Study Protocol

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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Study Title: The WHISE Study: Wellness, Hypertension, Information Sharing, Self-Management and Education. Empowering WHISE women

Short Study Title: WHISE

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i. Background

One out of three Americans is affected by hypertension.[1] Although many Americans are affected, the prevalence of hypertension is highest among African American women.[2] African American women are diagnosed earlier, live with hypertension longer, and die at an earlier age than other women.[3, 4] African American women also have higher blood pressure readings when compared to other women, and they have been found to have deficits in expected knowledge related to hypertension.[4, 5] Hypertension, or high blood pressure, is a serious global issue. As a dangerous chronic illness, hypertension has almost no early signs. It is one of the leading causes of morbidity and mortality in the United States and those with hypertension have an elevated risk of cardiovascular disease and stroke.[2] Additional research is needed about ways to eliminate health disparities in hypertension that affect African American women.

One approach to responding to the goals outlined in the Precision Medicine Initiative is to better understand differences in brain activity in response to health information. *Previous research was used to inform the scientific premise of this study.* Previous studies have used functional magnetic resonance imaging (fMRI) 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.[6] A review of the literature highlights the importance of fMRI studies in determining how the brain responds to health information, and how this process leads to behavior change.[7] Using fMRI, researchers have been able to predict how likely patients are to stop smoking and how often individuals will use sunscreen.[7-9] Few studies have looked at how brain activity predicts blood

pressure self-management behavior, such as making dietary changes, or taking anti-hypertensive medication. Gaining knowledge of how our brains differ in processing information is an important step forward in improving hypertension self-management.[10, 11] This knowledge will assist in the design and testing of culturally tailored interventions for African American women that potentially are more effective than current self-management interventions.

A strength of the evidence available is that the neuroscience literature reveals that we can, in fact, "rewire" our brains.[12] Interventions that focus on self-management are designed to do just that, but we have yet to determine the underlying neurological pathways. Appropriate measures of the brain-behavior interaction are needed to deepen our understanding of how interventions modify the brain and related self-management behaviors.[11] Exploring the relationships between behavior and neuroprocessing will help scientists and practitioners better understand why messaging leads to behavior change in some cases, but not in others.[10] Gaining knowledge of how our brains differ in processing information is an important step forward in improving hypertension self-management.[10, 11]

For this proposal, we will design the WHISE intervention (enhanced with an information sharing component), to improve blood pressure control among AAW. We will conduct a randomized controlled pilot study to determine the feasibility and acceptability of WHISE, and obtain data to conduct a power analysis for a large, multisite randomized controlled trial that will be proposed in the subsequent R01 application.

ii. Specific Aims

Aim 1: Conduct a randomized controlled pilot study to determine the feasibility and acceptability of WHISE, and to obtain data to conduct a power analysis for a subsequent full-scale randomized controlled trial.
Hypothesis: Participants' health outcomes, and survey data will reveal acceptable satisfaction, feasibility ratings, and health outcomes; and provide information to fine-tune study implementation procedures towards a multisite WHISE trial.

Aim 2: Characterize brain activity in a subset of the sample, providing neurobiological evidence supporting the hypothesis that those completing WHISE have improved ability to differentiate between analytic and empathetic tasks, compared to women in the control group.

iii. Study Population

i. *Inclusion criteria for full study participation*:
   i. Participants must be adults aged 18-65, AND
   ii. Self-identify as African American, AND
   iii. Self-identify as a woman AND
   iv. Self-report being diagnosed with hypertension, AND
   v. Have two individuals who would be able to participant in limited study activities with them (peers), AND
   vi. Live in Southeast Michigan zip codes in Wayne County, Oakland County, Washtenaw County, and specifically Flint township (for a detailed listing of these zip codes please refer to the appendix in section five below), AND
   vii. Own a smart phone

ii. *Inclusion criteria for peer participation:*
   i. Peers must be adults over the age of 18 AND
   ii. Own and regularly use a smartphone AND
   iii. Be willing to download and use the WHISE app

iii. *Exclusion criteria*:
   i. Participants outside of the age range.
   ii. Participants who do not self-identify as African American.
   iii. Participants who self-report not being diagnosed with hypertension.
   iv. Participants who do not live in Southeast Michigan zip codes in Wayne County, Oakland County, Washtenaw County, and specifically Flint township.
   v. Participants who do not own a smart phone.

iv. Additional fMRI exclusion criteria:
   i. Participants who have with ferromagnetic metallic or electronic implants in the body
   ii. Participants who are pregnant or trying to become pregnant.
   iii. Participants who have been diagnosed with major depressive disorder
   iv. Participants who are claustrophobic
   v. Participants who are unable to be still for at least 60 minutes
   vi. Participants with permanent makeup
   vii. Participants with tattoos that were not done by a professional or have a metallic component
   viii. Participants with braces
   ix. Participants with non-removable wigs
   x. Participants with non-removable piercings

v. *Recruitment process*: The survey will be distributed via Facebook Business—a social networking site which has approximately 230 million monthly active users in the United States in January 2018.[1] Facebook Business utilizes Instagram to help advertise the study. The survey will be designed using the Qualtrics survey programming software and will be accessed by clicking on banner advertisements. On Facebook we will ask those who have decided to partner with us, such as Chi Eta Phi Sorority (Professional Nursing Sorority) Lambda Chi Chapter (Detroit) and Southfield Alumnae Chapter, Delta Sigma Theta Sorority, Inc. to share the advertisements on their Facebook pages. The advertisements will target female users ages 18-65 and up who live in Southeast Michigan zip codes and who express a "multicultural affinity" through their profile self-identification or through posted content to being African American. We will target users who live in Southeast Michigan zip codes in Wayne County, Oakland County, Washtenaw County, and specifically Flint township. Please refer to the appendix in section seven for a detailed listing of these zip codes. This will allow us to target specifically adult AAW living in our area of interest. We anticipate opening the survey for several weeks to gather a maximum of 500 responses. Not everyone who expresses interest in being a part of the study will qualify and as soon as we have reached 50 active participants, recruitment will stop. All zip codes and IP addresses will be deleted after study verification of location. IP addresses are collected automatically by Qualtrics and will only be used to ensure that each response is individual. Zip codes are collected only to verify that an individual lives in the Southeast Michigan area.

vi. *Recruitment materials*: We will use designed advertisements on the Facebook and Instagram websites to direct participants to our Qualtrics survey tool. The advertisements will briefly indicate the purpose of the study and select inclusion criteria for participation. They will also include stock images of AAW as well. The survey website (Qualtrics) that participants are directed to will contain additional information about the details of the survey, contact information of the study staff, and the informed consent.

iv. Study Design

i. *Categories of survey questions for recruitment*:

i. Eligibility questions to ensure inclusion criteria are met (see above).

ii. Contact information (name, email address, mailing address, phone).

ii. The proposed study is a randomized intervention study comparing fMRI-derived analytic and empathetic differentiation outcomes for women randomized to the WHISE intervention or controls, pre- and post-intervention.

i. Participants will be assigned a randomized study ID number that will be used to refer to their study related information. A copy of the participant's contact information and their study ID will be kept in a separate crosswalk document for the duration of the study until all data is collected and the participant has been compensated. Participants will be asked if they would be interested in completing the FMRI portion of the study.

ii. Only participants who choose to participate in the study and meet all eligibility criteria will have their contact information maintained in the crosswalk document. This document will be maintained on UofM's Dropbox and will be password protected for participant privacy. The document will be destroyed according to UofM's guidelines after all data analysis has been executed.

iii. The study ID number will begin with "WHISE" followed by 5 numbers. This is so the Study ID will be consistent with the format used by the fMRI Lab. This will be assigned sequentially as participants are enrolled. After being assigned a study ID number, participants will be randomized to the control or the intervention group and will not know which group they are in. This designation will also be documented in the crosswalk document.

iv. The participant will provide the email address of her two chosen peers. The peers will be emailed a copy of the consent form and if they agree, will be sent a link to download the WHISE app.

v. A study team member schedules a Zoom visit with the participant where the Qualtrics questionnaire will completed.

vi. We will use the address provided by the participant in the crosswalk document to mail the blood pressure cuff and 2 A1C kits.

vii. The study team member will be present to tell the participant their study ID number to be entered into the Qualtrics survey. After the participant enters the study ID, a study team member will suggest that the participant turn off their camera and mute their microphone, if they would like privacy while they complete the surveys. The study team member will remind the participant that they will remain on the Zoom call, in case the participant has any questions or has technical difficulties. Th participants will complete the following surveys: Chronic Disease Management and Self-efficacy Scale, COVID-19 and blood pressure self-management, Everyday Discrimination Questionnaire, Index of Self-Regulation, Modes of Health Information and Acquisition, Sharing and Use Scale, Patient Activation Measure, and PROMIS Global Scale.

iii. Participants will complete two 24 hour dietary recalls over the phone with a trained Dietitian at both the Baseline timepoint and at the 6month timepoint.

iv. Participants will receive an email that includes: a link to the mobile application to download it, a brief overview of the application and how to use it, and instructions on who to contact to set up an optional Zoom to receive additional assistance in using application. Both the control and intervention group will use the mobile app and receive the same

modules with education on the DASH (Dietary Approaches to Stop Hypertension) diet, exercise and medication adherence.

v. For 6 weeks, women will engage in modules on hypertension management topics such as diet, medication adherence and exercise. The only difference is that the intervention group will be prompted to share the information from the module. After downloading the WHISE app, participants in the intervention group will be prompted to identify two peers to share with. The app will create a message that the participants can send to each peer, who will also download the app on their mobile devices. After participants in the intervention group have completed each module, they will be prompted to share a least one component they found interesting with their peers. All sharing activities will take place within the app. Those in the control group will not be prompted to share the information they learned in the module.

fMRI Component of the Study
******Please reference the fMRI Master Protocol uploaded in 5.1.1 of this application******

vi. In the Baseline Survey, there is a brief description of an fMRI and one question that asks participants if they are interested in undergoing an fMRI. Of those who state that they are interested, 20 will undergo an fMRI before the intervention and again in six months. If there is enough interest, interested participants will be randomly selected to undergo the fMRI scan (10 participants from the intervention group and 10 from the control group). During the enrollment process, the participant can share their availability to help the research team schedule fMRI dates.

vii. A study team member will contact the participant to confirm fMRI appointment and eligibility, as well as email the directions that are provided by the fMRI lab. Additionally, these participants will go through the fMRI safety screener (no metal in the body, not pregnant, etc.) provided by the fMRI lab.

   i. When participants arrive at the fMRI lab, they will take a pregnancy test, a researcher and fMRI tech will go through the fMRI consent and all of the information on the fMRI safety screening checklist will be confirmed. The fMRI itself, will take roughly an hour.

v. Risks:

i. 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.

ii. Risks associated with fMRI may include anxiety from being confined in the space of the MRI scanner, discomfort from the loud noises made by the scanner, or slight dizziness, light-headedness, or nausea during or immediately after the scanning session. Because of the strong electromagnetic fields, there is a risk that lose objects outside of your body could be accelerated by the magnetic field and strike you. There is also a risk that the magnetic fields could disturb a metal fragment in your body, interfere with an implanted device, such as a pacemaker or neurostimulator, or cause metal (including foil-backed medication patches) on or in your body to heat up, causing you harm. Additionally, this study has the potential to cause "peripheral nerve stimulation" (PNS), a light touching sensation on the skin surface, lasting only for a few seconds. It may cause mild discomfort, but is not harmful to you. There is a possibility that the MRI may reveal an abnormality that is already in your head or brain, such as a cyst or tumor. There is also a risk of a

breach in confidentiality. All of the above are considered to be "rare" and no more than minimal based on the fMRI guidance sheet.

iii. The researchers will try to minimize these risks by: making sure that you meet the criteria for participation in the study, based off the information that you provide. Related to the fMRI – you will be asked to remove all jewelry and change out of clothing containing metal. You will also fill out an fMRI safety questionnaire that allows us to screen you for metals that cannot go in the scanner.

iv. There is the potential that a fMRI may reveal an abnormality that is already in your head or brain, such as a cyst or tumor. Many such abnormalities are not clinically significant, but you may need or want to investigate them further. Such a finding might require additional studies, and maybe even treatment, which would not be paid for by the investigators, the sponsor, or the University of Michigan. However, you should also know that your scan images will not be routinely examined by a specialist trained to make medical diagnoses. Any abnormalities that you may currently have may not be noticed in the images obtained in this experiment. If you have any current health concerns, you should consult your doctor.

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

vi. *Additional protections against risks:*

i. The following confidentiality protection steps will be taken: (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) participants will be informed that they can withdraw from the study at any time; and (d) all data collection will take place online. Sensitive information will be obtained from the participants and several mechanisms will be put in place to protect this information. There will be two databases. The personal information database will contain all personal identifiable information such as name, address, and phone number. Only the principal investigator will have access to this database.

ii. The participant will be assigned a study identification number. Identifiers, data, and keys will be placed in separate, password protected/encrypted files and each file will be stored in a different secure location. Data will be stored under the study identification number, therefore there is no risk that this study will generate information that might place the subjects at risk of personal safety, criminal or civil liability, or damage to their financial standing, employability, or reputation. All presentations and publications will only use aggregate data. Digital data will be encrypted and coded to prevent unauthorized access.

iii. We will protect against breeches of confidentiality by only collecting IP address alongside survey responses for validation purposes. For participants interested in participating in the WHISE study or future research opportunities, the provision of email address, address, and phone number will be collected at the end of the survey. The WHISE survey data collected separately. For the recruitment survey link containing the screener and WHISE survey questions, the participant's IP address will automatically be collected by the Qualtrics software in order to validate that each individual row response is from an individual IP address without duplicates. Survey data and disconnected contact information will be stored through UofM's DropBox with access privileges restricted only to IRB-approved study staff.

iv. We will minimize the risks of participant discomfort by including a detailed description of the content of the survey before participants agree to participate, such that the potential participants are aware of the nature of the questions they will be asked. In the WHISE survey, we will also allow participants to skip any questions they do not wish to answer and allow participants to exit the survey at any time without penalty.
v. We minimize fMRI risks by making sure that participants meet the criteria for participation in the study, based off the information and medical history that they provide to us. Participants will be asked to remove all jewelry, change out of clothing containing metal, fill out an fMRI safety questionnaire that allows screening for metals that cannot go in the scanner.
vi. We will provide the contact information for the study staff and the IRB should any participants wish to contact us with questions or concerns about the research study.

a. *Confidentiality:*
vii. Participation in the survey portion of the study will be coded and voluntary. IP addresses are automatically collected by Qualtrics and only used to make sure that each answer is unique and not from a "bot" or one person submitting multiple inquiries. The collection of zip codes is only to verify that the individual lives within the Metro-Detroit area, as this is part of the exclusion criteria, listed above. We will collect participant contact information separately from the survey data responses so that no one, not even members of the study team, will have the ability to connect responses with individual subjects at any time, directly or indirectly. These data will be destroyed according to UofM's guidelines after all data analysis has been executed.

b. *Benefits:* The study is not designed to benefit the participants directly. However, participation in the WHISE study will help us to 1) pilot an app that may help AAW in controlling their blood pressure 2) gain knowledge about how to continue to tailor self-management interventions for AAW 3) provide feedback from AAW on their experience with the app and how we can improve it to better suit their needs and (4) to allow the researcher to use this data to design and conduct a full scale study.

$75 gift card for your completion of all study activities. The breakdown of the study is listed below:
$10 for completing each of the app modules for a total of $60
$15 for completing the online survey portion of the study
Those who chose to participate in the optional fMRI portion of the study will receive an additional 25$ gift card for each fMRI.

Those who participate as peers for the study, will not receive any compensation.

c. *Costs:* There will be no costs to the participants to complete this study.

d. *Consent Process and Documentation of Consent*:
We will apply for a waiver of documentation of informed consent because the research presents no more than minimal risk of harm to the subject and involves no procedures for which written consent is normally required outside of the research context.

viii. The first page of the survey will contain the information sheet of informed consent. The information sheet will contain a description of the purpose of the study, risks and benefits of taking part in the study, and contact information for the researchers conducting the study and the IRB. By clicking "I Agree" at the bottom of this information page, volunteers will agree to participate in the study. This will serve as a substitute for their signature of informed consent. They will then be taken to the recruitment survey questions.

ix. A participant's chosen peers will be emailed a copy of the consent and asked to reply with an affirmative response. If they do, they will then be sent a link to the WHISE app link.

x. Participants who undergo fMRIs will complete fMRI consent by a study team member and an fMRI tech in a private room within the fMRI facility. The participant will sign two copies of the consent. A copy will be given to the participant and one will be maintained by the lab in a locked cabinet, in a locked room at the University of Michigan School of Nursing Building.

xi. Lab fMRI schedule times come out two weeks before the next month. When fMRI times are set for the 6-month mark, a study team member contacts the participant via phone to schedule the second fMRI.

e. *Results*

i. We will ask all participants if they are interested in hearing about the results of the study. If they express interest and provide their name and email address, we will email the participant a summary of the study results.

vi. Appendix (Zip Codes for Inclusion)

Wayne County

Allen Park 48101	Belleville 48111	Canton 48187
Canton 48188	Dearborn 48120	Dearborn 48124
Dearborn 48126	Dearborn 48128	Dearborn Heights 48125
Dearborn Heights 48127	Detroit 48201	Detroit 48202
Detroit 48204	Detroit 48205	Detroit 48206
Detroit 48207	Detroit 48208	Detroit 48209
Detroit 48210	Detroit 48211	Detroit 48213
Detroit 48214	Detroit 48215	Detroit 48216
Detroit 48217	Detroit 48219	Detroit 48221
Detroit 48223	Detroit 48224	Detroit 48226
Detroit 48227	Detroit 48228	Detroit 48234
Detroit 48235	Detroit 48238	Detroit 48242
Detroit 48243	Ecorse 48229	Flat Rock 48134
Garden City 48135	Grosse Ile 48138	Grosse Pointe Park 48230
Grosse Pointe Woods 48236	Hamtramck 48212	Harper Woods 48225
Highland Park 48203	Inkster 48141	Lincoln Park 48146
Livonia 48150	Livonia 48152	Livonia 48154
Melvindale 48122	New Boston 48164	Northville 48168

Plymouth 48170
River Rouge 48218
Southgate 48195
Wayne 48184
Wyandotte 48192
Redford 48239
Rockwood 48173
Taylor 48180
Westland 48185
Riverview 48193
Redford 48240
Romulus 48174
Trenton 48183
Westland 48186

Oakland County

48326 (Auburn Hills)
48072 (Berkley)
48009 (Birmingham)
48302 (Bloomfield Hills)
48304 (Bloomfield Hills)
48301 (Bloomfield Hills)
48346 (Clarkston)
48348 (Clarkston)
48017 (Clawson)
48382 (Commerce Township)
48350 (Davisburg)
48331 (Farmington)
48334 (Farmington)
48335 (Farmington)
48336 (Farmington)
48220 (Ferndale)
48025 (Franklin)
48030 (Hazel Park)
48357 (Highland)
48356 (Highland)
48442 (Holly)
48070 (Huntington Woods)
48320 (Keego Harbor)
48359 (Lake Orion)
48360 (Lake Orion)
48362 (Lake Orion)
48367 (Leonard)
48071 (Madison Heights)

48380 (Milford)

48381 (Milford)

48165 (New Hudson)

48167 (Northville)

48375 (Novi)

48374 (Novi)

48377 (Novi)

48237 (Oak Park)

48363 (Oakland)

48462 (Ortonville)

48370 (Oxford)

48371 (Oxford)

48069 (Pleasant Ridge)

48341 (Pontiac)

48342 (Pontiac)

48340 (Pontiac)

48309 (Rochester)

48306 (Rochester)

48307 (Rochester)

48073 (Royal Oak)

48067 (Royal Oak)

48178 (South Lyon)

48076 (Southfield)

48075 (Southfield)

48034 (Southfield)

48033 (Southfield)

48084 (Troy)

48098 (Troy)

48083 (Troy)

48085 (Troy)

48390 (Walled Lake)

48329 (Waterford)

48328 (Waterford)

48327 (Waterford)

48324 (West Bloomfield)

48323 (West Bloomfield)

48322 (West Bloomfield)

48386 (White Lake)

48383 (White Lake)

48393 (Wixom)

Genesee County

Flint 48502	Flint 48503	Flint 48504
Flint 48505	Flint 48506	Flint 48507
Flint 48532		

Washtenaw County

48103 (Ann Arbor)
48104 (Ann Arbor)
48105 (Ann Arbor)
48108 (Ann Arbor)
48109 (Ann Arbor)
48118 (Chelsea)
48130 (Dexter)
48158 (Manchester)
48176 (Saline)
48189 (Whitmore Lake)
48190 (Whittaker)
48191 (Willis)
48197 (Ypsilanti)
48198 (Ypsilanti)

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