

Healthy Living Anson

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Consent to Participate in a Research Study

IRB Study # 24-2854

Title of Study: Healthy Living Anson

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Funding Source and/or Sponsor: Westat, Inc.

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CONCISE SUMMARY

The purpose of this research study, Healthy Living Anson, is to better understand how healthy food can help improve the health of people with common chronic diseases like high blood pressure or risk factors like high cholesterol.

As a participant, you will be asked to enroll in a two-part study. First, you will be assigned for 4 months to either a healthy food and nutrition education group or a physical activity coaching group. After a 1–2-month break, you will be placed in the other group for another 4 months. The total program will last 9-10 months.

You will be asked to complete a survey and come in-person to a central location in Anson County 3 times to provide measurements of your height, weight, blood pressure, and skin carotenoids (a simple finger scan of how many fruits and vegetables you eat). You will receive a \$20 gift card after each survey and measurement visit, totaling \$60.

You will receive education and guidance from a Community Health Worker during 2 in-person group sessions and 2-3 telephone/Zoom calls (your choice) when in the food and physical activity groups. While in the physical activity group, you will also receive up to 3-4 text messages a week encouraging you to be active.

In the food group, a benefit to you will be the receipt of frozen meals and produce boxes worth approximately \$680. The meals will be made according to the “Med-South” diet which is food based on the Mediterranean diet that has been shown to be beneficial in improving health and is prepared with the familiar flavors of southern cooking. Your frozen meals and/or produce box will be delivered to you or you may pick them up.

In the physical activity group, you will attend physical activity education classes with demonstrations. The exercises aim to meet you where you are and not push you past your physical health limits such as walking, stretching, chair exercises, stretchy bands, and light weights. The Community Health Worker will send you up to 3-4 text messages a week encouraging you and offering suggestions on how to be more physically active. You will receive a towel, exercise band, a water bottle, and a list of local physical activity resources by participating.

Possible risks associated with this study include soreness or mild injury from engaging in physical activity and learning about your blood pressure and weight.

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

What are some general things you should know about research studies? You are being asked to take part in a research study. Joining the study is voluntary. You may choose not to participate, or you may drop out of the study, for any reason, without penalty. 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 study.

What is the purpose of this study? The purpose of this study is to better understand how healthy food can help improve the health of people with common chronic illnesses like high blood pressure or risk factors like high cholesterol.

How many people will take part in this study? Approximately 120 people

How long will your part in this study last? Not including travel, the estimated time for all study activities will be about 16 hours over 9-10 months. This includes both in-person measurement/classes and phone calls from your Community Health Worker.

What will happen if you take part in the study? You will complete a survey and come in-person to a central location in Anson County 3 times for measures of your height, weight, blood pressure, and skin carotenoids. Carotenoids are nutrients that make fruits and vegetables the color they are. When you eat fruits and vegetables those nutrients can be detected in your skin, and we can measure the amount of nutrients you have using an LED light to scan the skin on your finger.

The study staff will randomly assign you (like flipping a coin) to either Group 1 or Group 2. Group 1 will receive the food part for 4 months and then switch into the physical activity portion of the study for 4 months. Group 2 will start with the physical activity portion of the program for the first 4 months, then move to the food part of the program.

You will be assigned a Community Health Worker who will share information with you on healthy living. Community Health Workers are public-health professionals that promote health and well-being in communities. In both parts of the study, you will meet in-person for a one-and-a-half-hour group nutrition or physical activity education class twice and receive phone calls/Zoom meetings (your choice) focused on nutrition/physical activity counseling twice. The calls offer time to talk through ways to improve your nutrition/physical activity and ask questions, as well as discuss goals and create plans.

In the food part of the study, you will receive 5 frozen meals a week for 2 months, then receive 3 frozen meals a week along with a box of produce at least once a month for the next 2 months. The frozen meals and/or produce box will be delivered to you or you may pick them up. In the physical activity part of the study, you will receive counseling and class sessions focused on physical activity along with up to 3-4 text messages a week with motivational reminders and suggestions on how to be more physically active from the Community Health Worker.

Including the in-person measurements and the in-person group sessions, you will need to travel to a central Anson County location 7 times during the study.

What are the possible benefits from being in this study? Research is designed to benefit society by gaining new knowledge. The possible benefits to you personally from being in this study may be a nutritious diet that may improve your overall health as well as gaining new knowledge about nutrition and physical activity.

What are the possible risks or discomforts involved from being in this study? We anticipate few risks from participating in this study. We collect very limited sensitive information, however there is a chance for loss of privacy as research team members will have access to the data. As stated in the section below, we will do all we can to make sure this does not happen. Your name and contact details will not be stored with the data. Other possible risks may include psychological distress in learning about your health status (e.g. blood pressure, etc.). You may be slightly sore after walking or doing chair exercises, and there is a small chance you can sprain an ankle or experience muscle strain. The diet and physical activity interventions are both appropriate for pregnancy with no risk for the baby. If you are pregnant, you can choose not to participate in any physical activity that is uncomfortable at your stage of pregnancy.

What if we learn about new findings or information during the study? The research team will inform you of any new information that might affect your willingness to continue your participation.

How will your privacy be protected? You will be assigned a study ID number so that your information will not be connected directly to your name. We will secure this information on a private and secure computer accessible by only the principal investigator. Participants will not be identified in any report or publication about this study. We will use only de-identified data (no names or contact information) from this study in future research; Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information.

This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information, documents or biospecimens that may 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 personnel of 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 (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as 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 subjects or for any purpose you have consented to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

What if you want to stop before your part in the study is complete? You can withdraw from this study at any time, without penalty and skip any question for any reason. The investigators also have the right to stop your participation if you have an unexpected reaction, have failed to follow instructions, etc.

Will you receive anything for being in this study? Will it cost anything? You will receive a \$20 gift card for completing the survey and the body measurements each time, for a total of \$60. Your only out of pocket cost for participation would be your time and travel to the 7 in-person educational classes and measurement visits. When you are part of the food group, you will receive \$680 worth of food.

Who is sponsoring this study?

This research is funded by Westat, Inc. (the sponsor). This means that the research team is being paid by the sponsor for the study. In addition, Dr. Alice Ammerman, a co-investigator on this study, participates in separate unpaid activities, which are not part of this study, for Equiti Foods, LLC, a component of the intervention in Anson County. These activities may include consulting, service on advisory boards, giving speeches, or writing reports. If you would like more information, please ask the researcher listed on the first page of this form.

What if you have questions about this study? You have the right to ask, and have answered, any questions you may have about this research. Contact the principal investigator listed above with any questions, complaints, or concerns you may have.

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? All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. This study is funded by the NIH and has been approved by the UNC-CH Institutional Review Board, #24-2854. If you have any questions or concerns, or if you would like to obtain information or offer input, please contact the IRB at 919-966-3113 or by email to IRB_subjects@unc.edu

Participants will be shown a link that says, “I consent.”