Document Coversheet

Study Title: A Randomized Controlled Trial to Examine a Healthy Lifestyle Intervention With Families to Prevent Cardiovascular Disease and Type 2 Diabetes in Hispanics/Latinos

Institution/Site:	University of Kentucky
Document (Approval/Update) Date:	2/9/2016
NCT Number:	NCT03196024
IRB Number	48332
Coversheet created:	2/21/2024

For ORI Use Only:

Consent to Participate in a Research Study

TITLE OF THE STUDY: *Corazón de la Familia* (Heart of the Family)WHY

ARE YOU BEING INVITED TO TAKE PART IN THIS RESEARCH?

You are being invited to take part in a research study about prevention of type 2 diabetes and heart disease. You are being invited to take part in this research study because you are at risk for type 2 diabetes or heart disease or because you are a family member of someone who is at risk for type 2 diabetes or heart disease. If you volunteer to take part in this study, you will be one of about 440 people to do so.

WHO IS DOING THE STUDY?

The person in charge of this study is Gia Mudd-Martin, PhD, RN of the University of Kentucky, Collegeof Nursing. There may be other people on the research team assisting at different times during the study.

WHAT IS THE PURPOSE OF THIS STUDY?

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.

ARE THERE REASONS WHY YOU SHOULD NOT TAKE PART IN THIS STUDY?

Reasons you should not participate in this study are if you are not Latino/Hispanic; if you do not speakand understand Spanish; if you are less than 18 years of age; or if you do not have a family member who will also participate in the study and who lives in the same house with you or near where you live (within 25 miles). The educational program for the study is provided online, therefore if you do not have access to internet service, you should not participate. Other reasons you should not participate are if you have a medical condition that limits your physical activity or are on a special diet for a medical condition or if you have a serious psychiatric disorder such as schizophrenia. If you are pregnant or planning to become pregnant within the next 12 months you should not participate since healthy behaviors for women whoare pregnant are different than behaviors we address in this study. Finally, you should not participate ifyou do not want to participate in the study for 12 months.

ONLY for the member of the family who is at risk for type 2 diabetes or heart disease:

You should also not participate if you have had a heart attack or a stroke, have heart failure, or if youhave had a physician tell you that you have type 1 or type 2 diabetes or you have been prescribed medications to control your diabetes.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

Some research procedures will be conducted at the University of Kentucky College of Nursing RICH Heart Research Center, 2200 Regency Rd., Lexington 40503-2302, or in a community center or other convenient location. Other study activities will be conducted online using Zoom. The study will last for approximately one year.

WHAT WILL YOU BE ASKED TO DO?

If you agree to participate in this study, after consenting to participate you will be asked to fill out several questionnaires that will take about 1½ hours to complete. After filling out the questionnaires, you and your family member will be invited to participate in one of two groups. You and your family member will have a 1 out of 2 chance, or a 50% chance, of being selected to participate in Group 1 or in Group 2. A member of the research staff will contact you to let you know if you will be participating inGroup 1 or Group 2 in about a week.

If you and your family member are selected by chance to participate in Group 1, the family member who is at risk for type 2 diabetes or cardiovascular disease will be asked to complete data collection at3 points during the study, to participate in education sessions that will be provided over Zoom, and to have monthly follow up conversations with research personnel. All activities will take place over about a period of 12 months and will require a total of about 40 hours of time.

Each data collection time will take about 2 to 2½ hours. During each data collection time, the family member who is at risk for type 2 diabetes or cardiovascular disease will be asked to fill out questionnaires about such things as social support, anxiety, depression, views about health, experiences of discrimination or other life experiences that might affect health, how often you follow health recommendations, your health behaviors, eating patterns, medical history and family health. Research personnel will also conduct health checks such as measuring your blood pressure and your height and weight. You will also be asked for a blood and saliva sample so that we can measure such health indicators as cholesterol levels, hemoglobin A1c (a measure of blood sugars), C-reactive protein (a measure of inflammation), and indicators of health behaviors such as smoking and diet. You will also be asked to wear a wristband device for approximately 1 week to measure your physical activity and sleep. If wearing a wristband is uncomfortable, there are other options for wearing the device. For the questionnaires, you will have the option to complete these online by yourself, over Zoom with assistance from one of the research staff, or in-person with or without the assistance of research staff. All other measurements will be in-person.

The first data collection time will be before the group education sessions begin. After the data collection, you will be asked to attend 8 group education sessions. The sessions will be held aboutonce a week for 8 weeks with each session lasting approximately 1 to 1½ hours. Sessions may be audio or video recorded. During the sessions you will complete activity logs and questionnaires about your risks and your family risks for heart disease or diabetes. Once the 8 sessions are completed, you will be asked to complete the second data collection visit. After this, you will be asked to talk with a member of the research team by phone or by email or through another convenient means once a month for approximately 15 minutes for about 10 months. After this will be the final data collection visit. All in-person data collection will take place in a location convenient to you.

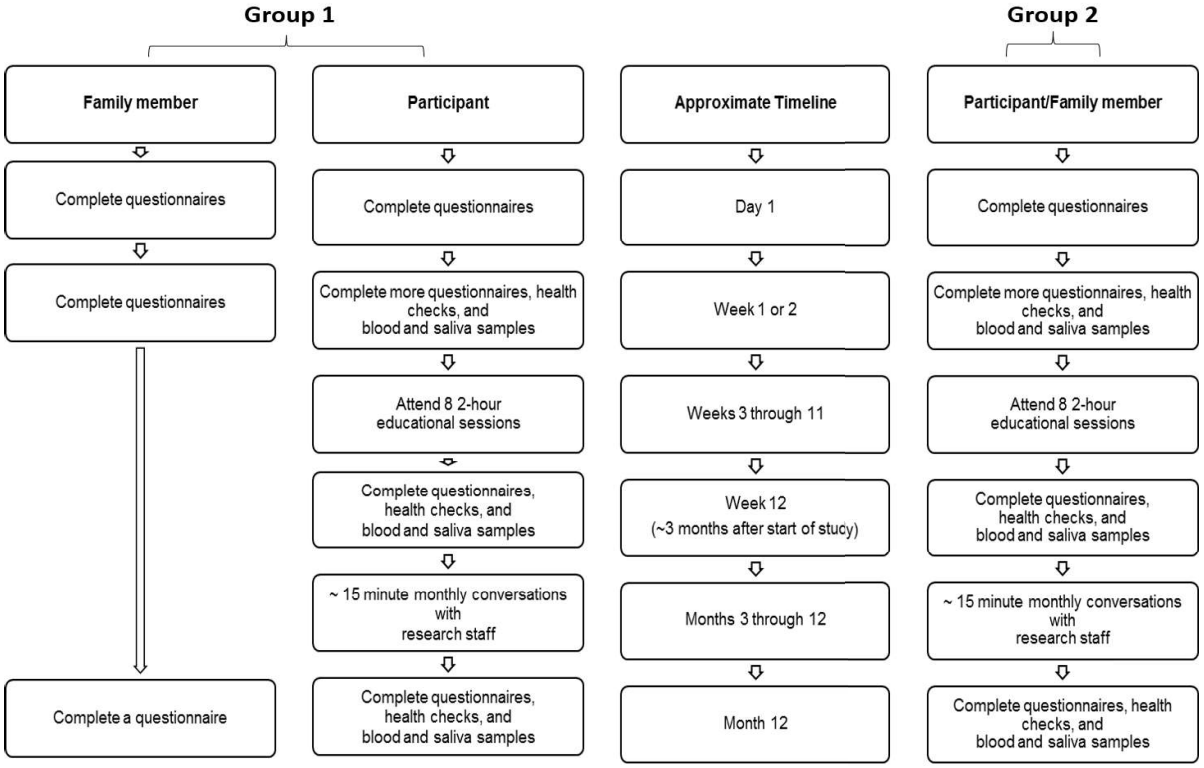
If you are selected by chance to participate in Group 1 and are the family accompanying the person with type 2 diabetes or cardiovascular disease risk, , we will ask you to complete data collection at 2 times: once at the beginning of the study and once at the end of the study (in approximately one year). Each time you will be asked to complete questionnaires that are similar to those your family member will complete. It will take about 2 hours to complete the questionnaires at each point. For the questionnaires, you will have the option to complete these online by yourself, over Zoom or by phone with assistance from one of the research staff, or in-person with or without the assistance of research staff. You will be asked to participate voluntarily in the study for approximately 1 year for a total of approximately 4 hours after today's visit.

If you and your family member are selected by chance to participate in Group 2, you and your family member will be asked to complete data collection at 3 points during the study, to participate in group education sessions provided on Zoom, and to have follow up conversations with research personnel. All activities will take place over about a period of 12 months and will require a total of about 40 hours of time.

Each data collection visit will take about 2 to 2½ hours and will include filling out questionnaires about such things as social support, anxiety, depression, views about health, experiences of discrimination orother life experiences that might affect health, how often you follow health recommendations, your health behaviors, eating patterns, medical history and family health. Research personnel will also conduct health checks such as measuring your blood pressure and your height and weight. You will also be asked for a blood and saliva sample so that we can measure such health indicators as cholesterol levels, hemoglobin A1c (a measure of blood sugars), C-reactive protein (a measure of inflammation), and indicators of health behaviors such as smoking and diet. You will also be asked to wear a wristband device for approximately 1 week to measure your physical activity and sleep. If wearing a wristband is uncomfortable, there are other options for wearing the device. For the questionnaires, you will have the option to complete these online by yourself, over Zoom with assistance from one of the research staff, or in-person with or without the assistance of research staff. All other measurements will be in-person.

The first data collection point will be before the group education sessions begin. After the data collection visit, you will be asked to attend 8 group education sessions. The sessions will be held about once a week for 8 weeks with each session lasting approximately 2 hours. Sessions may be audio or video recorded. During the sessions you will complete activity logs and questionnaires about your risk and your family risk for heart disease or diabetes. Once the 8 sessions are completed, you will be asked to complete the second data collection point. After this, you will be asked to talk with a member ofthe research team by phone or by email or through another convenient means once a month for approximately 15 minutes for about 10 months. After this will be the final data collection point.

Depending on which you group you are randomly selected to participate in, your participation will looklike one or the other of the following:



Although a woman who is pregnant or who plans to become pregnant during the next 12 months should not participate in this study because the education we will provide is not appropriate for women who are pregnant, it is possible that pregnancy may occur during the study. Participating in the study has the potential to improve health. However, your dietary and physical activity needs will be different during pregnancy than what is taught during the educational sessions. Therefore, if you become pregnant while participating in the study, please call the principal investigator, Gia Mudd-Martin, as soon as possible at: 859-494-7073 to let her know. If you are in the group that is completing only questionnaires, your pregnancy will in no way affect your participation in the study. If you are participating in the group that receives education, we will decide the best course of action depending on how far along in the study you are and other factors. It is possible that we will decide that withdrawing from the study will be best for you and the health of your baby. Regardless of which group you are participating in, in addition to advising the principal investigator, Gia Mudd-Martin, please be sure to seek appropriate health care attention for your pregnancy.

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 cardiovascular disease or type 2 diabetes or another disease and that this awareness may make you feel uncomfortable. In this case, please feelfree to contact the principal investigator, Gia Mudd-Martin, at (859) 494-7073. She is a nurse and willbe 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 blood sampling. This risk occurs occasionally. Any such reaction should be immediatelyreported to the researchers 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?

There is no guarantee that you will get any benefit from taking part in this study. Your willingness to take part, however, may, in the future, help healthcare providers better understand and/or treat otherswho are at risk for cardiovascular disease or type 2 diabetes.

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 benefits or rights you would normally have if you choose not to volunteer. You can stop at anytime during the study and still keep the benefits and rights you had before volunteering.

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?

All educational sessions and study tests will be conducted free of charge.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

We will make every effort to keep private all research records that identify you to the extent allowed bylaw.

Your information will be combined with information from other people taking part in the study.
When we write about the study to share it with others, we will write about the combined information we have gathered. You will not be personally identified in these written materials. We may publish theresults of this study; however, 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 will be stored in locked file cabinets, in offices or in a suite with limited access. All information kept on computers is encrypted andpassword protected.

You should know, however, that there are some circumstances in which we may have to show your information to other people. For example, if we discover any life-threatening health conditions or that the results of any lab tests are extremely abnormal, we will talk to you about speaking with your doctor and if you do not have one, we will help you get one. We will then share the health-related informationwith the doctor of your choice so that she or he can participate in your care. Other examples include cases in which the law may require us to show information to a court or to tell authorities if your report information about a child being abused or if you post a danger to yourself or someone else. Officials ofthe National Institutes of Health or the University of Kentucky may also look at or copy pertinent portionof records that identify you.

It is possible that many of the questionnaires you will fill out during the study will be completed using a computer with your responses entered directly into a system called REDCap. It is also possible that wewill enter data we gather during the health checks and the results from the blood and saliva tests into the REDCap system. Additionally, one questionnaire used in the study to help us better understand your dietary habits is completed using an online format that is maintained through a company that specializes in analyzing diet information.

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.

Please be aware, while we make every effort to safeguard your data once received on our servers, given the nature of online questionnaires, as with anything involving the Internet, we can never guarantee the confidentiality of the data while still en route to our systems. It is also possible that the raw data collected through the company that specializes in analyzing diet information for research purposes may be used for marketing or reporting purposes by the online company after the research isconcluded, depending on the company's Terms of Service and Privacy policies.

CAN YOUR TAKING PART IN THE STUDY END EARLY?

If you decide to take part in the study you still have the right to decide at any time that you no longerwant to continue. You will not be treated differently if you decide to stop taking part in the study.

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

You may be able to take part in this study if you are currently involved in another research study. It is important to let the investigator of this study know if you are in another research study. If the investigator is certain that your participation in the other study will not affect your participation in this study, you will be able to participate in this study. You should also discuss with the investigator of thisstudy before you agree to participate in another research study while you are enrolled 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, immediately and they can 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 youare harmed by this study. The medical costs related to your care and treatment because of research 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?

If you participate in this study, we will give you a $35.00 gift card for the first and second data collection points and a $50.00 gift card for the third data collection points. The total amount you will receivein gift cards is $120.00 if you complete the entire study.

If you are a family member in Group 1, you will participate only in completing questionnaires at the beginning and end of the study and you will receive a $35.00 gift card for completing questionnaires at the beginning of the study and a $35.00 gift card for completing the questionnaires at the end of the study. The total amount you will receive in gift cards is $70.00 if you complete the entire study.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS, CONCERNS, OR COMPLAINTS?

Before you decide whether to accept this invitation to take part in the study, please ask any questions that might come to mind now. Later, if you have questions, suggestions, concerns, or complaints aboutthe study, you can contact the investigator, Gia Mudd-Martin at 859-257-4204. If you have any questions about your rights as a volunteer in this research, contact the staff in the Office of Research Integrity at the University of Kentucky between the business hours of 8am and 5pm EST, Mon-Fri at 859-257-9428 or toll free at 1-866-400-9428. We will give you a signed copy of this consent form to take with you.

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

If the researcher learns of new information in regards to this study, and it might change your willingnessto stay in this study, the information will be provided to you. You may be asked to sign a new informed consent form if the information is provided to you after you have joined the study.

POTENTIAL FOR US TO CONTACT RESEARCH PARTICIPANTS FOR FUTURE STUDIES

Do you give your permission to be contacted in the future by the investigator of this study, Gia Mudd- Martin, regarding your willingness to participate in future research studies about how to prevent, detect,or treat cardiovascular disease or diabetes?

Yes_____ No_____ _____ Your Initials

Do you give your permission to be contacted in the future by the investigator of this study, Gia Mudd-Martin, regarding your willingness to participate in future research studies about cancer or cognitive function diseases such as Alzheimer's, or other similar chronic diseases?

Yes_____ No_____ _____ Your Initials

WHAT ELSE DO YOU NEED TO KNOW?

There is a possibility that the data and samples collected from you may be shared with other investigators in the future. If that is the case the data and samples will not contain information that canidentify you unless you give your consent/authorization or the UK Institutional Review Board (IRB) approves the research. The IRB is a committee that reviews ethical issues, according to federal, stateand local regulations on research

with human subjects, to make sure the study complies with these before approval of a research study is issued. A description of this clinical trial will be available on 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 website at any time.
The National Institutes of Health/National Institute of Nursing Research is providing financial support forthis study.

Signature of person agreeing to take part in the study Date

_____ _____

Printed name of person agreeing to take part in the study

_____

Name of authorized person obtaining informed consent Date

_____ _____

Signature of Principal Investigator or Sub/Co-Investigator Date

_____

Please indicate if you would like to participate in a sub-study of this research protocol.

GENETIC SUB-STUDY: This sub-study involves the collection of a saliva sample to explore genes thatmight impact cardiovascular disease or type 2 diabetes risk or risk for other diseases. You will be compensated with a $10 Walmart gift card for providing the saliva sample at the same time you are participating in other parts of the study or are providing other data or samples for the main study. Your decision whether or not to participate in the sub-study in no way affects the care that you will receive in the main research study.

WHERE WILL INFORMATION OR SPECIMEN SAMPLES BE STORED AND FOR HOW LONG?
The saliva sample you provide will be securely stored at the College of Nursing Regency Research Center until it can be transferred to a secure lab at Sanders-Brown of the University of Kentucky Healthcare Center where your DNA, or genetic information, will be isolated from the saliva. Your DNAwill be stored at the Sanders-Brown lab until the sample is exhausted or can no longer be used for research.

WHAT ELSE DO YOU NEED TO KNOW?
There is a possibility that the data and samples collected from you may be shared with other investigators in the future and may be used to investigate genes associated with diseases other thanwith cardiovascular disease and type 2 diabetes. If that is the case the data and samples will not contain information that can identify you unless you give your consent/authorization or the UKInstitutional Review Board (IRB) approves the research.

ARE THERE RISKS FROM ALLOWING YOUR INFORMATION OR SPECIMEN SAMPLES TO BESTORED FOR FUTURE RESEARCH?

Include if genetic or genomic testing is possible:

Even without your name or identifiers, genetic information is unique to you making it possible for someone

to trace it back to you. The results of genetic research apply to both you and your family members. Genetic information used improperly to discriminate or support negative stereotypes could cause you or your family distress. There is a federal law called the Genetic Information Nondiscrimination Act (GINA). Generally, GINA makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. Be aware that GINA does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. It also does not prohibit discrimination on the basis ofan already known genetic disease.

Unknown:

There may be risks that at this time are unknown. As technology advances, there may be new ways oflinking information back to you that we cannot foresee now.

☐ Yes, I would like to participate in the sub-study and provide a saliva sample.

Initials _____

☐ No, I would not like to participate in the sub-study and will not provide a saliva sample.

Initials _____