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Study Title	Stress and Hypertension in Dementia Caregivers (MIM-DASH)
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INTRODUCTION

No demographic group is more at risk for the double jeopardy of caregiving stress and hypertension (HTN) than African American women caring for a family member with Alzheimer's disease and related dementias (ADRD). Both situations lead to reduced quality of life and cardiovascular disease—a complication of uncontrolled hypertension. Maintaining the health of these caregivers is critical to support the well-being of the care recipients. Although some multi-component interventions have addressed ADRD caregiver's stress and quality of life, **gaps remain** in targeting interventions to address the complexity of chronic caregiving stress and hypertension self-care in African American women.

This pilot study builds on our earlier work which showed that stress, blood pressure knowledge, and complex diet information deficits all interfered with older African American women's hypertension self-care. Lifestyle changes (stress management, reducing sodium, eating fruits/vegetables, and physical activity) are effective in managing hypertension. Our Stage I pilot study is based on the **scientific rationale** that we can promote these lifestyle changes by addressing stress reactivity/stress resilience, the psychological and physiological response of the body to stress, as the underlying mechanism to facilitate behavioral change. In this way we can improve health outcomes (caregiver stress, quality of life, cardiovascular disease risk).

A small-scale two-group randomized controlled (RCT) pilot study of 28 African American female caregivers, age 40 and older with hypertension, will be conducted. We will determine the feasibility and acceptability of Mindfulness in Motion (MIM) plus the Dietary Approaches to Stop Hypertension (DASH). Participants will be randomized to either the MIM DASH intervention or the Alzheimer's Association Caregiver Training (attention control) delivered in 8 weekly, 1-hour group sessions via telehealth (video and telephone access). After completion of the intervention, both groups will receive four bi-monthly follow-up calls over the 9 months. To our knowledge, this is the **first** study that a) systematically employs one of the **Science of Behavioral Change key mechanisms underlying successful adoption** of health behaviors—**stress reactivity/stress resilience** and b) focuses solely on African American female caregivers of people living with dementia. The study aims are to:

AIM 1. Determine the feasibility and acceptability of MIM DASH and Caregiver Training for African American female caregivers with hypertension. Hypothesis: MIM DASH and Caregiver Training groups will be feasible and acceptable to caregivers. Method: We will track *feasibility*: screening to enrollment, attendance, attrition, completion of data collection procedures; and *acceptability*: treatment-specific preference ratings (pre-post intervention). The Credibility Scale will capture attitudes towards the treatment condition and the participants' expectation of benefit once the treatment has been explained. Analysis: Feasibility and acceptability will be examined through descriptive statistics.

AIM 2. Explore the impact of MIM DASH as compared to Caregiving Training on caregiver stress and QOL. Hypothesis: MIM DASH group will have improved caregiver stress and QOL as compared to the Caregiver Training group. Method: The Perceived Stress Scale will be used as a measure of *caregiver stress* and the level of cortisol extracted from hair will be a proxy measure of *chronic stress*. The World Health Organization-5 will be used to measure QOL. The data will be collected in person and documented in REDCap at baseline, 3, and 9 months post-intervention. Analysis: We will conduct intent-to treat analysis and the fixed effect of MIM DASH intervention will be examined by mixed effects models.

AIM 3. Investigate the potential mediation effects of stress reactivity/stress resilience between MIM DASH or Caregiver Training and self-care behaviors. Hypothesis: Higher stress reactivity will diminish the relationship while higher stress resilience will enhance the relationship between MIM DASH and the adoption of self-care behaviors. Method: Daily Inventory of Stressful Events and the Pittsburgh Stress Battery will be used to measure stress reactivity/stress resilience. Self-care behaviors will be measured using the Stress Management Practices survey and the Block Food Frequency Questionnaire for the DASH eating index (includes physical activity). The 4-Item Krousel-Wood Medication Adherence Scale will be used to measure medication adherence. The data will be collected in person and online survey at baseline, 3, and 9 months post intervention. Analysis: The mediation analysis will be employed to examine this pathway.

Impact. This pilot will make a substantive contribution to the science of behavior change by identifying basic mechanisms, in the adoption of healthy behaviors that can be used to implement self-care interventions to reduce health disparities in African Americans. **Findings from the pilot study will inform the infrastructure for a larger trial.**

BACKGROUND AND RATIONALE

African American women are disproportionately burdened with informal caregiving. In 2019, informal caregivers provided 18.6 billion hours of unpaid care to people living with Alzheimer's disease and related dementias (PLWD) with African American women providing 60% of this type of care. Although African American women generally endorse positive feelings about caregiving and express cultural justifications for providing care, they endure the adverse effects of chronic caregiver stress—increased cortisol and HTN. Indeed, HTN is the leading cause of cardiovascular disease (CVD) among African American women affecting 56.7%. **Yet, to our knowledge no behavioral intervention studies have** addressed the dynamic interplay of chronic caregiving stress and HTN self-care in African American women. Our intervention, study thus addresses a significant gap.

"Caring for myself is not self-indulgence, it is self-preservation, and that is an act of political warfare." ~Audre Lorde

Current caregiver interventions are not as effective for African Americans as compared to other populations. Three key studies: Resources for Enhancing Alzheimer's Caregiver Health (REACH II), Savvy Caregiver, and Enhanced Physical Activity Intervention had a sufficient samples size of African Americans. However, in these studies, African Americans were less likely to experience

success as other populations. The uptake of the intervention was lower among African Americans than other races and no there were no changes noted in self-care or quality of life. None of these studies included mindfulness as a part of the intervention. One study currently underway of African American caregivers by Gaylord et al., is using telephone-delivered mindfulness-based stress reduction. Our intervention, Mindfulness in Motion plus the Dietary Approaches to Stop Hypertension (MIM DASH) compare to the one in Gaylord et al and thus may provide stronger benefit.

There is a strong need for culturally sensitive strategies. Solid empirical evidence demonstrating the effectiveness of the DASH diet in reducing blood pressure. However, African Americans are less likely than Whites to be adherent to the DASH diet. We hypothesize that there are other confounders impacting adherence, specifically chronic caregiver stress.

Stress reactivity/stress resilience is hypothesized as one of the key mechanisms underlying successful change in behaviors. *Stress reactivity* is the physiological response of the body to stress—activation of the cardiovascular system by increasing heart rate and BP. *Stress resilience* is the process of adapting well in the face of significant sources of stress such as caregiver stress. Both are key mechanisms underlying successful change in behaviors. Thus, our multi-model intervention that includes targeting stress resilience/stress reactivity has strong potential.

Rigor of the Prior Research. Qualitative studies show that African American caregivers desire more support and education regarding self-care and diet to manage chronic conditions. However, few studies of a culturally-tailored DASH diet have lacked methodological rigor. None have investigated the mechanism of change in caregivers' behaviors. While the REACH II and Savvy Caregiver studies use randomized control trial (RCT) design, psychoeducation, and translation across multiple settings, these studies have lacked equipoise in the attention control groups and did not to examine the underlying mechanistic principles of behavior change. Questions remain unanswered regarding the stress and blood pressure self-care among African American women caregivers.

Significance of the Expected Research Contribution. Our study will address gaps in prior studies by providing equal attention to the intervention group and control group and using messaging appealing to African American women, focusing on the mind-body integration to promote self-care as opposed to caregiver burden. To our knowledge, **our study will be the first** to provide substantive information regarding the mechanistic action of stress reactivity/stress resilience, psychological and physiological response of the body to stress, and on self-care practices in African American female caregivers. These findings will lead to a larger RCT to examine the effectiveness of MIM DASH among African American female caregivers of PLWD.

INNOVATION

This proposal presents several innovations: 1) Use of the **Information-Motivation-Behavioral** Skills model in this setting is novel among African American women caregivers, 2) **Methodological shift** by combining mindfulness and healthy eating to address two high risk factors for adverse health outcomes—caregiver stress and HTN; and 3) **Examining** the impact of the **underlying mechanism** of stress reactivity/stress resilience for this intervention.

PRELIMINARY WORK

Our preliminary work spans three studies of HTN self-care in older African Americans: an examination of self-care facilitators and barriers, a pilot of a co-created health education intervention, and MIM DASH. The

Figure 1. Preliminary research results across three studies in African American older adults

Recruitment Retention ⁴⁻⁶	HTN self-care quasi-experimental ⁶ N=31	MIM DASH 3-arm RCT older adults ⁷ N=38
<ul style="list-style-type: none"> • 31 African Americans in 30 days • Zero drop out • 90% attended 100% of sessions 	<ul style="list-style-type: none"> • Identified facilitators to HTN self-care <ul style="list-style-type: none"> • Group support • Access to health professional • Family support • Identified barriers to HTN self-care <ul style="list-style-type: none"> • Interpersonal communication stress • Complex diet regimens 	<ul style="list-style-type: none"> • True control group 50% attrition rate • Clinically significant reduction in systolic BP in the MIM DASH group (-7.2mm Hg) relative to the attention only group (-.7) • Intervention fit within routine and culture

findings demonstrate our ability to recruit, retain, and deliver health behavior interventions to African Americans. Our interprofessional team is well-poised to conduct this intervention study given our preliminary work that can be transferrable to hypertensive African American women caring for PLWD. The primary investigator has over 6 years' experience conducting culturally informed research in this population.

We incorporated the Information-Motivation-Behavioral Skills model in our conceptual framework to promote health behavior change. The antecedents are biologic characteristics that may influence outcomes. The intervention has three components: knowledge of basic **information** regarding an illness/disease (HTN), **motivation** through learning in a socially supportive environment, and **behavioral skills** to manage stress and HTN. The Science of Behavior Change indicates stress reactivity/stress resilience affects behavior change. Through implementation of Mindfulness in Motion to affect stress reactivity and promote stress resilience, we can change the body's response to stress and influence the adoption of DASH self-care behaviors, lowering caregiver stress and improving QOL.

STUDY PROCEDURES

RESEARCH DESIGN

Randomized-controlled trial.

SAMPLE

Sample. A sample of 28 African American women (age 40 and older) with a diagnosis of hypertension, who are caregivers of persons living with dementia (PLWD).

Setting. In an effort to facilitate trust with potential participants, we intend to hire research staff who are ethnically similar to the participants. PI Wright and co-I Adams are both African American researchers and will assist study staff to explain study aims and protocols to the key stakeholders in the community. The study will take place in via telehealth with data collection occurring in-person.

Sampling Plan. Our prior work in hypertensive African Americans demonstrates that we can enroll N=28 caregivers. The total enrollment includes 28.6% oversampling to account for attrition. The composition of Blacks in the Columbus area is representative of the United States population at 22.86%. Forty-seven percent of Blacks in Ohio have hypertension. Most of the potential participants will be recruited from the African American Alzheimer's and Wellness Center—sampling frame of 242 middle-aged African American women. From prior experience, we do not anticipate difficulty recruiting participants for this study.

Eligibility Criteria: Inclusion criteria are (1) diagnosis of HTN treated with an antihypertensive medication; (2) age 40 and older (3) a caregiver rating of the PLWD of 2 or greater on the Alzheimer's Dementia-8 scale; (4) caregiver provides unpaid care to a PLWD at least 10 hours per week or assists with at least one instrumental activity of daily living (5) self-identifies as Black/African American; (6) English speaking; and (7) access to a telecommunications device such as the internet via desktop, laptop/tablet, smartphone, or telephone.

Exclusion criteria are (1) expect to move out of the area within 9 months; (2) diagnosis of resistant HTN (blood pressure that remains above goal despite concurrent use of a diuretic/water pill and at least two other antihypertensive agents of different classes); or (3) active participation in mindfulness/yoga program. The NIA Common Data Screening and Enrollment forms will be used to track data.

Recruitment. We will recruit participants for the study from the African American Alzheimer's and Wellness Association, the Ohio State University College of Nursing Total Health and Wellness clinic, Ohio State University Wexner Medical Center—Center for Cognitive Impairment, and Division of Geriatrics outpatient clinic. We will also advertise at churches, the Alzheimer's Association Central Ohio Chapter webpage, Research Match, and on Facebook. The estimated daily results from Facebook would reach from 1.1k - 3.3k persons and link clicks at 17-49 Columbus area. PI has an established relationship with members of the clergy in the African American community and is seen as a trusted source for health information and collaboration. The project coordinator and PI will reach out to contact persons at each clinical and community site weekly to identify potential participants who meet inclusion criteria.

In the future, we may have similar research studies. The consent form will also include the opportunity for participants to partner with us for potential future studies that are related to hypertension and health in Black and African Americans. The scope of the request for the participant's contact information will be access to the following by the study team/PI:

The contact information will not be provided to other investigators for similar research projects without further informed consent (e.g., recruitment registry).

- a. First and last name.
- b. Address
- c. Phone number (cell/home)
- d. Email

The consent form will also provide an opportunity to participate in future research. We will obtain the participant's permission to contact them in the future (yes/no). They are not required or obligated to provide their contact information for future research opportunities. The contact information of participants, who agree to be contacted in the future, will be stored in the secure R:drive at the College of Nursing.

Recruitment and Participant Online Consent

The steps to consenting are as follows:

- a. Potential participants would access the Verbal Script for Obtaining Informed Consent The Ohio State University Consent to Participate in Research via REDCap link provided on the study recruitment materials.
- b. The consent link will have a prescreen feature.
- c. If a person says no to one of the inclusion criteria questions, they would be thanked and told that they do not qualify
- d. If the person meets the eligibility criteria, then the verbal script for obtaining online consent will appear.
- e. At the end of the consent form, the person would click a checkbox to be enrolled in the study. If the person says no, then they will be thanked for their time.
- f. If the person checks yes, another box would open to request their contact information (phone, email, mailing address) and query as to whether or not they want documentation linking them to the research.

Flyers will be posted at the respective study recruitment sites for potential participants, family members and staff to view. Research personnel will provide an overview of the study at staff meetings and community center gatherings (e.g., salons, barbershops, churches, and senior centers). Those who are interested in participating will inform the research personnel of their desire to participate.

Documentation of Consent. A Consent Checklist form will be used for all participants. All research staff will complete the elements of the checklist for every participant. Elements include that a copy of the consent was provided to the participant. The Consent Checklist Form will be kept in the participants' file folders in the CON R:Drive.

MEASUREMENT/INSTRUMENTATION

The **data collection** pis will be administered in both groups at baseline, 3, and 9 months. Data collection will take no longer than 120 minutes for each data collection session. Data collection will take place in the setting that is most convenient for the participant. For example, home or at the College of Nursing. Participant demographics and comorbidities will be collected at baseline. All other measures will be collected at baseline to 3, and 9 months as listed in Table 1. To accommodate the participants, who are caregivers, we will have the option for the study visits to be broken up into smaller 1 hour visits. Additionally, data that does not require an in person visit, such as questionnaires/surveys may be completed via phone or Zoom.

At baseline, we will administer the 6-item Newest Vital Sign as to measure health literacy. The Newest Vital Sign has high internal consistency (Cronbach's Alpha = 0.74). Validation against the Test of Functional Health Literacy in Adults demonstrated a Pearson's r of 0.49 and an area under the ROC curve of 0.81 (Table 1). Scores range from 0-6 with lower scores indicating lower health literacy.

For feasibility of recruitment, we will track the number screened per month; number eligible; number enrolled per month; average time delay from screening to enrollment; and the completion of data collection.⁵⁶ For acceptability, we will track treatment-specific preference ratings (pre- and post-intervention). For acceptability, we will track treatment-specific preference ratings (pre- and post-intervention). The participants will complete the Acceptability of Participant Preferences 13-item Likert-type survey ranging from 1 (strongly disagree) to 5 (strongly agree). Interventionists will keep detailed intervention session records describing participant response to the intervention. For the MIM DASH group, we will collect data regarding usage of self-care equipment (home BP monitor and MyPlate) from follow-up calls. We will use a credibility scale for both groups regarding the expectation of benefits of the study. The *Credibility Scale* ($\alpha = 0.86$) measures attitudes towards the treatment condition and the participants' expectation of benefit once the treatment has been explained.^{59,60}

Table 1. Data collection table of variables, measures, months, and reliability/validity statistics for instruments.

Variables	Measures	Psychometrics			
		Baseline	3M	9M	
Pre-Enrollment	AD8	X			
	NIA COMMON DATA SCREENING				
Post-Enrollment	NIA COMMON DATA ENROLLMENT	X			
Biologic	Age in years	X			
	List of comorbidities	X			
Newest Vital Sign	Measure health literacy (VS Score Sheet)	X			$\alpha = 0.74$
Self-care behaviors	Stress skills management practices	X	X	X	$\alpha = 0.71^{75}$
	Block food frequency questionnaire (FFQ Booklet)	X	X	X	Test-retest reliability, $r=0.59^{76}$
	DASH index-calculated from the block food frequency questionnaire	X	X	X	Mean correlation coefficient between frequencies of intake of 55 foods assessed by 2 FFQ 12 months apart = 0.57. ⁷⁷
	Medication list and BP log	X	X	X	
	Krousel-Wood Medication Adherence	X	X	X	C statistic= 0.704 ⁷⁸
Stress reactivity	Daily inventory of stressful events	X	X	X	(Kappa) ranged from 0.66 to 0.95 ⁷⁹

Variables	Measures	Psychometrics		
/stress resilience	Pittsburgh stress battery	X	X	X
Stress/QOL	Perceived stress scale (caregiver stress)	X	X	X
	Folkman 1 question regarding what is most stressful.	X		
	Hair cortisol (chronic stress proxy)	X		X
	WHO-5 (QOL)	X	X	X
Depression Anxiety Stress Symptom Scale (DASS-21)	21 has contains 21 items to evaluate mild, moderate, or severe depression, anxiety, and stress	X	X	X
Revised Memory and Behavior Checklist	32-item check-list that assess activities of daily living and problem behaviors in people living with ADRD	X	X	X
Credibility	Credibility Scale		X	
Acceptability	Acceptability of Participant Preferences		X	

The scale consists of 5 questions rated on a 0 (not at all confident) to 10 (very confident). Higher scores, up to 45, will indicate greater credibility of the treatment condition. This will also aid in determining participants' willingness to be randomized for future studies.

The Perceived Stress Scale has 10-items one a Likert scale with a reference range of 0-30 regarding stress over the past month. Hair cortisol (HC) will be used as a proxy for chronic stress. To collect the hair samples, approximately 25-75 mg of hair (approximate width of shoelace tip when bunched) will be cut from the posterior vertex region of the scalp as close to the scalp as possible. The posterior vertex has the lowest variation in cortisol levels, and is the preferred area for sampling. Participants will be surveyed on corticosteroid use as these medications may suppress cortisol levels, and on their hair care practices, such as frequency of washing, chemical treatments and hair product use. To prep for assay, the hair sample is cut, then washed twice with isopropanol and dried over 1 to 3 days. A total of 10-75 mg of hair is placed into a microcentrifuge tube, minced, and then ground in Retsch 400 Mill. A total of 1.1 ml of HPLC-grade methanol is added to the ground sample, and incubated for 18-24 hours at room temperature with constant agitation. The tubes are centrifuged at 5000g for 5 min at room temperature to pellet the powdered hair. The entire amount (~1 ml) of supernatant is transferred to a clean microcentrifuge tube and the methanol is removed by evaporation using a stream of air for 6-8 hours at room temperature. The cortisol extract is reconstituted in 100ul of Salimetric immunoassay cortisol analysis diluent buffer. Samples are assayed in duplicate and inter- and intra-assay coefficients of variation calculated. HC levels are expressed in hair as pg/mg and generally logged due to skewed distributions as needed. Our team has experience collecting and processing hair samples from African Americans. The World Health Organization (WHO-5) is a short questionnaire consisting of five Likert scale statements of well-being over the past 2-weeks. Scores range from 0-25. The Depression Anxiety Stress Symptom Scale (DASS-21) and the Memory Behavior Checklist to assess psychological comorbidity of the caregiver and health status of the person living with ADRD. The DASS-21 has contains 21 items to evaluate mild, moderate, or severe depression, anxiety, and stress ($\alpha = 0.79$). Scores range from 0-37 with higher scores indicating more symptoms. The Memory Behavior Checklist ($\alpha = 0.84$) is a 32-item check-list that assess activities of daily living and problem behaviors in people living with ADRD. Scores range from 0-96 with higher indicating more behavioral problems in the care recipient. These data will be collected at baseline, 3, and 9 months.

Hair cortisol (HC) will be used as a proxy for chronic stress. To collect the hair samples, approximately 25-75 mg of hair (approximate width of shoelace tip when bunched) will be cut from the posterior vertex region of the scalp as close to the scalp as possible. The posterior vertex has the lowest variation in cortisol levels, and is

the preferred area for sampling. Participants will be surveyed on corticosteroid use as these medications may suppress cortisol levels, and on their hair care practices, such as frequency of washing, chemical treatments and hair product use. To prep for assay, the hair sample is cut, then washed twice with isopropanol and dried over 1 to 3 days. A total of 10-75 mg of hair is placed into a microcentrifuge tube, minced, and then ground in Retsch 400 Mill. A total of 1.1 ml of HPLC-grade methanol is added to the ground sample, and incubated for 18-24 hours at room temperature with constant agitation. The tubes are centrifuged at 5000g for 5 min at room temperature to pellet the powdered hair. The entire amount (~1 ml) of supernatant is transferred to a clean microcentrifuge tube and the methanol is removed by evaporation using a stream of air for 6-8 hours at room temperature. The cortisol extract is reconstituted in 100ul of Salimetric immunoassay cortisol analysis diluent buffer. Samples are assayed in duplicate and inter- and intra-assay coefficients of variation calculated. HC levels are expressed in hair as pg/mg and generally logged due to skewed distributions as needed. Hair samples will be collected at baseline and 9 months.

Daily Inventory of Stressful Events was taken from the Science of Behavioral Change Research Network list of instruments recommended to assess stress reactivity/stress resilience. The instrument is a semi-structured survey in which participants report whether any stressful events had occurred within the past 24 hours. This instrument yields several variables for each reported stressor including: (a) content classification of the stressor for example, work overload, argument over housework, or traffic problem); (b) subjective severity of stressors; (c) primary appraisals (areas of life that were at risk because of the stressor); and (d) perceived control of the situation." Scores range from 0 to 27. *Pittsburgh Stress Battery* is a test of BP response to stress that is indicated as a measure of stress reactivity by the Science of Behavior Change Research Network. The participants are given a series of tests that include the Stroop test, mirror tracing, and mental math. For example, participants will be given three trials of basic arithmetic problems lasting one minute per trial. Participants who scores 60% or greater, will advance to the Random-Medium level; those who do not will , repeat Easy. Prior to the 3rd trial, the data collector will place the BP cuff on the participants left arm unless contraindicated. At the 30-second mark of the 3rd math trial, the data collector will use an automatic BP machine (clinician grade) to measure systolic BP, diastolic BP and heart rate. Significant Other Collaborator, Nguyen is a neuropsychologist and will assist with training data collectors to administer the test and interpretation of data. *Self-care behaviors* are measured using *Stress Management Practices survey part A*, a list of 13 statements such as "I am able to use muscle relaxation techniques to reduce any tension I experience" that is measured on a Likert scale. Scores range from 0 to 52 with higher scores indicating greater use of stress management strategies. *Block Food Frequency Questionnaire* (includes physical activity) is a validated measure with a food and beverage list that includes 127 items, plus supplementary questions to allow for the adjustment of fat, protein, carbohydrate, sugar, and whole grain content. The questionnaire ascertains the frequency with which each food or beverage was usually consumed, and offers nine continuous responses ranging from "never" to "every day" for most foods. The DASH Index that is calculated using data from the Block Food Frequency Questionnaire uses a quintile system to score foods related to the DASH diet. All of the components are equally weighted. Intake of vegetables, fruits (including fruit juice), nuts and legumes, whole grains were scored from 1 (lowest quintile) to 5 (highest quintile). The overall DASH component scores range from 8 to 40. *The 4-Item Krousel-Wood Medication Adherence Scale* captures four domains of adherence behavior.⁷⁸ Scores range from 0 to 4 with a score of 1 or greater indicating lower adherence. These data will be collected at baseline, 3 and 9 months.

A Manual of Operations will detail all procedures related to the protocol, including participant recruitment, data collection, database usage, and database management.

INTERVENTION

MIM DASH Intervention. A trained MIM provider and dietitian will deliver the MIM DASH group intervention in eight 1-hour (~30 minutes MIM and ~30 minutes DASH) sessions via telehealth (video and telephone access). Participants will receive session materials such as PowerPoint slides so they can follow along by phone or videoconferencing. Each MIM session consists of material related to mindfulness—the somatic mind/body connection, relaxation, yoga, meditation, self-awareness, and bodily cues relating to emotional reactivity. Group interaction centers on sharing ideas toward effective practice and practical daily challenges to being mindful. Each class begins with a prompt for participant contemplation during the next hour that reference a

unique weekly theme which will be reiterated in the session materials. Handouts. Then the participants will be led through a body scan, gentle stretching, yoga, progressive relaxation, and/or an eating meditation, and then into formal meditation. Each participant will receive a compact disk player or digital Mp4 file with mindfulness practice recordings as well as a weekly diary to document study activities. Participants will be instructed to perform mindfulness meditations at least five times a week and record the time in their diary. The DASH portion, led by the Registered Dietitian, focuses on education to increase vegetables, fruits, whole grains and decrease intakes of fat and sodium, sugar sweetened beverages and sweets. Education includes adapting traditional "Soul" food dishes to meet the DASH dietary guidelines. Participants will be provided with practical tips to incorporate DASH in daily life. They will receive an individual MyPlate displaying serving sizes and food groups comprising a balanced meal and a home BP monitor. PI Wright will provide training on the use of the BP monitor and American Heart Association infographics and video. Repetition of key concepts will be embedded throughout the sessions to increase critical thinking and problem solving. After completion of the 8-week sessions, the MIM DASH participants will receive eight weekly and then four monthly coaching calls to review sessions and support the adoption of self-care behaviors. Our team has experience in delivering the MIM DASH intervention for older African Americans with hypertension.

Caregiver Training-Attention Control. A trained interventionist will deliver the Caregiver Training. Participants in this group will attend eight 1-hour group lessons via telehealth for 8 weeks. We will use Alzheimer's Association caregiver training resources on topics such as Healthy Living for Your Brain and Body: Tips from the Latest Research; Dementia Conversations: Driving, Doctors Visits, Legal and Financial Planning; and Understanding and Responding to Dementia-Related Behavior. Similar to the MIM DASH group, participants will receive educational materials so they can follow along using videoconferencing or phone. Participants will have group discussion and role play using case study scenario. They will receive eight weekly and then four monthly social calls to maintain participants' involvement and enhance participant retention. Our team has experience working with attention control groups for African Americans. At the end of the study, the Caregiver Training group will receive a home BP monitor, a MyPlate, and American Heart Association home BP infographic and video. They will also have the opportunity to receive a short video describing MIM DASH after the study ends. The MIM DASH group will receive instead the Caregiver Training materials.

There will be additional short video and educational materials for MIM DASH and Caregiver Training will be submitted as an amendment for IRB approval.

The participant can enter Zoom sessions by invitation only. If the participant does not have access to a touch screen tablet or computer, they may be able to borrow an iPads from the College of Nursing. This would be mailed to the participant with return postage paid.

1. Meetings will require a password by default. These passwords will be embedded in the meeting URL (link) by default.
2. Annotations will not be available to participants by default.
3. The ability to join a meeting before the host or alternate host joins will be disabled by default.
4. Participants will not be able to change their names by default.

Participant protection and Zoom. Using the **Only authenticated** users can join setting will prevent guests who do not have an Ohio State Zoom account from entering the session. Since the meeting includes non-university participants, the PI will use the following strategies to control who can attend.

- ♣ Participants only with access can join
- ♣ Turn off the option to Join before Host
- ♣ Turn on the Waiting Room
- ♣ Meeting will be password protected

Participants will be informed that the Zoom group sessions will be recorded using a hand held recorder. Additionally, we will obtain the participant's permission in advance. Participants will be encouraged to use their camera to facilitate interaction. However, participants will be given the choice to turn off their camera and microphone and use the Zoom Chat if they prefer. Participants may use an avatar image of themselves in the

Zoom room. Each cohort will choose a pseudonym for their cohort. Participants may share their contact information, not required, if they would like to support one another in their health goals. The study staff will not provide participants with each other's' contact information. The eight 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. The audio recording of the group classes will be then destroyed.

Field Notes

Research staff may describe their thoughts about factors they observed that contributed to the quality of each encounter by writing a brief field note. The field notes will be documented in REDCap. A descriptive qualitative analysis will be conducted to categorize themes.

Intervention fidelity (Table 2) will be evaluated to provide assurance that MIM DASH and Caregiver Training are implemented as intended and will assure reproducibility of the protocol. The MIM DASH group will receive the Caregiver Training materials at the conclusion of the study.

Component	Data used to Evaluate Intervention Fidelity	Table 2. Intervention Fidelity
Design	Detailed protocol manual for intervention sessions and common problem areas and weekly review of interventionist field notes.	
Training	Research Staff Training: Pre-study simulations and observed data collection. Data collection accuracy at start-up and maintenance will be >.90. Interventionist Training: Each interventionist will complete training to competence under the supervision of PI Wright and Co-I's Klatt, and Adams. All training will be video-recorded with feedback provided and corrected performance observed.	
Delivery	Delivery of Intervention: Field notes will be recorded for all sessions as evidence of completion and to document barriers and facilitators to progress. Interventionist will complete key component check list following each session to provide documentation of participant progress. Audio recordings of randomly selected sessions will be reviewed to assure adherence to intervention protocol.	
Receipt	List of participant responses to each intervention session.	
Enactment	Weekly de-briefing of participants regarding performance of skills and strategies in "real-world" settings. Participant comments will be recorded in interventionist session logs. Participant logs and diaries.	

Data Validity/Integrity It is the responsibility of the Principal Investigator to ensure that all team members handle data and related documentation appropriately. All participant information, including source documents must be reviewed by the PI and clinical team and entered into the REDCap database. There will be ongoing processing of data and quality checks by the study statistician and or PI.

Recruitment:

Participant recruitment will be tracked and reviewed in the research team meetings. In order to maintain confidentiality, the list, which includes the names of all potential participants, will be kept separately from the documentation and tracking spreadsheet in the College of Nursing R: Drive (duo authentication). Tracking will be carried out to determine which and how many individuals are interested in study participation, are eligible for study participation, enroll in the study, and complete the first assessments. Enrolled participants will be given code numbers and their study participation will continue to be tracked via spreadsheet in the College of Nursing R: Drive using and Excel spreadsheet. This will include documenting the occurrence and date of completion of data collection at each time point and their participation in the intervention.

Quality Assurance:

To minimize data-entry error and data-management miscoding, data will be entered into REDCap directly and we will have a paper forms as a back-up. If the data has to be transcribed into REDcap from a paper form, we will do a double data entry process. PI Wright and or designated study staff will review the data collected and all related documentation.

Data Storage:

Consent forms will be stored in REDCap. Participant lists (ID number and demographic information) will be stored in the College of Nursing R:Drive on a spread sheet. The PI and designated study staff will have access to data. All participant data collected via REDCap will be labeled only with a code number. These coded data will be kept separate from the master list that links participants to their consent forms. Only the PI and designated research study staff will have access to the data.

This study will utilize REDCap (Research Electronic Data Capture), a software toolset and workflow methodology for electronic collection and management of clinical and research data, to collect and store data. The OSU Center for Clinical and Translational Science (CCTS) Research Informatics Services will be used as a central location for data processing and management. REDCap provides a secure, web-based application that provides an intuitive data manipulation interface, custom reporting capabilities, audit trail functionality, real-time data monitoring/querying of participant records, and variations of data exporting/importing. REDCap is hosted by OSUWMC IT in the Ackerman Datacenter (640 Ackerman Road; Room 345)

REDCap instance is located on internal OSUWMC network. Remote access to this network can be obtained over an encrypted VPN tunnel (AnyConnect) This VPN uses Protocol: DTLS and Cipher: RSA_AES_128_SHA1. Background checks are performed on all staff that are on the network or obtaining VPN access.

Termination for Significant Risk: Although the study is deemed low risk and adverse events are not anticipated, diligent monitoring will occur as specified above under Adverse Events Protocols. A participant that expresses concern about his or her participation or reports distress associated with receiving the intervention may be asked to discontinue participation in the study if there is concern about participant safety and wellbeing or about the safety and wellbeing of others. Likewise, if one of the research assistants, interventionists or supervising members of the Research Team expresses a concern about a participant's safety or wellbeing, the Office of Responsible Research Practices Adverse Events Reporting process will be used and it is possible that the participant could be asked to discontinue participation if there were concern about his or her, or others, safety and wellbeing.

Protection of Privacy. For all potential participants, the data collection interviews will take place in a private room with closed door. All research team members will be certified with The Ohio State University (OSU) IRB, HIPAA, and CITI training. Careful training and supervision of all study staff will ensure procedures are carried out in accordance with established protocols. Timely team meetings (at least twice monthly) will be conducted to evaluate consent procedures, study data collections, and other study activities to ensure consistency with planned study procedures. Should an adverse event occur, PI Wright will report this to the OSU IRB.

Protection of Confidentiality. Study staff will be carefully trained to protect participant confidentiality. They will work with participants to devise a plan for contacting them by phone, email, text messaging, or some other means determined by the participant, and decide whether or not messages may be left. Participants will be assigned a study identification number, and a master log will be created associating participant names and study number. The master log will be stored separately from data in the CON R: Drive folder. Only the PI and designated study staff will have access to the master log, and the master log will be destroyed at the end of the study. Study staff access to study data will be determined based on the relevance to their responsibilities. Only aggregate data will be reported for the dissemination of study findings.

Consents and any other forms with identifiable subject information will be maintained in a locked file separate from the filed study data which will be identified only by subject numbers. Audio recordings will be stored on REDCap, a secured, encrypted web-based data base. Data from questionnaires will be entered into REDCap. Destruction of paper logs and forms will follow OSU protocols. Findings will be reported in a manner in which individual data for specific participants are not identifiable.

To mitigate the risk that participants violate the privacy and confidentiality of others in their group sessions, we will ask that those participants (and their family/support person) refrain from discussing other participants outside the group. Likewise, they will be asked not to acknowledge having met if they encounter each other elsewhere. These steps are not foolproof, and participants will be informed of the associated risks at the time of consent.

Protection against Physical Harm. The study poses minimal risks to the participants. All participants will receive the Blood Pressure Categories flyer from the American Heart Association and instructed to consult their provider if they have a systolic blood pressure higher than 180 mm Hg or diastolic blood pressure higher than 120 mm Hg. the participant would be instructed to seek immediate assistance or contact their provider. The designated research staff member will attend all sessions.

Protection against Psychological Harm. Survey questions are asked in a private setting and participants are reassured that they can refuse to answer any questions. To further promote participant comfort, frequent breaks will be taken during data collection. From our previous experience, participants are able to complete the study questionnaires without a sense of burden. To minimize emotional distress during the group sessions, interventionists and group leaders will be trained in observation for psychological or emotional discomfort as well as in how to deliver material in a supportive, nonjudgmental fashion. If the interventionists or group leader observes discomfort, then the designated study staff member and or interventionist will take the participant to a quiet area to provide support. The designated study staff member will also notify PI Wright.

Advisory Board

We will rely on the Advisory Board to assist us with accessing the community by making introductions of study staff to key community leaders and members and identifying community assets (e.g., resources, organizations) to support the project. The Advisory Board will have a role in tailoring of the intervention and recommendations to promote sustainability of the project, dissemination, and problem-solving with the research team. The Community Advisory Board will meet bi-monthly via Zoom, more if needed. We will work closely with the Community Advisory Board to ensure that our de-identified summary of findings are fair and accurate and provide input on how best to disseminate the results back to the community. The Study PI is in charge of the meetings and no participant information will not be shared with the Advisory Board.

INTERNAL VALIDITY

The study is a RCT with equal attention for both conditions. We will repeat surveys measures over three time points (baseline, 1 month, 9 months) to reduce regression to the mean as an internal validity threat. We have also employed strategies to improve participant retention.

Retention. Participants will be enrolled for 9 months. We anticipate low drop out during this time. However, should a participant drop out for any reason (illness, refusal, etc.), then additional participants will be enrolled to maintain sample size. In studies longitudinal studies, a threat to internal validity is selection bias or selection threat. This can occur due to study drop out. To decrease the risk of participants dropping out of the study, we have employed several strategies.

- a. Data collection and intervention delivery option for weekends and evenings.
- b. Intervention delivery option for weekends and evenings.
- c. Reminder calls to participants for data collection and sessions.
- d. Participants will also receive a home blood pressure monitor and a MyPlate depicting a well-balanced diet of protein, fruit/vegetables, and carbohydrates.
- e. Free parking or round trip transportation is provided for data collection.
- f. With permission from the participant, we will send text messages, emails, and or phone call reminders for visits.
- g. Incentives include a \$50 retail gift card or check for \$50.00 given to participants at each data collection point (baseline, 3 and 9 months).
- h. Data collectors will be available to go to the participant's preferred location if they do not want to come to the College of Nursing.

Since participants may have a wait before baseline data are collected and the start of the group sessions, we have several incentives. We will send reminder greeting cards, postcards, and unexpected token gifts (each valued at under \$7, e.g., water bottle, cinch bag) to participants. In our experience, participants bond to such staff and remain in studies to a large degree because of the personal relationships and trust; a key component to working with the African American community. PI Wright has established community relationships with key stakeholders including the American Heart Association, Franklin County, Franklin County Hypertension Network, and local churches. If an increase in missed visits occurs, the PI and the project coordinator will review with the RAs the root cause for the missed visits and review procedures for contacting participants.

Dr. Wright will monitor any adverse events that arise in the course of the study. Any adverse events will be reported in writing to Ohio State University IRB. The PI will stop any data collection for the aim in which there has been an adverse effect until the adverse effect is resolved. A Safety Officer will be appointed to provide oversight of data collection and analyses. If the needs arise, a data safety and monitoring board will be formed. Given the low risks associated with lighting intervention (non-pharmacological education intervention), we do not foresee a need for a DSMB, but we will be working with a Safety Officer who can provide independent oversight of the project.

DATA ANALYSIS

Aim 1. Analysis. We will conduct descriptive data analyses to check data accuracy, summarize participant characteristics, and examine variable distributions. Data anomalies once identified will be fully investigated and remedial strategies will be considered as appropriate. We will use descriptive statistics to examine the feasibility and acceptability of the MIM DASH intervention and Caregiver Training, including a) approach-to-enrollment ratio; b) proportion of participants that complete all eight sessions of assigned intervention arm and attention control arm; c) frequency of completion of the follow-up calls; d) proportion of days the study protocol is fully adhered to and proportion of protocol deviation among interventionists; e) mean rating of MIM DASH intervention; and f) proportion of participants rating the MIM DASH intervention positively (4 or above). We will report point estimates along with 95% confidence intervals to indicate the precision of the estimates. Based on our experience enrolling African American participants in studies, feasibility will be defined by: a) enrolling at least 40% of potentially eligible patients and b) completion of at least 75% of the assigned intervention. Acceptability will be defined by an average rating of 4 and at least 80% participants rating the intervention positively.

Aim 2 Analysis. We will conduct intent-to treat analysis. Descriptive statistics including mean and standard deviation will be used to summarize each primary outcome and secondary outcome. We will also report mean differences, 95% confidence intervals, and effect sizes for both within- and between-group differences at each visit. The fixed effect of MIM DASH intervention will be examined by mixed effects models

Aim 3 Analysis. We will conduct mediation analysis for both groups. Each variable will be first summarized by descriptive statistics. Then we will examine the mediation effects of stress reactivity/stress resilience between the MIM DASH intervention or Caregiver Training and behavior change. The estimated mediation effects and 95% confidence intervals will be reported