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Operating Under Resilience (OUR) Project: Stress and emotion Management for Black/African American Women with Hypertension In a Covid-19 Social Distancing Society

Covid-19 has brought to light the chronic stress of socioeconomic disadvantage experienced by African Americans. Thirty percent of Covid-19 patients are African Americans, despite the fact African Americans make up around 13% of the population in the United States. The body's response to chronic stress results in systemic inflammation and adverse cardiovascular and cognitive health outcomes.[1,2] Chronic stress is an important risk factor for poor blood pressure control[1] and cognitive decline.[3] African American (Black) women are at even greater risk of cognitive decline due to a high prevalence of hypertension, obesity, sleep disturbance, unhealthy eating, and exposure to adversity in the form of discrimination stress.[4] Emotional dysregulation, as a result of chronic stress, also contributes to cardiovascular disease, anxiety, and depression.[5-8] In previous work Co-Created Health Education InterventioN (Co-CHIN) study was created and implemented to promote resilience and healthy behaviors in Black women with hypertension. We collaborated with hypertensive black adults (age ≥ 60) to develop Co-CHIN for hypertension self-care management.[9-11] The Co-CHIN intervention was feasible and acceptable in several ways: We rapidly recruited participants (31 black adults in less than 30 days; 87% women), zero participants dropped out, and 86.7% of participants self-reported that Co-CHIN was applicable to their lifestyle. Ninety-three percent of the women attended all four weekly Co-CHIN sessions. Knowing that lack of physical activity is a risk factor for poor health outcomes, we enhanced Co-CHIN to incorporate physical activity goals into daily routines.

Covid-19 is an additional stressor Black women have to deal with that may interfere with hypertension self-care management. Social connectedness is a source of resilience for Black women to promote mental and physical health. Unfortunately, in the face of the Covid-19 pandemic, social distancing is a challenge further isolating Black women from their networks. How do we promote social connectedness to manage stress and emotional well-being in a social-distancing society for Black women with hypertension? We proposed a synchronous web-based version of Enhanced Co-CHIN (eCo-CHIN) that build the success and best practices derived from the original intervention. A Covid-19 session will be included as a way of helping Black women to maintain resilience and self-care during stressful times. The eCo-CHIN intervention is **innovative and timely** because we are using a synchronous platform preparing Black women on how to deal with Covid-19 while taking care of self. The primary investigator for this pilot study (Dr. Wright) is a Black Early Stage Investigator and former KL2 awardee. Our interdisciplinary team has the expertise and resources to deliver this Enhanced Co-CHIN intervention.[9,12,13]

The **purpose** of this pilot study is to determine the feasibility, acceptability, and adherence to a nurse and dietitian-led, health education program (eCo-CHIN) via Zoom (synchronous web-based platform) to improve stress and emotional regulation in Black women with hypertension. The intervention consists of four weekly 1.5-hour synchronous (synchronous web-based) group sessions focused on blood pressure (BP) knowledge and calibration of home BP monitors, managing Covid-19 stress and interpersonal relationships, mindful awareness, sleep hygiene, physical activity, healthy eating, and patient communication of self-care goals to their healthcare provider. We will employ the Cardiovascular Risk Factors, Aging and Dementia scale (CAIDE) to obtain a dementia risk score. **Our rationale** is that the adherence to healthy self-care behaviors reduces poor nutrition, altered sleep, sedentary behavior, psychosocial stress, and emotional dysregulation, thereby reducing negative impacts on the brain, since all these factors contribute to neural inflammation and increased BP.[14-17] Health-promoting self-care behaviors have the known short-term effect of enhanced cognitive function (processing speed, attention, and executive function) through the use of The Repeatable Neuropsychiatric Battery (RBANS)[18]which is also an innovative component of eCo-CHIN. Thirty-two middle-aged Black women (45-65 years old) with a self-reported diagnosis of hypertension will be enrolled. The development of this group-delivered intervention will be an iterative process, and we will use this pilot data to submit a grant for a 12-week intervention through the National Institutes on Aging.

Impact: Our short-term goal is to pilot test a synchronous web-based intervention, eCo-CHIN (Covid-19 stress management and BP self-care) to promote resilience through stress management and emotional regulation. **Our long-term goal** is to establish the efficacy of the intervention to improve stress and emotional regulation in persons with hypertension to prevent cognitive decline and dementia.

I. Objectives

The purpose of this quasi-experimental pilot study is to determine the feasibility, acceptability, and adherence to a nurse and dietitian-led web-based health education program (eCo-CHIN) to improve stress and emotional regulation in Black women with hypertension. Thirty-two women will be enrolled in 3 cohorts of 6-8.. The feedback from each cohort will be incorporated, in an iterative fashion, to improve delivery of the intervention to the following cohort.

The study aims are to:

Aim 1: Determine the feasibility, acceptability, and adherence to a synchronous web-based health education program, eCo-CHIN, to engage in Covid-19 stress management and BP self-care for Black women with hypertension.

H.1. We hypothesize that the intervention will be feasible, acceptable, and that participants will adhere to eCo-CHIN. Weekly attendance will be recorded. We will use open-ended questions after the 4-week sessions and elicit feedback from participants regarding feasibility and acceptability of eCo-CHIN. A sleep diary, self-reported physical activity, Food Frequency Questionnaire Block, and anthropometric data (weight, BMI, waist circumference) will be collected at baseline, 1 month, and 6 months.

Aim 2: Determine the initial efficacy of eCo-CHIN to reduce stress and improve emotional regulation and BP self-care (BP knowledge, resilience, mindful awareness, diet, sleep hygiene) for Black women with hypertension.

H.2. We hypothesize that there will be an improvement in perceived stress, emotional regulation, and BP self-care from baseline to post-intervention. We will collect psychosocial data using the All of Us Cope COVID-19 survey (which includes sleep, stress , and a resilience scale), Beck Anxiety and Depression measures and surveys of stress, and emotion regulation, , at baseline 1 month, and 6 months.

Aim 3: Explore the feasibility of collecting cognitive performance data (processing speed, attention, and executive function) via teleconference. The Repeatable Neuropsychiatric Battery (RBANS) will be collected at baseline and 6 months. The CAIDE will be assessed at baseline, 1 month and 6 months.

Aim 4: Explore a preliminary economic evaluation of the cost to deliver the intervention over the duration of the study. Research staff will track time and resources needed for implementing the study including personnel, training, facilities, materials, equipment, other inputs, and required client inputs monthly.

II. Background and Rationale (one paragraph each)

As the United States population ages, a new case of Alzheimer's disease will develop every 33 seconds by the year 2050 (Alzheimer's Association, 2019).[19] Nearly two-thirds of Americans living with Alzheimer's disease are women. Presently, 5.7 million Americans have Alzheimer's disease; African Americans, here after referred to as Blacks, are twice as likely to develop Alzheimer's

disease than Whites. Reducing risk factors for Alzheimer's disease and dementia related disorders (ADRD) can delay its onset ; even a 5-year delay in the average onset would decrease the prevalence of ADRD by 45%.[16] **Hypertension is a significant risk** factor of ADRD.[20-26] The prevalence of hypertension among U.S. Blacks is 40%, **among the highest levels in the world (American Heart Association).[27]** Moreover, the lifetime risk **of** having a single BP reading of 130/80 mmHg is 85.7% for **Black women** and 69.3% for White women.[28] Control of hypertension is attained in only 44.4% of Blacks with hypertension.[29] The good news is that controlling BP, even by a 10 mmHg reduction in SBP, reduces the risk of developing cognitive decline.[30]

The risk factors for Blacks to develop hypertension include genetics, age, sex (postmenopausal), obstructive sleep apnea, diabetes, smoking, alcohol use, and discrimination stress.[20-25,27,28,31-35] Management of hypertension in Blacks is **complex** given the multitude of risk factors.[36,37] For Black women, obesity[38] and neurocognitive symptoms (depression and anxiety)[20,39-41] are significant challenges that contribute to uncontrolled hypertension. A multimodal approach to manage hypertension that is acceptable to Black women is essential to promote healthy lifestyle behaviors.[42-44] There is an urgency to develop and test culturally informed, **rigorous, and reproducible** nonpharmacologic interventions that reduce risk factors for developing ADRD by promoting stress management and emotional regulation in hypertensive Black women. Few studies of such interventions exist.

Emotion Regulation
(PA-19-095 Emotion Regulation, Aging and Mental Disorder https://grants.nih.gov/grants/guide/pa-files/pa-19-095.html) to promote resilience and mental health in middle-age and older adults. Older adults are motivated towards goals of emotional well-being. According to socioemotional selectivity theory, older adults tend to reduce their rates of interaction with others likely to evoke negative emotional experiences in favor of mental well-being.[45] This results in the use of disengagement-based strategies (e.g., distraction, avoidance) to cope with stressful interpersonal interactions to maintain a sense of "peace."[45] Unfortunately, operating in this mode increases the risk of mental disorders such as anxiety, depression, and substance abuse.[46] There are also biological sex and racial differences in the use of disengagement-based strategies, in that these strategies are used more by women and Blacks as compared to White men.[6,7] Co-CHIN, is a multi-component intervention that could help to normalize emotion dysregulation and or strengthen emotional resilience for Black women. The interpersonal communication and mindfulness training component of the intervention may help these women avoid the use of disengagement-based strategies.

Preliminary work.
Our team established a multi-strategy 6-step process to develop the Co-CHIN intervention and ensure rigor and reproducibility. First, we used a business management methodology, co-creation, to gather a small group of stakeholders (i.e., Blacks with hypertension) to solve a complex problem, that is, overcoming barriers to BP self-care management and work toward an acceptable solution.[9-11] The participants prioritized the barriers to BP management and created solutions together with our research team. Second, we developed probing questions and held four audio-recorded focus groups of 10-16 participants each. Prior to each focus group session, we shared previously identified barriers and solutions to BP self-management as a validity check. During the final focus group session, we employed a graphic recorder who drew the co-created intervention on a large poster board[10] as the facilitator (PI Wright) verified themes with participants. The third step towards rigor and reproducibility was to conduct a content analysis of the audio-recorded focus groups. Our team used inductive coding to complete three rounds of independent analysis by three members of our research team.[10]

Transcriptions were coded using Dedoose software (SocioCultural Research Consultants, LLC, 2017), manual notes, and field notes. The three research team members mutually agreed upon the final themes, categories, and codes. Fourth, we tested a prototype of the co-created intervention with 22 hypertensive Blacks over 4 weekly group meetings, lasting 2 hours each. These sessions consisted of a mix of didactic teaching by a Registered Nurse or Dietitian on topics of BP self-monitoring, interpersonal communication (e.g., family, friends), sleep hygiene, stress management, and healthy eating in proper proportions, and small group practice (2-3 people) of the newly learned skills. Seventy-two percent of the participants attended all four sessions. Fifth, using guidelines for developing feasibility studies, we surveyed participants to determine the acceptability of the intervention. On a 10-point scale, one being 'very poor' to ten being 'excellent', the participants rated the following: (1) satisfaction with the intervention, (2) intent to continue using the intervention, (3) perceived appropriateness of the intervention, and (4) the fit of the intervention within their routine and culture (Cronbach's alpha 0.77). The majority of participants rated these items ≥ 8 (Table 1). Based on participant feedback, we increased the number of weekly sessions in the planned intervention from 4 to 6. A standardized manual for the delivery of the Co-CHIN intervention to middle-aged and older Black adults with hypertension was the sixth and final step towards rigor and reproducibility. Because physical activity is an integral part of brain health and BP management we added setting goals for physical activity to each weekly module. The manual's content covers the following nonpharmacologic interventions: BP information and calibration of home BP monitors, stress and interpersonal relationship management, sleep management, physical activity, and healthy eating.

Our preliminary work supports our ability to successfully recruit Blacks and traditionally unheard groups.[9,10,47] Co-CHIN was created with participants who resided in low-income neighborhoods in Cleveland, Ohio; this makes the Co-CHIN a good candidate for generalizability in low-income areas. Our targeted neighborhoods in Columbus are also low-income neighborhoods. The scientific premise is that the practice of health-promoting self-care behaviors reduces poor nutrition, altered sleep, sedentary behavior, and psychosocial stress and, thereby, reduces negative impacts on the brain, since all these factors contribute to neural inflammation and increased BP.[14,15] Physiologically, increasing physical activity, managing stress, and eating a healthy diet improve BP and improve cognitive function by decreasing glycemic spikes, triglycerides, cholesterol, and neuroinflammation.[15] Additionally, a lack of social support and a lack of social participation are among the most powerful predictors of morbidity and mortality, even after controlling for relevant lifestyle (e.g., eating, smoking, drinking, exercise) and physical (e.g., increased serum cholesterol and BP) variables. The sharing of BP health information between Black women is associated with greater use of the BP information.[48] Co-CHIN also uses social interaction, support and mindfulness awareness to promote health behavior change.

Innovation

Through stress management and emotion regulation, our study addresses a recent National Institute on Aging call to action for controlling hypertension in order to prevent sequelae, including mild cognitive impairment, a precursor to ADRD. The proposed study is innovative because we use a culturally informed intervention to impact two of the greatest threats to the health and well-being of Black women: ADRD and hypertension. The eCo-CHIN addresses multiple lifestyle risk factors and harnesses the strength of social support to promote engagement in healthy self-care behaviors during Covid-19. Our study's innovations include:

- Maximizing social interaction in a social distancing environment (Covid-19) with peers and health professionals (nurses and dietitians) via a synchronous web-based platform.

- Cultural tailoring by use of culturally familiar terms in the educational materials, connecting mindful awareness to spiritualty, and delivery of sessions in a familiar setting (home).

- The use RBANS via a web-based platform to explore the use of eCo-CHIN to enhance cognitive function (processing speed, attention, and executive function).

III. Procedures/Approach

Introduction. The theoretical framework for our intervention is adapted from the Information-Motivation-Behavioral Skills model.[49,50] The intervention has three components that include knowledge of basic information regarding an illness/disease (hypertension), motivation though learning in a socially supportive environment (eCo-CHIN), and behavioral skills acquired to manage a chronic illness through improving self-efficacy (confidence in managing hypertension) to cope with stress and support emotional regulation. Demographic, clinical, and lifestyle factors and neurocognitive factors are proposed to influence the adoption of eCo-CHIN, stress management and emotion regulation strategies. Cognitive function is an exploratory feasibility aim to administer testing via teleconference.

A. Research Design

Quasi-experiment pre/post design to test the eCo-CHIN intervention in Black women with hypertension.

The intervention consists of four web-based weekly group sessions, lasing 90 minutes each that are delivered by a Registered Nurse (RN) and a Licensed Dietitian (LD).

B. Sample

Thirty-two Black women age 45-65 (middle-age as defined by the U.S. Census) will be enrolled in 3 cohorts (6-8 participants), with one new cohort beginning every 4-6 weeks. Inclusion criteria are English speaking, self-identification as Black/African American, diagnosis of hypertension (treated with medications and or lifestyle management), female sex, and access to a smart phone or a computer capable of connecting to the Internet (80% of Blacks have a smartphone).[51] Exclusion criteria are no access to computer with internet or Smartphone or diagnosis of resistant hypertension defined as blood pressure that remains above goal despite concurrent use of three antihypertensive agents of different classes, one of which should be a diuretic/water pill.

Measurement/Instrumentation

Table 1 displays all study measures. We have carefully chosen measures based on their appropriateness for this population, validity, reliability, and level of burden. The study team has experience with all measures. Instruments either have been used by the study team in prior work or have been pilot tested for the purpose of the proposed application. Most of the questionnaires use Likert-type scales and consist of 1-30 items averaging 10 items or less. Burden of the study procedures on participants was a major consideration in the selection of the study measures and thus, we chose measures that are short and easy to administer. Study staff will offer breaks to participants to use facilities as needed. In our previous experiences, it takes no longer than 90 minutes to complete the visit. To minimize the risk of Covid-19 transmission, all data will be

collected remotely and will not require in-person contact. Participants will be provided with instructions and phone support to self-collect blood pressure and anthropometric data (weight and waist circumference).
Participants will receive the links to YouTube Videos- How to take their own BP and waist measurements via email. The Weight/Waist/BP Measurement document in REDCap will be used by the research staff to record information.

TABLE 1	MEASUREMENT	DATA COLLECTION			RELIABILITY/VALIDITY
Enrollment		**Base**	**1-month**	**6 months**	
All of Us Covid Cope	Demographics, exposure, and preventative practices Demographics will not be repeated at 1 month and 6 months	X			
Education and age	Years	X			
Income	All of Us Covid Cope	X			
Alcohol use	All of Us Covid Cope	X			
Smoking	All of Us Covid Cope	X			
Comorbidities	Self-report list of chronic conditions	X			
Anthropometric measures	Waist and weight	X	X	X	
Risk factor for dementia	CAIDE	X	X	X	Sensitivity = .77, specificity= .63 and negative predictive value= .98.
Co-CHIN (4 weekly sessions)					
Information, Motivation and Behavioral Skills	Attendance and weekly check-in for adherence to eCo-CHIN homework, sleep diary, and physical activity and blood pressure logs.		X		
Outcomes					
Feasibility	Investigator generated open-ended questions		X		
Stress	All of Us Covid Cope Which contains the perceived stress scale Daily Inventory of Stressful Events	X X	X	X X	Cronbach α = 0.83 Cronbach α .71

	Folkman Stress Questions-Investigator generated				
Emotion regulation	Difficulties in Emotion Regulation Scale Beck Depression Inventory-II (BDI-II) Beck Anxiety Inventory (BAI)	X X X	X X X	X X X	Cronbach α = 0.94 Cronbach α = 0.90 Cronbach α = .94
BP knowledge	Form E WHO Covid	X	X	X	
Diet	The Block Food Frequency Questionnaire	X	X	X	Test-retest reliability, r=0.59
Cognitive function	Detailed in text. (RBANDS) Oral Trail Making Test SAGE	X		X	test-retest or inter-rater reliability r=.70 SAGE-Spearman rank correlation between SAGE and neuropsychiatric battery =.84

C. Detailed study procedures

Enrollment

World Health Organization (WHO) Covid-19 survey http://www.euro.who.int/__data/assets/pdf_file/0007/436705/COVID-19-survey-tool-and-guidance.pdf?ua=1 (Form E WHO Covid) adapted for persons with hypertension This survey takes approximately 20 minutes to complete. The survey is designed to help improve actions taken in response to the coronavirus pandemic (Covid-19) and to inform researcher about the response to similar future outbreaks. The questions cover items relating to the coronavirus about knowledge, attitudes, and concerns about Covid-19 and how it has impacted the participant's health, including self-managing hypertension and stress. Age and Education will be self-reported in years. Income will be reported in US dollars, monthly. The All of Us Covid Cope form includes questions regarding tobacco and alcohol use. The All of Us Covid Cope survey that include the participant's ID will be mailed to the participant to complete. They will received a postage paid envelope to return the survey to the PI at the College of Nursing. The participants' name will not be on the survey. The study staff will enter survey responses in REDCap. Comorbidity data will be gathered using a self-report check-list of the 21 Medicare/Medicaid chronic conditions which includes diabetes. The CAIDE instrument is a 8 item instrument that measures cardiovascular risk factors that can contribute to dementia at an older age.[52] The risk factors include age (>53), education (0-6 years), male gender, SBP (>130mmHg), total cholesterol (>200mg/dL), and 30 minutes of physical activity for at least 30 minutes four days per week. The total score ranges from 0-15 with a score of 9 or above indicating intermediate to high risk profile.[52]

eCo-CHIN

In our use of the Information-Motivation-Behavioral Skills model, Information will be measured by means of a weekly check-in for homework completeness (none, partial, complete). Motivation will be measured by weekly attendance (range 1-4).

Outcomes

Primary outcome. Feasibility, whether or not the intervention is manageable for the participants and investigators, will be measured by recording weekly attendance. Acceptability will be assessed using open-ended questions are focused on the participant's satisfaction with the intervention, intent to continue using the intervention, perceived appropriateness of the intervention and the fit of the intervention within their routine and culture. In a future study, we will determine the sustainability of health behaviors. Audio tapes of recorded, using a hand held recorder, sessions will be reviewed to identify participant's perception of the usefulness of eCo-CHIN and potential challenges. We will also ask questions regarding the ease/challenges of using Smartphone, self-collection of data (weight, BP, waist circumference), and the frequency of use of the self-care supplies (pill box, BP monitor, weight scale, kick stand for phone). Adherence to eCo-CHIN health self-care behaviors will be assessed by reviewing homework, sleep diary, and physical activity and blood pressure logs. Since we will have a wide age range (45-65) we will query participants' opinions regarding the mix of ages. This will inform our larger study and whether we will need to stratify randomization by age in the future.

Secondary outcome. Covid-19 World Health Organization contains a series of questions regarding self-protection, management of health, stress, resilience, and sleep.[53]

> "The Block FFQ 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 offered nine continuous responses ranging from "never" to "every day" for most foods. In addition, portion size is asked for each food/beverage item, with pictures provided to improve accuracy of estimation. The FFQs were self-administered and took approximately 30 min to complete. The participant will have a copy of the food portion handout to reference portion sizes. The analyzed food and nutrient intake data from the FFQ were then used to calculate diet quality based on the Healthy Eating Index 2010 (HEI) scores. The HEI is a validated diet quality measure that assesses how closely an individual's dietary pattern conforms to the recommendations of the Dietary Guidelines for Americans.[54] It includes 12 components, nine of which (total fruit, whole fruit, total vegetables, greens and beans, whole grains, dairy, total protein foods, seafood and plant proteins, fatty acids) are recommended to be consumed in adequate amounts, and three of which (refined grains, sodium and empty calories) are to be consumed in moderation.[55]. For all components, higher scores demonstrate compliance with dietary guidelines, i.e., higher scores of the "adequacy" components correspond to higher intake of theses dietary components, while higher scores on "moderation" components are indicative of lower intake of these components.[55] The standards for determining adequacy and moderation scoring standards are described in details elsewhere.[55]. Briefly, it includes: (1) identifying the group of foods under consideration (e.g., the total amount of foods consumed in a day), (2) linking these foods to relevant databases to determine the amounts of each relevant dietary constituents in these foods, and (3) deriving pertinent ratios to compare to relevant standards for

scoring.[56] A total HEI score (range 0–100) is calculated from the 12 component scores with higher HEI scores indicative of a better diet quality and greater adherence to dietary guidelines.[54] In the current study, both total HEI score and subcomponents were examined. It should be noted that national average derived from the National Health and Nutrition Survey also used the HEI 2010 and Block FFQ-2005 (Adams et al., pp. 4)[57,58]"

2.2. Perceived Stress Scale is a 10-item Likert scale questionnaire regarding stress over the past month with higher scores indicating higher levels of stress (Included in the All of Use Covid Cope).[59] We have also included two investigator generated questions based upon the work of Folkman and Lazarus as follows: Describe the event or situation that you have been most concerned about during the past month and how concerned are you about the situation?[60] "We will use the Daily Inventory of Stressful Events[61] Stress is a multidimensional construct with different areas of stress potentially having differential relationships with short-term and long-term outcomes. The Daily Inventory of Stressful Events (DISE) is a semi-structured survey in which participants report whether any of a series of stressful events had occurred within the past 24 hours. This end-of-day measure consists of a brief set of stem and conditional questions that can be can be administered via smartphones. An example stem question is "Did you have an argument or disagreement with anyone in the past 24 hours?" An example follow-up questions is "How stressful was this?" "How much control did you have over the situation?" This instrument yields several variables for each reported stressor including: (a) content classification of the stressor (e.g., work overload, argument over housework, traffic problem); (b) subjective severity of stressors; (c) primary appraisals (i.e., areas of life that were at risk because of the stressor); and (d) perceived control of the situation."[61] (cite)Participants will be administered the Difficulties in Emotion Regulation Scale to examine changes in degree of self-reported emotion dysregulation following mind-body interventions.[62]This measure has 18 items, each measured on a 5-point rating scale. One total score will [62]be calculated by summing the individual item responses. Higher scores represent greater perceived difficulties in emotion regulation capabilities. To further examine the components of emotion regulation, will be evaluate by functional outcomes major domains of cognitive and affective functioning (e.g., anxiety and depression), with standardized, norm-referenced measurements (allowing quantification of whether there has been a significant differences of: (a) neuropsychological functioning; (b) emotional functioning; (c) and quality of life. For example, for every 10mm Hg increase in systolic BP (also known as the " top number") there was an increase in risk for poor cognitive function of (9%).21 We will use the following questionnaires to characterize mood and quality of life variables: (1) Beck Depression Inventory-II (BDI-II)[63]: The BDI-II24 is a 21-item, self-report mood measure of depressive symptomatology; (2) Beck Anxiety Inventory (BAI)[64]: The BAI25 is a 21-item measure of primarily physiological symptoms of anxiety; and (3) Quality of Life Inventory is a 32-item questionnaire where participants rate the importance of, and satisfaction with, 16 life domains, such as health, community, and friends.[65]

Behavioral Skills will be assessed by the Form E COVID-19 Coachman questionnaire that has 8 questions regarding self-efficacy to manage hypertension. Responses range from 1 (not confident at all) to 10 (totally confident) for each question. Higher scores are indicative of greater self-efficacy. We will ask investigator generated questions regarding their medication adherence as follows: Have you missed taking your blood pressure mediation over the past 4 weeks? If yes, how many days did you miss taking your medication? Was cost of the medication a barrier to taking your blood pressure medication?

Exploratory outcome. Each participant will be administered a brief neuropsychological battery of tests taking approximately 1 hour to administer and consisting of standardized clinical instruments designed to assess a broad range of cognitive skills and emotional functioning. The Repeatable Battery for the Assessment of Neuropsychological Status (RBANS) is a widely used screening instrument in neuropsychological assessment. The RBANS consists of 12 subtests that assess cognitive domains such as Immediate and Delayed Memory, Language, Attention, and Visuospatial/Construction and takes about 30 minutes to administer. Different aspects of processing speed, complex attention, and executive functioning will be measured with the Trail Making Test Part A and B, a measure of processing speed, mental flexibility, and set-shifting; the COWAT, a measure of phonemic verbal fluency; and the Stroop Color Word Test. The exam will be tailored to deliver via teleconference.[18] To facilitate assessment virtually, we are removing the complex figure drawing and coding tasks. They are being replaced with the Self-Administered Gerocognitive Examination (SAGE)[66] that includes a clock drawing and the oral trail making test.[67,68] SAGE covers cognitive domains of orientation, language, memory, executive function, calculations, abstraction, and visuospatial abilities.

We established a BUSINESS ASSOCIATE AGREEMENT with BrainTest, INC SEZC to obtain access to the Self-Administered Gerocognitive Screen online. Participants shall only be able to access their BrainTest on submission of a unique Identification number to be created by OSU (the "ID"). BrainTest shall not accept any personally identifiable information from any of the Participants. BrainTest will provide the following:
1. BrainTest shall provide OSU with a unique internet URL where only the Participants shall have access to take the BrainTests from OSU's or the Participants' own touch screen tablets or touch screen computers.
2. BrainTest shall develop a web based portal for the recording of all Participants BrainTests scores (the "Portal"). The Portal shall be password protected and shall be for the sole use of OSU. OSU shall be able to download all data in the Portal in .xls format, at any time prior to the termination of this Agreement.
3. BrainTest shall use its Core Scoring Lab to score all the BrainTests submitted by the Participants. All the scoring of the Participants' BrainTests shall be completed within 48 hours of the BrainTests being submitted by the Participants. All Participants' scores shall be uploaded to the Portal by BrainTest using each Participants' ID as the identifier.

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 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.

Detailed study procedures

Recruitment. Participant recruitment will be through advertisement at local primary care clinics, Family Medicine's Research Network, ResearchMatch, churches, and community organizations with flyers and online social networks (e.g. websites, Facebook, LinkedIN). Participants may self-refer or be referred by a provider. All recruitment efforts will begin once approval from the IRB is received. The primary recruitment in the proposed study is ResearchMatch (attached Guidance and Message Template for IRB Submission for Use of ResearchMatch.org). I am requesting the use of ResearchMatch.org for participant recruitment on this protocol. In addition, we will use other social media because as many as 68% of adults in the US use Facebook regularly. Permission from the appropriate party (e.g, moderator of Facebook page) will be gained prior to the posting of any recruitment materials. Once approval is received, the study team will post a flyer (see attachment) in each respective online location. The flyer contains general information about the study including university affiliation, time commitment, confidentiality, compensation availability, and contact information for eligibility and screening procedures. We will also provide recruitment information to the Women's Place at The Ohio State University. We will also use snowball recruiting where participants inform their contacts about the study to enable their contacts to potentially be enrolled in the study.

Participant ID: Participants will be assigned a REDCap auto-generated ID number which will identify them at all data collection points.

Retention Plans.
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.

1. Data collection and intervention delivery option for weekends and evenings.
2. Reminder calls to participants for data collection and sessions.
3. Participants will be remunerated for their assessment time according to the following schedule:

After completion of the COVID ALL OF US COPE survey at baseline, you will receive a $10.00 Amazon gift card.

After completion of the 1-month data collection, participants will receive items donated by the Alcohol Drug and Mental Health (ADAMH) of Franklin County system that includes a resource directory, grocery bag that includes an ink pen, stress ball, bag clip, and hand sanitizer, Additionally, The Ohio State University James Cancer Center has donated a scarf, insulated cup, and lip gloss.

After completion of the study, at 6 months, the participant will have the option of either receiving a $75.00 Amazon gift card or retain their self-care monitoring equipment (Home BP monitor and weight scale). If the participant selects the Amazon card, then we will provide them with a postage paid package to return the self-care equipment.

After completion of the COVID ALL OF US COPE survey at 6 months, you will receive a $10.00 Amazon gift card.

Participants will also waist tape measurer, pill box, and kick stand for their smartphone.

The reason for any participant's discontinuation and the date of withdrawal will be recorded in the participant's case file. The participant's case file, which will be completed up to the point of withdrawal, will be retained for five years. The study report will include reasons for participants' withdrawals as well as details relevant to the withdrawal. Each participant will be encouraged to complete the full course of the intervention assignment and study assessments. However, it is made clear to participants that they may discontinue study participation at any time for any reason. The reason for early withdrawal must be documented in the participant's case file and in the participant tracking document.

Handling of withdrawal. If a participant is withdrawn from participation in the study at any time at his or her request, or at the IRB or Principal Investigator's discretion, the reason(s) for discontinuation shall be documented thoroughly in the source documents and participant's case file. All participants who are withdrawn prematurely will undergo the procedures outlined in the discharge visit.

Procedures overview. Using an IRB approved script, we will recruit, screen and enroll participants until we have 32 qualified participants. An initial visit will be scheduled to obtain baseline survey data (approximately 90 minutes), and complete the baseline cognitive function testing (60 minutes). Per participant's preference, the survey data and cognitive function testing may be done on two separate days.

Procedures.

Informed consent. Interested participants will be given access to the self-initiating process to provide information (email and phone) and to contact a member of the study team with questions, prior to consent. This will also serve as pre-screening to review inclusion/exclusion criteria for the eligibility of the participants. The eligible participants will be consented using a REDCap-based electronic consent form. The consent form has been developed in REDCap, a secure, web-based, HIPAA-compliant, data collection platform with a user management system allowing project owners to grant and control varying levels of access to data collection instruments or data (e.g. read only, de-identified-only data views). Self-initiating process can be done on personal portable electronic devices using posted QR codes or web-links on study fliers, social media, or websites.

The steps to consenting are as follows:

1. 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.

2. The consent link will have a prescreen feature.
   a. If a person says no to one of the inclusion criteria (black/African American, female, diagnosis of hypertension, age 45-65) questions, they would be thanked and told that they do not qualify.

b. This would also be yes for any of the exclusion criteria (no access to computer with internet or Smartphone, diagnosis of resistant hypertension defined as blood pressure that remains above goal despite concurrent use of three antihypertensive agents of different classes, one of which should be a diuretic/water pill).
c. If the person meets the eligibility criteria, then the verbal script for obtaining informed consent will appear.

3. 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.

4. 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.

5. We will contact the participant to confirm eligibility for the study, answer any questions they may have about the consent form, verify verbal consent (logged in REDCap), and schedule the first study visit. We will mail a copy of the consent form to the participant for their records.

Baseline survey data will be collected as listed in Table 1. Data will be collected using a private room via phone or Zoom secure video conference. The participant can enter by invitation only. If the participant does not have access to a touch screen tablet or computer, they may be able to borrow one of our two IPads from the College of Nursing. This would be mailed to the participant with return postage paid.

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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.
5. The questions to surveys will be read to the participant and answers recorded on survey forms and entered into REDCap under the participant's study ID number. Response cards will be given to participants to follow along with the interviewer.

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.

Intervention Protocol. The eCo-Chin and group sessions will be recorded, using a hand held recorder, to monitor fidelity and to retrain the RN, LD, and AC group leader as needed. Before each eCo-CHIN session, the RA will conduct a check-in to measure BP and review the sleep and physical activity logs (see below). At the end of each session, the participants will identify one goal that is specific, measurable, acceptable, relevant, and time-bound (SMART). They will also receive, via U.S. mail, the Daily Food and Physical Activity Diary and the National Sleep Foundation Sleep Diary to complete as homework. The diaries will be collected weekly as a measure of treatment enactment.

Interactive PowerPoint presentations of educational content will be delivered via Zoom.

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 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. The four 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.

Presented at the National Minority Quality Forum April 2020, the Coronavirus Anxiety Workbook (https://thewellnesssociety.org/free-coronavirus-anxiety-workbook/) uses evidence based stress reduction techniques to promote mental well-being during a pandemic. The following topics are listed in the workbook: Planning Your Information Diet; My Spheres of Influence Worksheet; Practical Wisdom for Tolerating Uncertainty; Reducing Anxiety With Thought Challenging; Reducing Anxiety Through Distraction Activities; Starting a Planning Practice; Starting a Daily Gratitude Practice; Starting a Daily Breathing Practice; Improving the Quality of Your Social Connections; Developing a Regular Exercise Routine; and Creating Your Stress-Resilience

Action Plan. Each session will begin with a 15-30 minute check in on what went well, challenges, and Coronavirus Anxiety workbook. The Coronavirus Anxiety Workbook topics are complementary and the sessions will tie together the themes of comprehensive stress and emotional management through blood pressure knowledge/self-monitoring, diet, interpersonal communication skills building, and sleep hygiene.

Session 1 (LD Dietitian Interventionist). "DASHing Through Life provide an overview of the DASH eating plan and why it is important for African Americans. The goal is to help these women to make daily life changes. The content was developed by a Registered Dietitian Nutritionist using evidence based materials from Academy of Nutritional dietetics and the American Heart Association. Critical Thinking Strategies were used to engage participants to think about barriers and solutions to the incorporation of the Coronavirus Anxiety Workbook skills to reduce emotional eating. Part of the Critical Thinking Strategies is goal setting and review. We will review modifications to healthy eating of traditional "soul food/southern" meals. At the end of the session, participants can use Critical Thinking Strategies to have their food diary reviewed by the dietitian and the group. For homework, participants will complete Coronavirus Anxiety Workbook on Developing a Regular Exercise Routine; and Creating Your Stress-Resilience Action Plan.
Session 2 (RN Interventionist). The session will begin with a review of foods that promote stress reduction followed by monitoring Your Blood Pressure covers diagnosis, causes, risk factors, symptoms, interventions, and how to self-monitor BP. This includes an interactive didactic lecture and slide presentation and distribution of personal arm-automatic BP monitors. Research assistants will work with participants to demonstrate use of the home BP monitor. The participants will watch a video and practice measuring their BP. Reviewing stress related factors that may increase blood pressure. Building resilience and managing emotions in stressful times. Participants will receive the Coronavirus Anxiety Workbook-A tool to help build resilience during difficult times. For homework, participants will identify strategies to reduce information overload and complete the Spheres of Influence worksheet.

Session 3 (RN Interventionist). The session will begin with a review of blood pressure monitoring followed by stress and emotion regulation management through interpersonal communication skills training. We cover effective communication (verbal and nonverbal), thinking, listening, and speaking. Participants learn about communication and the effects of stressful communication on the body's physiological responses. They are encouraged to talk about their positive and negative experiences communicating with family and friends in the context of the Black culture. Participants learn problem solving skills to address communication breakdown and practice what they have learned. For homework, review Improving the Quality of Your Social Connections from the Coronavirus Anxiety workbook; Practical Wisdom for Tolerating Uncertainty; and Reducing Anxiety With Thought Challenging. Participants will also complete a sleep diary.

Session 4. (RN Interventionist). Sleep lifestyle. The session will begin with emotion regulation review followed by the RN review of barriers and facilitators to good sleep, sleep management practices, and relaxation before bedtime. This will include a review of foods that help with sleep. Participants practice a 10-minute mindfulness body scan. Identification of preferred physical activities is introduced by the RN as a tool to improve sleep. Throughout the session, the RN reinforces collaboration with their health providers to seek treatment for sleep problems. The

group will review the sleep diaries that they completed the previous week and share strategies. For homework, participants will review Reducing Anxiety Through Distraction Activities and Starting a Planning Practice and Starting a Daily Gratitude Practice from the Coronavirus Anxiety workbook. They will be contacted by study staff via phone to review their final homework assignment.

The sessions will be recorded using Zoom so that those who miss a session can access and listen to the lesson.

Using an investigator-generated form, trained research staff will provide a self-care coaching call to participants (approximately 10-20 minutes) to review questions and provide ongoing support of self-care. The calls will be made twice a month for four months. The data will be entered into the REDCap Coaching call form.

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.

Incidental findings. Blood pressure. The following guidelines will be used to triage unanticipated blood pressure findings; if average systolic BP is >150 or diastolic BP is >110, we will instruct the participant to follow up with health provider or an urgent care center if the participant does not have a health provider.

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 weekly meetings of the research team. 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 documentations weekly.

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 eCo-CHIN 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.

D. Internal Validity

The quasi-experimental design is a limitation but it is an acceptable design for a feasibility study. We will repeat measures of stress and emotion regulation over three time points (baseline, 1 month, 6 months) to reduce regression to the mean as an internal validity threat.

E. Data Analysis

We will use descriptive statistics to examine variable distribution, check for outliers and summarize sample characteristics and outcome measures at each time point. For Aim 1, we will use descriptive statistics to quantify the rates of recruitment, attendance, and attrition for feasibility. Using a semi-structured list of open-ended questions, we will elicit participant feedback regarding the acceptability of the intervention. The Consensual Qualitative Research Method (CQR) [69] will be used to analyze qualitative data. The responses to open-ended questions will be transcribed. The transcripts will be reviewed by three members of the research team to determine core domains (themes).

> "The preliminary lists will be presented to on another, providing examples from the transcripts. After deliberation, a list of the domains will be agreed upon. Each team member will then review the data and verify the quality of the consensually chosen domains, and subsequently met again to discuss and arrive at a consensus on a final list of domains. Categories will be labeled based on the frequency of occurrence of themes in the data (Nguyen et al., 2013, pp. 3-5)"

For Aim 2, we will first use descriptive statistics and trend plots to examine the outcomes (stress and emotional regulation) over time (baseline, 1-month, and 6-months). Next, Paired T-tests will be performed to examine the change of each outcome at 1-month (vs. baseline) and at 6-months (vs. baseline). Sample size from this pilot study will not have sufficient power to detect small-to-medium effect sizes for within-group difference (e.g., 54% power to detect a Cohen'd of 0.5 with a two-sided significance level of 0.05). Therefore, we will not rely on statistical significance. Instead, we will estimate point estimates, 95% confidence intervals and effect sizes. These estimates along with clinical significance will guide our results interpretation and inform the sample size determination for a future NIH funding mechanism. For Aim 3, changes in RBANDS measure will be analyzed using the same approach for Aim 2 (baseline and 6 months). For Aim 4, Co-I Chyongchiou J. Lin, Health Economist, will use descriptive statistics, trends, and plots to evaluate allocations of resources and estimate costs of the intervention at various stages.

F. Project Timeline

The development of this group-delivered intervention will be an iterative process, and we will use this pilot data to submit an external grant for a 12-week intervention through the National Institutes on Aging in 12-18 months.

Table 2. Project timeline.

Activity	1-2 months	3-4 months		5-6 months	7-8 months	9-10 months	11-12 months
IRB application	X						
Recruitment		X		X			
Data collection (baseline, 1-month, 6-months)		X		X	X	X	
Delivery of Intervention		X		X	X		
Preliminary data analysis of baseline data for an NIH grant in February 2022				X	X	X	X
Final data analysis						X	X
Dissemination							X

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