Official Title:	OUR Stress/ Emotion Management for Black/African American Women With Hypertension
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REDCAP Script for Obtaining Informed Consent
The Ohio State University Consent to Participate in Research

Hello, my name is Dr. Kathy Wright. I am an Assistant Professor at The Ohio State University in the College of Nursing, and I am undertaking research-titled Operating Under Resilience (OUR) Project: Stress and emotion Management for Black/African American Women with Hypertension In a Covid-19 Social Distancing Society.

This is a consent form for research participation. It contains important information about this study and what to expect if you decide to participate.

Your participation is voluntary.

Please consider the information carefully. Feel free to ask questions before making your decision whether or not to participate.

Purpose: By age 55, three-fourths of black men and women have developed high blood pressure, compared to just 55% of white men and 40% of white women. Covid-19 is an additional stressor African American women have to deal with that may interfere with hypertension self-care management. The purpose of this project is to determine if a nurse and dietitian-led group intervention on the web, will help to manage stress and emotions.

Procedures/Tasks:
If you agree to participate in this study we will provide you with hair kit and self-care supplies that include a home blood pressure monitor, tape measure for your waist, weight scale and pill box. You will be asked to report your blood pressure, measure your waist and provide a weight periodically throughout the study. We will also have you do some tests to measure your mood and memory.

You may be advised, for informational purposes only, to contact a health provider if your blood pressure is above a certain threshold at any time during the study.

We will ask you to complete three virtual (telephone and or Zoom video conference) study visits. Zoom is a video conferencing system that has been used successfully for interviews with clinicians in our organization and by others. The virtual visits, for the collection of data, will not be audio or video recorded. The *first visit* (baseline) at the time of enrollment, will be to ask you survey questions about stress and Covid-19, and memory evaluation conducted by our study staff and a brain test. You will also receive a unique internet URL where only you will have access to take the brain test using a touch screen tablet or touch screen computer. If you do not have access to a touch screen tablet or computer, you may be able to borrow one, at no charge to you, from our computer lab.

, The memory evaluation and brain test are only conducted at the baseline and 6 month visits. Once we have enrolled the first 6-8 people, you will begin the group online classes held by the dietitian or a nurse. The four weekly group classes will be audio recorded using a hand held recorder. The recorded sessions will be converted and stored electronically in a secure system called REDCap and at this time your audio recording of the group classes will be destroyed.

In the group sessions on Zoom, if you do not want to disclose your identity please let the study team know. The study team will show you how to attend the sessions without showing your face on the video or using your actual name for your privacy. You will also have the option of creating an avatar. You will need the internet or SmartPhone to get into the classes. Devices that have a larger screen such as a laptop or IPad, are preferred to access Zoom but it is not required. The class will be held in the evening, once a week for 4 weeks. The classes will last 60-90 minutes. In the class you will learn:

- how to manage stress during Covid-19,
- taking blood pressure,
- interpersonal relationships skills,
- mindful awareness,
- restful sleep,
- physical activity,
- and healthy eating.

You will be given "homework" to practice what you have learned. You will receive a diary to keep track of your physical activity and sleep. After you have completed the four weekly sessions on Zoom, a member of our study staff will provide you with self-care coaching calls. The coaching calls, lastly approximately 10-20 minutes, are to review your questions and provide ongoing support of healthy self-care. The calls will be made twice a month for four months.

When you have completed the 4 week intervention, we will schedule the *second virtual visit* (approximately 1-3 weeks after you complete the online group classes.) We will repeat all of the same surveys except the memory testing.

After you have completed the 4 week intervention, we will call you twice a month for 4 months to provide health coaching.

The memory testing will be done again approximately 6 months for the *final virtual visit*. At the final virtual visit, you will be asked survey questions and complete the memory evaluation.

Duration:

The study is projected to last 6-12 months at most. Your active participation will be for a course of 60 days however we might like to contact you for up to one year after you start the study, in case we have questions.

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

Risks and Benefits:

There may be no direct benefit to you. However, your participation may provide data which will provide insight into ways African American women can reduce their blood pressure and improve their overall health.

What risks, side effects or discomforts can I expect from being in the study?

You will be asked about topics such as your stress, emotions, socioeconomic status, and your feelings which might create awkwardness or discomfort for you. Some of the questions may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you may skip it and go to the next question. Wearing the inflated blood pressure cuff may cause some temporary numbness and tingling in your hands.

As we are using the Internet, there is a chance that someone could access your online responses without permission. In some cases, this information could be used to identify you. While data may be coded, it will exist for an extended period of time, which could be affected if there is a data breach. Your data will be stored on a password protected database.
While we ask other group participants to keep the discussion in the group confidential, we cannot guarantee this. Please keep this in mind when choosing what to share in the group setting.

Confidentiality:

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law. Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;

- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor, if any, or agency (including the Food and Drug Administration for FDA-regulated research) supporting the study.

Will my de-identified information be used or shared for future research?

Yes, it may be used or shared with other researchers without your additional informed consent. The de-identified information may also be shared with University of North Carolina Charlotte collaborator.

Incentives:

Each data collection visit will take approximately 1-3 hours to complete and it can be done over two separate days if desired. You will receive a waist tape measurer, pill box, and kick stand your smartphone.

After completion of the COVID ALL OF US COPE survey at baseline, you will receive a $10.00 Amazon gift card.

After completion of the 1 month data collection, you will receive a polyester grocery bag with a variety of items (e.g., community resource guide, scarf, hand sanitizer, and an insulated cup). These items were donated from the Alcohol Drug and Mental Health (ADAMH) of Franklin County and The Ohio State University James Cancer Center.

After completion of the COVID ALL OF US COPE survey at 6 months, you will receive a $10.00 Amazon gift card.

After final data collection at 6 months, you will have the option of either receiving a $75.00 Amazon gift card or keeping your self-care monitoring equipment (Home Blood Pressure monitor and weight scale).

If you chose the $75.00 Amazon card, then we will provide you with a postage paid package to return the self-care equipment to The Ohio State College of Nursing.

By law, monetary incentives are considered taxable income.

Participant Rights:

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By agreeing to participate in the study, you do not give up any personal legal rights you may have as a participant in this study.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of research participants.

Conflict of Interest

Dr. Douglas Scharre, a researcher helping to perform this study, is a paid consultant for Brain Test, Inc., a company involved in the research. Ohio State could also benefit financially from the sale of Brain Test's products. A conflict of interest committee at Ohio State has reviewed this information and determined that the financial interests present no additional significant risk to the study's participants. Any questions about this information can be answered by Dr. Kathy Wright at 614-292-0309.

Contacts and Questions:

For questions, concerns, or complaints about the study, or you feel you have been harmed as a result of study participation, you may contact the principal investigator Kathy D. Wright at 614-292-0309 or email wright.2104@osu.edu

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Responsible Research Practices at 1-800-678-6251.

Do you have any questions about this research?

Do you agree to participate

☐Yes **☐No**