Informed Consent

Scaling up the Med-South Lifestyle Program to Reduce Chronic Disease in Partnership with Rural Communities - Phase II

NCT number NCT05067816
Document Date 07/27/2021

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

Consent Form Version Date: July 27, 2021
IRB Study # 21-1281
Title of Study: Scaling up the Med-South Lifestyle Program to Reduce Chronic Disease in Partnership with Rural Communities - Phase II
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Funding Source and/or Sponsor: Centers for Disease Control and Prevention (CDC) [Federal]

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CONCISE SUMMARY

This is a research study to test how best to get health departments and community health centers to deliver proven programs that help adults change their eating and physical activity behaviors to improve heart health. The program in this study promotes a Southern-style Mediterranean dietary pattern that has been shown to improve heart health. Our focus in this second phase will be on increasing the number of sites offering the program and seeing how well program participants do in changing their lifestyle behaviors.

You are invited to participate in this second phase (Phase 2) which includes 20 health departments and community health centers, each of which will be asked to enroll up to 15 participants. You will be asked to participate in a program that lasts 4 months and includes 4 monthly counseling sessions (with a health counselor or coach) and 3 brief interim phone calls. In the 6 months following completion of the program, there will be 2 follow up phone calls to see how things are going. At the start and end of the program, staff at UNC will call you to ask questions about your general health and lifestyle behaviors (eating and physical activity habits). We will also call you one last time at the end of the study. If you decide to participate in this study, you could benefit by lowering your risk of heart disease, and there is little to no risk of harm, other than a minimal risk of breach of confidentiality. Your confidentiality is protected by keeping your personal information separate from your study data using a unique identification number.

The sections below provide details on what to expect if you decide to be a part of this study.

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

You are being asked to take part in a research study. To join the study is voluntary.

You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

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

What is the purpose of this study?
The purpose of this research study is to test how best to get health departments and community health centers to deliver proven programs that help adults change their eating and physical activity behaviors to improve heart health.

You are being asked to be in the study because health professionals at your local health department, federally qualified health center, or clinic felt that you might benefit from a lifestyle intervention.

Are there any reasons you should not be in this study?
You should not be in this study if you are not between the ages of 18-80, if you are not English speaking, or if you are not able to make decisions about what you eat. You should also not be in this study if you have advanced kidney disease or if you have been diagnosed with a malignancy or cancer.

How many people will take part in this study?
Approximately 300 people at multiple institutions will take part in this study.

How long will your part in this study last?
Your participation in this program will last 10-12 months; starting with 4 monthly counseling sessions with a health counselor or coach (lasting 45-60 minutes each) and 3 brief interim phone calls (lasting 10-30 minutes) and ending with 2 follow up phone calls within the 6 months after you complete the program.

What will happen if you take part in the study?
Your participation in this program will include 4 monthly counseling sessions with a health counselor or coach (lasting 45-60 minutes each), 3 brief interim phone calls (lasting 10-30 minutes) between monthly sessions, and 2 follow up phone calls within the 6 months after you complete the program. Counseling sessions will cover information about a healthy eating pattern and how you can incorporate healthy changes into your diet. The phone calls are to discuss your

goals and progress in making lifestyle changes. Even though the program is 10 months long, it may take additional time if scheduling your program visits or survey calls take more time than expected. At the start and end of the program, and at the end of the study, staff at UNC will call you to administer surveys about your general health and lifestyle behaviors (eating and physical activity habits). These surveys should last about 45-60 minutes each time.

What are the possible benefits from being in this study?
Research is designed to benefit society by gaining new knowledge. The benefits to you from being in this study may be lowering your risk of heart disease.

What are the possible risks or discomforts involved from being in this study?
The only risk to you might be if your identity were ever revealed. However, this risk is very small. All participants will be assigned a study ID number that will be linked to their names only in a confidential list stores on a password-protected database. All research data other than that needed for contacting participants to schedule program visits will be stored with the study ID number.

There is a small chance that some of the questions may make you feel uncomfortable. You don't have to answer those questions if you don't want to. In fact, you don't have to answer any question that you choose not to answer. And that is fine. We will just skip that question and go on to the next one.

What if we learn about new findings or information during the study?
You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will information about you be protected?
All the information collected from you, including your name and any other identifying information, will be strictly confidential and will be stored in a password-protected database.

Participants will not be identified in any report or publication about this study. We will not use de-identified data from this study in future research without additional consent.

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. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

Study Communications
The study team would like to message you by email and/or text message, however you may say "no" to receiving these messages and still participate in this study. If you say "yes", messages may contain personal information about you and may be sent or received by the study

team's personal electronic devices or in a method that is not able to be encrypted (protected) and there is the risk your information could be shared beyond you and the study team. This information may include information such as reminders and notifications to contact the study team.

If you wish to stop receiving unprotected communication from the study team or have lost access to your device, please notify the study team using the study contact information on the first page of this consent form. After the study is complete and all research activities finished, or you withdraw from the study or request to stop receiving unprotected communication, you will no longer receive unencrypted (unprotected) messages specific to this study.

_____ Yes, I consent to the study team utilizing the following (insert mechanism; e.g. cell phone number, email) to send communication: _(List e-mail, cell-phone #)_____

_____ No, I do not consent to receive un-protected communication from the study team.

What will happen if you are injured by this research?

It is not likely that you will be injured by this research, but all research involves a chance of injury. If a medical problem occurs, the researchers or site staff will help you get medical care, but costs for this care will be billed to you and/or your insurance company. The University of North Carolina at Chapel Hill has not set aside funds to pay you for injuries or medical care. However, by signing this form, you do not give up any of your legal rights.

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. The research team or site staff also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or did not follow instructions, or because the entire study has been stopped. If you withdraw or are withdrawn from this study all data collected up until the point of withdrawal will be retained, however no additional information will be collected unless you provide additional written permission for further data collection at the time of your withdrawal.

Will you receive anything for being in this study?

You will receive $120 total ($40 each of the 3 times we ask you to answer study questions by phone, which will be at the start and end of the program, and the end of the study).

Will it cost you anything to be in this study?

The only costs to you are for travel to your local site for in-person visits (at the first and final sessions).

Who is sponsoring this study?

This study is being paid for by the Centers for Disease Control and Prevention (CDC). Portions of Dr. Carmen Samuel-Hodge's and her research team's salaries are being paid by this funding.

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. 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?

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

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 Consent

_____
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