Document Coversheet

Study Title: Heart of the Family: A Cardiovascular Disease and Type 2 Diabetes Risk Reduction Intervention in High-Risk Rural Families

Institution/Site:	University of Kentucky
Document (Approval/Update) Date:	5/26/2024
NCT Number:	NCT04891575
IRB Number	60980
Coversheet created:	3/5/2026

IRB Approval
5/26/2024
IRB # 60980
IRB1

PRIMARY PARTICIPANT

KEY INFORMATION FOR "HEART OF THE FAMILY IN RURAL KENTUCKY":

You are being invited to participate in a research study about preventing type 2 diabetes and heart disease. We are asking you because you are at risk for type 2 diabetes or heart disease and because you have a family member who is willing to participate with you if you are selected by chance to participate with a family member. This page is to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

By doing this study, we hope to learn how useful an educational program about healthy lifestyles is for preventing heart disease and type 2 diabetes. For this reason, you will be asked to take part in an educational program that includes attending 8 classes that are about 2½ hours in length, with one class provided weekly. After this, we will talk with you once a month for about 1 year. Each conversation will be approximately 15 minutes in length and are opportunities to touch base. Before and after the educational program and again in one year, we will collect information and check health-related measures related to heart disease and type 2 diabetes risk. All of the activities for this study take place during approximately one year and require more or less 40 hours of your time. If you are selected by chance to participate with a family member, the family member will participate in each of these activities with you. For a complete description of the study and what you will be asked to do, refer to the Detailed Consent.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

During this study you will learn about how to live more healthily, that may improve your health, although there is no guarantee that you will benefit from taking part in this study. Your willingness to take part may also help us to be able to better help people who are at risk for cardiovascular disease and type 2 diabetes to reduce their risks for disease. For a complete description of benefits, refer to the Detailed Consent.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You may not want to volunteer for this study if you are concerned about learning about heart disease or type 2 diabetes and risk factors you may have for these diseases; if it is too difficult to attend 2-hour educational sessions each week for 8 weeks; or if you will not be able to participate in the study for one year. For a complete description of risks, refer to the Detailed Consent.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study contact Gia Mudd-Martin, PhD, MPH, RN, of the University of Kentucky, College of Nursing at 859-257-4204.

If you have any concerns or questions about your rights as a volunteer in this research, contact staff in the University of Kentucky (UK) Office of Research Integrity (ORI) between the business hours of 8am and 5pm EST, Monday-Friday at 859-257-9428 or toll free at 1-866-400-9428.

DETAILED CONSENT:

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

You do not qualify for this study if you are not at-risk for developing type 2 diabetes or heart disease. You also do not qualify if you have had a heart attack or a stroke, have heart failure, or if you have had a physician tell you that you have type 1 or type 2 diabetes or have been prescribed medications to control diabetes.

Other reasons you would not qualify for this study are: (1) if you are less than 18 years of age; (2) if you do not speak and understand Spanish or English; (3) if you cannot participate in the study during the next 12 months; (4) if you do not have access to internet service since the intervention is provided online; (5) if you have a medical condition that limits your physical activity or requires a special diet; (6) if you have a serious psychiatric disorder such as schizophrenia; or (7) if you are pregnant or planning to become pregnant within the next 12 months since healthy behaviors for women who are pregnant are different from behaviors we address in this study.

To participate, you will need to have a family member who would be willing to participate with you and who lives in the same house with you or near where you live (within 25 miles). Your family member may or may not be invited to participate, depending on whether you are selected by chance to participate with a family member. If you are selected by chance to participate with a family member, the family member may or may not have diabetes or heart disease and may or may not have risk factors for diabetes or hear disease. All other reasons you would not qualify for the study are the same reasons your family member would not qualify.

Even though you choose to participate in this study, if you are selected by chance to participate with a family member but the family member does not qualify for the study or chooses not to participate, you will not be eligible to participate in the study.

WHERE WILL THE STUDY TAKE PLACE AND WHAT IS THE TOTAL AMOUNT OF TIME INVOLVED?

Some research procedures will be conducted in-person at a community center or other location that is convenient for you. Other study activities will be conducted online using Zoom. The study will last for approximately one year.

For research procedures that will be conducted in-person, you will need to come 3 times during the study for data collection. Each of those visits will take about 2 hours. You will also need to come once after each data collection visit. These will be short visits that will last about 30 minutes and are for the purpose of dropping off and picking study materials. You and your co-participating family member will together participate in 8 educational sessions that will be provided virtually. These will be provided weekly and each session is approximately 2 hours long. We will also talk with you and your co-participating family member by phone once a month during the year after the end of the sessions; each phone call will last about 15 minutes. The total amount of time you will be asked to volunteer for this study is approximately 30 hours over the next year.

If you are selected by chance to participate with a family member, you will participate in the data collection visits, the educational sessions, and the monthly phone calls with your family member.

WHAT WILL YOU BE ASKED TO DO?

You and your co-participating family member will be asked to participate in 8 educational sessions that will be given over Zoom. The sessions will be about once a week for 8 weeks with each session lasting approximately 2 hours. You may attend the sessions with a group of other participants who are in the study. Sessions may be audio or video recorded. During the sessions you will receive information about heart disease and diabetes. You will also learn about how to stay your healthiest. You will take part in activities such as developing personal goals and goals to support your co-participating family member to improve health, and complete questionnaires about health.

After the sessions end, you and your family member will talk with a member of the research team by phone or Zoom or another convenient means once a month for about 1 year. These monthly contacts are generally no longer than 15 minutes and provide an opportunity for you and your family member to ask questions or just receive support from the research team for engaging in healthy behaviors.

In addition to the educational sessions and monthly conversations, we will collect data that will include questionnaires and measurements related to health. You will complete online questionnaires about such things as social support, anxiety, depression, views about health, experiences that can affect health, health behaviors, medical history and family health. You will have the option to complete the questionnaires by yourself or with assistance from research personnel by Zoom or phone. If there are difficulties completing the questionnaires using the internet, you can get in-person assistance from research staff.

The research staff will also meet with you in-person to conduct the health-related measurements that include such measures as blood pressure and height and weight. We will do a finger stick so that we can measure such health indicators as cholesterol levels and hemoglobin A1c (a measure of blood sugars) and take a saliva sample to assess nicotine exposure. We will also ask you to wear a wristband device for a short time to measure such things as your physical activity and sleep. If wearing a wristband is uncomfortable, there are other options for wearing the device.

We will collect data 3 times during the study: before the educational sessions, immediately after the sessions, and at the end of the study. Each time, it will take approximately 1 to 1½ hours to complete the questionnaires and approximately 1 hour for each in-person data collection visit. You will also need to come once after each data collection visit; these will be short visits that will last about 30 minutes.

All activities will take place during a period of approximately o12 months and require about 40 hours of your time.

If you are selected by chance to participate with a family member, you will participate in the data collection visits, the educational sessions, and the monthly phone calls with your family member.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

It is possible that there are risks associated with participating in this study. It is possible that you may become aware during the study that you are at risk for heart disease or type 2 diabetes and that this awareness may make you feel uncomfortable. If you have heart disease or diabetes, you may receive information about your disease that makes you feel uncomfortable. In this case, please feel free to contact the principal investigator, Gia Mudd-Martin, at (859) 494-7073. She is a nurse and will be glad to discuss these concerns with you. Also, if indicated, we will refer you to follow up with your medical provider or, if you do not have one, will assist you to find a medical provider for follow up.

Another potential risk is soreness, bruising, pain, infection, fainting or bleeding from the finger stick. This risk occurs occasionally. Any such reaction should be immediately reported to one of the research team members who will attend to you. If such a reaction happens after you have left the research site, please contact the investigator, Gia Mudd-Martin at 859-494-7073, and she will assist in determining the best course of action.

In addition to the risks listed above, you may experience a previously unknown risk or side effect. Any difficulty that occurs or concerns, please contact the investigator, Gia Mudd-Martin, at 859-257-4204 or the University of Kentucky Office of Research Integrity at (859)257-9428.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

During this study you will learn about how to live more healthily, that may improve your health and the health of your co-participating family member, although there is no guarantee that you will benefit from taking part in this study. Your willingness to take part may also help us to be able to better help people who are at risk for cardiovascular disease and type 2 diabetes to reduce their risks for disease.

IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

If you do not want to be in the study, there are no other choices except not to take part in the study.

WHAT WILL IT COST YOU TO PARTICIPATE?

It will not cost you anything to participate. However, you and/or your insurance company, Medicare, or Medicaid will be responsible for the costs of all care and treatment that you would normally receive for any conditions you may have. These are costs that are considered medically necessary and will be part of the care you receive even if you do not take part in this study.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

When we write about or share the results from the study, we will write about the combined information. We will keep your name and other identifying information private.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. All information we collect in hard copy form (on paper) will be stored in locked file cabinets that are in an office suite with limited access. Electronic data with identifying information will be stored on a secure server behind a secure firewall maintained by the University of Kentucky and/or on a University computer that is encrypted and password protected.

You should know that in some cases we may have to show your information to other people. For example, if we discover any life-threatening health conditions or if the results of any lab tests are extremely abnormal, we will talk to you about speaking with your health professional and if you do not have one, we will refer to one. We will then provide you with health-related information to share with the health professional so that she or he can participate in your care.

Other examples are when the law may require us to share your information with:

- a court or agencies, if you have a reportable disease/condition;
- authorities, if you report information about a child being abused;
- or if you pose a danger to yourself or someone else.

To ensure the study Is conducted properly, officials of the National Institutes of Health and the University of Kentucky may look at or copy pertinent portions of records that identify you.

We will be using certain online data collection systems. We will make every effort to safeguard your data, but as with anything online, we cannot guarantee the security of data obtained by way of the Internet. Third-party applications used in this study may have Terms of Service and Privacy policies outside of the control of the University of Kentucky.

Among web-based programs we will use is REDCap. This is a secure, web-based program to capture and store data at the University of Kentucky. We will make every effort to safeguard your data in REDCap. However, given the nature of online surveys, we cannot guarantee the security of data obtained by way of the Internet.

Regarding the use of Zoom for providing the educational sessions, we will be using the HIPAA-approved and secure University of Kentucky Zoom program for all sessions.

To help us protect your privacy, this research has a Certificate of Confidentiality. The researchers can use this Certificate to refuse to disclose information that may identify you to anyone not connected with this study, or in any legal proceedings. The exceptions to this rule are release of information:

- to the sponsor (e.g., National Institutes of Health) or agency auditing the research (e.g., THE University of Kentucky);
- about child or elder abuse, neglect, or harm to yourself or others; and
- about you if it involves a reportable disease.

This policy does not prevent you from releasing information about your own participation in this study.

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study.

If you choose to leave the study early, data collected until that point will remain in the study database and may not be removed.

The investigators conducting the study may need to remove you from the study. You may be removed from the study if:

- you are not able to follow the directions,
- we find that your participation in the study is more risk than benefit to you, or
- the agency paying for the study chooses to stop the study early for a number of scientific reasons.

ARE YOU PARTICIPATING, OR CAN YOU PARTICIPATE, IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may take part in this study if you are currently involved in another research study. It is important to let the investigator know if you are in another research study. You should discuss this with the investigator before you agree to participate in another research study while you are in this study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or if you get sick because of something that is due to the study, you should call the study investigator, Gia Mudd-Martin, at 859-494-7073. Gia Mudd-Martin will determine what type of treatment, if any, is best for you at that time. If you are experiencing any type of emergency, you should call 911 immediately.

It is important for you to understand that the University of Kentucky does not have funds set aside to pay

for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of Kentucky will not pay for any wages you may lose if you are harmed by this study. Medical costs related to your care and treatment because of study-related harm will be your responsibility. You do not give up your legal rights by signing this form.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

You will receive a $35.00 gift card upon completing data collection before the educational sessions, a $35.00 gift card upon completing data collection immediately after the educational sessions; and a $50.00 gift certificate upon completing data collection at the end of the study. The total amount you will receive in gift cards is $120.00 if you complete the entire study.

With a few exceptions, study payments are considered taxable income reportable to the Internal Revenue Service (IRS). A form 1099 will be sent to you if your total payments for research participation are $600 or more in a calendar year.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

We will tell you if we learn new information that could change your mind about staying in the study. We may ask you to sign a new consent form if the information is provided to you after you have joined the study.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE RESEARCH TESTS?

Generally, tests done for research purposes are not meant to provide clinical information. We will provide you with information about some of your risk factors for heart disease and type 2 diabetes but these are NOT clinical tests and are only general indicators of your risk for these diseases.

There is a possibility that during a research project, we could discover something that could affect your health. If this occurs, we will encourage you to visit your healthcare provider. If you do not have a healthcare provider, we will assist you to access one.

WILL WE CONTACT YOU WITH INFORMATION ABOUT PARTICIPATING IN FUTURE STUDIES?

The research staff would like to contact you in the future with information about participating in additional studies. If so, it will be limited to 3 times per year.

Do you give your permission to be contacted in the future by Gia Mudd-Martin or a member of the research team regarding your willingness to participate in future research studies?

☐ **Yes**

☐ **No**

Please type in your initials to indicate that you give your permission to be contacted in the future: _____

WHAT ELSE DO YOU NEED TO KNOW?

If you volunteer to take part in this study, you will be one of about 540 people to do so.

The National Institutes of Health is providing financial support and/or material for this study.

WILL YOUR INFORMATION (OR SPECIMEN SAMPLES) BE USED FOR FUTURE RESEARCH?

All identifiable information (e.g., your name or date of birth) will be removed from the information or samples collected in this study. This means that no link or code to your identity will be kept. After all identifiers have been removed, the information or samples may be used for future research or shared with other researchers without your additional informed consent. Once you give your permission to have your de-identified information or samples stored, they will be available indefinitely and cannot be

INFORMED CONSENT SIGNATURES

This consent includes the following:

- **Key Information Page**
- **Detailed Consent**

You will receive a copy of this consent form after it has been signed.

Please indicate if you are or are not willing to volunteer for this study.

☐ **Yes, I am willing to volunteer for this study.**

☐ **No, I am NOT willing to volunteer for this study.**

Signature of research subject: _____

Date: _____

Printed name of research subject: _____

Printed name of authorized person

obtaining informed consent: _____

Date: _____

Signature of the Investigator or the Project Director: _____