INTRODUCTION

Due to health and wealth disparities, no demographic group is more at risk than African American women for the double jeopardy of stress from caregiving for persons living with dementia (PLWD) and stress associated with hypertension (HTN). This double jeopardy puts those they care for in jeopardy as well: Reduced quality of life and longevity, disability, cognitive decline, and stroke associated with HTN[1] impede caregiving activities and resultant health and well-being for persons living with Alzheimer's disease and related dementias (ADRD). Although successful multi-component interventions have addressed ADRD caregiver stress (REACH II) and the Savvy Caregiver program, **to our knowledge there are no interventions that target the complexity of chronic caregiving stress and HTN self-care for African American women caregivers of persons living with ADRD.**

This project will test two interventions for their effectiveness in improving outcomes for the target group: Mindfulness in Motion (MIM) and the Dietary Approaches to Stop Hypertension (DASH). Dr. Maryanna Klatt developed MIM, which includes mindful awareness and movement from a seated position, breathing exercises, healthy sleep, and guided mindfulness meditation.[2] The DASH component will be tailored for Black Americans. It uses a critical thinking approach that involves problem solving, participant-centered goal setting, health coaching, reflection, and development of self-efficacy (confidence) to promote physical activity and healthy eating. Solid empirical evidence demonstrates its effectiveness in reducing blood pressure among mixed-race samples.[3-6]

Our long-term goal is to develop effective interventions to reduce cardiovascular health disparities and improve health outcomes among African American women. Given this gap in knowledge (i.e., interventions targeting caregiving stress and hypertension self-care), our **Stage I pilot study focuses on a) caregiver stress and b) self-care for hypertension, the most prevalent chronic condition among African American women caregivers of PLWD**. We know lifestyle changes are effective in managing HTN, but they will not make a difference in controlling hypertension if individuals do not engage in these health behaviors. Unfortunately, African American women are less likely to engage in self-care (such as diet and exercise behaviors) if they believe their hypertension is caused by stress.[7] Indeed, our past research demonstrates that stressful interpersonal communication problems, blood pressure knowledge deficits, and complex diet information all interfered with older African American women's blood pressure self-care.[8,9] **Thus, we investigate the hypothesis that by addressing stress reactivity/stress resilience as the underlying mechanism to facilitate behavioral change, the intervention will be successful in enhancing HTN self-care.**

A small-scale, Stage I, three-group randomized controlled trial (RCT) will investigate the feasibility of MIM plus DASH to improve blood pressure self-care in African American caregivers, as compared to MIM only or DASH only. Each intervention will be delivered in eight weekly 1-hour group sessions via telehealth.

To our knowledge, this is the **first** study that systematically a) examines impact on self-care behaviors and b) employs one of the **Science of Behavioral Change key mechanisms underlying successful change** in health behaviors-**stress reactivity/stress resilience** among a large, underrepresented demographic group. PI Wright will recruit 90 women with hypertension who are caring for persons living with ADRD, 30 per group (MIM DASH, MIM only, or DASH only). We will collect data at baseline, 3-months, and 6-months. The interprofessional team pursuing this project has worked together for 3 years. Our aims will be as follows:

AIM 1. Determine the feasibility of MIM DASH, MIM, and DASH for African American women caregivers of family/friends living with dementia. *Hypothesis:* African American women caregivers with hypertension will participate in the MIM DASH as well as the active control groups (MIM or DASH).

Aim 2. Examine pilot efficacy of the MIM DASH intervention to improve stress and self-care as compared to active control groups (MIM or DASH). *Hypothesis:* Stress will be reduced and self-care will be improved in the MIM DASH group as compared to active control groups (MIM or DASH).

AIM 3. Examine the pilot efficacy of the combination of MIM plus DASH for improvement of systolic blood pressure (SBP) as compared to active control groups (MIM or DASH). *Hypothesis:* Relative to baseline assessment, the MIM DASH group will exhibit lower SBP at 3 and 6 months as compared to active control groups (MIM or DASH).

Impact: **Our short-term goal** is to complete the project in years 1-4 of the ADMFP. After preliminary findings, our **intermediate goal** is to launch a larger scale project to train community health workers to disseminate this intervention. The larger trial will also include wearable sensory technology to assess emotional responses to stressors and gather ecological momentary assessment data. PI Wright's primary mentor, **Dr. Karen Rose,** has experience and will guide me in the use of this technology. The curriculum and training for the MIM DASH intervention can be disseminated to all 88 counties in Ohio, including OSU employees, through an existing mechanism—OSU Extension. In addition, PI Wright has established a relationship with the Columbus African American Alzheimer's and Wellness Association and Central Ohio Area Agency on Aging. These relationships with key community partners will allow us to disseminate MIM DASH on a national scale in the future. Our **long-term goal** is to establish the efficacy of the intervention to improve cardiovascular health outcomes and reduce cost for African American women.

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, with African American women providing 60% of this care.[10,11] Although African American women generally endorse positive feelings about caregiving and express cultural justifications for providing care,[11-15] they endure the adverse effects of chronic caregiver stress—increased cortisol[16,17] and HTN.[18] Indeed, HTN is the leading cause of cardiovascular disease (CVD) among African American women, affecting 56.7% of the population with CVD.[19] **Yet, to our knowledge no behavioral intervention studies have** addressed the dynamic interplay of chronic caregiving stress with HTN self-care in African American women. Our intervention thus has potential to serve a vast population underrepresented in many scientific studies

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),[20] Savvy Caregiver,[21] and Enhanced Physical Activity Intervention had a sample sizes of African Americans sufficient to draw significant conclusions.[22] All three demonstrated lower success of the intervention among African Americans.[23] 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 a program similar to MIM DASH, except that the mindfulness-based stress reduction intervention is delivered by telephone.[23]

There is a strong need for culturally sensitive strategies. Suggesting the importance of cultural tailoring of interventions, the uptake of REACH II was lower among African Americans than other races and there were no changes evident in self-care or quality of life among those who did participate.[20] Likewise African Americans are less likely than Whites to adhere to the DASH diet.[24] PI Wright hypothesizes that chronic caregiver stress may also impact adherence.

Stress reactivity/stress resilience is hypothesized as one of the key mechanisms underlying successful change in behaviors.[25] *Stress reactivity* is the physiological response of the body to stress—activation of the cardiovascular system by increasing heart rate and blood pressure. *Stress resilience* is the process of adapting well in the face of significant sources of stress such as caregiver stress.[26,27] Both are key mechanisms underlying successful change in behaviors.[25] Thus, our multi-modal 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.[12,13,28-30] However, studies of the culturally tailored DASH diet have lacked methodological rigor.[31-36] None have investigated the mechanism of change in caregivers' behaviors. While the REACH II and Savvy Caregiver studies use RCT design, psychoeducation, and translation across multiple settings,[37,21] these studies have lacked equipoise in the attention control groups and did not to examine the

underlying mechanistic principles of behavior change. Questions remain regarding the stress and blood pressure self-care of African American women caregivers.

Significance of the Expected Research Contribution. The 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.[30,38,39] To my knowledge, **this 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

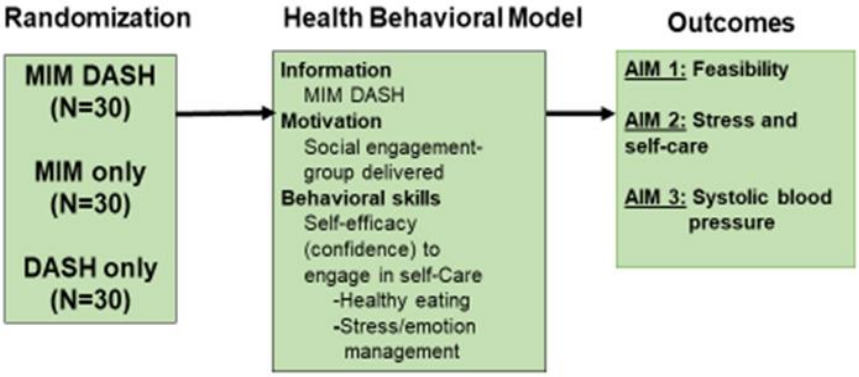
This proposal presents several innovations: 1) Use of the **Information-Motivation-Behavioral** Skills model among African American women caregivers in the community setting, 2) combining mindfulness and healthy eating to address two high risk factors for adverse health outcomes represents a **methodological shift**; and 3) **Examining** the impact of the **underlying mechanism** of stress reactivity/stress resilience for the 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.[8,9,40,41] Preliminary findings indicate that MIM DASH works in older adults with mild cognitive impairment as SBP reduced by 7 mm HG, which is clinically significant, in the intervention group compared to 0.7mmHG in the active control group., leading to the hypothesis that the intervention will be effective with hypertensive African American women caring for PLWD. The study also demonstrated the need for and feasibility of the current study. We saw the stress of African American women caregivers who were trying manage their own hypertension while keeping their family member with mild cognitive impairment safe. Demonstrating our ability to recruit, retain, and deliver health behavior interventions to African Americans, recruitment was smooth, with 30 participants signing up in 31 calendar days. It may be even smoother this time, as participants in those past studies educated us not to use the word “diet” which has a negative connotation (“diet means die”). I also witnessed the human aspect of this.

The intervention has three components: knowledge of basic **information** regarding HTN, **motivation** though learning in a socially supportive environment, and **behavioral skills** to manage stress and HTN (Figure 1). The conceptual framework on which its promotion of health behavior change incorporates the Information-Motivation-Behavioral Skills model.[40,42] The antecedents are biologic characteristics such as age and co-morbidities that may influence outcomes. The Science of Behavior Change[9] indicates stress reactivity/stress resilience affects behavior change.[43-46] Through the implementation of MIM to affect stress reactivity and promote stress resilience, we seek to change the body's response to stress and influence the adoption of DASH self-care behaviors, lowering caregiver stress and improving SBP.

Figure 1. Information, motivation, and behavioral skills model



STUDY PROCEDURES

RESEARCH DESIGN

Randomized-controlled trial.

SAMPLE

Sample. A sample of 90 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 via Zoom teleconference.

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 and Instagram. 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 consent form 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 Informed Consent

The steps to consenting are as follows:

a. Potential participants would access the Informed Consent to Participate in Research via REDCap link provided on the study recruitment materials.
b. The consent link will have a prescreen feature (Self-Screening Form).
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 script for obtaining informed 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 survey would open to request their contact information (phone, email, mailing address)
g. Participants who have reached this point will be contacted by research staff to complete a verbal screening including the AD-8 questionnaire and Post Completion of Online Consent form.

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. Informed consent will be obtained as described above. Only those study staff members that have completed CITI training will be permitted access to the participants.

Documentation of Consent. An Informed Consent Checklist form will be used for all participants. All research staff will complete the elements of the checklist for every participant during the first Zoom meeting. Elements include a check that the consent is in REDCap, the consent form is completed in full, the RA verifying that the consent form was completed, and that PI Wright reviewed medication list. The Informed Consent Checklist Form will be kept in the participants' electronic file folders in the CON R:Drive.

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 iPad 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

Zoom intervention sessions will not be recorded. Participants will be encouraged to use their camera to facilitate interaction. However, participants will be a 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 chose 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.

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.

AIMS AND MEASUREMENT/INSTRUMENTATION

The **data collection** measures will be administered in both groups at baseline, 3, and 6 months. Data collection will take no longer than 120 minutes for each data collection session. Data collection will take place via Zoom. . Participant demographics and comorbidities will be collected at baseline. All other measures will be collected at baseline, 3 months, and 6 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. To maximize flexibly for participants, they will have an option to receive the surveys electronically via REDCap to an email. Completed electronic questionnaires will be reviewed by the research coordinator for quality issues; he/she will follow up via text message when clarification is required. Text messages will be sent from Mosio via Short Messaging Service (SMS) or Multimedia Messaging Service (MMS). Participants will provide their cell phone numbers to add to the text-messaging platform, Mosio, to receive study communications.

AIM 1. Determine the feasibility of MIM DASH, MIM, and DASH for African American women caregivers of family/friends living with dementia. (Months 1- 42)

Introduction and Rationale. The overall objective of Aim 1 is to provide data on processes to further hypothesis development and the successful implementation of a large RCT to test the effectiveness of MIM DASH on caregiver stress, self-care, and SBP. This Stage I pilot study is based on the *rationale* that we can promote healthy lifestyle behaviors by addressing stress reactivity/stress resilience (psychological and physiological response of the body to stress) as the underlying mechanism to facilitate behavioral change.

Design. PI Wright will conduct a two-arm RCT using 1:1:1 randomization to MIM DASH, MIM or DASH group sessions. All randomization will occur after the participants' baseline data collection is completed.

Setting and Sample. *Biological variables*. The study will include only African American women in this study because they: a) provide 60% of care to PLWD in the United States;[10,11] b) have a lifetime risk of a single blood pressure reading of 130/80 mmHg, signifying Stage I HTN, of 85.7%;[46] c) are at increased risk of CVD due to the high prevalence of obesity, hyperlipidemia, HTN, and diabetes, particularly in association with chronic stress;[46,47] and d) are 4.6 times more likely to have a stroke—a common consequence of uncontrolled HTN—than African American men.[48] A *convenience sample* of 90 African American women throughout the United Stateswill be enrolled. *Inclusion criteria* are (1) diagnosis of HTN treated with an antihypertensive medication or risk of HTN that includes obesity and high cholesterol; (2) age 40 and older[49] (3) a caregiver rating of the PLWD of 2 or greater on the Alzheimer's Dementia-8 scale;[50] (4) providing unpaid care to a PLWD at least 10 hours per week or assisting with at least one instrumental activity of daily living[51,52] (5) self-identifies as Black/African American; (6) English speaking; and (7) has access to a telecommunications device such as the internet via desktop, laptop/tablet, smartphone, or telephone. *Exclusion criteria* are (1) 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 (2) active participation in mindfulness/yoga program.

Recruitment procedures. Referrals will be obtained from the African American Alzheimer's and Wellness Center, the Ohio State University (OSU) College of Nursing Total Health and Wellness clinic, Center for Cognitive Impairment, and Division of Geriatrics outpatient clinic. Advertising will also appear at churches, the Alzheimer's Association Central Ohio Chapter, Research Match, and on Facebook—advertising throughout the United States.

Study Procedures Overview. *Enrollment.* Consecutive potential participants will be screened and consented from the community or referral to the study staff. *Consenting.* Participants will complete a consent form and screening via secure

electronic survey such as REDCap. *Data collection.* Prior to scheduling baseline data collection via video/phone conference, trained study staff will obtain a medication list and administer the Alzheimer's Dementia-8 scale. The Alzheimer's Dementia-8 contains eight items that test for memory, orientation, judgment, and function (Cronbach alpha 0.84).[50] PI Wright or a designated co-I will review the medication list to verify that the participant is prescribed an antihypertensive. Other Significant Contributor (Addison-cardiologist and AMFDP Fellow[53]) is available to answer subject-specific expertise questions as they arise regarding HTN. Baseline data will be over the 2-4 weeks prior to the start of the eight weekly group intervention sessions. To minimize burden, data will be collected from the participants via videoconferencing or phone. PI Wright has prior experience using this format for data collection for African American women.[54] Using a REDCap database, the study staff will read data collection surveys to the participant and collect BP data per protocol in described in the study *AIMS*. Trained study staff will collect baseline measures. *Randomization.* Upon completion of baseline data, participants will be randomized to MIM DASH, MIM, or DASH.

Intervention Arms-Overview. Randomized participants will receive the MIM DASH, MIM or DASH intervention in eight weekly, 1-hour group sessions via telehealth (video and telephone access). Participants will receive session materials such as PowerPoint presentations so they can follow along by phone or videoconferencing. After completion of the eight weekly sessions, the participants will receive two follow-up calls per month to total 6 calls. The 3- and 6-month data will be collected as listed in the study *AIMs*. A manual of operations will detail all procedures related to the protocol, including participant recruitment, data collection, database usage, and database management.

Variables and data collection procedures. For feasibility of recruitment, PI Wright 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.[55] For acceptability, PI Wright will track treatment-specific preference ratings (pre- and post-intervention) and track treatment-specific preference ratings (pre- and post-intervention). The participants will complete a program acceptability 13-item survey using a Likert-type scale (1=strongly disagree, 5=strongly agree).[56] Interventionists (trainers) will keep detailed intervention session records describing participant response to the intervention. The credibility scale consists of five statements for which participants indicate their confidence, with 1 being not at all and 10 being very confident. Higher cumulative scores, up to 50, will indicate greater credibility of the treatment condition. This will also aid in determining participants' willingness to be randomized for future studies.

PI Wright will use the research effectiveness, adoption, implementation, and maintenance (RE-AIM) model framework to strategize scalability of the project.[57] Re-AIM has five components: our ability to **reach** the target population, **efficacy** of the program, degree to which participants **maintain** health behaviors, the consistency of

implementation of the program, and the willingness of the interventionists to **adapt** to deliver the program.

Analysis. PI Wright 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. Descriptive statistics will indicate the feasibility and acceptability of the MIM DASH, MIM and DASH intervention, 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 the interventions; and f) proportion of participants rating the intervention positively (4 or above). The results of the analysis will include point estimates along with 95% confidence intervals to indicate the precision of the estimates. Based on our experience enrolling African American participants in past studies, we have set feasibility at 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. Examine pilot efficacy of the MIM DASH intervention to improve stress and self-care as compared to active control groups (MIM or DASH). (6-42 months)

Introduction and Rationale. Stress reactivity/stress resilience is a key mechanism 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 blood pressure.[26] Stress resilience is the process of adapting well in the face of significant sources of stress such as caregiving.[26,27] Mindfulness practice, as a stress management behavior, may have an indirect effect on the adoption of healthy self-care behaviors by increasing perceived control over thoughts and elicitation of the relaxation response.

Randomization Procedure. PI Wright will implement the randomization scheme generated by the study statistician to assign participants to the three treatment groups (MIM DASH, MIM, or DASH). Using a computer-generated random number sequence the study statistician will randomly allocate 90 recruited participants with a ratio of 1:1:1 The assignment will be recorded in a secure database accessible only to the PI and pertinent study staff. The Research Assistant data collectors will be blinded to the assignment.

MIM DASH (Intervention Group) Description. A trained MIM provider (layperson) and a registered 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 that references a unique weekly theme which will be reiterated in the session materials. 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 mindfulness digital 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 (Figure 1 lists weekly topics by intervention group).

The DASH portion, led by a registered dietitian, focuses on education to increase vegetables, fruits, and 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 cost-effective and practical tips to incorporate DASH in daily life. Repetition of key concepts will be embedded throughout the sessions to increase critical thinking and problem solving. After completion of the eight 1-hour sessions, the MIM DASH participants will receive six coaching calls (two per month for 3 months) to review MIM DASH principles/activities and support the participants’ continuation of self-care behaviors (mindfulness practice, healthy eating, and physical activity).

Figure 1. Weekly topics by intervention group.

MIM DASH, MIM, and DASH Group Weekly Topics

Week	MIM DASH	MIM	DASH
1	• Introduction to MIM • What African Americans should know about hypertension and consequences	• Introduction to MIM	• What African Americans should know about hypertension and consequences
2	• Mindful sleep • Understanding blood pressure overview	• Mindful sleep	• Understanding blood pressure overview
3	• Visions of self • Clearing up myths about hypertension	• Visions of self	• Clearing up myths about hypertension
4	• Mindful eating • Basics of the DASH diet	• Mindful eating	• Basics of the DASH diet
5	• Balance through movement • Be a DASH detective-Sodium the culprit	• Balance through movement	• Be a DASH detective-Sodium the culprit
6	• Sensation • DASH-Throughout your day-Breakfast-lunch-dinner	• Sensation	• DASH-Throughout your day-Breakfast-lunch-dinner
7	• Clarity and release • DASH-When eating out	• Clarity and release	• DASH-When eating out
8	• Staying grounded and moving forward • DASH-Diet is only part of the story	• Staying grounded and moving forward	• DASH-Diet is only part of the story

The MIM-only intervention group will receive the MIM education only in eight weekly sessions of 30 minutes each. To maintain equipoise among the intervention groups, this group will also have 30 minutes of "social time" to interact with the trainer and peers. To avoid cross contamination, the interventionist will not also deliver the intervention to the MIM DASH group. Each participant will have access to the digital meditations 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. After completion of the eight weekly sessions, these participants will receive six coaching calls (two per month for 3 months) focused on mindfulness practice.

The DASH-only group will receive the DASH education only in eight weekly sessions of 30 minutes each. This group will also have 30 minutes of "social time" to interact with the trainer and peers, will receive their education from a different interventionist (also a registered dietician) and receive two coaching calls per month for 3 months, in this case focused on healthy eating DASH principles.

Intervention fidelity (Table 1) will be evaluated to provide assurance that MIM DASH, MIM, and DASH are implemented as intended and will assure reproducibility of the protocol**.**

Table 1. Intervention Fidelity[58]

Component	Data used to Evaluate 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. 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. Each interventionist will complete key component check list following each session to provide documentation of participant progress.
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.

Variables and Data Collection Procedures. Measures have been chosen based on their appropriateness for the study population, validity, reliability, and level of burden (Table 2). Records will include the participant's self-report of *age in years* and *list of comorbid diagnoses*. The name, dose, and frequency of medications and supplements will be recorded from the participants' bottles/containers at the baseline, 3-, and 6-month visits. If participants do not bring their medication bottles to study visits, they can self-report medication information.

The Science of Behavioral Change (recommended) Daily Inventory of Stressful Events will be used to measure stress reactivity/stress resilience. This end-of-day measure consists of a brief set of stem and conditional questions that can be can be administered via smartphone.[59] Using ecological moment assessment methodology, the Daily Inventory of Stressful Events will be administered once a day for seven days at each data collection point—baseline, 3, and, 6 months. Additionally, [60] the PHQ-9, GAD, Everyday Discrimination Stress in the Healthcare Setting, Super Woman Schema, and the Memory Behavior Checklist will be used to quantify ADRD caregiver stress (stress inventories).[61] The Perceived Stress Scale has 10-items one a Likert scale with a reference range of 0-30 regarding stress over the past month.[62] Ten items on a Likert scale with a reference range of 0-30 regarding stress over the past month.[62] The PHQ-9 is a measure of depression and each item is scored on a scale of 0-3. The total ranges from 0-27 (scores of 5-9 are mild depression; 10-14 as moderate depression; 15-19 as moderately severe depression; and 20 severe depression). The Generalized Anxiety Disorder Assessment (GAD-7) is a seven-item instrument that is used to measure or assess the severity of generalized anxiety disorder (GAD). The GAD-7 represents an anxiety measure based on seven items which are scored from zero to three. The whole

scale score can range from 0 to 21 and cut-off scores for mild, moderate and severe anxiety symptoms are 5, 10 and 15 respectively. The Everyday Discrimination Stress in the Healthcare Setting is a 7-item scale that examines the frequency and experiences of mistreatment while getting healthcare. The scale has a Cronbach α of 0.89 and a test re-test reliability of .58 ($p < .0001$). The Superwoman Schema (SWS) will be measured using the Giscombe Superwoman Schema Questionnaire which consists of 35 items and five subscales to assess cognitive, behavioral, and affective endorsement and utilization of Superwoman characteristics by African American women 1. The score for each item ranges from 0 to 3 (0=This is not true for me, 1= This is true for me rarely, 2= This is true for me sometimes, and 3= This is true for me all the time). The scoring will be conducted with the sum of each item, and possible scores range from 0 to 105. The summed scores will be averaged to indicate the superwoman schema. Higher scores indicate a greater degree of superwoman schema. In a previous study, Cronbach's alpha of the total scale was 0.95, and the internal reliability of five subscales ranged from 0.72 to 0.89.

*Hair cortisol (*will be used as a proxy for chronic stress. Hair samples will consist of approximately 25-75 mg of hair (approximate width of shoelace tip when bunched) cut from the posterior vertex region of the scalp as close to the scalp as possible.[63-66] The posterior vertex has the lowest variation in cortisol levels, and is the preferred area for sampling.[66] 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.[67] 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, which is incubated for 18-24 hours at room temperature with constant agitation. The tubes are centrifuged at 5000g for 5 minutes 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. Cortisol levels are expressed in hair as pg/mg and generally logged due to skewed distributions as needed.[68] Participants will receive a hair kit and instructions for self-collection of the hair sample and a hair care practices survey (e.g., washing, coloring, or perming hair).

Self-care practices will be measured using the Behavioral Risk Factor Surveillance System-physical activity[69] and the Diet History Questionnaire (DHQ) III (sodium, fruits and vegetables, and fiber intake) for diet.[70] [71] She will provide additional support and training regarding data collection and interpretation of findings.

Sample Size for Point Estimates (*Power)* based on AIM 2. We propose a sample of 90 (30 per group) based on the feasibility of recruiting 90 participants within 42 months and retaining at least 24 participants per group for 6 months of follow-up

(based on a dropout rate of 20%). Based upon other longitudinal studies with African Americans, we will sample in anticipation of a 30% all-cause attrition at 12-months.[72,73] In keeping with the pilot nature of this study, the sample size lacks the power to detect a small-to-medium effect size. On one of the primary outcomes, caregiver stress measured by the Perceived Stress Scale, the power ranges 41% - 65% to detect a fixed-effects of MIM DASH intervention with a medium effect size of 0.5 and a two-sided significance level of 0.05, assuming a residual standard deviation of 6 and a between-visit correlation of 0.1 - 0.5.

Statistical 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% confidences 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. Examine the pilot efficacy of the combination of MIM plus DASH for improvement of systolic blood pressure as compared to active control groups (MIM or DASH).
(6-42 months)

Our rationale is that mindfulness practice will elicit a relaxation response.[74-76] DASH recommendations (physical activity, stress management, low-fat, low sodium, and high in fish, fruits, fiber and vegetables) will lower SBP and reduce the risk of CVD.[3,77]

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. At baseline, PI Wright will provide training on the use of the BP monitor and American Heart Association infographics and video.[79] The trained research assistant will obtain a remote measure of SBP using a Bluetooth automatic blood pressure Omron device under the direction of PI Wright. The participant will be instructed to sit quietly for 5 minutes, and take three measurements.[80] The Omron is well-accepted equipment used in HTN research.[81,82]

Sample Size and Power. Since this is primarily a feasibility study, the sample size (30 per group may not have sufficient power to detect small-to-medium effect sizes for between-group difference (e.g., 34% power to detect a Cohen's d of 0.5 with a two-sided significance level of 0.05). Therefore, the study will not rely on statistical significance. Rather, PI Wright will examine whether the intervention can achieve a clinically meaningful significant reduction in SBP defined as ≥ 5mm Hg.[83] These estimates along with clinical significance will guide our results interpretation and inform the sample size determination required for an efficacy trial.

Analysis. PI Wright will conduct intent-to treat analysis. Descriptive statistics including mean and standard deviation will be used to summarize each outcome. While controlling for use of medication for HTN, as measured on the Krousel-Wood

Medication Adherence,[78] I will use mixed-effects linear modeling to estimate the between-group difference in each outcome. From the mixed-effects modeling, I will derive estimates of the within-group difference of 3-months versus baseline measures, 6-months versus baseline measures, and between-group (MIM DASH vs. MIM only and DASH only) difference in the change from baseline, adjusting for clustering from cluster randomization and repeated measures. This analysis will reveal whether, as hypothesized, SBP is reduced in the MIM DASH group as compared to both active control groups.

MEASUREMENT/INSTRUMENTATION

Table 2. Variable, measures, months, and reliability/validity

Variables	Measures	Months (M)			Reliability/validity
		Baseline	3M	6M	
Feasibility	Acceptability Participant Preferences feasibility/acceptability survey, enrollment, attendance, and participant feedback	X	X	X	
	Credibility scale		X		
SBP	Home blood pressure monitor	X	X	X	
	Krousel-Wood Medication Adherence	X	X	X	C statistic= 0.704[78]
Stress resilience /reactivity	Daily Inventory of Stressful Events (seven days)	X	X	X	(Kappa) ranged from 0.66 to 0.95[59]
	Perceived Stress Scale	X	X	X	α= 0.8367
	Hair cortisol	X		X	Hair correlation with 30-day saliva (r = 0.42, p = 0.041)[84]
	PHQ-9	X	X	X	α = 0.84 for patient behavior & 0.90 for caregiver reaction

Variables	Measures	Months (M)			Reliability/validity
	GADMemory & Behavior List	X	X	X	α = 0.92
	Super Woman Schema	X	X	X	
	Everyday Discrimination	X	X	X	α = 0.72 to 0.89
	Stress in the Healthcare Setting	X	X	X	α = 0.89
Physical activity	The Behavioral Risk Factor Surveillance System	X	X	X	α = 0.70[69]
Dietary intake	Diet History Questionnaire III	X	X	X	Correlation for energy between estimated truth and the DHQ = 0.45 for women.[70]

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 or 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 informed 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. 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 informed 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 offerto provide support privately. 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, 6 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. With permission from the participant, we will send text messages via Mosio, emails, and or phone call reminders for visits.
e. Incentives include a $25 retail e-gift card given to participants at each data collection point (baseline, 3 and 6 months).

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 text messages 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. 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.

Mosio will be used as a two-way communication to participants

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