Consent Document

Title: Building a Multidisciplinary Research Program to Address Hypertension Disparities: Exploring the Neurocognitive Mechanisms of a Self-Management Intervention for African American Women

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UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: The WHISE Study- Building a Multidisciplinary Research Program to Address Hypertension Disparities: Exploring the Neurocognitive Mechanisms of a Self-Management Intervention for African American Women with Hypertension

Company or agency sponsoring the study: This study is funded by the National Heart, Lung, and Blood Institute (NHLBI), the NIH, and the University of Michigan School of Nursing.

Principal Investigator: Dr. Lenette M. Jones, Ph.D, RN

Study Coordinator: Priya Tripathi

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to sign this form before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site in Ann Arbor or elsewhere. This may require you to arrange travel, change work schedules, find childcare, or make other plans. In your decision to participate in this study, consider all these matters carefully.

2. PURPOSE OF THIS STUDY

2.1 Study purpose: Hypertension (high blood pressure) is a chronic illness that has an increased risk of stroke and premature death. The purpose of the WHISE (Wellness, Hypertension, Information Sharing, Self-Management, Education) study is to better understand how social factors and eating patterns are related to high blood pressure management, as well as brain-behavior connections among African American women with high blood pressure. The WHISE study is about a mobile application (app) designed to help African American women living in southeast Michigan and to better understand how social factors and eating patterns are related to blood pressure management. A better understanding of brain-behavior connections will help scientists and practitioners understand how health information changes the brain and enhances self-management behavior. It will also help scientists and practitioners better understand why health messaging leads to behavior change in some cases but not in others.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this research project is voluntary. You do not have to participate, and you can stop at any time. Please take time to read this entire form and ask questions before deciding whether to take part in this research project.

3.1 Who can take part in this study?

The WHISE study will include African American females ages 18-65 years who live in Southeast Michigan zip codes and have been diagnosed with hypertension (high blood pressure) by a health care provider, and who own and regularly use a smartphone. Study participants will have to be able to invite two friends or family members (peers) who also own smartphones to participate in the study with them. These individuals must be willing to download the WHISE app. When 50 participants have been screened and found to qualify for the study, study enrollment will be closed. Not everyone who expresses interest in the study will qualify.

Using a standard research method, we will randomly assign participants to two different groups (as though by a coin toss). You will have a 50/50 chance of being in one group or the other. All participants will use the smartphone WHISE app and all participants will interact with their chosen "peers" using the WHISE app. All participants will be required to complete 6 weekly modules provided by the app and complete the surveys (details in 4.2). The only difference between the two groups is that one group will share information with the study team while the other will not.

3.2 How many people are expected to take part in this study?

50 women are expected to participate in the full WHISE study.
100 individuals are expected to participate as peers.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

If you agree to be part of the research study, you must also provide contact information to the study team members of the peers who agree to be in the study with you: names, emails, phone numbers. Consent forms will be emailed to peers after research team members get emails. Peers will reply to that research team member's email to indicate their agreement to participate in this study. A research team member will call/email peers to get their mailing addresses. Peers will receive a $25 gift card to download the WHISE software application on their smartphone to interact with you through the "chat function" for six weeks.

Before sending instructions to use the WHISE app, a research team member will ask you to complete a survey, take your blood pressure, and prick your finger to mail a blood sample for A1c Test, whole blood mail-in test to check your glucose status with the help of one of our study team members. After that, we will ask you and your peers to download and use the WHISE app. As mentioned above, peers can only interact with you through the "chat function".

After completing the 6-week WHISE app, the study team will contact you after one month and again in 6 months to arrange for you to complete another set of surveys.

We are recruiting 50 participants for this study; among 50 participants, a subset of 20 women will undergo two voluntary functional magnetic resonance imaging (fMRI) scans, once at the beginning of the study and once after six months.

*Note: fMRI is used as a tool to observe brain activity. Through measuring blood flow changes in the brain in response to different prompts, fMRI is a technique that uses standard MRI scanners to map processes to different parts of the brain.

After all study activities, you will be emailed a survey asking about your experience with the WHISE app.

4.2 How much of my time will be needed to take part in this study?

For all participants:
6 weekly app modules = 6 hours (1hour x 6 weeks)
Survey Responses= 3 hours (1 hour x 3 survey sessions)
Exit Survey = 5 minutes
Total: 9 hours and 5 minutes

For participants who choose to complete the optional FMRI:
6 weekly app modules = 6 hours (1hour x 6 weeks):
Survey Responses= 3 hours (1 hour x 3 survey sessions)
2 FRMI's = 3 hours (1.5 hrs for each FMRI)
Exit Survey= 5 minutes
Total: 12 hours and 5 minutes

A separate consent form will be given for fMRI portion of the study.

4.3 When will my participation in the study be over?
Your study participation will be complete after you have completed the 6 weeks of the WHISE app and completed your one-month and six-month follow-up surveys.

For those who choose to take part in the fMRI portion of the study, your participation will end after you complete six weeks of the WHISE app modules, two fMRI scans (one Just after we enroll you in the study and one after six months), as well as your one-month and six-month follow-up surveys

All participants will be asked to complete a brief satisfaction survey after completing all study activities.

4.4 What will happen with my information used in this study?
With appropriate permissions, collected information may be shared with other researchers, here, around the world, and with companies.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?
The risks associated with gathering information from participants by properly trained, supervised research assistants and staff is rare and includes risks of breach of confidentiality and psychological distress. We are prepared to deal with such events by making sure that all staff members are familiar with referral resources available at the University of Michigan. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

There is minimal risk associated with the A1c test. Approximately 3-4 drops of blood will be removed by finger stick using the lancet provided with kit. This standard method is used to obtain blood for routine hospital laboratory tests. You may have slight pain or bruise at the spot where the needle was put in, but most symptoms go away quickly. Other than this momentary pain, the discomfort of the finger stick should be minimal. However, in about 10% of the cases, a small amount of bleeding under the skin will produce a bruise (hematoma). A small scar may persist for several weeks. The risk of local infection is less than 1 in 1,000. Please wash your

hands with soap and warm water and be sure they are thoroughly dry, as leftover water droplets on your finger may affect your blood sugar reading.

Getting an injury caused by a blood pressure cuff is an uncommon event. However, please ensure that the blood pressure cuffs size is right. A wrong-size cuff can lead to incorrect blood pressure readings and misdiagnosis.

If you participate in the study's fMRI portion, the associated risks will be explained in a separate consent document.

As with any research study, there may be additional risks that are unknown or unexpected.

See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

5.2 What happens if I get hurt, become sick, or have other problems because of this research?
The researchers have taken steps to minimize the risks of this study. Please tell the researchers if you have any injuries or problems related to your participation in the study. The University may be able to assist you with obtaining emergency treatment, if appropriate, but you or your insurance company will be responsible for the cost. By signing this form, you do not give up your right to seek payment if you are harmed because of being in this study.

5.3 If I take part in this study, can I also participate in other studies?
Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?
You may not receive any personal benefits from being in this study. However, other African American women with hypertension may benefit from the knowledge gained from this study. Both groups will receive valuable health information that could potentially help with self-manage of hypertension.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?
Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?
Participation is completely voluntary and if you do not want to participate the other option is to not participate.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?
You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10. "Contact Information". If you choose to tell the researchers why you are leaving the study, your reasons may be kept as part of the study record. The researchers will keep the information collected about you for the research unless you ask us to delete it from our records. If the researchers have already used your information in a research analysis it will not be possible to remove your information.

The researchers may choose to remove you from the study if, at any six weekly app modules time point, you no longer have and regularly use a smartphone. You will be removed from the fMRI portion of the study if the study team learns that you have, or have developed any of the exclusion criteria for undergoing fMRI..

7.2 Could there be any harm to me if I decide to leave the study before it is finished?
There is no harm to you if you choose to leave the study before it is finished. You will receive compensation for any of the activities you did complete.

7.3 Could the researchers take me out of the study even if I want to continue to participate?
Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?
You will not be billed for any of your participation in the study.

8.2 Will I be paid or given anything for taking part in this study?
You will receive a $75 gift card for your completion of all study activities. The breakdown of the study is listed below:
• $35 for completing baseline measures
• $40 for completing all study measures

Those who choose to participate (n=20) in the optional fMRI portion of the study will receive:
• an additional $25 gift card for each fMRI (2) • $40 for gas reimbursement for their visit to the Functional MRI Laboratory, Ann Arbor, MI 48109.

Note:
We are recruiting 50 participants for this study; among 50 participants, a subset of 20 women who choose to participate in the optional fMRI portion of the survey will be eligible to earn over $100 in a single calendar year and will provide their SSN for every incentive payment. However, collected information is only for tax reporting purposes.

The other 30 participants who do not choose to participate in the optional fMRI portion will receive a maximum of $75 in a single calendar year for completing all activities.

8.3 Who could profit or financially benefit from the study results?
No person or organization has a financial interest in the outcome of this study.

Research can lead to new discoveries, such as new tests, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

9.1 How will the researchers protect my information?
The following confidentiality protection steps will be taken to protect your information: (a) all research assistants and study investigators will participate in initial training, follow-up training, and ongoing monitoring and supervision to ensure their understanding of ethical issues involved in the research; (b) any personal identifiers linked to data will be removed and replaced by code numbers in all records; (c) all data collection will take place in an office or space that is private. Data will be stored in two databases. The personal information database will contain all personal identifiable information such as name, address, phone number, date of birth. Only the principal investigator will have access to this database.

9.2 What information about me could be seen by the researchers or by other people? Why? Who might see it?

This research holds a Certificate of Confidentiality (CoC) from the National Institutes of Health.

This means that we cannot be forced to disclose any research information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. In general, we will use the Certificate to resist any demands for information that would identify you, except as described below.

We will disclose your information for any purpose to which you have consented, as described in this informed consent document. If required by local or state law, we may disclose your information to the appropriate authorities if we suspect or learn about cases of child or elder abuse or neglect, or that you may harm yourself or others.

Please note that a CoC does not prevent you or a member of your family 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 we will not use the Certificate to withhold that information.

More detailed information about Certificates can be found at the NIH CoC webpage: https://humansubjects.nih.gov/coc/index

"If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes."

9.3 What happens to information about me after the study is over or if I cancel my permission to use my information?

We may use or share your research information for future research studies. If we share your information with other researchers, it will be de-identified, which means that it will not contain your name or other information that can directly identify you. This research may be similar to this study or completely different. We will not ask for your additional informed consent for these studies.

We would like to hold on to your identifiable information to invite you to be a part of any new studies for which you may be eligible. We will ask for your consent to do so at the end of this form. You can be a part of this current research project without agreeing to this future use of your identifiable information.

We will keep the information we collect about you during the research for future research projects. Your name and other information that can directly identify you will be stored securely and separately from the research information we collected from you. The researchers may contact you again as part of this project.

The results of this study could be published in an article or presentation but will not include any information that would let others know who you are.

There are reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- University, government officials, study sponsors or funders, auditors, and/or the Institutional Review Board (IRB) may need the information to make sure that the study is done in a safe and proper manner.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

9.4 When does my permission to use my information expire?
Your de-identified information will be stored indefinitely unless you ask us to remove it from our records.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by the National Institutes of Health (NIH). 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.

This trial will be registered and may report results on www.clinicaltrials.gov. This site 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.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?
Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Dr. Lenette M. Jones, PhD, RN
Email: lenettew@umich.edu
Phone: 734-763-1371

Study Coordinator: Priya Tripathi, Ph.D.,
Email: WHISE2023@umich.edu
Phone: 734-649-1757

If you have questions about your rights as a research participant, or wish to obtain information, ask questions or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies, include the appropriate calling codes.)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

You can also contact the University of Michigan Compliance Hotline at 1-866-990-0111.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

You are welcome to print out a copy of this document for your records.

12. CONSENT TO PARTICIPATE IN THE RESEARCH STUDY

The WHISE app eligibility Qualtrics survey's first page contains information about the study and a link to this informed consent form. By clicking "I Agree" to the WHISE eligibility Qualtrics survey, you consented to participate in the study, and that check mark serves as a substitute for your signature of informed consent. Consent form documents will be emailed to you after the research team members get your email via the WHISE app eligibility Qualtrics survey. You can keep this copy for your records.