STUDY INFORMED CONSENT

Reducing Cardiovascular Risk in Perimenopausal Latinas: Pilot Study of a Multi-Component Intervention

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THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

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

Consent Form Version Date: __12-23-2020___
IRB Study # 19-2756
Title of Study: Reducing Cardiovascular Risk in Perimenopausal Latinas: Pilot Study of a Multi-Component Intervention
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Funding Source and/or Sponsor: National Institute of Minority Health and Health Disparities

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CONCISE SUMMARY

The purpose of this research study is to explore the effectiveness of a nutrition, exercise, and stress program in reducing the risk of cardiovascular disease in perimenopausal Latinas. Study participants will receive three months of nutrition, physical activity, and stress management classes once a week in a community site. Next, participants will receive three months of monthly support sessions. During your participation, you will meet with a researcher from our team on three occasions to answer questions related to your health and well-being, experiences of stress, and opinions about our health program. We will also take your height, weight, blood pressure, and a small sample of blood and hair on two occasions that will be analyzed for your blood sugar, cholesterol, and stress markers.

Minimal risks associated with this study include: potential for loss of confidentiality, discomfort associated with the blood test (e.g., excessive bleeding, a clot, bruising on the arm) and hair sample. Participants have the potential to benefit from improved CVD risk awareness and health behaviors (e.g., nutrition, physical activity, coping strategies, self-efficacy)

If you are interested in learning more about the study, please read the following.

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?

Since menopause can affect the cardiovascular health of women, it is important to monitor the health of midlife women. Heart healthy behaviors during the menopause transition include eating healthy, exercising, and managing stress. **The purpose of this study is to learn if a program of nutrition, exercise, and stress management can reduce the risk of cardiovascular disease in women during the menopause transition.** In addition, we want to learn the opinions of the participants about the health program. The results of this research study will be used to inform the development of preventive strategies for cardiovascular diseases in women during midlife.

You are being invited to participate in this research study because you identify yourself as a Hispanic / Latina woman, are between 40-60 years of age, and your last menstrual was 3 to 24 months ago, or you have noticed that your menstrual periods are irregular (e.g., skipping months, shorter in duration). Research studies only include people who decide to participate voluntarily. Please read this consent form carefully and take your time to decide whether you would like to participate. Please ask the study team to explain any words or information that you do not understand. The nature, risks, inconveniences, and other important information about the study are explained below.

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

You should not be in this study if you are pregnant, have a history of heart attack, stroke, coronary heart disease, heart murmur, congenital heart disease, or difficulty exercising.

How many people will take part in this study?

Approximately 80 Hispanic/Latino women between the ages of 40 to 60 years of the Triangle area will participate in this study.

How long will your part in this study last?

This research study will be carried out for one year. You will meet with the team three times during a year. The visits will last approximately one hour.

If the blood sample or other biological measure cannot be obtained or processed, you will be contacted after your original visit to schedule a secondary visit for collection.

You can choose to withdraw from the study at any time. This would not affect the relationship you have with UNC or the community.

If you become pregnant during the study, please inform the study team. We will help you contact a medical provider and withdraw you from the study.

What will happen if you take part in the study?

If you agree to participate in this study, you will be asked to sign this consent form. In addition, the following will occur:

- **Assignment to study group** - The study will consist of two groups; one group will receive the health program consisting of three months of weekly classes and then three monthly support sessions. Six months after the first group finishes the health program, we will offer the three months of weekly classes to the second group. The groups will be assigned at random and all the participants of a unit (e.g., a parish) will belong to the same group.
- **Intervention (i.e., the health program)** - All participants will receive three months of nutrition, physical activity, and stress management classes once a week at a place in their community (e.g., the parish). These classes will last approximately 120 minutes. Some topics covered in the classes include:
  - Nutrition - (1) the benefits of a healthy diet; (2) how to prepare healthy, easy, and fun meals at home; (3) how to choose healthy meals when you go out to eat with your family and friends.
  - Physical activity: (1) use of a pedometer for exercise, (2) benefits of exercise during perimenopause; (3) exercises (e.g, walk, stretch, Zumba, dance).
  - Stress management: Stress management techniques include breathing, meditation, and positive thoughts.
  - Support sessions - After the weekly classes, participants in the intervention group will receive 3 monthly sessions of support and advice on how to maintain a healthy lifestyle consisting of healthy nutrition, physical activity, and less stress.
- **Meeting with researcher** - You will meet with a researcher from our team every six months for a year for a total of 3 times. These visits will last approximately two hours and take place in your home, unless you prefer to meet in an office in the community. During these visits, we ask you to answer questions related to your demographic data, your health behaviors, your experiences of stress, and your health and well-being.
  - This will include a survey that the researcher will complete with you. This part of the visit can be completed over the phone, or virtually.
  - Allow the researcher to take measurements of your body such as height, weight, waist circumference, and blood pressure.
  - Allow the researcher to take a blood sample (20ml or 1.5 tablespoons) that will be analyzed for blood sugar, cholesterol, and inflammation markers. A member of the research team who is a registered nurse in the State of North Carolina, or an individual certified by UNC to draw blood, will take the sample. The same procedures as those used in your doctor's office or in a clinic will be used.

- Allow the researcher to cut a 3cm long sample of hair to analyze cortisol, a good marker of the levels of chronic stress that someone has been exposed to in the last 3 months. The sample of hair will be cut close to the scalp with scissors.
- Allow the researcher to collect a measure of arterial stiffness. The procedure of measuring arterial stiffness is similar to the procedure of taking blood pressure. You will be in reclined position at a 30^{o} angle. Two cuffs will be placed (one on the leg and one on the neck) and inflated for less than two minutes. The following images demonstrate the steps:

1. Place cuff around right thigh.

1. Place cuff around neck.

3. Measure distance between cuffs using tape measure.

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 gaining an understanding about strategies to reduce the risk of cardiovascular diseases in women during perimenopause. The benefit to you from participating in this study is more knowledge about menopause and your heart health. You will have the opportunity to learn about healthy nutrition, physical activity, and how you handle your stress.

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

Risk of loss of confidentiality and distress: There are minimal risks associated with this study. However, there is a potential risk of loss of confidentiality. Every effort will be made to maintain the confidentiality of your information; however, this cannot be guaranteed. It is possible that some of the questions we will ask you will be uncomfortable, sad, or distressing. You can refuse to answer any of the questions and you can take a break at any time during the study. You may also withdraw from this study at any time. In the case of psychological distress, the investigator will connect you with mental health services as needed.

Health program risks: There are minimal risks associated with the health program. You may be injured during physical activity classes. You can rest at any time during the exercise sessions. There will be a physical activity professional and a member of the research team during the classes. In case of any injury, a member of the research team will connect you with health services as necessary and remain with you until you receive the services

Risks of blood tests: The risks associated with taking blood samples from your arm are momentary discomfort and/or the possibility of a bruise. It is also possible that an infection, excessive bleeding, a clot, or fainting may occur, but it is not likely.

Risks of the hair test: The risks associated with taking a hair sample is physical discomfort. It is also possible that you may feel some anxiety over having a few strands of hair cut close to the scalp using scissors.

Risks of measurement of arterial stiffness: There are minimal risks associated with the measurement of arterial stiffness. You may feel momentary pain and discomfort as the cuff inflates, or dizziness from reclining.

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.

Will I receive any other clinical results?

Other clinically relevant results of this research will be communicated with you. During each visit with the researcher you will receive a postcard with the following measures: your weight, body mass index, and blood pressure. The blood and hair analyses in this study are done only for the purpose of this study. The results of the study will not be reported to your doctor/healthcare provider. If you would like a copy of these tests, please let the research team know, and we will send them to you by mail. If any result of the blood tests indicates that you must follow-up with your healthcare provider, someone from the research team will contact you to advise you to go to your healthcare provider's office or clinic.

How will information about you be protected?

Personal Identifying Health Information (PHI) such as your name, birth date, and contact information will be stored on password-protected computers, with only a study number as an identifier. The key linking your name to the study ID will be kept in a separate file on a secure password-protected computer, and destroyed at the conclusion of the study. Only Dr. Cortés and the project coordinator will have access to the link between the research ID code and PHI. Questionnaires and results from the blood and hair tests will only record your study ID. Study records will remain in our office for up to six years after the study is completed. These will not be a part of your medical history and will be destroyed after that time.

Participants will not be identified in any report or publication about this study. We may use de-identified data and/or specimens 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.

We will request to audio record a 15-minute exit interview. The recording will not identify you by name. The recording is optional and you can request the that the recording be turned off at any time. The recording will be stored in a separate file on a password-protected computer on a secure server. Recordings will be destroyed after three years.

Check the line that best matches your choice:

_____ OK to record me during the exit interview

_____ Not OK to record me during the exit interview

What is a Certificate of Confidentiality?

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 will happen if you are injured by this research?

All research involves a chance that something bad might happen to you. If you are hurt, become sick, or develop a reaction from something that was done as part of this study, the researcher will help you get medical care, but the University of North Carolina at Chapel Hill has not set aside funds to pay you for any such injuries, illnesses or reactions, or for the related medical care. Any costs for medical expenses will be billed to you or your insurance company. You may be responsible for any co-payments and your insurance may not cover the costs of study related injuries.

If you think you have been injured from taking part in this study, call the Principal Investigator at the phone number provided on this consent form. They will let you know what you should do.

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 withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to 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 be reimbursed $40 for expenses related to your participation for your first visit with a researcher (e.g., completing surveys and biologic samples). You will receive $45 for the second visit, and $50 for the third visit. You will also receive a $5 voucher to assist with transportation to each intervention session.

You will receive your compensation at the end of the visit. If you decide to withdraw from the study, you will receive compensation only for the parts of the study that you completed.

Any payment provided for participation in this study may be subject to applicable tax withholding obligations

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 is funded by the National Institutes of Health, National Institute of Minority Health and Health Disparities. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

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