Collaborate and Leverage Evidence in an African American Rural Network (Co-LEARN): Implementation of Heart Matters Evidence-based Program

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University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants

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IRB Study #: 21-1366
Title of Study: Collaborate and Leverage Evidence in an African American Rural Network (Co-LEARN): Implementation of *Heart Matters* Evidence-based Program
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CONCISE SUMMARY

Study Purpose: We want to see if a healthy lifestyle program called *Heart Matters* helps improve heart health for African Americans in rural areas. This study will help us improve heart health in rural communities.

Participation: You would be part of this study for about 12 months, during which you would participate in a heart health program called *Heart Matters*.

Heart Matters includes 26 group and 7 individual sessions aimed at helping you eat healthily, be more physically active, lose weight, and lower your blood pressure. Each group session will last 90 minutes and each individual session will last 30-to-60 minutes.

You would also be asked to complete surveys and provide information about your health at 3 time points: today, 6 months from now, and 12 months from now. Data collection at each of these 3 timepoints will last about 30-to-60 minutes.

The research team would periodically email, call, and/or text you to share information about the study and send you surveys.

You might feel uncomfortable sharing personal information in this study. You might also help your community, learn more about taking care of your heart, and improve your health.

What are some general things you should know about research studies?

You are being asked to join a research study. Joining this study is optional. You can decide not to join, or you can leave the study at any time without penalty. Deciding not to be in the study or leaving the study before it ends will not affect your relationship with the researcher, your health care provider, or the University of North Carolina (UNC) at Chapel Hill. If you are sick, you do not have to join the study to get medical care.

Research studies help us learn new things. This new information might help people in the future. You might directly benefit from being in the research study. There are also risks to being in research studies.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will receive a copy of this consent form. You should ask the researcher named above, or staff members who assist them, any questions you have about this study at any time.

What is the purpose of this study?

This study's purpose is to see if a healthy lifestyle program called *Heart Matters* improves heart health for African American adults in rural, eastern North Carolina (NC). We are inviting you to the study because you are an African American adult living in rural, eastern NC and because you have at least one heart disease risk factor. Examples of heart disease risk factors that people in this study might have are pre-diabetes, diabetes, high blood pressure, obesity, family history of early heart disease, or a past heart disease diagnosis.

Are there any reasons you should not be in this study?

You should not be in this study if you have active or unstable heart disease. If you are unsure, please check with your medical provider before joining this study.

How many people will take part in this study?

About 334 adults in rural, eastern NC will take part in this study.

How long will your part in this study last?

If you choose to join this study, you would participate for 12 months.

What will happen if you take part in the study?

In this study, you would be enrolled in a 12-month long *Heart Matters* program. This program includes 26 group and 7 individual sessions. You would also be asked to complete surveys about your beliefs and past experiences. Additionally, you would be asked to share information about your diet, physical activity, and stress. A registered nurse would measure your weight, height, blood pressure, and waist circumference. This nurse would also prick your finger to measure how much sugar, triglycerides, and cholesterol are in your blood. Surveys and health information will be collected at 3 time points: today, 6 months from now, and 12 months from now.

Participating in *Heart Matters* is voluntary. You can choose to stop attending the *Heart Matters* sessions at any time. You can be part of the study even if you cannot attend all sessions. You can also choose not to answer a survey question for any reason or to not participate in body measurements or finger pricks.

Program facilitators will periodically email, call, and/or text you to share information related to the program.

What are the possible benefits from being in this study?

Research is designed to learn new things. Joining in this study might benefit your community. You might learn more about taking care of your heart and improve your health.

What are the possible risks or discomforts involved from being in this study?

You might be uncomfortable when sharing your thoughts during group sessions. You might also feel uncomfortable when sharing your personal and medical information to a registered nurse, including having your weight and blood pressure measured. Lastly, you may feel uncomfortable during the finger prick to measure your A1C (blood sugar), triglycerides, and cholesterol levels.

The person you speak to about joining this study will inform you that your participation is optional and that you do not have to answer any questions or provide any information that would make you uncomfortable.

We will tell all participants that comments made during group sessions should be kept private, but participants might repeat comments outside of the group.

You can leave the study at any time without penalty.

What if we learn about new findings or information during the study?
We will tell you if we learn new information that might affect whether you want to continue being in the study.

How will information about you be protected?
Everyone working on this study has completed training on privacy and confidentiality, HIPAA, and human subjects' protection to keep your information private and safe. Only the people working on the study will see your information, and they will use secure, password-protected devices. Any paper records will be kept in locked files at the Center for Health Equity Research at UNC-Chapel Hill. To protect your identity, your information will be coded. This means your name and other private details will not be used in any reports or publications. Instead, a special code will be used. Only approved research team members will have the key to this code. Your information might be used in future research without us asking you again, but it will not have your name on it.

We will do everything we can to keep your information private. However, very rarely, the law might require us to share your records, including personal information. If this happens, UNC-Chapel Hill will try to protect your privacy as much as possible. Sometimes, people from the University, research sponsors, or government agencies (like the National Institutes of Health) might look at your information to make sure everything is done correctly and safely.

What is a Certificate of Confidentiality?
This research is covered by a Certificate of Confidentiality. This means the researchers cannot share information that could identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration.

The Certificate does not stop the researchers from sharing information required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or

benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research participants or for any purpose you have agreed to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily sharing information about yourself or your involvement in this research. If you give written permission to an insurer, employer, or someone else to get your research information, the researchers cannot use the Certificate to keep your information private.

Will you receive results from research involving your clinical data?
Your health information will not go into your medical record. Your information might be used to make money, but you would not get paid for this.

This study's results might be published in reports and academic journals that people can read. Your information will be kept confidential, and your name will never appear in any publication.

What will happen if you are injured by this research?
If you think you have been injured because of taking part in this study, tell the contact on the front page of this document as soon as possible. You can provide this information in-person or call them at the phone number listed in this consent form. The study team can help you get the care you need. If you are injured because of this study, UNC-Chapel Hill will provide necessary medical treatment. You can also see another doctor for treatment. If you have an urgent injury, call 911.

UNC-Chapel Hill has not set aside money to pay you for any such injuries, illnesses or reactions, or for the related medical care. Any medical expenses would be billed to you or your insurance company. You might be responsible for any co-payments and your insurance might not cover the costs of study-related injuries.

By signing this form, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.

What if you want to stop before your part in the study is complete?
You can leave this study at any time, without penalty. The researchers also have the right to stop your participation at any time. If you leave the study, all the information collected up to that point will be kept, but no new information will be collected unless you give written permission to do this at the time of your withdrawal.

Will you receive anything for being in this study?
You will receive $40 in cash for each of the 3 data collection timepoints in this research for a total of $120.

Will it cost you anything to be in this study?
It will not cost you anything to be in this study.

Who is sponsoring this study?
This research team is receiving money from the National Heart, Lung, and Blood Institute to conduct

this study. The researchers do not have a direct financial interest with the sponsor or in the results of the study.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you have about this research. If you have questions about the study (including payments, complaints, concerns, or if a research-related injury occurs), you should contact the researchers listed on the first page of this form.

A description of this clinical trial will be available on www.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.

What if you have questions about your rights as a research participant?
A committee that works to protect your rights and welfare reviews all research on human participants. If you have questions or concerns about your rights as a research participant, or if you would like to get information or offer input, please call the Institutional Review Board at 919-966-3113 or email IRB_subjects@unc.edu.

Consent Addendum for Unencrypted Communication
The study team will message you by email or text, however you may say "no" to receiving these messages and still participate in this study. These messages may include appointment reminders, requests to contact the study team, or reminders to complete study activities. The study team will ask you to provide your preferred email address or cell phone number. These messages may be sent by the study team's personal electronic devices. If you respond to the message, your message may be received by a study team member's personal device. This means there is the risk your information could be shared beyond you and the study team.

If you wish to stop receiving unprotected communication from the study team or have lost access to your device or email account, please notify the study team using the study contact information on the first page of this consent form.

_____ Yes, I consent to the study team sending unprotected messages

Participant cell-phone number: _____

Participant e-mail address: _____

_____ No, I do not consent to receive un-protected messages. I wish to receive messages through secure email.

Participant cell-phone number: _____

Participant e-mail address: _____

_____ No, I do not want to receive messages. Please call me by telephone

Participant cell-phone number: _____

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____ _____

Signature of Research Participant Date

_____

Printed Name of Research Participant

_____ _____

Signature of Research Team Member Obtaining Consent Date

_____

Printed Name of Research Team Member Obtaining

_____ _____

Signature of Witness if applicable; e.g. literacy issues, visually impaired, physically unable to sign, witness/interpreter for non-English speaking participants using the short form) Date

_____

Printed Name of Witness