7-19-2016

A Home-Based Biofeedback Intervention in A Hypertensive African American Sample: A Pilot Study

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A HOME-BASED BIOFEEDBACK INTERVENTION IN A HYPERTENSIVE AFRICAN AMERICAN SAMPLE: A PILOT STUDY

by

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A Dissertation

Submitted in Partial Fulfillment of the

Requirements for the Degree of

Doctor of Philosophy

Major: Psychology

The University of Memphis

August 2015

Dedication

I would like to dedicate my dissertation to my wonderful husband, daughter, family, friends, and advisor. What is it you say, “for better or worse?” I can say that my husband’s dedication to me and this degree and his unwavering support and patience with my long nights and “afterhours” working on this degree is how it came to be. To my precious daughter, Naomi, who will only read this years from now. Thank you for being my motivation for perseverance and opening my eyes to a whole new world. I can hardly wait to know you! To my family and friends who have given their ears, support and continued acceptance of my commitment to this. I am so grateful to all of you who have been a part of this journey.

Acknowledgements

This dissertation would not have been possible without the guidance and the help of several individuals who in one way or another contributed and extended their valuable assistance in the preparation and completion of this study.

First and foremost, my utmost gratitude to Dr. Frank Andrasik, my advisor throughout graduate school, whose sincerity and encouragement I cannot forget. You “took me in” when I thought I wanted to throw in the towel; thank you for your constant encouragement, support, and kindness. Most of all, your ability to keep that smile on your face is something I will treasure for years to come.

Drs. Hayden and Patterson, for your support and belief in this idea. Without both of your support for this study, this collaboration would not have been possible. Your clinic welcomed me in with open arms. Thank you.

George Relyea, for your statistical knowledge, guidance, and time spent helping me appreciate the numbers-in classes and in this document.

Drs. Murphy and Neimeyer, for your thoughtful participation on my committee and your ability to question.

Breya Walker, for your help collecting data and enthusiastic attitude towards this area of research.

Abstract

Frankfurt, Paige A. Ph.D. The University of Memphis. August, 2016 A Home-Based Biofeedback Intervention in A Hypertensive African American Sample: A Pilot Study. Frank Andrasik, Ph.D.

Approximately 70-80 million people in the US have hypertension. Left untreated, it can lead to heart disease and stroke, the 1st and 2nd leading causes of death in the US, respectively. African Americans (AA) are at particular risk for developing hypertension and, when present, they experience increased morbidity and mortality, in comparison to other races, as well as elevated risk of psychological distress. Further, when treated with the prevailing approaches, AAs experience more adverse side effects and often face a greater number of challenges with adherence. Despite some successful efforts at reducing high BP in general hypertensive populations, AAs continue to struggle greatly with this condition. The primary purpose of this research was to test the utility of the RESPeRATE, a home-based biofeedback device approved for treatment of hypertension, in augmenting care of AAs currently receiving medical treatment but who were not responding at an optimal level. A secondary aim of this study was to examine the impact of treatment on psychological effects of individuals with hypertension. This was accomplished in a small-scale pilot investigation comparing those continuing on their current treatment, or Treatment as Usual (TAU), to those continuing TAU + the addition of the RESPeRATE device. Multiple measures were collected at baseline, immediate post-treatment, and follow ups at 3 and 6 months. In addition to ongoing assessments of BP, the Perceived Stress Scale (PSS), Beck Depression Inventory (BDI), Beck Anxiety Inventory (BAI), and the Quality of Life Questionnaire (QoL) were collected for 2 purposes: as potential predictors of treatment response and to track collateral improvements over time. Gender, specifically being female, significantly predicted reductions in systolic blood pressure at the end of the intervention

(β=8.34, *SE* = .66, t (28) = 12.63, p <.001). Similarly, age significantly predicted successful reductions in systolic BP at the end of the intervention β=-.26, *SE*= .04, t(28)=.6.52, p< .001.

Keywords: African Americans, hypertension, high blood pressure, home-based, biofeedback

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Introduction

The Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure defines hypertension as an elevated systolic blood pressure (BP) of $\geq$150 mmHg and diastolic BP of $\geq$ 90 mmHg, in adults 60 years and older, or 140mmHg and diastolic BP of $\geq$ 90 mmHg, in adults younger than 60 (James et al., 2014). Left untreated, it can lead to heart disease and stroke, the 1st and 2nd leading causes of death in the US, respectively (World Health Organization (WHO), 2011). Approximately 70-80 million people in the US have hypertension (American Heart Association, 2012; Center for Disease Control, 2011). High BP imposes a huge weight on society as a whole, varying as a function of gender and race (among other aspects), with this condition worsening with age due to the stiffening of the arterial walls. By age 64, more women are affected than men. The economic burden of hypertension, when left untreated, is large. Recent studies found that the overall economic burden of high BP is approximately $156 billion dollars per year [in healthcare services and costs, missed days of work, and general medications (Department of Health and Human Services (DHHS), 2012)], and, by 2030, it is projected to increase to nearly $200 billion dollars per year (Heidenreich et al., 2011).

Multiple causes of hypertension have been identified including biology, genetics, drugs and diseases, and lifestyle choices. Therefore, interventions have focused efforts for reducing BP on these areas. Studies typically have focused on reducing BP through lifestyle/diet modifications, administering antihypertensive drug therapy (ADT), providing education and stress-reduction approaches using biofeedback, meditation, and paced breathing techniques (Appel et al., 1997; Barnes, Treiber, & Johnson, 1997; DeSimone & Crowe, 2009; Lochner, Rugge, & Judkins,

2005; Rankins, Sampson, Brown, & Jenkins-Salley, 2005; Svetsky et al., 1999; Tilburt, Dy, Weeks, Klag, & Young, 2008). Despite some successful efforts at reducing high BP in general hypertensive populations, AAs continue to struggle with BP (Rankins et al., 2005; Svetkey et al., 1999). In non-AA samples, significant reductions in BP from lifestyle/diet modifications and ADTs have been found. However, research has shown that AAs experience more adverse side effects and challenges with adherence to these treatments, an alarming situation since these approaches are the gold standard at present for effective high BP intervention (Fongwa et al., 2008; Lloyd-Jones et al., 2010; Mellen, Gao, Vitolins, & Goff, 2008; Mozaffarian et al., 2015).

In addition to the above-mentioned problems, AAs have been found to exhibit different physiological reactions in response to psychosocial and emotional stress (anger, depression, anxiety), as compared to their Caucasian, Hispanic, or Asian counterparts (Artinian, Washington, Flack, Hockman, & Kai-Lin, 2006; Gonzales & Thomas, 2011; Horowitz, Tuzzio, Rojas, Monteith, & Sisk, 2004; Merritt, Bennet, Williams, Sollers, & Thayer, 2004; Taylor, Washington, Artinian, & Lichtenberg, 2008). Anderson and Nurckhardt (1999) posit that AAs experience stress more chronically than European Americans, suggesting one possible reason for the higher rates of hypertension in AAs. When humans experience hyperactivity of the Sympathetic Nervous System (SNS) (i.e., increases in heart rate, respiratory rate, blood pressure and metabolic rate) in the face of acute and chronic stressors, an imbalance in the autonomic nervous system occurs. Over time, this imbalance can lead to deterioration of renal functioning, increased production of sodium-retaining hormones, stiffening of and reduced strength of the arterial walls, and, ultimately, increased blood pressure and cardiovascular disease (Oparil, Zaman, & Calhoun, 2003). Research has shown that the majority of AAs are genetically predisposed to increased sodium retention, which is associated with hypertension. When

considering the abovementioned stress response that AAs experience, it stands to reason that prolonged physiological reactions to stress in AAs (i.e., discrimination) helps to explain the higher rates of hypertension (Dusek & Benson, 2009; 2000; Knox, Hausdorff, & Markowitz, 2002; Merritt et al., 2004).

The disparate rates of hypertension (HTN) among African Americans arise in part due to several psychosocial stressors that have been identified as barriers to medical treatment and overall life stressors (Kaplan & Nunes, 2003; Paradies, 2004, 2006), including lower socioeconomic status (SES), lack of access to health care services and accurate health information, cultural beliefs and attitudes, and limited social support (Borzecki, Oliveria, & Berlowitz, 2005; Centers for Disease Control and Prevention, 2005). One such cultural belief/ attitude is embodied in the John Henryism (JH) theory, which has been applied to African Americans and suggests that prolonged exposure to stressors, including social discrimination, results in compromised physiological effects (i.e.,hypertension). Specifically, it suggests that high effort, combined with sustained active coping, but with limited socioeconomic resources to draw upon (lower education, income, etc.) sets the occasion for blood pressure to increase. This view has found support in several studies (Fernander, Duran, Saab, & Schneiderman, 2004; James, Keenan, Strogatz, Browning, & Garrett, 1992; Merritt et al., 2004). Furthermore, research suggests that use of an active coping when few socioeconomic resources are available may not only increase the risk of HTN but also cardiovascular disease. These increased risks can occur as a result of heightened sympathetic nervous system activity, cardiovascular reactivity, and delayed resilience to stress (Merritt et al., 2004).

One possible theory whose application could help reduce cardiovascular reactivity and resilience to stress focuses on the relaxation response (RR) in an attempt to slow down the SNS.

As discussed above, the role of SNS activation as a contributing factor to HTN has led investigators to explore alternative ways of counteracting this factor. Different forms of relaxation, including regulated breathing techniques, mindfulness including yoga and meditation, and physical activity, have been shown to help counteract the stress response by decreasing SNS (Benson, 2000; Duraimani et al., 2015; Park, Lyles, & Bau-Wu, 2014) and allow the arteries to relax (dilate) and increase blood flow, thereby reducing blood pressure. Despite the availability of several effective programs aimed at reducing high BP in individuals with hypertension in general, including lifestyle and diet modifications (i.e., behavioral modification to diet and activity levels), ADTs, education and stress reduction, meditation and paced breathing techniques, AAs remain somewhat unaffected by these approaches often leading them to seek alternative ways to treat hypertension beyond lifestyle modifications or ADT's (Artinian et al., 2008; Dennis, Markley, Johnston, Vander Wal, & Artinian, 2008; DeSimone & Crowe, 2009; DHHS, 2012; Knox et al., 2002; Lochner et al., 2005; Svetsky et al., 1999). Given the adverse effects that AAs have with some ADTs, challenges they experience with lifestyle modifications, and their desire for treatment, it is important to explore possible treatments that address such barriers.

Biofeedback, an intervention specifically designed to decrease SNS activity, may be one such alternative approach. Available research suggests it may well serve as a useful adjunctive aid, one that is absent of unwanted side effects of ADT's and that may more easily overcome known barriers to hypertension treatment in this population (Linden & Moseley, 2006). A number of biofeedback approaches have been shown to be of value in treating hypertension; however most of them require extensive interaction with highly trained therapists and utilize very specialized equipment. To reduce these costs, investigators have begun to explore the utility and

effectiveness of portable compact, self-contained biofeedback BP devices, ones that can be used in a home setting and require minimal therapist instruction. One such device is the RESPeRATE, which is FDA-approved for hypertension. Of note, breathing relaxation interventions, such as that employed by the RESPeRATE, have been more effective in producing both short and long term significant reductions in blood pressure than forms of relaxation that utilize mental means- a component of meditation (Kaushik, Kaushik, Mahajan, & Rajesh, 2006). Elliot and Izzo (2006) provided the initial evidence of efficacy of this device in a case report. Upon using this unit, which they termed a "Biofeedback-Assisted Breathing Relaxation" (BARB) device, a Caucasian female was able to effectively lower her BP 17/14 mm Hg, in an 8-week period, without unwanted side effects, and when used either alone or when combined with lifestyle modifications or ADTs. However, follow up data collection was minimal (and the report was, of course, uncontrolled).

Several subsequent studies with this home trainer have shown significant initial reductions in BP, following an 8-week treatment period, that were maintained throughout the day and even up to 6 months after usage of the BARB device (Meles et al., 2004; Rosenthal, Alter, Peleg, & Gavish, 2001; Schein et al., 2007). The average reduction of BP in these studies was 14/8 mm Hg, compared with control treatments of 9/4 mm Hg (p = .008 and p = .002, respectively for systolic and diastolic BPs). The differences were independent of gender and medication status.

Recognizing the added costs of seeking treatment solely in the medical office setting has led some investigators to explore ways for patients to apply aspects of treatment within their homes. This research was spurred, in part, by the findings of Tilburt et al. (2008), who examined associations between hypertension home-remedy use and self-reported adherence among a poorly controlled hypertensive urban AA population (N = 183, drawn from the 1999-2004 Inner

City Hypertension and Organ Damage study). Home remedy in their investigation was defined as any non-pharmacological self-administered healing approach using everyday life items (i.e., herbs, spices, vegetables, over-the-counter medications, and items traditionally used for cooking that are used to treat a variety of ailments). Participants were asked if they used home remedies for their general health and their hypertension and if so, which ones. Home-remedy use was found to be independently and positively associated with greater medication adherence; hence, the idea to build upon the seeming preference by some AAs to self-treat at home. Feldman et al. (2009) conducted a 3-arm randomized controlled trial that focused on field nurses, nurses who work out in the field (i.e., home settings) who tested 3 strategies in African Americans to improve hypertension management and outcomes. This study was completed in a decentralized service setting serving a home care population. Once admitted [to the study], field nurses were randomized to usual care (TAU), a basic, or augmented intervention condition. Nurses assigned to the "basic" intervention provided key evidence-based reminders to home care nurses and patients while the patient received traditional postacute home health care; nurses assigned to the "augmented" intervention did the same as the basic intervention plus transitioning patients to an ongoing Hypertension Home Support Program that extended support for 12 months. Patients in both intervention groups received a home-based automated blood pressure monitor. The TAU condition proved substantial improvements in controlling BP and created a high comparative effectiveness threshold for future studies providing supporting for treatment of AA's with hypertension in the home setting.

The previous studies examining the RESPeRATE have shown significant reductions in BP. However none of these studies has researched the effectiveness of the RESPeRATE in an AA sample specifically or included follow up periods beyond 8 weeks (Elliot et al., 2004; Schein et

al., 2001, 2007). The convenience and ease of operation and administration of a device like the RESPeRATE, which at the same time helps to mitigate a number of associated barriers to effective treatment, led us to explore whether this device could augment medical office-based treatment and lead to further reductions in BP in AAs diagnosed with hypertension. If so, devices like the one examined here could be more readily and easily disseminated throughout medical clinics.

This study was thus implemented to address a number of problematic issues reviewed above, chief among them being the previously mentioned barriers to successful hypertension treatments in AAs by attempting to minimize the demands placed upon patients. First, the home device selected allows patients to easily and independently complete a specially guided breathing technique in the convenience of their own homes and at times that best fit the demands of their schedules. This alone could potentially result in increased adherence. Second, if effective, use of the device could reduce the frequency of physician office visits and amount and type of medication needed, which in turn would reduce both transportation and lost wages associated with seeking treatment and medication expenses. Third, the RESPeRATE provides individuals with immediate feedback of proper usage, which may enhance motivation. Fourth, should patients attain meaningful reductions in BP and the reductions remain over time, the monetary savings resulting from reduced office visits and lowered medication costs ccould quickly offset the moderate cost of this or similar biofeedback or relaxation units ($200-300). Fifth, the RESPeRATE can be altered in order to collect user data, permitting researchers to examine dose versus response analyses and study patterns of usage. Having this kind of information could be very helpful for tailoring and adjusting treatments in the future. Finally, the efficacy of the RESPeRATE has been proven in nearly 11 clinical trials. However, those trials were supported

by manufactures or individuals involved with device (Mahtani, Nunan, & Heneghan, 2012). Taken together, it seems reasonable to believe that, based on previous RESPeRATE studies, this device could serve as an effective adjunctive aid for lowering high BP in AAs who are hypertensive by reducing potential barriers to effective treatment as well as allowing for analysis of real world implications of usage of the RESPeRATE, taking science one step closer to preparing medical providers to be able to disseminate treatment much more broadly.

Method

Participants

Participants were recruited from a local urban mid-south internal medicine clinic. Medical charts were reviewed to identify patients meeting the following inclusion criteria: between 18 and 75 years of age (CDC, 2011), prior diagnosis of hypertension by a physician (elevated systolic BP of $\geq$ 140 mmHg and diastolic BP of $\geq$ 90 mmHg (James et al., 2014; WHO, 2011) within the past 12 months but whose condition was not currently adequately controlled or had previously experienced challenges in reducing their blood pressure in the past 12 months, as defined by one or more of the following: self-reported limited transportation to medical clinics; high medication costs; convenience; and low medication adherence (if on medication), $\leq$ 40% of the regimented time, as defined by categories set forth by Mazzaglia et al. (2009; high (proportion of days covered, ≥80%), intermediate (proportion of days covered, 40% to 79%), and low (proportion of days covered, ≤40%). Exclusion criteria included: any severe psychiatric, medical or comorbid conditions—uncontrolled diabetes, heart disease, pregnancy, or a known pulmonary disease, or having excessively high and uncontrolled BP, defined as either SBP above 190 mmHg, DBP above 100mmHg, or both.

Research indicates that African Americans are at higher risk for developing hypertension than are Caucasian and Mexican Americans, and that this is especially so for AA females (Roger et al., 2012). Our recruitment aims, therefore, were to enroll a representative sample of AA individuals, for whom alternative treatments had not previously worked optimally.

Procedure

A member of the research team contacted all interested and referred participants to conduct a formal screening to determine their study eligibility, inviting all who qualified. Participants deemed eligible, but who declined to participate, were provided with contact numbers for local hospitals/emergency services. Individuals judged ineligible were thanked for their interest and informed of possible treatment options at a local community health center. Nearly 100 participants were assessed for eligibility at the start of the study and 65 declined to participate. Sixty-two participants were uninterested in participation and three participants were unable to commit to the requirements for the study. In sum, 33 participants agreed to participate and 14 were randomized to the TAU condition and 19 to the ReSPERATE condition. At the start of the study 14 participants were randomized to the TAU condition and 19 to the ReSPERATE. Twelve participants remained in the TAU condition; two were removed before the EOI due to missing appointments. Similarly, 16 participants received the ReSPERATE intervention; three were withdrawn over the intervention period due to missing appointments. At the end of the 6-month study period 1 additional participant was withdrawn from the TAU condition and 5 participants from the ReSPERATE condition, leaving 33 total participants.

Participants who met full study criteria and who wished to partake in the study were informed of the necessary commitments: an initial 1.5 hr training session on how to measure their blood pressure accurately (administered by the medical professional on site—Physician's

Assistant (PA) or Nurse), psychoeducational information about high blood pressure, the treatment rationale and components for participants, an informed consent process, and a comprehensive battery of measures including: general demographic information, level of stress, perceived stress (as more perceived stress has been associated with higher BP), symptoms of anxiety and depression, medication dosage and adherence, and quality of life. All participants were carefully followed and monitored over an 8-week period, until the end of the intervention (EOI) period, and throughout the duration of the study. All patients received immediate post-treatment BP readings, and follow ups at 3 and 6 months. Informed consent was explained and obtained from each participant in accordance with the "Ethical Principles of Psychologists and Code of Conduct" (American Psychological Association, 2013), with all being informed of their right to withdraw participation at any time without penalty. IRB approval was obtained before commencement of the study.

During the session in which participants completed the abovementioned measures, they were informed that they would receive monthly pre-scheduled phone calls (at select times) from research staff to monitor their progress, answer questions, and clarify any other needs. Participants were asked to return to the local medical clinic every 4 weeks with the hopes of being able to retrieve adherence data (the maximum amount of data storage for the device) for brief consultations, at which time the researchers downloaded the data from the RESPeRATE[1]. The first 2 months entailed the patient education component, initial data collection, and intervention. During months 3-6, researchers called participants once a month to monitor their progress, answer any questions, and clarify any other needs.

At the conclusion of the study, participants completed a 5-question survey developed by the PI to assess satisfaction with RESPeRATE. Questions addressed ease and utility of the device as

[1]Technical problems precluded collection of sufficient data to permit meaningful analyses

well as general feedback about potential improvements to the study and any other factors. Participants received a $10 gift card upon completion of each assessment and all scheduled intervention sessions, for a maximum of $70.

Data Safety and Monitoring. An expert interdisciplinary team of researchers, physicians, nurses, and faculty members from the School of Public Health (SoPH) collaboratively and consistently monitored participant progress throughout this study. Incorporating health care providers (HCP) from the community had the added benefit of providing a larger recruitment pool as well as truly engaging the Community in our efforts.

All identifiable information provided by participants was stored separately on a secure database; each participant was assigned a non-identifiable subject number and the de-identification process occurred within 72 hrs of receiving confidential information. All additional information obtained from participants was entered into a second database identified only by participant number. Only members of the trained research team entered the data into the database. The two databases were stored on two separate computers, backed up on separate external hard drives that were stored on servers behind a firewall. The PI and her faculty mentor had access to the identifiable dataset. Participant information is currently stored behind three locked doors and a password protected computer (and a separate password protected document on the computer).

Additionally, a three-person Data Safety and Monitoring Board (DSMB) was assembled to ensure the safety of the participants. The DSMB was comprised of an expert in one of each of the following areas: biofeedback, statistics, and a medical doctor. The DSMB purpose was to identify any signal detection problems including: a pre-specified level of deterioration in blood pressure, reaching a hypertension crisis stage of systolic blood pressure of 180 or higher *or*

diastolic of 110 or higher, blood spots in the eyes, facial flushing, dizziness, severe headaches, severe anxiety, shortness of breath, or nosebleeds, and to clearly define the steps that would have been taken and implemented should a crisis arisen during the study; this did not occur (AHA, 2012).

Treatment Conditions. Eligible participants were assigned to 1 of the 2 below conditions (Treatment as Usual (TAU) compared to TAU combined with the addition of the RESPeRATE), via a free online random number generator, taking care to achieve an equal number of males and females per condition (and balanced for age as well to the extent possible).

Control/Treatment as Usual (TAU). Much discussion has appeared in the literature about the ethical design of control conditions. Upon a careful examination of the literature (e.g., Freedland, Mohr, Davidson, & Schwartz, 2011; Smelt, Van der Weele, Blom, Gussekloo, & Assendelft, 2010), we determined that TAU was the most ethical and practical (pragmatic) control condition to include, especially given the site in which this investigation was conducted—an actual medical clinic. By design, all participants were currently receiving some type of treatment for their high BP (chiefly medication). Participants were requested to continue their current treatments to minimize sources of medication confounds (with concurrence of their treating physician) and to refrain from making any adjustments, unless instructed to do so by their treating physician. They were carefully followed, medications checked, and seen by study medical personnel at all key assessment time points. Patients assigned to the TAU condition were offered an opportunity to receive the RESPeRATE (described below) at the end of the study.

Intervention/ TAU + RESPeRATE Device. The RESPeRATE is designed to systematically shape reductions in sympathetic outflow of the autonomic nervous system, one of the key

underlying causes of cardiovascular disease, and to promote balance between sympathetic and parasympathetic systems. It has three main features: a breathing sensor (consisting of an elastic band wrapped around the chest), a computerized display, and headphones. As the user inhales and exhales, the breathing sensor and the onboard computer analyze breathing patterns and play back two personalized guiding tones, one for inhaling and the other for exhaling. Breathing naturally synchronizes with the tones. As an individual sits and listens to the tones, the RESPeRATE prolongs the tones, guiding the user to slow breathing effortlessly to the desired frequency (approximately 6 cycles per minute). This more relaxed rate of breathing is presumed to facilitate dilation of the muscles surrounding the small blood vessels, which permits blood to flow more freely, subsequently reducing blood pressure.

Measures

Literacy level was assessed using two questions from the International Adult Literacy and Life Skills Survey (ALL), in order to ensure that participants understood the above-mentioned measures. This survey was normed on both 4th and 8th graders and was designed for a 4th grade reading level (U.S. Department of Education, 2012). Selected participants included individuals who answered both questions correctly to ensure each had a literacy level of at least 4th grade. No participants were screened out on this basis.

Medication usage was assessed by asking participants to self-report on 4 questions: “are you currently taking any medication (s)?”, if so, “what are they?”, “How many times during the day did your doctor tell you to take your medication for hypertension?”, and “what is the total number of pills that your doctor has told you to take each day?” Possible score values for number of medications ranged from 0 to 10. This information was used to understand how many ADT’s people were prescribed and if the RESPeRATE was effective enough to reduce medication

management of HTN. Names of medications were obtained for informational purposes only. Frequency of dosage was informative to researchers in the form of degree of HTN.

Demographic information including, age, race, gender, marital status, annual household income, zip code, date of birth, and highest level of schooling were collected. For the purposes of the rest of this paper, gender will refer to the gender with which they identified.

Primary Outcome Measures.

Blood Pressure. Medical staff naïve to the purposes of the study collected all BP measures to minimize potential for bias. They used automated cuffs and adhered to the guidelines established by the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (James et al., 2014). Participants were asked to enter the office/laboratory and sit calmly for 5 min and the average of 3 BP readings (with 2 -3 min between each reading) were taken to acquire baseline values for systolic and diastolic BP.

Secondary Outcome Measures. Participant's levels of psychosocial stress were examined through the usage of several measures:

Beck Depression Inventory–II (BDI–II). The BDI-II (Beck, Steer, & Brown, 1996) is a 21-item self-report instrument that is used to measure the severity of depressive symptoms in diagnosed patients as well as to detect possible depression in a normal population, as defined in the DSM-5 (including suicidality). The BDI–II has high internal reliability (Cronbach's alpha is .92 for clinical patients and .93 for non-clinical individuals) and test-retest reliability (r = .93). Most items on the BDI-II are rated on a 4-point scale ranging from 0 to 3, with 3 reflecting the more severe level. Several items have seven response options to discern differences in behavior or motivation. The BDI-II is scored by adding the ratings for the 21 items. Possible score values range from 0 to 63. Scores from 0 to 13 reflect minimal depression symptoms, 14 to 19 mild

levels of depression symptoms, 20-28 moderate levels of depression symptoms, and 29-63 severe depression symptoms.

The Beck Anxiety Inventory (BAI). The BAI (Beck, Steer, & Brown, 1993) is a 21-item scale that measures the severity of self-reported anxiety in adults and adolescents. It consists of descriptive statements of anxiety symptoms that are rated on a 4-point scale with the following correspondence: "Not at all" (0 points); "Mildly; it did not bother me much" (1); "Moderately; it was very unpleasant, but I could stand it" (2); and "Severely; I could barely stand it" (3). The BAI was designed to reduce the overlap between depression and anxiety scales by measuring anxiety symptoms shared minimally with those of depression. The BAI has high internal reliability ranging from .92 to .94 for adults and .75 test-retest reliability. The BAI total score is the sum of the ratings for the 21 symptoms. Each symptom is rated on a 4-point scale ranging from 0 to 3. The higher the BAI score the more severe the individual's anxiety is. Possible score values range from 0 to 63. Scores from 0 to 9 reflect minimal anxiety symptoms, 10 to 16 mild levels of anxiety symptoms, 17-29 moderate levels of anxiety symptoms, and 30-63 severe anxiety symptoms.

The Perceived Stress Scale-10 (PSS-10). The PSS, which has three versions [a 4-item (PSS4), 10-item (PSS10) and 14-item (PSS14)], was used to assess stressful events (Cohen & Williamson, 1988). The PSS10, a self-report instrument that has been used to measure the degree to which life situations are appraised as stressful and the extent of control participants perceive they have over such situations, was used in this study. Each item asks about participants' thoughts and feelings during the past month (Cohen, Kamarck, & Mermelstein, 1983). In each question, participants are asked how often they felt or thought a certain way. Items are rated on a 5-point scale and responses range from 0 (never) to 4 (very often). Scores are obtained by

reversing responses (e.g., 0 = 4, 1 = 3, 2 = 2, 3 = 1, 4 = 0) to the four positively stated items (4, 5, 7, 8) and then summing across all scale items. Total scores range from 0–40, with higher scores indicating greater perceived stress. The internal reliability of the PSS10 has been reported as .78 (Cohen & Williamson, 1988). In more recent studies with AAs, the PSS4 has demonstrated higher internal reliability, $\alpha = .85$ and $\alpha = .84$ (Artinian et al., 2006; Dennis et al., 2008). Despite the higher internal reliability, the PSS4 is generally used during interviews that assess briefer measures of perceived stress. The PSS10 inquires in greater detail about an individual's perception of stress and has slightly higher internal reliability than the PSS14.

Quality of Life Scale (QOLS). The Quality of Life Scale (QOLS; Flanagan, 1978) is a 16-item self-report measure (originally a 15-item measure) that was used to assess individual's quality of life across several domains: material and physical well- being, relationship with others, social, community, and civic activities, personal development and fulfillment, and recreation. Responses were scored on a 7-point Likert scale and included: "delighted" (7), "pleased" (6), "mostly satisfied" (5), "mixed" (4), "mostly dissatisfied" (3), "unhappy" (2), "terrible" (1). Flanagan's original 15-item QOLS did not report internal consistency reliability (Cronbach's alpha); however, the first study of 240 American patients with chronic illness indicated that the 15-item QOLS satisfaction scale was internally consistent ($\alpha = .82$ to .92) and had high test-retest reliability ($r = 0.78$ to $r = 0$ .84). Researchers have reported similar reliability estimates for the 16-item scale (Anderson & Burckhardt, 1999; Burckhardt & Anderson, 2003; Burckhardt, Anderson, Archenholtz, & Hägg, 2003; Burckhardt, Archeholtz, & Bjelle, 1992; Burckhardt, Woods, Schultz, & Ziebarth, 1989). The QOLS is scored by adding the scores for all items. The greater the QOLS score, the higher the quality of life. Possible score values range from 16 to 112 to reflect overall quality of life. Average total score for healthy populations is about 90.

Adherence Measures. Upon special request it is possible to have the manufacturer enable the RESPeRATE devices to track actual measures of use. However, a variety of technical problems occurred during attempts to collect this data, rendering us unable to have sufficient data for analysis.

Analysis

A power analysis, using OpenEpi with an alpha level of .05 and a power of .80, was conducted to determine the appropriate number of participants needed in each study condition in order to obtain meaningful statistical results. Assuming an equal number of participants per condition, a total sample size of 33-36 participants was desired, 17-18 per group. A mixed repeated measures model (MRMM) was conducted to determine the temporal relationship between the IV and DV variables. This analysis was selected because it accounted for within person variance, permitting a better understanding of the intra-correlations between changes in BP over time. A MRMM explains the variance by the individual error term, which better represents the internal structure of the data. Changes in relevant independent variables, over a 6-month period, were used to predict changes in BP over time. Sensitivity analyses revealed that random effects were too unstable for the model to withstand. Therefore, subsequent growth curve analyses and variations of regressions were completed. The best suited model of fit was a standard multiple regression model. The statistical programming software package R was used to perform all analyses. All IV and DV variables were included in the preliminary model with subsequent models removing non-significant predictor variables. The most suitable models included independent variables: gender, SES, age, and education level. Preliminary analyses were conducted to ensure no violations of the assumptions existed with respect to normality, linearity, multicollinearity, and homoscedasticity. No psychological measures were able to be

included in the overall model due to the small sample size, reducing the degrees of freedom available to the model. However, as this was a small-scale pilot investigation, t-tests were used to explore mean group difference for psychological variables at all key time points by conditions and gender. Tables 3-6 summarize changes in total scores and Cohen's d for all independent psychological measures from baseline to EOI, EOI to three months, and three months to six months, respectively, broken down by condition gender.

Results

Participants Completing the Trial

Figure 1, appearing on the next page, provides a summary of patient recruitment, selection, and participation rates at each stage of this pilot investigation, using the flow diagram recommended by the Consolidated Standards of Reporting Trials Group (www.consort-statement.org).

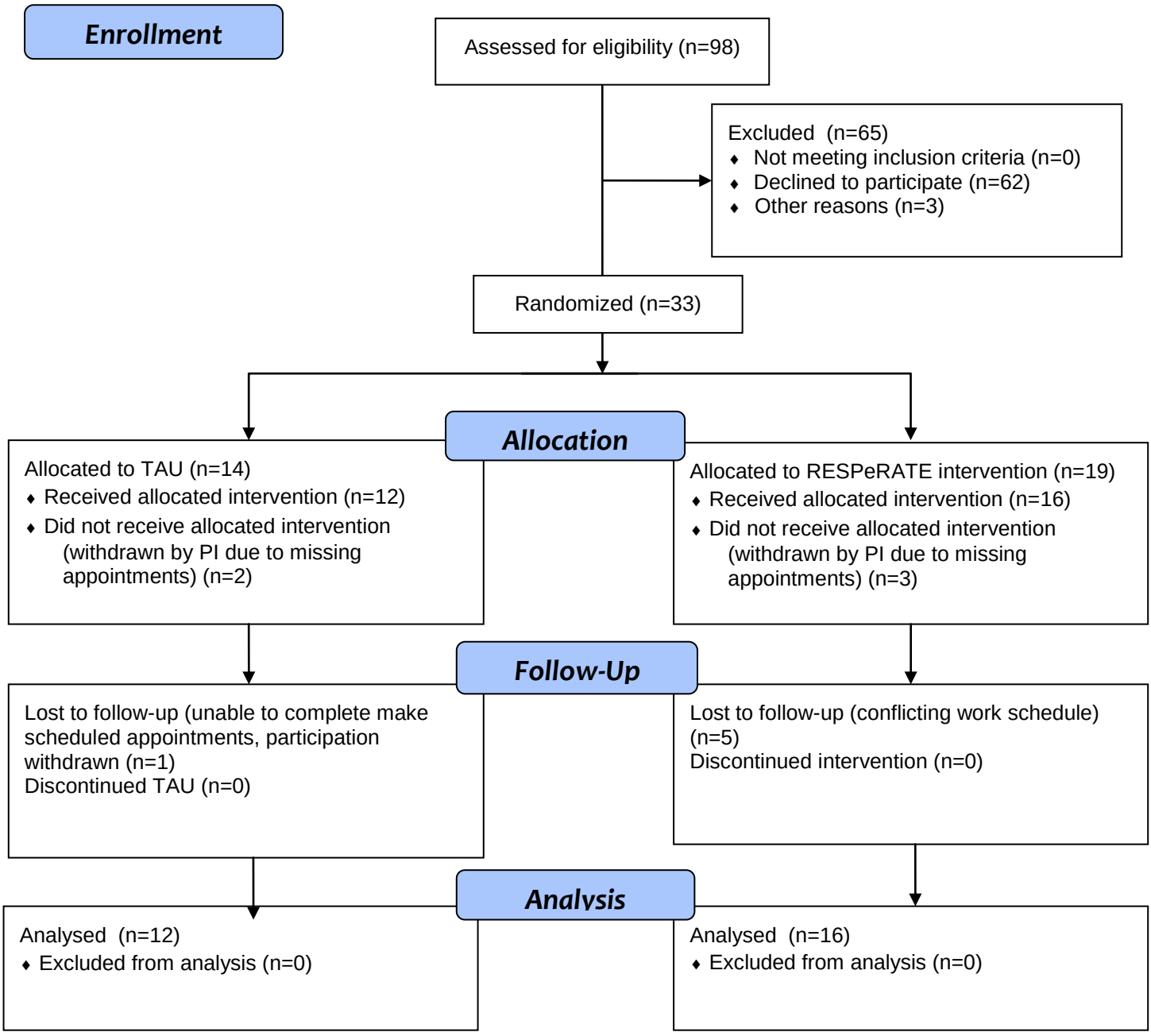

Figure 1. Consort reporting of trials flow diagram.

Table 1 below provides baseline demographic characteristics for the participants completing this pilot trial.

Table 1

Baseline Characteristics of Patients Completing the Study

	Intervention *n=16*	Control *n=12*
Baseline Systolic Blood Pressure		
Male	137.33±5.89	131±10.96
Female	133.00±13.34	129.67±2.08
Baseline Diastolic Blood Pressure		
Male	88±4.73	86±13.04
Female	80±10.26	76±8.72
Age		
Male	60±8.97	56.77±7.82
Female	60±10.11	47.67±19
Gender		
Male	6	9
Female	10	3
Number of HBP Medications		
Male	1.50±1.52	3.55±2.67
Female	1.60±.70	1.67±2.10

Overall Model

A standard multiple regression was used to determine if use of the home-based biofeedback device would significantly predict changes in blood pressure-both systolic and diastolic-from baseline to the end of the intervention period (8weeks). A four predictor model explained 98% of the variance ($R2 = .98$, $F(22,85) = 215.7$, $p<.001$). Findings indicated that gender, age, SES, and education level each uniquely and significantly predicted reductions in systolic blood pressure, respective of order of weight in the model (see Table 2).

Table 2

Standardized Coefficients and Associated T-Statistics

Variable	Systolic *β(SE)*	*t*	Diastolic	*t*
Age	-.26 (-6.52)**	--	--	--
Gender (Male)	8.35 (12.63)**	--	13.74 (3.24)	3.20*
SES			--	--
<10,000	29.23 (1.19)***	24.41		
$30,000-$39,999	6.31 (1.48)***	4.26		
$40,000-$49,999	2.73 (.92)**	2.97		
$75,000-$99,000	5.73 (4.99)***	1.15		
Education			--	--
Doctorate Degree	9.43 (1.48)***	6.35		
High School	7.62 (1.09)***	6.99		
Masters	-6.25 (.84)***	-7.47		
Professional Degree	4.86 (4.10)***	4.10		
Some College	5.13 (.95)***	5.37		
Voc. Training	9.48 (3.27)**	2.90		

Note. *p <.05. **p <.01. ***p <.001

Overall, gender, specifically being a female, significantly predicted reductions in systolic blood pressure at the end of the intervention (β = 8.34, *SE* = .66, t (28) = 12.63, p<.001). Similarly, age significantly predicted successful reductions in systolic BP at the end of the intervention (β = -.26, *SE* = .04), t (28) = -6.52, p<.001). Also, contributing predictor variables included SES and education level. For additional information on categorical breakdowns of SES and education level, see Table 2.

Baseline to Efficacy Endpoints. Primary endpoint analyses using a standard multiple regression were employed to test if those using the home-based biofeedback device would significantly predict changes in blood pressure-both systolic and diastolic-from baseline to the end of the intervention period (8weeks). A significant reduction in systolic blood pressure was found from baseline to the EOI in the intervention condition (β = .19, *SE*= .02, t (28) = 7.69,

F(22,85) = 215.7, p <.001). There were statistically significant differences between baseline systolic blood pressure reductions to the EOI systolic blood pressure reductions (β = .19, *SE* = .03, *t* (28) = *7.57*, p <.001) and from baseline to three months in systolic blood pressure reductions in the control group (β = -1, *SE* = .06, *t* (28) = -15.51, p <.001) as well. There were no significant reductions in diastolic blood pressure at any key follow up time points.

Systolic Blood Pressure in the RESPeRATE Group.

Three months. We found statistically significant reductions in systolic blood pressure from baseline to three months in the intervention group compared to TAU (β = .14, *SE* = .04, *t* (28) = 3.47, p <.001).

Six months. Systolic blood pressure reductions from baseline to six months was significant in the RESpeRATE group (β = .36, *SE* = .04, *t* (28) = 9.09, p <.001) compared to the TAU group.

Diastolic Blood Pressure. We found no significant reductions in diastolic blood pressure at any key study time points for either condition. As such, no overall predictors or values were reported.

Psychological Measures. Though psychological measures were not able to be included in the overall model, t-tests were used to explore mean group differences for all measures at all key time points by conditions and gender. No significant findings emerged for any mean group scores in psychological measures at any key time points. However, small, moderate and large effect sizes were seen. Tables 3-5 summarize changes in total scores and Cohen's d for all independent psychological measures from baseline to EOI, EOI to three months, and three months to six months, respectively, broken down by condition and gender. The relationship for baseline to the EOI changes in BAI and BDI group difference scores for TAU versus the intervention and for males versus females within each condition met criteria for the convention

of small and large effect sizes at baseline for BDI and at the EOI for BAI, (d = .80 and d = .46; Cohen's 1998), respectively. Examining group differences in scores from EOI to three months by condition and gender revealed moderate and large effect sizes, respectively, for changes in BDI and QoL total scores in the TAU condition (d = .56 and d = .91) and moderate effect sizes (d = .75, and d = .56) for BDI and PSS scores. Changes in group differences by condition and gender from three months to six months in BDI scores in the TAU condition exceeded Cohen's (1998) convention for moderate effect sizes (d = .58) and large effect sizes in the intervention condition (d = .95). Finally, the relationship for baseline to six month changes in group differences in BDI and QoL scores for males versus females within the TAU condition met criteria for the convention of small and moderate effect sizes at six months for BDI and QoL, (d = .58 and d = .26). Examining group differences in scores from baseline to six months in the intervention group by gender revealed a large effect size for changes in females in the intervention group (d = .94).

Table 3

Changes in Independent Variables from Baseline to End of Intervention (EOI)

	Males *M(SD)*	Females *M(SD)*	Cohen's d
Control (*n* = 12)	(*n* = 9)	(*n* = 3)	
BAI Total *M(SD)*			
Baseline	*4.00 (3.57)*	*4.33 (5.86)*	*-.07*
EOI	*5.06 (4.40)*	*3.33 (3.06)*	*.46**
BDI Total *M(SD)*			
Baseline	*6.44 (3.85)*	*8.88 (11.55)*	*-.28*
EOI	*5.37 (5.20)*	*5.10 (5.98)*	*.05*
PSS Total *M(SD)*			
Baseline	*18.00 (2.65)*	*22.00 (1.73)*	*-1.79*
EOI	*3.31 (.83)*	*16.60 (4.88)*	*-1.13*
QoL Total *M(SD)*			
Baseline	*84.33 (12.01)*	*87.67 (17.16)*	*-.23*
EOI	*91.31 (10.38)*	*89.40 (14.03)*	*.15*
Intervention (*n* = 16)			
BAI Total *M(SD)*	(*n* = 6)	(*n* = 10)	
Baseline	*7.17 (10.87)*	*4.44 (4.00)*	*.33**
EOI	*5.06 (4.40)*	*3.33 (3.06)*	*.46**
BDI Total *M(SD)*			
Baseline	*8.33 (6.59)*	*4.22 (2.91)*	*.80***
EOI	*5.37 (5.20)*	*5.10 (5.98)*	*.05*
PSS Total *M(SD)*			
Baseline	*18.83 (2.71)*	*18.33 (3.50)*	*.16*
EOI	*3.31 (.83)*	*16.60 (4.88)*	*-.88*
QoL Total *M(SD)*			
Baseline	*84.00 (16.80)*	*95.33 (8.27)*	*-.86*
EOI	*91.31 (10.38)*	*89.40 (14.03)*	*.15*

*small (0.2) ** medium (0.5) and ***large (0.8)

Table 4

Changes in Independent Variables from EOI to Three Months

	Males *M(SD)*	Females *M(SD)*	Cohen's d
Control (*n* = 12)	(*n* = 9)	(*n* = 3)	
BAI Total *M(SD)*			
EOI	*5.06 (4.40)*	*3.33 (3.06)*	*.46**
Three Months	*2.66 (2.87)*	*3.00 (3.46)*	*-.11*
BDI Total *M(SD)*			
EOI	*5.37 (5.20)*	*5.10 (5.98)*	*.05*
Three Months	*4.78 (4.38)*	*2.67 (3.06)*	*.56***
PSS Total *M(SD)*			
EOI	*3.31 (.83)*	*16.60 (4.88)*	*-1.13*
Three Months	*16.33 (2.00)*	*19.67 (4.16)*	*-1.02*
QoL Total *M(SD)*			
EOI	*91.31 (10.38)*	*89.40 (14.03)*	*.15*
Three Months	*97.11 (15.91)*	*84.33 (12.06)*	*.91****
Intervention(*n* = 16)	(*n* = 6)	(*n* = 10)	
BAI Total *M(SD)*			
EOI	*5.06 (4.40)*	*3.33 (3.06)*	*.46**
Three Months	*4.15 (3.06)*	*4.89 (4.55)*	*-.19*
BDI Total *M(SD)*			
EOI	*5.37 (5.20)*	*5.10 (5.98)*	*.05*
Three Months	*8.50 (6.32)*	*4.00 (5.72)*	*.75***
PSS Total *M(SD)*			
EOI	*3.31 (.83)*	*16.60 (4.88)*	*-.88*
Three Months	*18.83 (3.87)*	*16.67 (3.91)*	*.56***
QoL Total *M(SD)*			
EOI	*91.31 (10.38)*	*89.40 (14.03)*	*.15*
Three Months	*80.67 (14.05)*	*96.11 (5.95)*	*-1.43*

*small (0.2) ** medium (0.5) and ***large (0.8)

Table 5

Changes in Independent Variables from Three Months to Six Months

	Males *M(SD)*	Females *M(SD)*	Cohen's d
Control (*n* = 12)	(*n* = 9)	(*n* = 3)	
BAI Total *M(SD)*			
Three Months	*2.66 (2.87)*	*3.00 (3.46)*	*-.11*
Six Months	*2.67 (3.12)*	*2.67 (2.08)*	*.00*
BDI Total *M(SD)*			
Three Months	*4.78 (4.38)*	*2.67 (3.06)*	*.56***
Six Months	*4.44 (4.72)*	*2.33 (2.08)*	*.58***
PSS Total *M(SD)*			
Three Months	*16.33 (2.00)*	*19.67 (4.16)*	*.56***
Six Months	*17.00 (2.70)*	*20.33 (3.06)*	*-1.02*
QoL Total *M(SD)*			
Three Months	*97.11 (15.91)*	*84.33 (12.06)*	*.91****
Six Months	*91.50 (14.83)*	*88.00 (12.17)*	*-1.15*
Intervention (*n*=16)	(*n* = 6)	(*n* = 10)	
BAI Total *M(SD)*			
Three Months	*4.15 (3.06)*	*4.89 (4.55)*	*-.19*
Six Months	*2.33 (1.86)*	*3.55 (2.92)*	*-.50*
BDI Total *M(SD)*			
Three Months	*8.50 (6.32)*	*4.00 (5.72)*	*.75***
Six Months	*8.17 (8.08)*	*2.55 (2.28)*	*.95****
PSS Total *M(SD)*			
Three Months	*18.83 (3.87)*	*16.67 (3.91)*	*.56***
Six Months	*18.50 (2.17)*	*18.33 (5.98)*	*.04*
QoL Total *M(SD)*			
Three Months	*80.67 (14.05)*	*96.11 (5.95)*	*-1.43*
Six Months	*84.17 (12.35)*	*96.33 (3.94)*	*-1.33*

*small (0.2) ** medium (0.5) and ***large (0.8)

Table 6

Changes in Independent Variables from Baseline to Six Months

	Males *M(SD)*	Females *M(SD)*	Cohen's d
Control (*n* = 12)	(*n* = 9)	(*n* = 3)	
BAI Total *M(SD)*			
Baseline	*4.00 (3.57)*	*4.33 (5.86)*	*-.07*
Six Months	*2.66 (3.12)*	*2.67 (2.08)*	*.00*
BDI Total *M(SD)*			
Baseline	*6.44 (3.85)*	*8.88 (11.55)*	*-.28*
Six Months	*4.44 (4.72)*	*2.33 (2.08)*	*.58***
PSS Total *M(SD)*			
Baseline	*18.00 (2.65)*	*22.00 (1.73)*	*-1.79*
Six Months	*17.00 (2.70)*	*20.33(3.06)*	*-1.15*
QoL Total *M(SD)*			
Baseline	*84.33 (12.01)*	*87.67 (17.16)*	*-.23*
Six Months	*91.50 (14.83)*	*88.00 (12.17)*	*.26**
Intervention (*n* = 16)			
BAI Total *M(SD)*	(*n* = 6)	(*n* = 10)	
Baseline	*7.17 (10.87)*	*4.44 (4.00)*	*.33**
Six Months	*2.33 (1.86)*	*3.55 (2.96)*	*-.50*
BDI Total *M(SD)*			
Baseline	*8.33 (6.59)*	*4.22 (2.91)*	*.80****
Six Months	*8.17 (8.08)*	*2.56 (2.30)*	*.94****
PSS Total *M(SD)*			
Baseline	*18.83 (2.71)*	*18.33 (3.50)*	*.16*
Six Months	*18.50 (2.17)*	*18.33 (5.98)*	*.03*
QoL Total *M(SD)*			
Baseline	*84.00 (16.80)*	*95.33 (8.27)*	*-.86*
Six Months	*84.17 (12.35)*	*96.33 (3.94)*	*-1.33*

*small (0.2) ** medium (0.5) and ***large (0.8)

Discussion

In the first report released by Joint National Committee, in 1997, hypertension was defined solely on the basis of diastolic blood pressure, with the cutoff being > 90mm Hg (James et al., 2014); systolic blood pressure was not taken into account. It has long been thought that systolic hypertension, then termed isolated systolic hypertension (ISH), was unavoidable due to ageing and was exacerbated by hardening of arterial walls related to plaque buildup and subsequent loss of elasticity of the arterial walls. It was further assumed that diastolic blood pressure either stabilized or declined over time as a result of peripheral resistance, the resistance of the arteries to blood flow (Burt et al., 1995). When arteries constrict, resistance increases; as they dilate, resistance decreases and blood flow increases. Peripheral resistance is a function of the internal vessel diameter, vessel length, and blood viscosity. Over time, as researchers came to realize that other parameters needed consideration in order to more fully and accurately diagnose HTN, they found it was critically important to consider SBP as well in arriving at a diagnosis of HTN (Izzo, Levy & Black, 2000; Lloyd-Jones et al., 2000). Overlooking an elevated SBP can lead to a misclassification of blood pressure grade and contribute to untreated HTN. Just like traditionally classified HTN, high SBP can lead to long-term damage that is irreversible. Lloyd-Jones et al. (2000) were able to correctly classify 96% of individuals into the correct blood pressure stage when using subjects' systolic blood pressure values alone, but their classification accuracy decreased to 68% when using subjects' diastolic reading alone. Izzo, Levy, and Black (2000) similarly identified the overall importance of systolic blood pressure in older Americans, questioning the significance of diastolic blood pressure altogether as a determinant for a hypertension diagnosis. Regardless of the qualifying diagnostic cutoffs, systolic blood pressure continuously rises between the ages of 30-84 years, with the arterial walls developing plaque

build-ups along the way. Diastolic blood pressure, however, has a varying pattern with ageing, increasing until the fifth decade and slowly decreasing from the age of 60 to at least 84 years of age (Franklin, 1999). Drawing upon these findings, a case can be made for an accessible intervention that aids in the reduction of SBP and that is available for individuals struggling with traditional behavioral and medical interventions.

In the current exploratory study, we examined the efficacy of a home-based biofeedback intervention, delivered by the RESPeRATE, in a sample of AAs who were hypertensive. We found that utilization of the RESPeRATE in AAs diagnosed with hypertension over an eight week, 3-month, and 6-month period was effective in reducing systolic blood pressure with respect to TAU. This same device, however, was not effective in reducing diastolic blood pressure at those same key follow-up time-points. If ISH is a key component in controlling overall hypertension, future research needs to devote greater attention towards interventions (medical and other) for reducing it. Furthermore, given the inevitable rise in SBP (and the fluctuating course of DBP), devices like the RESPeRATE could prove to be a helpful tool for reducing SBP for all populations, and perhaps more specifically for those whose medications and lifestyle/diet modifications have not been sufficient.

Hypertension and cardiovascular disease are nearly equally contribute contributing to the growing cost of healthcare. If the findings from this pilot study hold upon replication, incorporating relatively low-cost, home-administered devices for individuals who have tried other interventions with limited success (i.e., the RESPeRATE), may yield favorable cost-benefit returns. Moreover, as home-administered devices can help to break down many treatment barriers for individuals with diminished resources, the impact for our overall health-care system could yield large-scale reductions in a number of ways over time: health care costs, burden on

medical providers, and less reliance on pharmaceutical interventions (Artinian, Washington, Flack, Hockman, & Jen, 2008; Dennis et al., 2008; Knox et al., 2002; Horowitz et al. 2004; Merritt et al., 2004).

Our results are consistent with past studies in which the efficacy of the RESPeRATE was shown for reducing BP (Elliot et al., 2004; Mahtani et al., 2012; Meles, 2004). Our work helps extend these findings to minority populations, specifically to AAs so diagnosed with hypertension and, while being treatment adherent to medication, have not experienced optimal results. Unlike previous studies, we did not find significant reductions in DBP at any key time points.

Socioeconomic status, age, gender and education level also significantly predicted reductions in systolic blood pressure at the end of our eight-week intervention and at 3 - and 6-month follow up. Socioeconomic status-a multi-faceted construct that is often measured by proxy of income, education, and/or occupation-often serves as a powerful predictor for health disparities and health-related outcomes (WHO, 2008), specifically in an AA sample (Non, Gravlee, & Muligan, 2012; Ostchega, Yoon, Hughes, & Lewis, 2008; Rooks et al., 2008). In the current study, SES was based on income, which was further broken down into ten distinct categories (see Table 2). Overall, research suggests a consistent strong inverse relationship between SES and health disparities (Williams, Mohammad, Leavell, & Collins, 2010). Individuals who fall into higher SES brackets experience overall fewer health disparities relative to their lower SES counterparts. Specifically, rates of hypertension and cardiovascular disease are higher among lower socioeconomic status populations (Steptoe & Kivimaki, 2013). The numbers of cases of hypertension are even more alarming among African Americans versus other minority groups. Some of the most robust associations of low SES and specific health disparities, specifically

hypertension, occur for African Americans (Steptoe & Kivimaki, 2013). This relationship has been demonstrated in studies in which education was used as a proxy for SES. Non and colleagues (2012) explored the associations of genetic ancestry and education with BP variation among African Americans in the Family Blood Pressure Program. Education level was divided into two groups – high school degree or greater versus less than a high school degree. Individuals with a high school degree or greater were found to display significantly greater reductions in overall BP. These authors found further that education significantly predicted BP variation in AAs ($b = -0.51$ mm Hg per year additional education; $p = .001$). Brummett et al. (2011) conducted a large scale cross-sectional study with over 15,000 young adult AA males and females ages 24-35 that permitted them to investigate the association between socioeconomic status and hypertension. Socioeconomic status was defined by educational level and household income. Similar to other researchers, they found an inverse relationship between education and BP, specifically for SBP, such that higher household income was associated with lower SBP. Older male AAs evidenced higher SBP even after controlling for various covariates (cardiac medication use, BMI, waste circumference, physical exercise, alcohol consumption, and smoking behavior).

The Framingham Heart Study, a large-scale longitudinal cohort study, documented that blood pressure increases with age (Franklin, 1999; O'Rourke, 1990). The abovementioned well known study began in 1948 by recruiting 5,209 men and women between the ages of 30 and 62 from the town of Framingham, Massachusetts. Participants were asymptomatic for cardiovascular disease, heart attack, or stroke when the study began. Since 1948, numerous offspring cohorts have been added: an offspring cohort was added to the study in 1971, the Omni Cohort in 1994, a third generation cohort in 2002, a new offspring spouse cohort in 2003, and a second generation Omni

cohort in 2003. Findings from the present study similarly point to age as a factor in predicting higher BP, as baseline BP was higher in older participants, and it served as a predictor for efficacy of the RESPeRATE. Given that the rates of hypertension are higher in AAs than CAs, the current study results are promising and indicative of the need for further research in this area. Investigating the effects of a home-based biofeedback or similar type intervention delivered in a medical setting and targeted at this population, in part to reduce the overall health care costs but more importantly to provide aid to a population so in need and seeking assistance, appears to warrant further exploration.

Although BP changes throughout a person's life as a function of gender and decade of life, gender remains a constant and robust predictor. Similar to previous findings, the women in our study displayed lower baseline BP readings as well as lower readings at all key time points. More importantly, the RESPeRATE was effective in significantly reducing systolic blood pressure in women at all key time points. The mechanisms involved in producing BP differences by gender are not fully understood. The limited information comes from studies examining androgens and renal salt processing (Maranon & Reckelhoff, 2013; Reckelhoff, 2001; Richardson, Freedman, Ellison, & Rodriguez, 2013). It may be the case that the lack of androgens reduces sodium handling in the kidneys, which protects against both early and later hypertension. Further support for this proposed mechanism comes from research showing overall BP increases in women who have had an ovariectomy (Pechere-Bertschi & Burnier, 2004). It could be that many of the women in our study had not yet experienced medical procedures that removed the protective sodium absorption hormones, thereby reducing the renal issues related to salt absorption.

One purpose of this study was to examine the impact of hypertension on an individual's overall psychological functioning. Findings from this study suggest meaningful clinical implications evidenced by the varying effect sizes seen by the mean group differences examined by condition and gender at previously mentioned key time points. The small effect size seen in mean group differences for BAI scores from baseline to EOI could be the result of enrolling in a clinical trial. However, given this small effect size this is very easily as likely to be anxiety related to white-coat syndrome that reduced as participants became less anxious after the initial visit. It could be that they developed an understanding of what was expected of them and what would happen at each visit (Cobos, Haskard-Zolnierek, & Howard, 2015). Similarly, group differences from EOI to three months yielded moderate to large effect sizes related to BDI, QoL, and PSS. As one's health profile improved over this timeframe, it is likely that these individuals not only felt better physically but also began to experience the world in a less stressful manner, which in turn led to lower BDI scores and overall improved QoL. Similarly, changes in mean group score differences from three months to six months in both conditions produced moderate to large effect sizes for BDI scores. Notably, the most consistent and larges effect sizes were seen in mean group differences for BDI scores. This strong positive relationship has been extensively demonstrated in studies with participants experiencing other chronic medical conditions (Gotlieb et al., 2004; Mendes de Leon et al. 2015; Taylor et al., 2015). In accordance with previous research, the effect sizes found in this study highlight the impact of physical well-being and psychological experiences and the need for further exploration of these aspects. Furthermore, because effect sizes were moderate to large not only for conditions but also by gender, it is possible that the renal renal processing of sodium plays a large role in this effective intervention. As people age, renal functioning worsens by gender.

Future Directions, Limitations, and Conclusions

In an area of research that seeks to understand such intricate and complex and not always well defined topics such as hypertension, race, and SES, there are countless directions to pursue and unanswered questions to address. Here we focus on what we believe to be some of the more important avenues including moving from a pilot study to a larger sample size and the psychological impact of hypertension. We performed this pilot study to provide sufficient preliminary data to determine the feasibility and logistics of a more definitive study. Because our sample size was small, the statistical models were not able to withstand inclusion of all of the psychological measures that were obtained. Given the limited sample size and the exploratory nature of this study, it is possible that our statistical model could have been over specified. However, after removing education from the predictor variables (due to multicollinearity with SES) and re-conducting our analyses, the overall model remained statistically significant, R2 = .92. A larger sample size would have permitted greater degrees of freedom, increasing the statistical power to conduct additional analyses. From those models, a greater degree of information might have been ascertained related to the psychological impact(s) of hypertension in an African American population. Therefore, one obvious next step is to conduct a larger-scale, more well-controlled evaluation of the efficacy of the RESPeRATE or similar devices for enhancing treatment of hypertension. Though there was sufficient power to substantiate some of the findings for the current study, a study with a larger sample size would be needed to better understand the impact the RESPeRATe might have in AAs diagnosed with hypertension. See Figure 1 for a detailed outline of patient flow and attrition. Similarly, it is possible that with a larger sample size significant reductions in diastolic BP could be detected.

Diet, exercise, and sodium intake, among many other health-related behaviors, are associated with hypertension (Bacon, Sherwood, Hinderliter, & Blumenthal, 2004). Less well researched is the psychological effect of hypertension. The body of literature addressing the adverse effects of stress on the body is vast, with mixed conclusions regarding the association of psychological effects of stress and hypertension (Carroll, Phillips, Gale & Batty, 2010; Gasperin et al., 2009; Linden & Moseley, 2006; Patten et al., 2009; Rutledge & Hogan, 2002). Although sodium intake is associated with high blood pressure, some individuals are able to consume sodium without adverse effects (i.e., hypertension). In a meta-analysis, Hermansen (2010) found that sufficient intake of potassium and calcium, rather than simply reducing sodium, could be one way to prevent high BP. This finding could be pursued in future studies. Finally, given the known consequences of stress on the body and the mind-body connection, the time may be ripe to begin exploring the utility of what has been labeled the "third wave" of cognitive behavioral therapy, which includes a focus on mediation, mindfulness, and acceptance (Hayes, 2004). Whether these newer treatments will prove of value for diverse populations, such as African Americans who are hypertensive, remains relatively unknown.

Finally, working with a population that historically has had- and continues at present to have- many barriers for receiving effective hypertension treatment presented many unique challenges. Of the nearly 100 participants initially recruited for this study, approximately 70 expressed interest, with the resulting number of enrolled participants who actually completed the study being much less. Transportation-related barriers or simply loss of interest when they learned of the commitments necessary for enrollment likely accounted in part for the attrition over time. Also, working within a medical practice versus a college clinic or laboratory presented some unique challenges. For example, participant's work schedules created conflicts with study

appointments. For low income individuals needing to take time off or time-away from an income producing job was not always an option. Due to missing appointments, researchers were forced to withdraw people from the study despite their desire to continue. More importantly, the ReSPERATE device only holds up to thirty days of data storage. Therefore, if a participant wanted to reschedule for a day that fell outside of the 30-day range, they had to be withdrawn from the study. The devices used in this investigation had to be altered in order to permit adherence data to be collected. A number of the devices were acquired from the company who developed the RESPeRATE, but along the way the ownership changed, with us purchasing the remaining needed units from another vendor. Various technical problems occurred along the way, mainly due to unstable and incompatible cable connections, resulting in adherence data loss. Once the developing company sold their product line, we were no longer able to obtain support for the devices purchased earlier[2]. Despite these study limitations, we believe our findings substantiate the need for further research in this area with devices of this type and support pursuit of larger-scale, more well-controlled clinical trials, with more extended follow up, particularly with respect to AA's who are hypertensive.

[2] Previous researchers who had worked with device were contacted and provided help as they could.

References

American Heart Association. (2012, August 27). Symptoms, Diagnosis & Monitoring of High Blood Pressure. Retrieved, August 30, 2012 from http://www.heart.org/HEARTORG/Conditions/HighBloodPressure/SymptomsDiagnosisMonitoringofHighBloodPressure/Symptoms-Diagnosis-Monitoring-of-High-Blood-Pressure_UCM_002053_Article.jsp

American Psychological Association. (2013). *American Psychological Association ethical principles of psychologists and code of conduct*. Retrieved June 18, 2013 from http://www.apa.org/ethics/code/index.aspx.

Anderson, K., & Burckhardt, C. (1999). Conceptualization and measurement of quality of life as an outcome variable for health care intervention and research. *Journal of Advanced Nursing, 29* (2), 298-306.

Appel, L., Moore, T., Obarzanek, E., Vollmer, W., Svetkey, L. , Sacks, F., ... Karanja, N. (1997). A clinical trial of the effects of dietary patterns on blood pressure. Dash Collaborative Research Project. *The New England Journal of Medicine, 336*(16), 1117-1124. doi.org/10.1056/NEJM199704173361601.

Artinian, N. T., Washington, O. G., Flack, J. M., Hockman, E. M., & Jen, K. C. (2006). Depression, stress, and blood pressure in urban African–American women. *Progress in Cardiovascular Nursing, 21*(2), 68-75. doi.org/10.1111/j.0889-7204.2006.04787.x

Bacon, S., Sherwood, A., Hinderliter, A., & Blumenthal, J. (2004). Effects of exercise, diet and weight loss on high blood pressure. *Sports Medicine, 34*(5), 307–31.

Barnes, V., Treiber, F., & Johnson, M., (1993). Impact of transcendental meditation on ambulatory blood pressure in African-American adolescents. *American Journal of Hypertension, 17*(4), 366-369. doi.org/10.1016/j.amjhyper.2003.12.008

Beck, A., Steer, R., & Brown, G., (1993). *Beck Anxiety Inventory Manual*. San Antonio, TX: The Psychological Corporation Harcourt Brace & Company.

Beck, A., Steer, R., & Brown, G. (1996). *Manual for the Beck Depression Inventory-II*. San Antonio, TX: Psychological Corporation.

Benson, H., Rosner, B., Marzetta, B., & Klemchuk, H. (1974). Decreased blood pressure in borderline hypertensive subjects who practiced meditation. *Journal of Chronic Diseases. 27*(3), 163–169.

Borzecki, A., Oliveria, S., & Berlowitz, D. (2005). Barriers to hypertension control. *American Journal of Hypertension*, *149*(5), 785-794. doi.org/10.1016/j.ahj.2005.01.047

Brummett, B., Babyak, M., Siegler, I., Shanahan, M., Harris, K., Elder, G., & Williams, R. (2011). Systolic blood pressure, socioeconomic status, and biobehavioral risk factors in a nationally representative U.S. young adult sample. *Hypertension*, *58*(2), 161–166. http://doi.org/10.1161/HYPERTENSIONAHA.111.171272

Burckhardt, C., Anderson K., Archenholtz, B., & Hägg, O. (2003). The Flanagan Quality of Life Scale: Evidence of construct validity. *Health and Quality of Life Outcomes, 1*(59).

Burckhardt, C., & Anderson, L. (2003). The quality of Life Scale (QoLS): Reliability, Validity, and Utilization. *Health and Quality of Life Outcome, 1*(60).

Burckhardt, C., Archenholtz, B., & Bjelle, A. (1992). Measuring quality of life of women with rheumatoid arthritis or systemic lupus erythematosus: A Swedish version of the Quality of Life Scale (QOLS). *Scandanavian Journal of Rheumatology, 21*(4), 190-195.

Burckhardt, C., Woods, S., Schultz, A., & Ziebarth, D. (1989). Quality of life of adults with chronic illness: A psychometric study. *Research in Nursing and Health, 12*(6), 347-354.

Burt, V., Whelton, P., Roccella, E., Brown, C., Cutler, J., Higgins,…Laborther, D. (1995). Prevalence of hypertension in the US adult population: Results from the Third National Health and Nutrition Examination Survey, 1988-1991. *Hypertension, (25)*3, 305-315.

Carroll, D., Phillips, A., Gale, C., & Batty, G.,(2010). Generalized anxiety and major depressive disorders, their comorbidity and hypertension in middle-aged men. Psychosomatic Medicine, *72*(1), 16–19.

Centers for Disease Control and Prevention (March, 2011). High Blood Pressure. Retrieved July 3, 2012 from http://www.cdc.gov/bloodpressure/facts.htm.

Cobos, B., Haskard-Zolnierek, K., & Howard, K. (2015). White coat hypertension: Improving the patient–health care practitioner relationship. *Psychology Research and Behavior Management*, *8*, 133–141. http://doi.org/10.2147/PRBM.S61192

Cohen, S., Kamarck, T., & Mermelstein, R. (1983). A global measure of perceived stress. *Journal of Health And Social Behavior, 24*(4), 385-396. doi:10.2307/2136404

Cohen, S., & Williamson, G. (1988). Perceived stress in a probability sample of the United States. In S. Spacapam & S. Oskamp (Eds.), *The social psychology of health: Claremont Symposium on applied social psychology*. Newbury Park, CA: Sage

Centers for Disease Control and Prevention. (2005). Racial/Ethnic disparities in prevalence, treatment and control of hypertension – United States, 1999-2002. *Journal of the American Medical Association*, *293*, 923-925.

Dennis, J., Markey, M., Johnston, K., Vander Wal, J., & Artinian, N. (2008). The role of stress and social support in predicting depression among a hypertensive African American population. *Heart and Lung*, *37*(2), 105-112.

Department of Health and Human Services, (2012, May). HHS Secretary Sebelius statement on National High Blood Pressure Education Month. Retrieved July 6, 2012, from http://www.hhs.gov/news/press/2012pres/05/20120502a.html

DeSimone, M., & Crowe, A. (2009). Nonpharmacological approaches in the management of hypertension. *Journal of The American Academy of Nurse Practitioners, 21*(4), 189-196. doi:10.1111/j.1745-7599.2009.00395.x

Duraimani, S., Schneider, R., Randall, O., Nidich, S., Xu, S., Ketete, M., …Fagan, J. (2015). Effects of lifestyle modification on telomerase gene expression in hypertensive patients: A pilot trial of stress reduction and health education programs in African Americans. *PLoS ONE 10*(11): e0142689. doi:10.1371/journal.pone.0142689

Dusek, J., & Benson, H. (2009). Mind-Body Medicine: A model of the comparative clinical impact of the acute stress and relaxation responses. *Minnesota Medicine, 92*(5), 47–50.

Elliot, W., & Izzo, J. (2006). Device-guided breathing to lower blood pressure: Case report and clinical overview. *Medscape General Medicine*, *8*(3), 23.

Elliott, W., Izzo J., White, W., Rosing, D., Snyder, C., Alter, A., Gavish, B., & Black, H. (2004). Graded blood pressure reduction in hypertensive outpatients associated with use of a device to assist with slow breathing. *Journal of Clinical Hypertension, 6*(10), 553–559.

Feldman, P., McDonald, M., Mongoven, J., Peng, T., Gerber, L., & Pezzin, L. (2009). Home-based blood pressure interventions for African Americans. *Circulation, Cardiovascular Quality and Outcomes, 2*(3), 241–248. doi.org/10.1161/CIRCOUTCOMES.109.849943

Fernander, A., Durán, R., Saab, P., & Schneiderman, N. (2004). John Henry Active Coping, education, and blood pressure among urban blacks. *Journal of the National Medical Association*, *96*(2), 246–255.

Flanagan, J. (1978). A research approach to improving our quality of life. *American Psychologist*, *33*(2), 138-147.

Fongwa, M., Evangelista, L., Hays, R., Martins, D. Elashoff, D., Cowan, M., & Morisky. (2008) Adherence treatment factors in hypertensive African American women. *Vascular Health and Risk Management*, *4*(1) 157–66.

Franklin, S. (1999). Ageing and hypertension: the assessment of blood pressure indices in predicting coronary heart disease. *Journal of Hypertension, 17* (5): S29–S36.S36

Freedland, K. Mohr, D., Davidson, K., & Schwartz, J., (2011). Usual and unusual care: Existing practice control groups in randomized controlled trials of behavioral interventions. *Psychosomatic Medicine*, *73*(4), 323-335.

Gasperin, D., Netuveli, G., Dias-da-Costa, J., & Pattussi, M.(2009). Effect of psychological stress on blood pressure increase: a meta-analysis of cohort studies. *Cadernos de Saúde Pública*, *25*(4), 715-726. https://dx.doi.org/10.1590/S0102-311X2009000400002

Gottlieb, S., Khatta, M., Friedmann, E.,…Thomas, S. (2004). The influence of age, gender, and race on the prevalence of depression in heart failure patients. *Journal of American College of Cardiology*, *43*(9), 1542–9. doi:10.1016/j.jacc.2003.10.064

Hayes, S. C. (2004). Acceptance and commitment therapy, relational frame theory, and the third wave of behavioral and cognitive therapies. *Behavior Therapy*, *35*(4), 639-665.

Heidenreich P., Trogdon J., Khavjou O., Butley, J., Dracup., Ezekowitz., M., ...Woo, Y. J. (2011). Forecasting the future of cardiovascular disease in the United States: A policy

statement from the American Heart Association. *Circulation*, *123*(8), 933–944. doi.org/10.1161/CIR.0b013e31820a55f5

Horowitz, C., Tuzzio, L., Rojas, M., Monteith, S., & Sisk, J. (2004). How do urban African Americans and Latinos view the influence of diet on hypertension? *Journal of Health Care for the Poor and Underserved*, *15*(4), 631-644. doi.org/10.1353/hpu.2004.0061

Izzo, J., Levy, D., & Black, H. (2000). Clinical advisory statement. Importance of systolic blood pressure in older Americans. *Hypertension, 15*(5), 1021-1024. doi:10.1161/01.HYP.35.5.1021

James, S., Keenan, N., Strogatz, D., Browning, S., Garrett, J. (1992). Socioeconomic status, John Henryism, and blood pressure in Black adults: The Pitt County study. *The American Journal of Epidemiology*, *135*(1), 59–67

James, P., Oparil, S., Carter, B., Cushman, W., Dennison-Himmelfarb, C., Handelr, J., …Ortiz, E. (2014). 2014 Evidence-Based Guideline for the Management of High Blood Pressure in Adults Report from the Panel Members Appointed to the Eighth Joint National Committee (JNC 8). *Journal of the American Medical Association, 311*(5), 507-520. doi:10.1001/jama.2013.284427

Kaushik, R., Kaushik, R., Mahajan, S., & Rajesh, V. (2006). Effects of mental relaxation and slow breathing in essential hypertension. *Complementary Therapies in Medicine, 14*(2), 120-126.

Knox, S., Hausdorff, J., & Markovitz, J. (2002). Reactivity as a predictor of subsequent blood pressure: Racial differences in the Coronary Artery Risk

Development in Young Adults (CARDIA) study. *Hypertension, 40*(6), 914-919. doi.org/10.1161/01.HYP.0000041417.94797.57

Krakoff, L., Gillespie, R., Ferdinand, K., Fergus, I., Akinboboye, O., Wiliams, K…,…Pepine, C. (2014). 2014 Hypertension Recommendations from the Eighth Joint National Committee Panel Members Raise Concerns for Elderly Black and Female Populations. *Journal of the American College of Cardiology, 64*(4):394-402. doi:10.1016/j.jacc.2014.06.014.

Linden, W., & Moseley, J. V. (2006). The efficacy of behavioral treatments for hypertension. *Applied Psychophysiology and Biofeedback, 31*(1), 51-63. doi.org/10.1007/s10484-006-9004-8

Lloyd-Jones, D., Adams, R., Brown, T., Carnethon, M., Dai, S., De Simone, G…Wylie-Rosett, J. (2010). American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Executive summary: heart disease and stroke statistics–2010 update: a report from the American Heart Association. *Circulation. 121(7),* 948–954. doi: 10.1161/CIRCULATIONAHA.109.192666

Lloyd-Jones D., Evans, J., Larson, M., O'Donell, C., Rocella, & Levy, D. (2000). Scientific contributions: Differential control of systolic and diastolic blood pressure: Factors associated with lack of blood pressure control in the community. *Hypertension, 36*(4), 594-599.doi:10.1161/01.HYP.36.4.594

Lochner, J., Rugge, B., & Judkins, D., (2005). How effective are lifestyle changes for controlling hypertension? *The Journal of Family Practice, 55*(1), 73-74.

Mahtani, K., Nunan, D., & Heneghan, C. (2012). Device-guided breathing exercises in the control of human blood pressure: systematic review and meta-analysis. *Journal of Hypertension 30*(5), 852-60. doi: 10.1097/HJH.0b013e3283520077

Maranon, R., & Reckelhoff, J. F. (2013). Sex and gender differences in control of blood pressure. *Clinical Science, 125*(7), 311–318. http://doi.org/10.1042/CS20130140

Mazzaglia, G., Ambrosioni, E., Alacqua, M., Filippi, A., Sessa, E., Immordino, V.,…Mantovani, L. (2009). Adherence to antihypertensive medications and cardiovascular morbidity among newly diagnosed hypertensive patients. *Circulation*, *120*(16):1598-605. doi: 10.1161/CIRCULATIONAHA.108.830299.

Meles, E., Giannattasio, C., Failla, M., Gentile, G., Capra, A., & Mancia, G. (2004). Nonpharmacologic treatment of hypertension by respiratory exercise in the home setting. *American Journal of Hypertension*,*17*(4), 370–374.

Mellen, P., Gao, S., Vitolins, M., & Goff, D. (2008). Deteriorating dietary habits among adults with hypertension: DASH dietary accordance, NHANES 1988-1994 and 1999-2004. *Archives of Internal Medicine*, *168*(3), 308-314. doi.org/10.1001/archinternmed.2007.119

Mendes de Leon, C., Dilillo, V., Czajkowski, S., Norten, J., Schaefer, J., Catellier, D., & Blumenthal, J. (2001). Psychosocial characteristics after acute myocardial infarction: The enriched pilot study. Enhancing recovery in coronary heart disease. *Journal of Cardiopulmonology of Rehabilitation, 6*(21), 353–362.

Merritt, M., Bennett, G., Williams, R., Sollers, J., & Thayer, J. (2004). Low educational attainment, John Henryism, and cardiovascular reactivity to and recovery from personally relevant stress. *Psychosomatic Medicine*, *66*(1), 49-55. doi.org/10.1097/01.PSY.0000107909.74904.3D

Mozaffarian, D., Benjamin, E., Go, A., Arnett, D., Blaha, M., Cushman, M…Turner, M. (2015). American Heart Association Statistics Committee and Stroke Statistics Subcommittee.

Heart disease and stroke statistics--2015 update: A report from the American Heart Association. *Circulation, 131*(4), e29–322.doi: 10.1161/CIR.0000000000000152

Non, A., Gravlee, C., & Mulligan, C. (2012). Education, genetic ancestry, and blood pressure in African Americans and whites. *American Journal of Public Health, 102*(8), 1559–1565. doi: 10.2105/AJPH.2011.300448

Oparil, S., Zamam, M. A., & Calhoun, D. (2003). Pathogenesis of hypertension. *Annals of Internal Medicine. 139,* 761-776.

O'Rourke, M. (1990). Arterial stiffness, systolic blood pressure, and logical treatment of arterial hypertension. *Hypertension (15)*4, 339-347.

Ostchega Y., Yoon, S., Hughes, J., & Louis, T. (2008). Hypertension awareness, treatment, and control--continued disparities in adults: United States, 2005-2006. NCHS Data Brief. *3*,1–8.

Park, J., Lyles, R. H., & Bauer-Wu, S. (2014). Mindfulness meditation lowers muscle sympathetic nerve activity and blood pressure in African-American males with chronic kidney disease. *American Journal of Physiology - Regulatory, Integrative and Comparative Physiology*, *307*(1), R93–R101. http://doi.org/10.1152/ajpregu.00558.2013

Patten, S., Williams, J., Lavorato, D., Campbell, N., Eliasziw, M.,& Campbell, T. (2009). Major depression as a risk factor for high blood pressure: epidemiologic evidence from a national longitudinal study. *Psychosomatic Medicine, 71*(3), 273–279.

Pechere-Bertschlitz, A., & Burnier, M. (2004). Female sex hormones, salt, and blood pressure regulation. *The American Journal of Hypertension, (17)*10, 994-1001.

Rankins, J., Sampson, W., Brown, B., & Jenkins-Salley, T. (2005). Dietary Approaches to Stop Hypertension (DASH) intervention reduces blood pressure among

hypertensive African American patients in a neighborhood health care center. *Journal of Nutrition Education and Behavior*, *37*(5), 259-264. doi.org/10.1016/S1499-4046(06)60281-9

Reckelhoff, J. (2001). Gender differences in the regulation of blood pressure. *Hypertension, 37*(5), 1199-1208. doi:10.1161/01.HYP.37.5.1199

Report of the Joint National Committee on detection, evaluation, and treatment of high blood pressure: A cooperative study (1997). *Journal of the American Medical Association, 237(3)*, 255-261

Richardson, S., Freedman, B., Ellison, D., & Rodriguez, C. (2013). Salt sensitivity: A review with a focus on non-Hispanic blacks and Hispanics. *Journal of the American Society of Hypertension: JASH, 7*(2), 170–179. http://doi.org/10.1016/j.jash.2013.01.003

Roger, V., Go, A., Lloyd-Jones, D., Benjamin, E., Berry, J.,… Turner, M. (2012). Heart Disease and Stroke Statistics—2012 Update: A Report From the American Heart Association. *Circulation*, *125*(1), e2–e220. http://doi.org/10.1161/CIR.0b013e31823ac046

Rooks, R., Simonsick, E., Klesges, L., Newman, A., Ayonayon, H., & Harris, T. (2008). Racial disparities in health care access and cardiovascular disease indicators in Black and White older adults in the Health ABC Study. *The Journal of Health Ageing and Health, 20*(6), 599-614.

Rosenthal, T., Alter, A., Peleg, E., & Gavish, B. (2001). Device-guided breathing exercises reduce blood pressure: Ambulatory and home measurements. *American Journal of Hypertension, 14*(1), 74-76. doi.org/10.1016/S0895-7061(00)01235-8

Rutledge, T., & Hogan, B. (2002). A quantitative review of prospective evidence linking psychological factors with hypertension development. *Psychosomatic Medicine, 64*(5), 758–766.

Schein, M., Alter, A., Levine, S., Baevsky, T., Nessing, A., & Gavish, B. (2007). High blood pressure reduction in diabetics with interactive device-guided paced breathing: Final results of a randomized controlled study [Abstract]. *Journal of Hypertension*, *25*(2), S192.

Schein, M., Gavish, B., Herz, M., Rosner-Kahana, D., Naveh, P., Knishkowy, B…Melmed, R. N., (2001). Treating hypertension with a device that slows and regularizes breathing: A randomized, double-blind controlled study. *Journal of Human Hypertension, 15*(4), 271-278.

Smelt, A., Van der Weele, G., Blom, J., Gussekloo, J., & Assendelft, W., (2010). How usual is usual care in pragmatic intervention studies in primary care? An overview of recent trials. *British Journal of General Practice, 60*(576), 305-318.

Steptoe, A., & Kivimäki, M. (2013). Stress and cardiovascular disease: an update on current knowledge. *Annual Review of Public Health* (34):337–54. doi: 10.1146/annurev-publhealth-031912-114452

Svetkey, L., Simons-Morton, D., Vollmer, W., Appel, L., Conlin, P., Ryan, D., Ard, J., & Kennedy, B. (1999). Effects of dietary patterns on blood pressure: Subgroup analysis of the Dietary Approaches to Stop Hypertension (DASH) randomized clinical trial. *Archives of Internal Medicine, 159*(3), 285-293. doi.org/10.1001/archinte.159.3.285

Tilburt, J., Dy, S., Weeks, K., Klag, M., & Young, J. (2008). Associations between home remedy use and a validated self-reported adherence measure in an urban African-American

population with poorly controlled hypertension. *Journal of The National Medical Association, 100*(1), 91-97.

Taylor, J., Smith, P., Babyak, M., Barbour, K., Hoffman, B., Sebring, D., Davis, R. … Blumenthal, J. (2015). Coping and quality of life in patients awaiting lung transplantation. *Journal of Psychosomatic Research, 65*(1), 71-79.

Taylor, J., Washington, O., Artinian, N., & Lichtenberg, P. (2008). Relationship between depression and specific health indicators among hypertensive African American parents and grandparents. *Progress in Cardiovascular Nursing*, *23*(2), 68–78.

United States Department of Education. Fast facts. *National Center for Education Statistics.* Retrieved. June 10, 2012. from http://nces.ed.gov/fastfacts

Williams, D., Mohammed, S., Leavell, J., & Collins, C. (2010). Race, socioeconomic status and health: complexities, ongoing challenges and research opportunities. *Annals of the New York Academy of Sciences*, *1186*, 69–101. http://doi.org/10.1111/j.1749-6632.2009.05339.x

The World Health Organization (June, 2011). The top 10 causes of death. Retrieved July 4, 2012 from http://www.who.int/mediacentre/factsheets/fs310/en/index.html.

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APPENDIX A

Consent to Participate in a Research Study

Enhancing Treatment for High Blood Pressure in African Americans

WHY ARE YOU BEING INVITED TO TAKE PART IN THIS RES*E*ARCH?

You are being invited to take part in a project that is comparing various procedures for reducing high blood pressure in individuals who are African American. You are being invited to take part in this research study because you are between 18 and 75 years of age, have previously been diagnosed as hypertensive by a physician (elevated systolic BP of >140mmHg and diastolic BP of > 90 mmHg) within the past 12 months and your condition is not currently controlled or you have previously experienced challenges in reducing your blood pressure in the past 12 months, as defined by one or more of the following: self-reported limited transportation to medical clinics, high medication costs, convenience, low medication adherence (if on medication), <40% of the time that your doctor asked you to take the medication. If you volunteer to take part in this study, you will be one of about 75-90 people to do so in Memphis.

WHO IS DOING THE STUDY?

The person in charge of this study is Ms. Paige Frankfurt (*Lead Investigator*) who is an advanced doctoral student in clinical psychology at the University of Memphis Department of Psychology. Dr. Frank Andrasik, Distinguished Professor and Chair of the Department of Psychology, is guiding her in this research. There may be other people on the research team assisting at different times during the study, as well as staff at various medical offices.

WHAT IS THE PURPOS*E* OF THIS STUDY?

By doing this study, we hope to learn if a brief form of educational counseling combined with a special home-based biofeedback device, called the RESPeRATE, can help individuals like yourself gain better control of your high blood pressure.

ARE THERE REASONS WHY YOU SHOULD NOT TAKE PART IN THIS STUDY?

Participants will not be eligible to participate if their blood pressure is presently under control, they are being treated for or have severe psychiatric disorders, a history of stroke, heart attack or heart failure, kidney and renal failure or disease, chronic Type I or II Diabetes Mellitus, severe asthma, morbid obesity, pregnancy, and recent surgery that could significantly affect blood pressure or previously mentioned conditions.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

The research procedures will be conducted at The University of Memphis Center for Behavioral Medicine (400 Innovative Drive) as well as at Midtown Internal Medicine (1533 Union Avenue), a Methodist Healthcare facility in Memphis, TN. Should you agree to participate in this study, you could need to come to one of these locations between 4 and 9 times during the study, plus an

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initial meeting that may last up to 90 minutes. Although the amount of time will vary according to the treatment you receive, the maximum amount of time will be about 11 hours over the next 6 months.

WHAT WILL YOU BE ASKED TO DO?

If you meet eligibility criteria and wish to partake in the study, you will be informed of the commitments: an initial training session (at the medical clinic) on how to measure your blood pressure accurately (administered by the PI and one medical professional on site—PA or Nurse), psychoeducational information for the treatment rational and components for participants, an informed consent process, and a comprehensive battery of measures including: general demographic information, level of stress, perceived stress (as more perceived stress has been associated with higher BP), symptoms of anxiety and depression, medication dosage and adherence, and quality of life. If relevant, you could be asked to complete a three day adherence measure in which you will be asked to report on how well and consistently *you* follow the management plan developed with your Health Care Provider (HCP).

The study will be comparing 2 different conditions: one being a waiting list that will involve you carefully tracking my current treatment (#1) and another involving the addition of specific educational strategies for improving my blood pressure control and an electronic breathing device to facilitate you becoming more relaxed and that may help provide further benefit (#2). You will be assigned on a random basis to the one of the 2 conditions. This means you will have a 1 in 2 chance of being assigned to any one of the above conditions.
You will be required to complete a number of inventories and have your blood pressure taken at the beginning of the project, with the inventories and blood pressure measurements being repeated at 2,3,4,5, and 6 months. You will be asked to keep a record of your current treatments (medications, etc.) throughout the entire project, no matter what condition you are assigned.
If you are assigned to the first condition you will continue any treatment that you are already doing. If you are not doing anything, you will continue doing that.
If you are assigned to the second condition you will need to meet with one of the researchers for training in how to maximize your current treatment. This will involve in person meetings and several brief telephone calls. You also will be provided with a home breathing relaxation device and trained in how to use it properly. You will need to meet with one of the researchers each month to ensure the device is working properly. You may be asked to periodically record your home blood pressure before and during your use of the breathing relaxation device.
A physician's assistant of registered nurse will conduct my blood pressure readings during the course of treatment.
All information collected will be reviewed only by the experimenter and persons overseeing the project. No information will be released to others unless you specifically request in writing that this should be done.
You may discontinue my participation in this study at any time without penalty. If you do so and want a referral for further or additional treatment, the researchers will provide you with a list of professionals to consider.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

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To the best of our knowledge, the things you will be doing have no more risk of harm than you would experience in everyday life.

This project is designed to help improve my blood pressure. If effective, there is a chance your blood pressure may lower too much or too quickly, resulting in you taking too much medication. This is one of the reasons your blood pressure will be monitored closely throughout the project so adjustments can be made by your treating physician if needed.
You realize as well that your blood pressure may actually increase, although this is very unlikely. You will be carefully monitored for this; should this occur, a referral made back to my physician should this occur.
At the start of the study, you will be provided with information that alerts me to when my blood pressure may be increasing or decreasing too much and what to do when this occurs.

You may find some questions we ask you (*or some procedures we ask you to do)* to be upsetting or stressful. If so, we can tell you about some people who may be able to help you with these feelings.

In addition to the risks listed above, you may experience a previously unknown risk or side effect. If this occurs, you will have been given the phone number of the Lead Investigator, and you should immediately call her. She will likely refer you to a local hospital or a medical facility.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

There is no guarantee that you will receive any benefit from taking part in this study. However, some people have experienced reductions in blood pressure when they have been given the special education and/ or used the RESPeRATE, the device that you could be asked to use. You may also be able to reduce some of your medications. If you are assigned to the waiting list condition and reductions in blood pressure are seen over the course of the study in either of the other two conditions, you can request that one of these 2 treatments be offered to you. Finally, your willingness to take part may, in the future, help society as a whole better understand hypertension and its treatment.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any benefits or rights you would normally have if you choose not to volunteer. You may stop at any time during the study and still keep the benefits and rights you had before volunteering. If you decide not to take part in this study, your decision will have no effect on the quality of care, services, etc., you currently receive.

IF YOU DO NOT WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

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If you do not want to take part in the study, there are other choices such as treatments at local community health centers, hospitals, or emergency rooms. We will do our best to help you find other such options.

WHAT WILL IT COST YOU TO PARTICIPATE?

There are no costs associated with taking part in the study. Any parking costs encountered by coming to the University of Memphis will be covered by the research project.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

You could receive anywhere from $40-$70 in gift cards for taking part in this study, depending on the condition to which you are assigned. Should you wish to withdraw your participation in the study at any time, you will no longer be eligible for the remaining gift card amounts. Depending on the condition you are assigned, you may also receive free use of the home training device.

WHO WILL *SE*E THE INFORMATION THAT YOU GIVE?

We will make every effort to keep private all research records that identify you to the extent allowed by law.

Your information will be combined with information from other people taking part in the study. When we write about the study to share it with other researchers, we will write about the combined information we have gathered. You will not be personally identified in these written materials. We may publish the results of this study; however, we will keep your name and other identifying information private.

<u>Safeguarding Data:</u>
All identifiable information provided by participants will be stored electronically separately on a secure database and each participant will be assigned a non-identifiable subject code. Only members of the trained research team will be allowed to enter data into the database. The two databases will be stored on University of Memphis servers behind a firewall. The PI and her faculty mentor will have access to the identifiable dataset. Upon project completion, this information will be destroyed (unless carry-on funding is secured).

Additionally, a three-person Data Safety and Monitoring Board (DSMB) will be assembled to ensure the safety of the participants. The DSMB will include the faculty mentor of this project, the local medical doctor from the health clinic where recruitment will take place, and a public-health focused biostatistician. The above-mentioned individuals will have access to the patient's medical information.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. All medically-related paper records will be

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stored in the local medical clinic files, which are HIPPA compliant, industry regulated privacy standards. All psychological outcome measures will be stored in a locked file cabinet in the faculty mentor's laboratory at the University of Memphis. Only the lead PI, the supervising faculty mentor, and relevant research team members will have access to that key. These records will be destroyed within 2 years of the date of completion of this project. The information within these measures will be transferred to a password-protected electronic database immediately after they are taken to the University of Memphis. Only the PI, her faculty advisor, and research team members will have access to this database.

We will keep private all research records that identify you to the extent allowed by law. However, there are some circumstances in which we may have to show your information to other people. For example, the law may require us to show your information to a court if subpoenaed. Also, we may be required to show information that identifies you to people who need to be sure we have done the research correctly; these would be people from such organizations as the University of Memphis.

CAN YOUR TAKING PART IN THE STUDY END EARLY?

If you decide to take part in the study you still have the right to decide at any time that you no longer want to continue. You will not be treated differently if you decide to stop taking part in the study.

The individuals conducting the study may need to withdraw you from the study. This may occur if you are not able to follow the directions they give you, if they find that your being in the study is more risk than benefit to you. There will be no consequences of withdrawing early from the study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or if you get sick because of something that is due to the study, you should call Ms. Paige Frankfurt, MS, Frank Andrasik, PhD, or Shawn Hayden, MD at 678-2146, 721-1200 or 911 immediately.

Frank Andrasik, PhD or Shawn Hayden, MD will determine what type of treatment, if any, that is best for you at that time.

It is important for you to understand that the University of Memphis does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of Memphis will not pay for any wages you may lose if you are harmed by this study.

Medical costs that result from research related harm cannot be included as regular medical costs. Therefore, the medical costs related to your care and treatment because of research related harm will be your responsibility.

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A co-payment/deductible from you may be required by your insurer or Medicare/Medicaid even if your insurer or Medicare/Medicaid has agreed to pay the costs. The amount of this co-payment/deductible may be substantial.

You do not give up your legal rights by signing this form.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS, CONCERNS, OR COMPLAINTS?

Before you decide whether to accept this invitation to take part in the study, please ask any questions that might come to mind now. Later, if you have questions, suggestions, concerns, or complaints about the study, you can contact the Lead Investigator, Paige Frankfurt at 901-678-2146 or by email at pmgdvitz@memphis.edu. If you have any questions about your rights as a volunteer in this research, contact the Institutional Review Board staff at the University of Memphis at 901-678-2705. We will give you a signed copy of this consent form to take with you.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

If the researcher learns of new information in regards to this study, and it might change your willingness to stay in this study, the information will be provided to you. You may be asked to sign a new informed consent form if the information is provided to you after you have joined the study.

WHAT EL*SE* DO YOU NEED TO KNOW?

The Center for Behavioral Medicine at The University of Memphis is providing material for this study. If you have questions about subjects' rights, contact Beverly Jacobik, Administrator for the Institutional Review Board for the Protection of Human Subjects, at irb@memphis.edu or by phone at 901-678-2705.

Statement of Consent: I certify that I have read and fully understand the Statement of Procedure and agree to participate in the research study described above. My permission is given voluntarily without coercion or undue influence. I understand that I may discontinue my participation at any time without penalty or loss of any benefits that I may be entitled. I will be provided a copy of this consent form. Any questions I have are written below and have been discussed with the experimenter

_____
_____
_____

_____ _____
Signature of person agreeing to take part in the study Date

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_____ _____

Printed name of person agreeing to take part in the study Date

_____ _____

Name of [authorized] person obtaining informed consent Date

APPENDIX B
DEMOGRAPHICS

Name:_____

Age:_____

Zip Code:_____

Date of Birth:_____ Gender: M/F_____

Please circle the answer that best described you:

1. **What is your race?**
   Caucasian
   Hispanic or Latino
   Black or African American
   Native American or American Indian
   Asian / Pacific Islander
   Other

2. **What is the highest level of schooling that you have completed?**
   No schooling completed
   Nursery school to 8th grade
   Some high school, no diploma
   High school graduate, diploma or the equivalent (for example: GED)
   Some college credit, no degree
   Trade/technical/vocational training
   Associate degree
   Bachelor's degree
   Master's degree
   Professional degree
   Doctorate degree

3. **What is your marital status?**
   Single, never married
   Married or domestic partnership
   Widowed
   Divorced
   Separated

4. What is your current household income in U.S. dollars?

Under $10,000
$10,000 - $19,999
$20,000 - $29,999
$30,000 - $39,999
$40,000 - $49,999
$50,000 - $74,999
$75,000 - $99,999
$100,000 - $150,000
Over $150,000
Would rather not say

5. Do you currently have medical insurance?

Thank you and please continue on to the next page. When you have completed this packet, please return it to the researcher, physician's assistant, or the front desk staff.

ID#

Literacy Items
Female Teachers - Document Literacy

Question:
What is the percentage of women in the teaching profession in Greece?

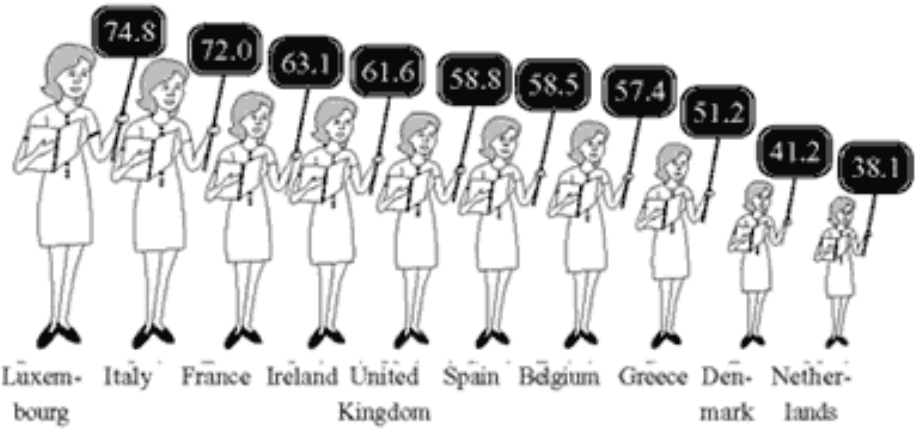
Answer:

Female Teachers - Document Literacy
Question:
List all the countries where the percentage of women teachers is between 60% and 75%.

Answer:

FEW DUTCH WOMEN AT THE BLACKBOARD

There is a low percentage of women teachers in the Netherlands compared to other countries. In most of the other countries, the majority of teachers are women. However, if we include the figures for inspectors and school principals, the proportion shrinks considerably and women are in a minority everywhere.



Percentage of women teachers (kindergarten, elementary, and secondary).

Medications

"Now we're going to ask you some questions about your HYPERTENSION medicines."

1. Are you currently taking pills or other medicines to treat your HYPERTENSION?

Yes **(Go to 2)**

No **(please continue to the next page)**

It is important for us to understand what people with HYPERTENSION are really doing with their pills or medicines. Please tell us what you are actually doing. We want to know what is really happening, not what you think we want to hear.

2. What are the names of the hypertension medications that you are taking (Please include mg)

3. How many times during the day has your doctor told you to take doses of medicine (pills or other medicines) to treat your HYPERTENSION?

Once a day

Twice a day

Three times a day

Four or more times a day

4. What is the total number of pills your doctor has told you to take each day? (please type in the total number of pills below)

|_____|_____| pills each day

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Hello,

The University of Memphis Institutional Review Board, FWA00006815, has reviewed and approved your submission in accordance with all applicable statuses and regulations as well as ethical principles.

PI NAME: Paige Frankfurt
CO-PI:
PROJECT TITLE: A Home-Based Biofeedback Intervention in a Hypertensive African American Sample: A Pilot Study
FACULTY ADVISOR NAME (if applicable): Sara Bridges
IRB ID: #3157
APPROVAL DATE: 4/25/2014
EXPIRATION DATE: 4/24/2015
LEVEL OF REVIEW: Expedited

RISK LEVEL DETERMINATION:No more than minimal

Please Note: Modifications do not extend the expiration of the original approval

Approval of this project is given with the following obligations:

1. If this IRB approval has an expiration date, an approved renewal must be in effect to continue the project prior to that date. If approval is not obtained, the human consent form(s) and recruiting material(s) are no longer valid and any research activities involving human subjects must stop.

2. When the project is finished or terminated, a completion form must be completed and sent to the board.

3. No change may be made in the approved protocol without prior board approval, whether the approved protocol was reviewed at the Exempt, Exedited or Full Board level.

4. Exempt approval are considered to have no expiration date and no further review is necessary unless the protocol needs modification.

Approval of this project is given with the following special obligations:

Thank you,

Ronnie Priest, PhD

Institutional Review Board Chair

The University of Memphis.

Note: Review outcomes will be communicated to the email address on file. This email should be considered an official communication from the UM IRB. Consent Forms are no longer being stamped as well. Please contact the IRB at IRB@memphis.edu if a letter on IRB letterhead is required.