*[USE THIS BIOMEDICAL PROTOCOL TEMPLATE IF YOUR PROJECT INVOLVES **ANY** PHYSICAL CONTACT OR MEDICAL INTERVENTIONS WITH PARTICIPANTS]*

PROTOCOL TITLE:

Self-Management and Resilience Trajectories in African American Adults with Hypertension

UH-PRINCIPAL INVESTIGATOR:

Name: **Mahboob Rahman, MD, MS**
Primary **Department: Nephrology and Hypertension, UHCMC**
Telephone Number: **216-844-4814**
Email Address: **Mahbooh.Rahman@Uhhospitals.org**

UH-PRINCIPAL INVESTIGATOR OF RECORD OF GRANT FUNDING

Name: **Carolyn H. Still, PhD, MSM, AGPCNP-BC, FAAN**
Primary Department: **Frances Payne Bolton, School of Nursing, CWRU**
Telephone Number: **216.368.6338**
Email Address: **Cwh11@case.edu**

Secondary Department: **UH Otis Moss-Cleveland Brain Health**

OTHER DEPARTMENTS INVOLVED IN THIS STUDY (IF APPLICABLE):

☒ **Clinical Hypertension Program, Department of Nephrology and Hypertension; Frances Bolton, School of Nursing, CWRU**

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Objectives

The purpose of this study explore the relationship among resilience precursors on hypertension (**HTN**) self-management behaviors, stress response, and the effects that these relationships have on health outcomes—health-related quality of life (**HRQOL**) and blood pressure (**BP**) in African Americans (**AA**) with HTN over a 6-month period.

The specific aims of this study are to:

Aim 1. Assess the association among *resilience precursors* (dispositional optimism and resilience, emotion regulation); *stress response* (physiological: cortisol, interleukins [**IL-6**] and psychological: depression cognitions, perceived stress); *hypertension self-management behaviors* (self-efficacy for chronic disease management, medication adherence to antihypertensives); and *health outcomes* (HQROL and BP) in AA with HTN at baseline and months 3 and 6.

Aim 2. Determine if *stress response* mediates the relationship between *resilience precursors* and *health outcomes* over time when controlling for *risk regulators.*

Aim 3. Determine if *self-management behaviors* mediates the relationship between *resilience precursors* and *health outcomes* over time when controlling for *risk regulators*.

Aim 4. Identify resilience trajectory patterns and factors that influence HTN self-management behaviors over time.

Background

Hypertension (HTN) rates have increased worldwide, but the most significant increase in the incidence of morbidity and mortality has been in African Americans (AA)[1,2] (43% vs 27% for other U.S. population groups).[3] Despite evidence of positive benefits from lifestyle modification (healthy diet, reduced sodium intake, increased physical activity, smoking cessation) and prescribed antihypertensive therapy (AHT),[4,5] many AA with HTN do not adhere to their treatment regimens.[3,6] Consistent, effective lifelong self-management is required to sustain optimal BP control and thus reduce morbidity and mortality.[5] However, self-managing HTN to a blood pressure (BP) <130/80 mm Hg presents challenges such as juggling multiple medications and health care providers, dealing with complex recommendations and treatment regimens, and coping with negative emotional states.[4] Few studies have examined the biopsychosocial mechanisms that foster effective HTN self-management and resilience among AA living with HTN. Understanding the mechanisms that influence HTN self-management and resilience in AA holds the promise of new modifiable targets for behavior-change interventions.

Research over the last decade has identified a link between resilience and self-management of chronic conditions such as cancer,[7] heart failure,[8] and diabetes.[9] Factors contributing to resilience are multiple and co-occurring, some of which are protective and others enabling, providing mechanisms for adapting to stressful experiences.[10,11] Moreover, resilience differs based on cumulative interactions at the community, family, individual, physiological, and

cellular levels across the life course,[12] and resilience may influence how an individual manages health-related challenges or self-management tasks for HTN.

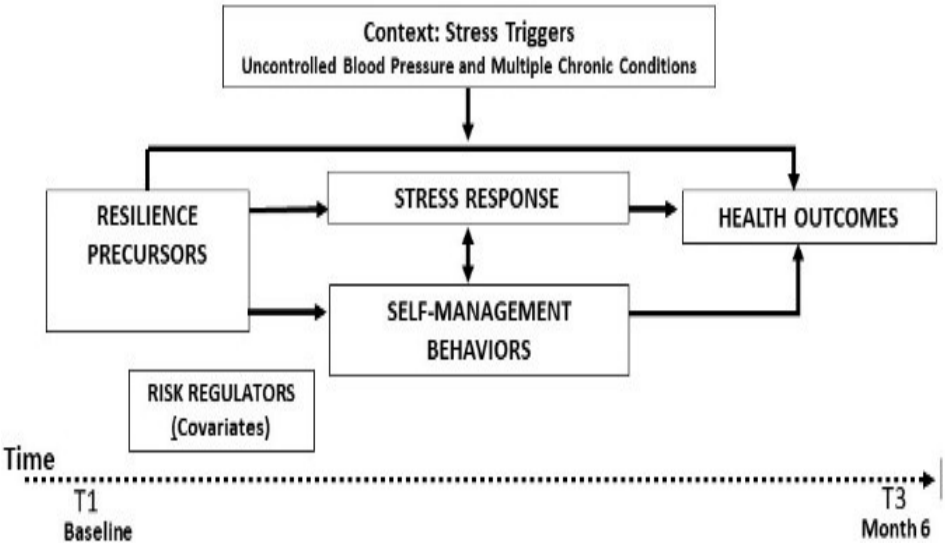

Figure 1. Conceptual Model

Thus, the scientific premise of the proposed study is that describing profiles of self-management and the resilience trajectories in AA with HTN can lead to culturally appropriate, patient-centered interventions that improve their HTN self-management, quality of life, and long-term compliance.

Design Overview: Using an observational, descriptive longitudinal cohort design, this study will identify distinct trajectories of resilience related to HTN self-management across three time points (baseline, Months 3 and 6) in AA with HTN. Figure 1 shows the proposed relationships among the major study variables and pathways. We will collect data using a battery of valid and reliable surveys and biological mechanisms of resilience (serum samples) as detailed in Table 1 (page 8). All research staff will be trained regarding enrolling subjects, obtaining consent, and administering study measures. This study will be conducted at CWRU's Health Research Center, and biological specimens will be collected at CWRU and the Dahm's Clinical Research Unit at University Hospitals Cleveland Medical Center (UHCMC). **See page 7 for more details on the study design.**

Inclusion and Exclusion Criteria

Screening. Subjects who indicate interest by phone call, email, message, or completing an online prescreening tool will be contacted using an IRB approved script to recruit, screen, and enroll.

a. For subjects that respond to study advertisements a trained study coordinator will screen subject for eligibility in clinic or by phone (using an IRB approved script).
b. Participants who meet our inclusion criteria will be scheduled for a baseline visit.

	Inclusion Criteria
1.	Self-identify as African Americans

2.	25 years of age or older
3.	Diagnosed with hypertension and prescribed one antihypertensive medication
4.	Systolic BP ≥130 - 170 mm Hg
5.	Have at least one additional chronic health conditions
6.	Able to read/understand English

	Exclusion Criteria
1.	Unable to give informed consent or judged to have impaired cognitive ability or severe memory
2.	Have experienced a major CVD event or procedure (e.g., myocardial infarction, stroke, heart surgery) within the past year

Number of Research Participants

Because of the exploratory nature of the study and resources available, a purposive sample of 125 subjects with hypertension will be recruited to participate from UHCMC.

Recruitment Methods

Describe how subjects will be identified (the source of potential research participants), and also how, when, and where they will be recruited. Describe all methods of contact / communication

We will recruit potential subjects from clinics affiliated with UHCMC, community centers, clinician referrals, and targeted advertisements (Research Match.org, Facebook). Similar recruitment methods were successful in the SPRINT trial, and approved by UH's IRB.[34] Materials used to recruit research participants will include a brief description of the study eligibility and study contact information, while flyers and study letters will include greater details about the study, eligibility, and contact information. The study recruitment materials are attached with this application.

We will identify eligible subjects by:

a. **Electronic Database Search:** We will request a Waiver of Consent/HIPAA Authorization to screen computerized patient data bases (electronic health records [EHRs]) for potential subjects from practice sites throughout UHCMC. To identify potential participants meeting study inclusion criteria, EHR databases will be searched initially by age ≥ 25 and ICD-10 codes for hypertension (401). Once potential participants are identified (and with provider permission), a letter of recruitment describing the study to the participant will be mailed. If no response within one week, a research assistant will follow-up by phone call.

b. **Physician referrals:** Selected physician (UH Nephrologist, Cardiologist, Family Medicine, Primary Care) at UH will be invited or contacted by email to refer any patients meeting inclusion criteria be referred to the study. Once a participant is identified, they will be contacted by mail or during in clinic visit (with provider permission), as stated above. In addition, IRB approved advertisements such as posters and pamphlets will be *provided to* physicians to view (breakroom, bulletin boards located above physician work stations.

c. **Community referrals and engagements**: Our recruitment efforts will extend to incorporate various community presentations and/or posting of advertisements (e.g., fliers or posters) of the research study. This will include religious facilities/churches and local community centers and platforms that will reach African Americans with HTN. In addition, we will engage in various

public forms and presentations to inform various community leaders, medical and health-related organizations and clubs, and the current research project.

d. **Electronic advertisement**: To aid in the recruitment process, we also will use targeted ads, Facebook, and social media and will register our project at Clinical Trials.Gov and ResearchMatch.org.

Facebook Advertisement will be used to evaluate potential eligibility for the study (See Hypertension study advertisement attached). This Facebook advertisement will be targeted African American 25 years and older with hypertension. The Facebook advertisement will be linked to a prescreening survey in REDCap where the potential participant can provide contact information to evaluate potential eligibility for the study. Example Facebook advertisements and the prescreening form are attached with the study application.

We plan to periodically post the following advertisements on our study Facebook page to assist in recruitment and keep the page active:

a. "Greetings from the Hypertension Study at Case Western Reserve University Frances Payne Bolton School of Nursing! We are actively recruiting for people who are concerned about their blood pressure and are willing to spend time learning more about high blood pressure and how to manage it using technology. If you are African American, 25 years and older diagnosed with hypertension living in the Cleveland area and would like more information about participating in our research study, please give us a call. Our office phone is (216-844-3798), and our email address is techsupportstudy@case.edu. We look forward to hearing from you!

b. "Are you African American, 25 years and older, diagnosed with hypertension living in the Cleveland area? Would you like to join a research study to learn more about high blood pressure and how to manage it using technology? Simply click the blue "Sign Up Now" button, fill out the form, and one of our study team members will be in contact with you soon."

c. "We are looking for African Americans 25 years and older diagnosed with hypertension living in the Cleveland area who are interested in participating in a research study to learn more about high blood pressure and how to manage it using technology. If you are interested, please feel free to contact us or click on the "Sign Up Now" button. [216-844-3798]. We look forward to hearing from you!

In addition, we will also incorporate the following recruitment methods using University Hospitals Resources:

a) UH Kiosk: updated flyer version will be displayed on UH Kiosk
b) On-hold messaging: Message script: "Are you African American, 25 years and older, diagnosed with hypertension living in the Cleveland area? Would you like to join a research study to learn more about high blood pressure and how to manage it using technology? To learn more, call 216-844-3798, that's 216-844-3798."
c) Post on UH CLINICAL TRIAL FINDER (https://clinicaltrials.uhhospitals.org/), once study IRB approved.

Setting

1) The sites and locations where your research team will conduct the research.

Data collection and procedures will primarily take place at research office at the France Payne Bolton's School of Nursing at Case Western Reserve University by a trained research assistant and staff.Study procedures could also take place at public locations that are conveniently and comfortably located for the participant including but not limited to, public libraries, recreation centers, coffee shops, etc. They could also be held at prospective and current study participants' residences. Study visits conducted at participant homes will follow the proceeding guidelines. 2 staff members will attend all home visits. Staff members conducting home visits will share geographic location through mobile device technology with all staff while conducting home visits. Staff members conducting home visits will text all staff members upon arrival to the participant's home, and when leaving. Staff will confirm home study visits the day before and day of before traveling to a participant's home. Staff will confirm safe parking before traveling to a participant's home. Staff will wear appropriate personal protective equipment prior to entering a participant's home. The project's main offices will be located on the second floor of the Frances Payne Bolton School ofNursing, CWRU. Laboratories to support the project are located both in the school of nursing and across the CWRU campus and are described in more detail below.

The Dahm's Clinical Research Unit (DCRU) a state-of-the-art research lab for subject screening, consenting, counseling, and assessment of psychosocial, physiological, and anthropomorphic measures. It is located within the clinical labs at UHCMC and maintains all clinical and technological resources necessary for research. This distinguished research resource provides dedicated facilitates to facilitate the successful completion of clinical research involving adults. The resources are available to all qualified investigators at CWRU. The research team will use the DCRU to obtain serum samples, as well as process, store, and analyze each sample.

2) Where your research team will identify and recruit potential research participants?

See page 4 under recruitment methods.

Brochures and flyers regarding the study will be provided to health care providers, and with permission, to local community organizations. Potential participants will contact the number provided on the flyer/brochure if they are interested in learning more about the study. A study staff member will use an IRB approved script to explain the study to the potential participant. The study staff member will ask the potential participant to answer a few screening questions. If the participant meets the inclusion criteria, then the participant will be scheduled for a baseline visit to review the study consent form and to obtain written consent.

Once potential subjects are identified, and subjects' physician agree to contact, a letter of recruitment describing the study will be mailed, followed by a follow-up phone call by a trained research assistant. The research assistant will screen subjects for eligibility by phone or in clinic to determine interest and eligibility. Those individuals meeting inclusion criteria, express interest, and able to provide consent will be scheduled for a baseline visit

3) Include the physical location where research procedures will be performed.

(a) This study will be conducted at the Frances Payne Bolton School of Nursing (private research space or room) and at the UHCMC's DCRU (See setting description above).

(b) First, consent will be obtained at a research space at the School of Nursing. Next, participants will complete surveys on tablet computers.

(c) After completing the baseline questionnaires, subjects will then be taken to the DCRU for height, weight, and blood specimen.

Consent Process

We will obtain consent after study procedures are fully explained and before any study procedures are conducted.

- ***Where the consent process will take place***
  Consent of participants and data collection procedures will take place at research office at the France Payne Bolton's School of Nursing at Case Western Reserve University.

  Any waiting period available between informing the prospective subject and obtaining the consent A trained research assistant will screen potential subjects for eligibility by phone or in-person. Eligible subjects will be scheduled for a baseline visit. Before any research procedures begin, the study will be fully explained and consent will be obtained by the research assistant at a research officeat FPB's School of Nursing. Although we have not specified a waiting period, participants will have flexibility to review the informed consent before providing consent. In addition, participants are not obligated to sign consent immediately; but will be encouraged and provided the opportunity to take consent home and review and/or discuss with family, then return at a later date/time to be consented with a research assistant. In event that there are key revisions to the study's protocol are made in terms of
  (1) study content and procedures, (2) change in organization or facility, and (3) the presentation of information that would facilitate a prospective subject's decision about whether to participate in the current research, and/or (4) required by the IRB, participants will be re-consented.

- ***The role of the individuals listed in the application as being involved in the consent process***
  Research staff trained and CITI certified will consent participants and completed data collection procedures.

- ***The time that will be devoted to the consent discussion***
  Based on the research team experience, the consent process for a study of this nature can take up to 30-45 minutes. However, participants will have flexibility to review consent before providing consent. In addition, participants are not obligated to sign consent immediately; but will be encourage and provided the opportunity to take consent home and review and/or discuss with family, then return at a later date/time to be consented with a research assistant.

- ***Any process to ensure ongoing consent***

- ***Steps that will be taken to minimize the possibility of coercion or undue influence***
  Participants are not obligated to sign the consent form immediately. Participants will have flexibility to review informed consent before providing consent. In addition, participants will be encouraged and provided the opportunity to take the informed consent home to review and/or discuss with family, then return at a later date/time to be consented with a research assistant.

- ***Steps that will be taken to ensure the research participants' understanding***
  Consent procedures will take place in a private room or office. Research assistants will read, review, and discuss informed consent forms with all potential participants prior to asking them to sign. We will ask questions to confirm understanding of the material covered in the consent procedure, open-ended (e.g., "Could you tell me what's going to happen if you enroll in the study?"). If the candidate appears confused or indicates a lack of understanding, the interviewer will attempt to identify the misunderstanding and to explain the form again. Any candidate who still does not comprehend the form will be excluded from the study.

Sharing of Results with Research Participants

In terms of the research results, data will be shared with participants by the way of newsletters, community event, or email communications at the end of the study. Only aggregate information (study findings/outcomes) generated from this study will published or presented.

☐ Results will **not** be shared with research participants
☐ Results will **not** be shared with research participants' doctors

Study Design

Subjects will undergo a battery of instruments to capture potential covariates, study variables, and observed outcomes at three time points (baseline, 3 months, and 6 months).

Table1. Study Measures and Time Points

VARIABLE	MEASURE	TIME Baseline	3mo	6mo
Health Outcomes (Resilience Presentation)				
Health-related Quality of Life	**PROMIS Global Health Scale-10** [13]	X	X	X
Blood Pressure Control	**Systolic and diastolic (BP)** [14,15]	X	X	X
Resilience Precursors (Traits)				
Dispositional Optimism	**Life Orientation Test** [16]	X	X	X
Dispositional Resilience	**Connor-Davidson Resilience** [17]	X	X	X
Emotion Regulation	**Gross & Johnson Emotion Regulation** [18]	X	X	X
Self-efficacy for Chronic Disease Management	**PROMIS Chronic Disease Management** [19]	X	X	X
Medication Adherence	**Hill-Bone Compliance Scale** [20]	X	X	X
Stress Response				
Neuroendocrine & Immunologic Response	**Interleukin 6 (IIL-6) blood sample**	X		X
BLOOD SAMPLES: Anti- and Pro-inflammatory cytokine	**High-sensitivity C- reactive Protein (CRP) serum (blood samples)**	X	X	X
Acute/Chronic Stress	**Hair for Cortisol Concentration**	X		X
	Saliva Samples	X	X	X
Psychological				
Depressive Cognitions	**Promis Depression Scale Short Form** [21]	X	X	X
Perceived Stress	**PROMIS Perceived Stress Scale-10** [22]	X	X	X
Risk Regulators (Covariates)				
Social & Community Conditions				
Social Support	**Duke Subjective and Instrumental Support** [23]	X	X	X
Marital Status	**Demographic Form**	X		
Discrimination	**Everyday Discrimination Scale** [24]	X	X	X
Material Conditions				
Employment	**Demographic Form**	X		
Income		X		
Education		X		
Personal Conditions	**Demographic Form**	X		
Age, Gender				
Chronic conditions	**Charleston Morbidity Index (adapted list)** [25]	X	X	X

Study Procedures

At Baseline (visit 1): For all subjects meeting eligibility criteria, we will (1) obtain informed consent, (2) collect sociodemographic profile and self-reported study measures, and (3) obtain blood and saliva samples. This baseline session is expected to last an hour and a half.
At Month 3 (visit 2), subjects will return for the administration of selected study measures and the collection of saliva and blood samples (cytokine profiles, serum and hair concentrations of cortisol).
At Month 6 (visit 3), subjects will return to the study site, where the same data as collected at visit 2 will be obtained.

Provide a description of all study-related research procedures being performed

Procedures

1. **Consent**. A research assistant (RA) will read, review, and discuss consent forms at *baseline* with all potential subjects prior to asking them to sign. If the subject appears confused or indicates a lack of understanding, the interviewer will attempt to identify the misunderstanding and to explain the form again. Any subject who still does not comprehend the form will be excluded from the study. We will ask questions to confirm understanding of the material covered in the assent/consent procedure (e.g., "Could you tell me what's going to happen if you enroll in the study?"). Consent procedures will take place in a private room or office. Consent forms will be kept by the in a secured file cabinet within a locked room 2203 at FPB school of Nursing.
2. **Surveys**. Data will be collected using UH REDCap on website accessible by computer, tablet, or smartphone). Data will be collected at baseline, 3 months, and 6 months **(See Table 1, page 8)** at FPB School of Nursing at Case in a private room or office.
3. **Other Assessment** will be conducted by registered nurses using a standardized protocol at the Dahm's Clinical Research Unit (DCRU) at UH or study coordinated at the .
    a. Anthropometric measures (height and weight) will be obtain at baseline. These measures will be used to calculate body mass index (BMI) as an estimate of total body fat independent of height. Height and weight will be collected at baseline, 3 months, and 6 months.
    b. Blood pressure will be obtain using a standard automated blood pressure measurement device (the OMRON HEM-907 XL Professional Digital Blood Pressure Monitor) baseline, 3 months, 6 months. After 5 minutes of reset, seated blood pressure and pulse will be measured three times at each clinic visit. The subjects should be seated with back supported, legs uncrossed, in a quiet room, with the elbow and forearm of the right arm resting comfortably on the armrest of the blood pressure measurement chair (or the table) with the palm of the hand turned upward. The average of these three measurements will constitute the visit blood pressure and pulse. BP will be collected at baseline, 3 months, and 6 months.
    c. Specimens, blood will be obtained at baseline, 3 months, and 6 months. Subjects will have blood samples (2 tubes, 1 teaspoon=5 ml each tube) drawn for Interleukin 6 (IIL-6) and High-sensitivity C-reactive Protein (CRP) and cortisol serum to assess (~10 minutes to complete). Blood specimens will be collected at baseline, 3 months, and 6 months. Because this is an observational study, we do plan to share results with patients.
    d. Specimen, saliva sample for cortisol (2 ml, ½ teaspoon in a tube) will be assessed at baseline, 3 months, and 6 months (~5 minutes to complete).
    e. Hair samples will be obtain at baseline and 6 months. small hair sample (5-6 strands of hair ~3 cm or longer) taken using scissors from the back of your head for cortisol stress.

*2) Include procedures being performed to monitor research participants for **safety or minimize risks***

Specimen, Blood: Some discomfort, bruising and/or bleeding where the needle is inserted for blood draws may occur. In addition, some people become dizzy, lightheaded, or feel faint. Infection may occur on rare occasions. Frequent donation of blood can result in low iron in your blood. To minimize risk**,** blood collection procedure will be guided by acceptable practices from the College of American Pathologists and AABB (http://www.cap.org) and UH Policy 2.4.4 (blood specimen collection, adult). The subject will be prep after informed consent obtained; then the blood draw procedure will be explained. Subject will be assessed for possible risks associated with venipuncture. If subject has history of fainting or adverse reactions to blood draws, then lab draws will not be collected. All subjects will be asked to sit for FIVE minutes' post-blood draw and asked/assisted to stand up slowly; then subjects will be assessed for lightheadedness and dizziness, as well as re-inspect of venipuncture site to ensure hematoma is not forming. Difficult lab draws will be sent to central lab or DCRU for lab draws.

3) Include all drugs and/or devices used in the research and the purpose of their use and their regulatory approval status

Omron Automatic Blood Pressure Monitor HEM-907 will be used to take blood pressures during study visit at baseline, 3 months, and 6 months guided by the American Heart Association recommendations.

4) Describe the source records including medical or educational records, which will be used to collect data about subjects.

Sources of materials: Research data will be collected via iPad-assisted (or other technology devices tablet PC, smartphone) questionnaires, demographics, blood pressure measurement, for research purposes only. All visit data (surveys/questionnaires) will be entered into the UH RedCap database.

All materials will be assigned a unique number that will be used to link data over time. A master list linking the ID number to the participant's name will be kept in a password-protected computer file, in a locked office, at the local site. This list will be kept entirely separate from the data so that responses cannot be linked to the individual participant.

All of the information that we collect from you will be treated as confidential, kept in a safe and secure place, and will be seen only by study staff. Research staff will be UH Research Credential and have a password protected area on the UH REDCap through which data will be entered and monitored. Documentation of the data entry system will be maintained by the Principal Investigator. In addition, training materials for measurement and data entry personnel will be available in downloadable format or study Manual of Procedures. At regular intervals, data queries will be carried out on the computerized databases to perform consistency checks on key variables and forms. Although much of this will have been done at the data entry level, this additional pass through the data serves as a quality control check. Paper records and computer files will be safeguarded from unauthorized access. Paper and/or electronic records for study participants will be stored in the Principal Investigators office (the Frances Payne Bolton, School of Nursing at CWRU, Room 2203). They will be stored in locked filing cabinets and/or filing rooms within secure office space. Only study personnel who have completed study training in data handling will have access to study forms.

Study Timeline

A 2-year time framed is planned. Staff hiring and training, refining study protocol, and building and testing the database will be completed in Months 1-3. Subject enrollment will commence by month 4 and will occur over 1-year, to be completed by Month 15, and the last enrolled participant will complete data collection measures in month 21. In the final 3 months, we will analyze the data, interpret results, and prepare reports on primary outcomes.

Data to be Collected for your study

Table 2. Timeline				
	Pre-Screening	Visit 1	Visit 2	Visit 3
Estimated time requirement of visit	30-45 minutes	1 hour 30 minutes	1 hours	1 hours
Informed Consent		30 minutes	30 minutes	30 minutes
Blood Pressure		5 minutes	5 minutes	5 minutes
Height and Weight		5 minutes	5 minutes	5 minutes
Blood and Saliva Specimen collection		10 minutes	10 minutes	10 minutes
Hair sample collection		10 minutes	10 minutes	10 minutes
Study questionnaires measures		30 minutes	30 minutes	30 minutes

(AFTER consent and HIPAA Authorization have been obtained)

List all data to be collected for the research study or attach a data collection sheet (e.g. laboratory values, physician notes, length of stay, etc.)

a) Diagnosis, CPT code
b) Age
c) Race/ethnicity
d) Interleukin 6 (IIL-6) and High-sensitivity C-reactive Protein (CRP) serum
e) Saliva & Hair Cortisol Concentration
f) Blood pressure

Data Analysis Plan

Directions: Describe the data analysis plan, including any statistical procedures. If applicable, provide a power analysis, describe primary and secondary study endpoints including safety endpoints.

Two types of analyses are contemplated to address the specific aims of this study. First, preliminary analyses using exploratory and descriptive statistical methods (correlation and regression analyses) will be performed to examine univariate distributions and bivariate relationships between resilience precursors, stress responses, HTN self-management behaviors, and health outcomes. The second and more comprehensive set of analyses that will be used as the primary tool for studying longitudinal trajectories of various response variables is Linear mixed effects model (LMM). Analyses for each aim are described below.

We will use correlational analysis will be used in determining statistically significant correlations among variables of interest. Significant correlations will be studied further in the regression analysis using LMMs. In the LMM with random intercept and slope, we will control the cofounding effects of risk regulators by adding them as covariates in the model. The association between resilience precursors will be determined by a nonzero regression coefficient, beta, and its 95% confidence interval (CI). Because the health outcomes (HRQOL and BP) are associated,

we will jointly model the outcomes for improve efficiency in the estimation of regression parameters and longitudinal correlations. To take into account the correlations, both types of outcomes will be modeled jointly by introducing first-order autoregressive process.[26] We will apply SAS PROC MIXED and/or PROC MCMC for jointly modeling health outcomes.

Risks to Research Participants

List the reasonably foreseeable risks such as breach of confidentiality, discomforts, hazards, or inconveniences to the research participants related to their participation in the research. Include a description of the probability, magnitude, duration, and reversibility of the risks. Include the physical psychological, social, legal, and economic risks.

The level of risk from the proposed study is minimal (**described above on page 9, last section**). The risks associated with gathering information from subjects by properly trained and supervised research assistants are low. Subjects may experience embarrassment or psychological distress from questions. Our investigators and staff are experienced interviewers and we have rarely encountered subject reactions more adverse than transient awkwardness, embarrassment, or mild discomfort, but we are prepared to deal with such events. Also, answering some questions may take longer than estimated time. However, all subjects will be instructed that they can stop the interview at any time or can choose to skip any question that they wish.

Participants will complete the self-report Patient-Reported Outcomes Measurement Information System (PROMIS-29), Depression Short Form domain. Data collectors and the research nurse will be instructed on the protocol regarding how to obtain assistance for psychological issues, should they arise and are describedbelow.

a. If a subjects' level of depressive symptoms is above the recognized clinical T score of 60 (raw score ≥11), a research nurse will follow-up with the subject.
b. Subjects will be informed of findings and instructed to contact his/her primary health care provider and provided additional resources to contact. Staff is required to document that action and inform Principal Investigator.
c. However, if further assessment by the nurse reveals signs or symptoms of major depression (i. e. hopelessness and/or helplessness) or the nurse will contact the Principal Investigator for additional assessment.
d. Per the nurse's/Principal Investigator judgment, the participant may be safe to leave the clinic with follow-up from either a PCP or mental health professional or require further assessment and treatment.

In rare cases, if a subject verbalize thoughts of harming themselves, the research nurse/Principal Investigator will assess for imminent risk of suicide and inform participant of a concern for their safety and the necessity for the subject to contact the Mobile Crisis Team from the Cuyahoga County 24-Hour Mental Health Crisis, Information and Referral Hotline immediately. In addition, the subject's physician (if the subject has given permission to do so) that he patient may have depression and further evaluation and treatment may be indicated, If necessary the nurse will make an appointment for the subject with an appropriate mental health provider (e.g. a psychiatrist).

Protection of participants' identities and confidentiality. The following confidentiality-protection steps will be taken: [1] Research assistants and staff will participate in initial training, follow-up training, and ongoing monitoring and supervision to ensure their understanding of ethical issues involved in this research; [2] consent forms will be maintained in locked files with limited access; and [3] Any personal identifiers linked to data will be removed and replaced by code numbers in all records. They also will be assured that their responses will be kept confidential and will not be used against them in any manner, including for reasons of legal action or medical treatment. All research data will be collected on standardized research forms with de-identified ID numbers, but without personal identifiers. Only study personnel will have access to research data which is kept in either locked cabinets or password computers in locked buildings. All personal data will be stored separately from de-identified research data. All presentations and publications will only utilize aggregate data.

Safety. We have conducted previous research protocols that involve vulnerable subjects and highly confidential or sensitive personal information. As a result, we have established protocols for quality assurance, emergency procedures, crisis intervention and referral, and initial and ongoing staff training. The research assistant will have had experience working with persons of low socioeconomic status, and racial/ethnic minorities.

Quality assurance. Research staff will attend ongoing bi-monthly supervision meetings where quality assurance and problem-solving topics will be discussed. A systematic procedure will be used for training the research assistant using a written protocol. We will further monitor self-reported measures for completion by having subjects enter survey data directly into UH REDCap.

Provisions to Protect the Privacy Interests of Research Participants

Protection of participants' identities and confidentiality. The following confidentiality-protection steps will be taken: [1] Research assistants and staff will participate in initial training, follow-up training, and ongoing monitoring and supervision to ensure their understanding of ethical issues involved in this research; [2] consent forms will be maintained in locked files with limited access; [3] Any personal identifiers linked to data will be removed and replaced by code numbers in all records. All research data will be collected on standardized research forms with de-identified ID numbers, but without personal identifiers. All presentations and publications will only utilize aggregate data.

Only study personnel will have access to research data which is kept in either locked cabinets or password computers in locked buildings. All personal data will be stored separately from de-identified research data. Our physical space is located at the Frances Payne Bolton School Nursing and our research team has five private offices approximately 200 square feet to accommodate each research assistant and project manager.

Potential Benefit to Research Participants

There is no direct benefit to participating in this study. Subjects' participation in this study may aid in our understanding of what methods help African Americans with high blood pressure better in terms of self-manage and control their hypertension.

Withdrawal of Research Participants

Describe the anticipated circumstances under which research participants will be withdrawn from the research without their consent.

Each subject will be encouraged to complete the full course of the study assessments. However, it is understood that the subject may discontinue study participation at any time for any reason. The reason for early withdrawal must be documented in the subject's case file and in the subject tracking document.
Reasons for Withdrawal. Subjects are free to withdraw from the study at any time for any reason.

a. Subjects should normally be withdrawn from the study if a serious adverse event (SAE) occurs.
b. Subjects must be withdrawn from the study if:
    1. They withdraw their consent;
    2. The investigator considers it in the best interest of the subject that he or she is withdrawn.

Also include the procedures that will be followed when a research participant withdraws or are withdrawn from the research, including partial withdrawal from procedures with continued data collection.

The reason for any subject's discontinuation and the date of withdrawal will be recorded in the subject's case file. The subject's case file, which will be completed up to the point of withdrawal, will be retained for three years. The study report will include reasons for subjects' withdrawals as well as details relevant to the subjects' withdrawals. Any subject withdrawn from the study prior to completion will undergo all procedures indicated in this protocol as being scheduled to occur at discharge or upon early withdrawal. Any subject withdrawn due to an adverse event (whether serious or non-serious) will be evaluated by the Principal Investigator or a monitor, and recommendation for follow up with health care provider. Relevant post-study procedures will be performed, wherever possible, on subjects who elect to withdraw.

Handling of Withdrawal. If a subject is withdrawn from participation in the study at any time at his or her request, at the IRB or Principal Investigator's discretion, the reason(s) for discontinuation shall be documented thoroughly in the source documents and subject's case file.

Alternatives to Participation

Because of the nature of this research (observational) the only alternative is to not participate in this study.

Costs to Research Participants

There are no costs to you or your insurance for taking part in this study. Laboratory tests and parking associated with this research are paid for by the study sponsor.
In an event that a you should become injured while participating in this study, the study cannot pay for health care costs that are not part of the study. There are no plans for payment of medical expenses or other payments, including lost wages, for any research related injury.

Research Participant Compensation

Participants in both groups can receive up to $100 honorarium over a 6 month period. This intended to cover any costs incurred from cell phone usages, and overall study participation. Each subject will receive a $25 gift card for the completion of both baseline and 3 month visits; and $50 for completion of 6 month visit for their participation. In addition, we will provide complementary parking passes per visit for each participant.

Provisions to Monitor the Data to Ensure the Safety of Research Participants

Describe how often the data will be monitored for completeness, accuracy and adherence to the protocol.

The study PIs Carolyn Still and Mahbooh Rahman will share responsibility for monitoring risks to human subjects and the implementation of monitoring the data. Serious adverse events will be reported promptly to the institution's IRB, and project officer of the funding source.

Multiple procedures to safeguard the wellbeing of study participants and to maintain the scientific integrity of the project while achieving the study's specific aims will be employed. Key components of the data and safety monitoring plan include weekly meetings of core members of the research team (at minimum, the Principal Investigators, Project Director and Research Assistants) and monthly meetings with the entire research team and other key personnel. The agenda for these meetings will include tracking of participant recruitment, enrollment, and retention; data collection and entry; and documentation and review of any participant concerns or adverse effects. These meetings will help ensure that the project timeline is being met.

To assess data quality, under the direction of Drs. Still and Sattar, research staff will conduct random auditing of the research records (i.e., data files, informed consent documents, etc.) to assess data integrity and regulatory compliance as described further below. Drs. Still and Rahman will have ultimate oversight over all aspects of the fidelity of the study protocol. However, other research staff members are assigned to provide direct (first line) monitoring over various aspects of the study as outlined in the table below. These aspects of the study protocol will be reviewed at the SMC meetings twice each year.

Study protocol	Timeline	First line supervision	Ultimate oversight
1. Recruitment process (includes posting of flyers, receiving calls, etc.)	From beginning of study until total sample size (N=125) is reached	Project Manager	PI Still/Rahman
2. Screening (for meeting inclusion criteria and ensuring we meet minority targets)	Within one week after potential participant contacts the study office, monthly	Project Manager	PI Still/Rahman
3. Monitoring of sample size (includes minority targets and attrition)	From beginning of study until sample size is reached, weekly	Project Manager	PI Still/Rahman
4. Random assignment to treatment groups	Within one week after enrolling in the study	Project Manager	PI Still/Rahman

5. Data collection, informed consent process, maintaining confidentiality, and scheduling of all data collection sessions)	First data collection scheduled within one week of enrolling in study followed by two more data collections at 3 and 6 months	Project Manager/Data Collectors	PI Still/Rahman
6. Data management (includes downloading data from REDcap and heart rate variability device into SPSS, and checking missing data and errors, attrition patterns, etc.)	Within one week of collecting data from subject	Project Manager/ Research Assistants	A. Sattar

Indicate if there will be a Data and Safety Monitoring Board or Committee. Provide information about the DSMB/C including the contact information of the committee member(s) (as applicable); whether it is independent from the study sponsor; how often it meets; the type of data that will be used; written reports, etc.

All elements of the data and safety monitoring plan will be reviewed by the IRB at relevant institutions (CWRU and any clinical sites) and provided to the NIH institute overseeing the project**.** While Dr. Mabhoob Rahman is the PI of record**,** the data plan identifies the Investigator, Dr. Still as the primary monitor of risks to human subjects. All adverse events will be reported per UH policy (as described below) to the institution's IRB and project officer of the funding source. Monitoring procedures and reporting and action plans for data and safety-related risks are described.

A Safety Monitoring Committee (SMC) will be formed:

1) This committee consists of three members who are independent of the study protocol who will review data from this study.
2) Twice annually throughout the project, this committee will review data regarding (1) all causes of mortality and (2) morbidity (hospitalizations, ER visits, and injuries/problems). Additionally, the rate of recruitment refusal (percent and reasons) and subject attrition (percent and reasons) will be tracked and reported at these reviews. Differential attrition from the experimental groups also will be monitored. If concerns or problems are identified by the SMC they will be reported to the IRB and NIH. Study protocols for human subjects monitoring and protection of risks and protection of confidential participant data will be reviewed by the SMC at the onset of each new study.
3) As they occur, all unanticipated events and adverse events will be reported to the principal investigator who will report them to the IRB according the IRB protocol reporting procedures for both serious and non-serious adverse event reporting. Adverse events (unexpected or serious) and unanticipated problems will be tracked and follow-through via referrals and follow-up as required by the University Hospitals of Cleveland Medical Center (UHCMC) Committees on Human Research. An adverse-event form will be developed detailing the incident, actions taken, supervisor notes, and follow-up steps. The form will be sent to the appropriate agencies, including the UHCMC IRB and the NIH (via Project Officer) by the Principal Investigator. Specifically, the following will be reported, in writing:
    - Adverse events that are Unanticipated Problems and are (1) unexpected, (2) possibly related to participation in the research, or (3) places the subject at greater risk of harm than listed on informed consent will be reported to both the UHCMC IRB and NIH (via Project Officer) within 14 calendar days of discovery of the problem or event.

- Unanticipated problems that are serious adverse events (e.g., death, a life threatening experience, inpatient hospitalization or prolongation of existing hospitalization) will be reported to both the UHCMC IRB and NIH (via Project Officer) within 7 days of discovery of the problem or event.
- Unanticipated problems that are non-serious and expected adverse events will be reported annually at continuing review to UHCMC IRB and annually to NIH (via Project Officer).

Any action recommended by the IRB (including those that indicate a change in risk to the participants or any action taken by the IRB in regards to the research) will be conveyed to the NIH (via the NIH Project Officer) by the Principal Investigator within 7 days. The Principal Investigator will be responsible for monitoring and reporting adverse events. The SMC will be consulted as appropriate.

1) These will be summarized in the twice annual reports to the SMC. Annual progress reports to the IRB and NIH will include a summary of the SMC's activities and findings as well as any adverse events regarding human subjects.

The Principal Investigator will report any adverse effects or problems noticed in the course of the study to the CHR and/or IRB on an annual basis and as described above. Any action recommended by the IRB (including those that indicate a change in risk to the participants or any action taken by the IRB, in regard to the research) will be conveyed to the NIH (via the NIH Project Officer) by the Principal Investigator within 7 days. The Principal Investigator will be responsible for monitoring and reporting adverse events. The SMC will be consulted as appropriate.

Drugs or Devices

Omron Automatic Blood Pressure Monitor HEM-907 will be used to take blood pressures at baseline, 3 month, and 6 month visits, guided by the American Heart Association recommendations by research assistant. Omrons will be stored in a locked office.

Additional Information

Directions: If you have any additional information regarding your study not covered in the template, please include it here.

N/A

Community-Based Participatory Research

N/A

International information

N/A

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