervention.

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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. The benefits include improved lifestyle, lower blood pressure, and lower cholesterol, which may reduce your risk of heart disease. We also hope that in the future the information learned from this study will benefit other people with your condition.

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.

As part of the study, results of your study-related laboratory tests, and procedures may be reported to NLHBI and its affiliates. In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives and affiliates of NLHBI, the Duke University Health System Institutional Review Board, and others as appropriate. If any of these groups review your research record, they may also need to review your entire medical record.

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.

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.
As part of this study, you will be asked to have certain tests performed. Some of these tests and/or procedures would have been done as part of your regular care. The study doctor will use these test results both to treat you and to complete this research. These test results will be recorded in your medical record and will be reported to the representatives and affiliates of NLHBI. Results of tests and studies done solely for this research study and not as part of your regular care will not be included in your medical record.

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.

This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations.

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?
You or your insurance provider will be responsible and billed for all costs related to your routine medical care, including copayments and deductibles. Routine medical care services are those that you would have received for your condition if you were not participating in this research study. Not all services are covered by insurance. Some procedures or scans may require pre-authorization by your insurance plan. We will notify you if we learn that a service is not covered by your insurance plan as part of the pre-authorization process. If it is not covered, you will be responsible for paying for it. The amount of your out-of-pocket expense will depend on your insurance plan. For beneficiaries with Medicare Advantage Plans, traditional Medicare is billed for the routine cost of a research study. You may have more or higher co-pays than with a Medicare Advantage plan. Please discuss the costs of the study with Dr. Nwora Lance Okeke. At your request, a Financial Counselor in the clinic may provide you with an estimate of costs for routine services.

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The study sponsor NLHBI has agreed to pay for services and procedures that are done solely for research purposes. There is no cost to you or your insurance for the research study including the research visits, the lipid panels, and the social workers.

We will monitor your DUHS patient care charges to make sure that costs are directed appropriately. If you have any questions or concerns about appropriate billing, contact your study team coordinator so that he/she can help find a resolution.

WHAT ABOUT COMPENSATION?
You will be reimbursed up to $25 upon completion of each of the visits for a total of $100 to compensate you for your expenses related to your participation (parking, gas, and time).

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.

For questions about the study or research-related injury, contact Dr. Nwora Lance Okeke at 919-684-2579 during regular business hours.

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 sent to the study sponsor.

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. Nwora Lance Okeke in writing and let him know that you are withdrawing from the study. His mailing address is 315 Trent Drive, Durham, NC 27710.

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. The sponsor or regulatory agencies may stop this study at any time without your consent. Reasons why this might occur include:

- if your health changes and the study is no longer in your best interest
- If new information becomes available
- If you do not follow the study requirements
- If the study is stopped by the sponsor or IRB Your data 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. If your identifying information is removed from your samples or data, we will no longer be able to identify and destroy them.

A description of this clinical trial will be available on https://clinicaltrials.gov/ as required by 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. Nwora Lance Okeke at 919-684-2579 or at lance.okeke@duke.edu during regular business hours or contact the primary Clinical Research Coordinator of the study, Kiran Grover at 919-669-1095.

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.

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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