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The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization

Study Title: Brain connections, self-care and blood pressure in Black and African Americans with problems with memory

Principal Investigator: Kathy D. Wright, PhD, RN, CNS

Sponsor: Chronic Brain Injury, Discovery Themes, The Ohio State University

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

1. Why is this study being done? Black and African Americans are more likely than other ethnic groups to have high blood pressure and problems with their memory. This is a study to see if Black and African American older adults with high blood pressure and problems with their memory want to do mindfulness mediation practice and healthy eating.

Functional MRI (fMRI) has become a major research tool in the developing science of the brain, mind, and behavior. It is an imaging method that uses a strong magnetic field and radio waves to make pictures of the body. fMRI is a type of specialized MRI scan use to measure

the change in blood flow related to neural activity in the brain. No X-rays or other radiation is used in fMRI

2. How many people will take part in this study?

Approximately 120 Black and African American men and women.

3. What will happen if I take part in this study?

You will complete questions about your memory, stress, mood, and physical activity. We will take your blood pressure with an automatic blood pressure machine. With permission, we will cut a small sample about the same amount of hair you get after combing or brushing. The hair sample allows us to measure a stress hormone. The site for the hair sample is covered by hair from the crown of your head and, thus, is not visible following the sample collection. Hair samples are only collected in the beginning and at 3 months. The visit where we ask questions and take your blood pressure will last about 90 minutes. The functional magnetic resonance imaging (fMRI) is done on a separate day and will take about 30 minutes.

The functional magnetic resonance imaging (fMRI) scanner is a powerful magnet that uses simple radio waves to take pictures of your brain. There is no pain associated with this procedure. You will be on a table that slides into a large tube, which is the inside of a large magnet. Some patients complain of claustrophobia or the sensation of being enclosed in a small space. If this occurs, we will stop the procedure and take you out of the magnet. During the scan, you will hear loud, rhythmic knocking sounds. Your ears will be covered to keep the noise at a minimum. Once the scan starts, you will need to lie still and only concentrate on the task the technician is asking of you. You will be able to end the scan at any time if you feel uncomfortable. We ask that you bring someone with you if possible for the fMRI scan. The fMRI scan are done at The Ohio State University Center for Cognitive and Behavioral Brain Imaging at 1835 Neil Avenue, Columbus, Ohio 43210.

You will not be given MRI contrast agent [chemicals that help imaging certain brain tissues or processes] or any other drugs in this study. And, the MRI scan you will receive in this study is not intended to be diagnostic and does not replace a clinical MRI scan reviewed by a qualified radiologist. The standard OSUMC and FDA screening and safety guidelines for MRI will be followed.

At the conclusion of this visit, you will be assigned to a study group by chance using a process similar to the flip of a coin. This process is called randomization. Neither you nor study staff will select the group to which you will be assigned. However, this information can be obtained if you have a medical emergency. You will be randomly assigned to the mindfulness and healthy eating group, the community education group, or the true control group.

If you are in the mindfulness /healthy eating group, you will come to a meeting room in the in the Columbus East area. The group meetings will be held weekly for 8 weeks. Each mindfulness/healthy eating meeting will last 2 hours and 30 minutes. During the meetings you will learn ways to reduce stress through meditation. You will learn about healthy eating on a

budget and setting health goals. The meetings will be audio-recorded. We will ask what you liked or did not like after each meeting.

If you are in the community education group, you will come to a meeting room in the in the Columbus East area. The group meetings will be held weekly for 8 weeks. Each community education meeting will last 2 hours and 30 minutes. During the meetings you will learn about things like fire safety, falls prevention and growing older in place. Transportation is provided if needed.

If you are in the mindfulness group, you will receive weekly calls during the study to provide you with the opportunity to ask questions between sessions, along with bi-weekly calls after the study to ensure you are practicing what you've learned.

If you are in the true control group, you will continue care as usual. You will receive a DASH diet pamphlet and healthy foods plate at the end of the study.

4. How long will I be in the study? You will be in the study for 6-8 months.
We will repeat collection of the information after the intervention at approximately 3-months while you are in the study.

5. Can I stop being in the study?

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.

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

You will be asked about sensitive topics such as racism and discrimination, 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.

Risk associated with the functional magnetic resonance imaging machine (fMRI) – There are potential risks for the people selected for fMRI analysis. You may experience negative psychological effects because of the closeness of the scanner bore, the noise, immobility, anxiety, fear or distress, and the expectations of the test results. You may also experience heating or sensations of warmth and load noise. Certain metals are not safe to go into an fMRI scanner. You will be asked to remove all jewelry and change out of clothing containing metal prior to the study. You will also fill out an MRI safety questionnaire that allows us to screen you for metals that cannot go into the scanner.

We will collect non-clinical personality measures either before or after the scan. These

measures may be correlated to brain activity and provide further information for us to interpret fMRI signals.

"The functional magnetic resonance imaging (fMRI) scan you will receive during the course of this study is for research purposes only. It is not a clinical scan intended for diagnostic or therapeutic purposes. The Center for Cognitive and Behavioral Brain Imaging is a research center. It is NOT a Clinical MRI facility in a hospital. There are no neuroradiologists at the Center for Cognitive and Behavioral Brain Imaging, therefore the staff are unable to make any medical comments about your scan. Should you want to know if your scan is normal or abnormal, the staff will not be able to tell you. However, all structural scans obtained in normal research subjects are sent to a Neuroradiologist for blind review. In the rare event the neuroradiologist detects an abnormality he will be given your name and contact, or that of a physician of your choice, so he can explain and discuss the finding with you. You will also be given the data of the structural images on a CD so you can consult with your physician. You may decline this offer."

7. What benefits can I expect from being in the study?

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

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. What are the costs of taking part in this study?

There no charge for participating in the study.

10. Will I be paid for taking part in this study?

Transportation to the functional magnetic resonance imaging (fMRI) appointments and weekly sessions is provided.

By law, payments to subjects are considered taxable income.

In addition, you will be paid a stipend to compensate your time.

- First visit (before randomizing): $30 for surveys, hair and blood pressure. If there is a gap of 4 or more months between the initial data collection and the start of the intervention, data will be recollected and you will receive another $30. The fMRI will only be done once before randomization and you receive $75.00 for the fMRI and $30.00 for one person that comes with you for the fMRI.

- Second visit (approximately 3 months): $30 for surveys, hair and blood pressure. $75.00 for the fMRI and $30.00 for one person that comes with you for the fMRI.

If you refer a friend or family member about possibly joining the study, you will receive $5 for each person who speaks to a study team member about the study (limit of 10 referrals). You will receive this payment even if the referred person decides to not join the study.

If you withdraw from the study, you will be paid for the portions that you completed.

11. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

12. What are my rights if I take part in this study?

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

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

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 participants in research.

13. Will my study-related information be kept confidential?

The NIH issues Certificates of Confidentiality for all NIH-funded studies, including this study. This Certificate provides extra protection for you and your study information, documents, or samples (blood, tissue, etc.). The Certificates are issued so that we cannot be required to disclose any identifiable information collected about you as a part of this study in

a lawsuit or legal proceeding. This is a layer of protection over and above the already existing protections in place for you and your information, documents, or samples.

However, these protections do not apply in some situations. For example, we may have to release your information if a law requires us to do so, if Discovery Themes CBI, that is funding this study requests the information, or if the FDA tells us to release this information. Please talk to your study team, or contact the Office of Responsible Research Practices at 614-688-8641, if you have questions.

Click here to learn more: https://humansubjects.nih.gov/coc/faqs
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;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;

A description of this clinical trial will be available on http://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 the website at any time.

14. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

- Past and present medical records;
- Research records;
- Records about phone calls made as part of this research;
- Records about your study visits;
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;
- Information gathered for this research about:
  Diaries and questionnaires
  The diagnosis and treatment of a mental health condition

II. Who may use and give out information about you?

Researchers and study staff.

III. Who might get this information?

- The sponsor of this research. "Sponsor" means any persons or companies that are:
  - working for or with the sponsor; or
  - owned by the sponsor.
- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic or physician's office record;

IV. Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
- Governmental agencies in other countries;
- Governmental agencies to whom certain diseases (reportable diseases) must be reported; and
- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

V. Why will this information be used and/or given to others?

- To do the research;
- To study the results; and
- To make sure that the research was done right.

VI. When will my permission end?

There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

VII. May I withdraw or revoke (cancel) my permission?

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the researchers. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

VIII. What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study and receive research-related treatment. However, if you are being treated as a patient here, you will still be able to receive care.

IX. Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my information?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

15. Who can answer my questions about the study?

For questions, concerns, or complaints about the study, or if you feel you have been harmed as a result of study participation, you may contact _Dr. KATHY WRIGHT at 614-292-0309 wright.2104@osu.edu
For questions related to your privacy rights under HIPAA or related to this research authorization, please contact _Dr. Mary Beth Happ at (614) 292-8336 or happ.3@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 Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Dr. KATHY WRIGHT at 614-292-0309 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 Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this combined consent and HIPAA research authorization form**.**

Printed name of subject	**Signature of subject**
	AM/PM
	Date and time
Printed name of person authorized to consent for subject (when applicable)	**Signature of person authorized to consent for subject (when applicable)**
Relationship to the subject	**AM/PM** **Date and time**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**
	AM/PM
	Date and time
Printed name of witness	**Signature of witness**
	AM/PM
	Date and time