The HARMONY Study: A Intervention to Reduce Cardiometabolic Risk in African American Women

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University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants
Consent Form Version Date: 27May2022
IRB Study # 20-2193
Title of Study: The HARMONY Study: A culturally-relevant, randomized-controlled, stress management intervention to reduce cardiometabolic risk in African American women
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CONCISE SUMMARY

The purpose of this study is to compare two culturally tailored nutrition and exercise programs for African American and Black women. Participants will complete surveys, have measurements taken (height, weight, blood pressure hip and waist circumference), complete a blood draw and fingerstick, have a Veggie Meter measurement, and be provided with an ActiGraph Activity Monitor (ActiGraph) to wear for 7 days at four separate times (baseline, 4, 8, and 12 months). In addition, participants will be asked to take part in a nutrition and exercise program every other week for 16 weeks, and then monthly for 6 months. Participants will also take part in a half-day retreat. Surveys will be given to participants and they will also be provided with a Fitbit to be worn throughout the study.

Participation in this study will last about 14 months.

The greatest risks of this study include the possibility of injury or sore muscles during exercise, bleeding, bruising, or infection during the blood draw, stress from answering surveys and participating in group sessions, and loss of confidentiality. The benefits to you from being in this study may include that you eat healthier and exercise more, which could lead to various health benefits. However, you may not benefit from being in this research study.

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. 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. UNC students or employees participation or unwillingness to participate will not affect their standing with the University.

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 compare two culturally tailored nutrition and exercise programs for African American and Black women.

Both programs will be led by a health educator and personal trainer and will focus on making healthy food choices and increasing physical activity. Our study is designed to see if one program is more helpful to the people who participate.

You are being asked to be in the study because you identify as an African-American or Black woman.

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

- Are less than 18 years old
- Do not speak English
- Are not willing to engage in moderate to vigorous exercise during the study
- Are pregnant or may become pregnant during the study
- Are taking any weight loss medication, or if you have taken weight loss medication in the past 6 months
- Are enrolled in any weight loss or meditation programs or have been enrolled in one of these programs in the past 6 months. We ask that you do not begin any of these programs during your participation in the study
- Have a diagnosis of diabetes
- Do not wish to be recorded during the online sessions

How many people will take part in this study?
Approximately 200 people will take part in this study. If you are eligible and agree to participate in the study, you will be placed in a group to receive a nutrition and exercise program with 12-13 other women.

How long will your part in this study last?
Your part in this study will last approximately 14 months.

What will happen if you take part in the study?

This study consists of in-person visits, group sessions, and questionnaires.

If you consent to the study, you will be randomly assigned to one of two groups. Each group will receive a culturally tailored nutrition and exercise program, both led by a personal trainer and health coach. During the study, you may also be asked to log various activities on your FitBit devices.

The specific procedures are listed below:

Screening Visit (by telephone)

- **You reviewed a verbal consent with our study team**
- **You completed a series of questionnaires with our study team**

In-Between Screening and Baseline Visit (virtual)

- **You completed various questionnaires that were sent to you.**

Baseline Visit (in-person):

- This informed consent will be reviewed with you.
- The study team will review criteria with you to ensure you are eligible for the study.
- The study team will ask how you are feeling, and if you've had any change in your health
- You will be provided with a Fitbit device to wear on your wrist for the duration of the study.
- You will be provided with an ActiGraph to wear on your wrist for the next 7 days. We will also provide you with a mailer to mail the ActiGraph back to the study team after the 7 days.
- You will complete questionnaires that address your levels of stress, eating habits, health history, and other topics. You do not have to answer any question that you don't want to.
- The study team will gather body measurements from you, such as your weight, height, and hip and waist circumference. A staff member will also talk to you about how to take care of your body during physical exercise.
- The study team will take your blood pressure.
- The study team will take a measurement using the Veggie Meter device. The Veggie Meter takes a scan of your finger to see how many vegetable and fruits you are eating.

You will place your finger inside the device to have the scan completed, similar to how your doctor uses a pulse oximeter to measure the amount of oxygen in your blood.

- You will have your blood drawn (about 6mLs) to test for various factors in the blood, including IL-6 and c-reactive protein measurements. Genetic testing will occur in this study as potential future research.
- You will have a fingerstick for hemoglobin A1c (your blood sugar)

Every Other Week Sessions (all virtual, 8 sessions total)

- All sessions will take place virtually.
- Each session will be led by a personal trainer and a health coach.
- Topics covered during the sessions include healthy eating and physical activity.
- The first session will last approximately 3 hours, and all other sessions will last 2 hours.
- The study team will ask how you are feeling, and if you've had any change in your health
- At some sessions, you will be asked to complete questionnaires.

Retreat (virtual, between sessions 5 and 6)

- The retreat will last approximately 3 hours, and will include the same topics as the every other week sessions.
- The study team will ask how you are feeling, and if you've had any change in your health
- You will be asked to complete questionnaires.

Monthly Booster Sessions (all virtual, 6 sessions total, one per month)

- After completing all 8 of the every other week sessions, participants will have monthly booster sessions.
- These sessions will also be led by a personal trainer and health coach.
- These sessions will last about 1.5 hours.
- The study team will ask how you are feeling, and if you've had any change in your health
- You will be asked to complete questionnaires

Follow Up Visit 1 (approximately 4 months after the first every other week session):

- You will be provided with an ActiGraph to wear on your wrist for the next 7 days. We will also provide you with a mailer to mail the ActiGraph back to the study team after the 7 days.
- You will complete questionnaires that address your levels of stress, eating habits, health history, and other topics. You do not have to answer any question that you don't want to.
- The study team will gather body measurements from you, such as your weight, height, hip and waist circumference.
- The study team will take your blood pressure.
- The study team will take a measurement using the Veggie Meter device. The Veggie Meter takes a scan of your finger to see how many vegetable and fruits you are eating. You will place your finger inside the device to have the scan completed, similar to how your doctor uses a pulse oximeter to measure the amount of oxygen in your blood.

- You will have your blood drawn (about 6mLs) to test for various factors in the blood, including IL-6 and c-reactive protein measurements. Genetic testing will occur in this study as potential future research.
- You will have a fingerstick for hemoglobin A1c (your blood sugar)
- The study team will ask how you are feeling, and if you've had any change in your health
- The study team will interview you to find out your opinions regarding the program

Follow Up Visit 2 (approximately 8 months after the first every other week session):

- You will be provided with an ActiGraph to wear on your wrist for the next 7 days. We will also provide you with a mailer to mail the ActiGraph back to the study team after the 7 days.
- You will complete questionnaires that address your levels of stress, eating habits, health history, and other topics. You do not have to answer any question that you don't want to.
- The study team will gather body measurements from you, such as your weight, height, hip and waist circumference.
- The study team will take your blood pressure.
- The study team will take a measurement using the Veggie Meter device. The Veggie Meter takes a scan of your finger to see how many vegetable and fruits you are eating. You will place your finger inside the device to have the scan completed, similar to how your doctor uses a pulse oximeter to measure the amount of oxygen in your blood.
- You will have your blood drawn (about 6mLs) to test for various factors in the blood, including IL-6 and c-reactive protein measurements. Genetic testing will occur in this study as potential future research.
- You will have a fingerstick for hemoglobin A1c (your blood sugar)
- The study team will ask how you are feeling, and if you've had any change in your health

Follow Up Visit 3 (approximately 12 months after the first every other week session):

- You will be provided with an ActiGraph to wear on your wrist for the next 7 days. We will also provide you with a mailer to mail the ActiGraph back to the study team after the 7 days.
- You will complete questionnaires that address your levels of stress, eating habits, health history, and other topics. You do not have to answer any question that you don't want to.
- The study team will gather body measurements from you, such as your weight, height, hip and waist circumference.
- The study team will take your blood pressure.
- The study team will take a measurement using the Veggie Meter device. The Veggie Meter takes a scan of your finger to see how many vegetable and fruits you are eating. You will place your finger inside the device to have the scan completed, similar to how your doctor uses a pulse oximeter to measure the amount of oxygen in your blood.
- You will have your blood drawn (about 6mLs) to test for various factors in the blood, including IL-6 and c-reactive protein measurements. Genetic testing will occur in this study as potential future research.
- You will have a fingerstick for hemoglobin A1c (your blood sugar)
- The study team will interview you
- The study team will ask how you are feeling, and if you've had any change in your health

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 include that you eat healthier and exercise more, which could lead to various health benefits. However, you may not benefit from being in this research study.

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

Physical Risk:

During the study, you will have your blood drawn by our study staff. Blood draw risks include bruising, bleeding, and infection at the site. You will also have a fingerstick performed to measure your glucose levels. This may cause temporary discomfort.

You will also be asked to participate in moderate to vigorous physical activity during this study. Because of this, your muscles may become sore or you may be injured. To minimize this risk, a personal trainer will be available to answer any questions you may have about your personal limits, and they will watch you as you exercise in the group sessions. We may also ask you to check in with your personal physician before starting the study to see if the study is a good fit for you. If you have any medical problems during this study, the study team will help you find medical care.

Psychological Risk:

During the sessions, you may talk to the group about your personal life and how you manage your day-to-day stress. This may cause some emotional distress or make your feel uncomfortable. You do not have to share any personal information with your group that you do not want to. In addition, if you experience emotional distress during the study, the study team will help you find assistance.

In addition, there may be questions on our surveys that may cause you to feel emotionally distressed. You may refuse to answer any question at any time.

Risk of Loss of Confidentiality:

There is a risk of loss of confidentiality. When we collect data about you for the research study, there is a chance that the data could be lost or seen by someone outside of the study team. The research team will make every effort to keep your information safe. However, due to the online nature of the group sessions, there may be a chance that someone in your home will accidentally see or hear elements of the session. Because of this, we ask you to please be in a private area during the sessions to ensure privacy. Please see the “how will information about you be protected” section below to learn more about how the research team will protect your information.

There may be uncommon or previously unknown risks. You should report any problems to the researcher. In addition, if you become pregnant or anticipate becoming pregnant while in the study, please let the research team know immediately. The interventions do not present a risk to

normal pregnancy. If you become pregnant during the study, we will ask you to consult with your maternity care provider regarding your continued participation in the study.

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?
Clinically relevant results of this research will be communicated with you if necessary. Specifically, we will let you know if your hemoglobin A1c measurement (your blood sugar) or blood pressure is out of normal range. Other results from the blood draw and other testing will not be given to you.

In addition, the study team is not providing direct standard-of-care health care or procedures to you during this study. You are responsible for arranging non-study related medical and mental health care with your primary care provider and other members of your clinical care team.

How will information about you be protected?

The research team will make every effort to protect your privacy and confidentiality. These efforts include:

- Storing paper study records in a locked filing cabinet.
- Storing electronic records on password protected, encrypted computers.
- Using a study ID to label any data we collect from you. The study ID will not include any information that could identify you, such as you name or birthday.
- Encouraging you and other participants to participate in sessions in private areas.
- Ensuring that the session group leaders are in private areas when leading discussions.

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.

In addition, as part of our study we will audio and video record all group sessions. We do this to ensure that the sessions are similar for all participants and that our session leaders are leading the sessions correctly. All recordings of the session will be kept on a password protected, encrypted computer. All recordings will be destroyed at the end of the study.

During your group sessions you may hear personal information about other participants. We ask that you please keep any information you hear from others private and do not share any information about others with anyone else.

Also, in this study, we will discuss your emotions and feelings. If the study team discovers that you are at risk for harming yourself or others, we will arrange for care to ensure your safety.

Research staff with authorize Fitabase (Small Steps Labs LLC) to access and download your Fitbit data for the duration of this study. This authorization will not require you to give an email address, password, or other personal information to the research staff. Research staff will use your coded Fitbit account information to authorize Fitabase to access your data. A study ID number will also be used within the Fitabase platform. This study ID number will not include any part of your name, date of birth, or any other information that could directly identify you. Research staff will access and download the following data gathered from your Fitbit account:

- Daily steps total
- Measured steps per minutes
- Estimated energy expenditure
- Distance moved
- Minutes of vigorous activity
- Minutes of moderate activity
- Minutes of light activity
- Minutes of sedentary time
- Sleep length, quality, and movement
- Heart rate
- Manually entered and automatically detected physical activities, such as walking or running

In order to access your Fitbit data research staff will authorize a third party, Fitabase, owned and operated by Small Steps Labs LLC, via an online form. Fitabase is a research platform that collects data from internet connected consumer activity devices. In order to authorize Fitabase to collect and store your Fitbit data research staff will connect Fitabase to the Fitbit account associated with the Fitbit device you will be given for the duration of this study. Fitabase, upon authorization, may collect the following data:

- Personal details added to your Fitbit user account, such as height, weight, gender and age.
- Information sent wirelessly from your Fitbit product to the service and that is stored in your Fitbit user account
- Information that was added manually to the Fitbit service and is stored in your Fitbit user account
- Accounts of when you elected to share data from your Fitbit user account with others.
- Minute-level data reported by devices including:

- Number of steps taken
- Calories burned
- Intensity of movement metrics
- Sleep data, including sleep quality
- Weight
- Body fat percentage
- Heart rate
- Automatically detected and manually entered activity behaviors
- Any manually reported food or exercise information provided to Fitbit.com

Your Fitbit username and password will not be accessed, viewed, or stored by Fitabase or Small Steps Labs, LLC. The study team will store your Fitbit account login credentials in a safe, encrypted location. Your Fitbit is capable of GPS collection, however, the study team nor Fitabase will access or download GPS data.

When you authorize Fitabase to access and store your Fitbit data you are agreeing to the Terms of Use and Privacy Policy set by Fitabase. A copy of those Terms of Use and Privacy Policy can be found at the following links: https://www.fitabase.com/Terms/ and https://www.fitabase.com/Privacy/. We ask that you review both the Terms of Use and Privacy Policy before agreeing to participate in this study. If you have any questions about your privacy and the Fitabase system, please contact the study team.

The study team would like to message you by text messaging and email, 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 un-encrypted (un-protected) messages specific to this study.

_____ Yes, I consent to the study team utilizing text and email to send communication by email and/or cell phone:

List email: _____ or check _____ N/A, I do not want to receive unencrypted communication to my email

List cell phone: _____ or check _____ N/A, I do not want to receive unencrypted communication to my cell phone

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

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 receiving up to $260.00 for taking part in this study, and you will also receive a Fitbit, headphones, and other gifts. Payment will be given to participants according to the following schedule:

Completion of baseline visit: $50.00

Completion of follow-up visit 1: $60.00

Completion of follow-up visit 2: $70.00

Completion of follow-up visit 3: $80.00

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

Your name, address, and U.S. tax payer identification number (SSN or ITIN) are required to process payments and/or to report taxable income to the IRS. You must complete a W-9 (for U.S. persons) or W-8BEN and the Foreign Vendor Withholding Assessment with supporting documents (for non-resident aliens) in order to receive payment for participation.

U.S. person participants must complete Form W-9 in order to receive payment for participation. If payment by UNC equals or exceeds $600 per calendar year for U.S. persons, UNC will report the amount to the Internal Revenue Service on Form 1099. Nonresident alien participants must complete Form W-8BEN and the Foreign Vendor Withholding Assessment with supporting documents in order to receive payment for participation. Payments to nonresident alien participants may be subject to tax withholding and are generally reported to the Internal Revenue Service on Form 1042-S. This information will not be linked to any of the study data and will only be used for payment purposes.

If you do not provide your SSN or ITIN, or complete the appropriate documentation noted above, we cannot issue you a payment for participation. However, you may still choose to participate in this study.

Will it cost you anything to be in this study?

If you enroll in this study, you may have costs which include:

- Childcare for when you are participating in the sessions and visits.
- If your physician needs to give permission for you to participate in the study, you will be responsible for paying for that office visit.
- Exercise equipment, clothing, and other related materials. This is not required to be in the study, but since this is an exercise-based program, you may purchase these items.
- Various healthy foods (such a fresh fruits and vegetables). The purchase of these items is not required to be in the study; however, you may spend more money than usual on groceries.

Who is sponsoring this study?

This research is funded by the National Institutes of Health. 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	