Title: Reducing Chronic Disease Risk among Rural Adults

NCT Number: NCT05611580 Unique Protocol ID: STUDY00003258

Document Date Consent Form: 7/22/2022

Permission to Take Part in a Human Research Study

Title of Study: Reducing Chronic Disease Risk among Rural Adults (Phase II)

Investigator: Laurie Abbott PhD, RN, DipACLM, PHNA-BC

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you are an adult living in a rural area who has expressed interest in learning more about possibly reducing your risk for developing a chronic disease or preventing worsening of an existing chronic disease.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

Chronic diseases such as heart disease, diabetes, and cancer contribute to increased death, disability, and health care costs in the United States. People living in rural areas are more likely to be diagnosed with a chronic disease they are managing at home. However, the risk for getting or worsening a chronic disease can be reduced. The purpose of this research is to test a health promotion and disease risk reduction program to among people living in rural areas to examine its effectiveness. We would also like to find out what the perceptions of participants are about the program and ways that information is collected. The information we find out can possibly benefit other people living in rural areas by assisting with decisions about developing and providing rural programs.

How long will the research last and what will I need to do?

If you decide to participate, we expect that you will be in this research study for a total 10 weeks. You will be asked to fill out surveys before the program sessions begin. The program will be provided in one session per week over six weeks. Then, you will be asked to fill out surveys when the six-week program ends and then again four weeks after the program ends. Some people will be asked to provide information through an interview with a research team member which will occur following the second set of surveys. More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

Is there any way being in this study could be bad for me?

A possible risk is that answering question will cause you emotional distress, but you have the right to refuse answering any question at any time or stop the survey altogether. There is also a slight chance that information you share could become known to another person. Every effort will be used to keep your information private, and only the person directly involved in the program will be allowed to see your answers on the study questionnaires. More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

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Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include learning about ways to reduce the risk factors for chronic diseases that can be changed to improve health.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate or not to participate. Your alternative to participating in this research study is to not participate.

Detailed Information: The following is more detailed information about this study:

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 850-322-8739 to speak directly with Dr. Laurie Abbott.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at 850-644-7900 or humansubjects@fsu.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team or want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

How many people will be studied?

We expect about 72-80 people will be in this second phase of the research study out of expected number of people (approximately 80-95) that will be recruited to participate in both study phases.

What happens if I say "yes" to being in this research?

You will be assigned into one of two groups (intervention and control) that will be chosen by chance, like flipping a coin. Neither you nor the research team will choose what group you are in. You will have an equal chance of being assigned to one group or the other. Participants in the "control group" will complete three sets of surveys (at the beginning of study participation, six weeks later, and then four weeks from that time). You can complete the surveys on your own by accessing them online, or you can decide to meet with a research assistant by telephone or online via Zoom to help you with completing the surveys. Participants in both groups will not need to travel to complete any part of the study because the study activities can be done at home. Participants in the "intervention group" will be asked to participate in a health program that has six sessions altogether. There will be one session per week that will last approximately ninety minutes to two hours. The six weekly sessions will be offered by a registered nurse online in a Zoom web-based format that participants will access by using their phones or home computers. The sessions will have groups of participants, and each participant can have cameras on or off and interact with others in the sessions or not, depending on preference. There will be three times that intervention group participants will be asked to complete surveys which will be before the sessions start, after the sessions are done, and then four weeks after the sessions are done. You can complete the surveys on your own by accessing them online, or you can decide to meet with a research assistant by telephone or online via Zoom to help you with completing the surveys. You may also be asked to participate in an interview with a research team member that will ask questions about your perceptions of the program, data collection methods, and processes. You will receive electronic reminders about the dates and times for study activities.

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What are my responsibilities if I take part in this research?

If you take part in this research and are in the "control group", you will be responsible to complete the surveys that will be collected at the start and end of the program and then four weeks later.

If you take part in this research and are in the "intervention group", you will be responsible to attend the six weekly sessions and complete the surveys that will be collected at the start and end of the program and then four weeks later. You may also be asked to participate in an interview.

What happens if I say "yes," but I change my mind later?

You can leave the research study at any time, and it will not be held against you.

Is there any way being in this study could be bad for me? (Detailed Risks)

The foreseeable risks and discomforts to you from participating in this study are minimal. A risk is that if you share information with other participants during sessions, they may not keep your information confidential. You may experience feelings of anxiety or sadness when answering survey questions about your chronic disease risk or the realities of living with a chronic disease. If this occurs, you can stop answering any questions that make you feel uncomfortable. Although only the research team will be allowed to see your answers on the questionnaires, there is a slight chance that information you share could become known to another person. Every effort will be to keep your information private.

What happens to the information collected for the research?

The data you provide will be entered into a statistical software system and analyzed with the information from other participants. There will be no identifying links between your information and your identity. Statistical analysis will facilitate conclusions and comparisons. The records of this study will be kept private and confidential to the extent permitted by law. In any sort of report that might be published, we will not include any information that will make it possible to identify an individual. Efforts will be made to limit the use and disclosure of your personal information that you share to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization. If identifiers are removed from your identifiable private information that are collected during this research, that information could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent. We may publish the results of this research. However, we will keep your name and other identifying information confidential to the extent allowed by law.

What else do I need to know?

If you agree to take part in this research study, you will be provided with gift card for your time and effort if you complete the study. $50 in gift cards will be given after completion of each of the data collection points. If you do not complete data collection or cease participation in the study, you will not continue to receive the gift cards.

Statement of Consent

Research staff have read the above information to me, or I have chosen to read it myself. I have sought answers to any questions that I have. I understand that I will be provided with a copy of this form.
Completion of the initial consent question at the beginning of the baseline surveys serve as my consent to participate in this research study.