A Pilot Randomized Controlled Trial Comparing the Efficacy of Problem-Solving Therapy to Enhanced Treatment as Usual for Reducing High Blood Pressure

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Dedications

To my family, for all of your love and support.

In honor of Sweetpea, for carrying my heart and teaching me more about life than I could ever have known.

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Abstract

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High blood pressure is a highly prevalent and modifiable risk factor for cardiovascular disease that has substantially contributed to disability, morbidity, mortality, health disparities and economic burden in the United States. Although relatively easy to diagnosis and inexpensive to treat, controlling high blood pressure, thereby reducing its sequelae, remains difficult, particularly for Black individuals, due to a host of psychosocial, biological, and environmental factors. There is a need to identify an efficacious stress-reduction intervention for lowering uncontrolled high blood pressure that can be effectively translated into practice.

In the current pilot study, the preliminary efficacy and feasibility of Problem-Solving Therapy (PST), compared to telephone-delivered enhanced treatment as usual (ETAU), were evaluated on measures of blood pressure, social problem solving ability, medication adherence, perceived stress, depression, and health-related quality of life (HRQOL) at baseline, posttreatment, and 3-month follow up. Recruitment from outpatient medical clinics yielded a sample of 14 participants, predominantly Black and female, with uncontrolled high blood pressure, who were randomly assigned to PST or ETAU. Mean differences between conditions from baseline to posttreatment assessments were examined using a series of intent-to-treat ($N = 12$) t-tests and repeated measures ANOVAs, none of which were statistically significant. Inspection of effect sizes and clinical significance indicated a trend toward efficacy of PST to improve medication adherence [$F\ (1, 10) = 2.54$, $p = 0.14$, $\eta_p^2 = 0.20$] and physical HRQOL

[F (1,10) = 2.54, p = 0.14, η_p^2 = 0.20], as well as slightly more frequent clinically meaningful changes in systolic blood pressure, mental HRQOL, and depression for those who received PST. In terms of feasibility, about 13% of 108 recruited patients were enrolled, the rate of attrition was below 20% for treatment initiators, retention of treatment initiators was 100% for PST (n_{PST} = 6) and 83.3% (n_{ETAU} = 5) for ETAU at posttreatment, and about 80% of participants rated the treatments as credible and effective. Three-month follow up assessments were too few to conduct meaningful analyses. Although a trend toward efficacy of PST was indicated, challenges in recruitment limited sample size, and, therefore, the aforementioned preliminary results must be interpreted with caution.

Keywords: high blood pressure, hypertension, Problem-Solving Therapy

CHAPTER 1: INTRODUCTION

1.1. High blood pressure: High blood pressure (BP) is the leading cause of preventable death in the United States, a major risk factor for cardiovascular disease (CVD), a substantial contributor to morbidity and disability, an important factor in health disparities, and an economic burden on the health care system in the U.S. (Chobanian et al., 2003; IOM, 2010; Lloyd-Jones et al., 2010; Nwankwo, Yoon, Burt, & Gu, 2013; Roger et al., 2012). Despite the recognition that high BP has a significant impact on the health of the nation, as denoted by the *Healthy People 2020* objective HSD-12 (i.e., increasing the proportion of adults whose high BP is controlled), the comprehensive report by the *Institute of Medicine's (IOM) Committee On Public Health Priorities to Reduce and Control Hypertension in the U.S. Population* (2010) described the problem as largely neglected. Although high BP relatively easy to diagnose and low-cost to treat, "millions of Americans continue to develop, live with, and die from hypertension because we are failing to translate our public health and clinical knowledge into effective prevention, treatment, and control programs" (IOM, 2010, p. 2).

The effective translation of evidence-based intervention into practice is challenging, and requires a multi-pronged approach because barriers exist at multiple levels, including environmental, health care system, and individual (Ogedegbe, 2008; Scisney-Matlock et al., 2009). Both population-wide interventions (e.g., reduction of salt intake through legislation, salt reduction agreements with industry, health education through mass media) and individual interventions (e.g., individual education and treatment for high BP) are useful in reducing health care burden, with findings suggesting that population-based interventions are more cost-effective, but less clinically effective than individual-based strategies (e.g., IOM, 2010). Furthermore,

population-based strategies may disproportionately benefit highly educated, affluent subgroups, leading to greater health disparities (IOM, 2010).

1.1.1. Definition: Blood pressure (BP) refers to the force of blood against the walls of the arteries; when elevated over time, it is referred to as *high blood pressure* (Chobanian et al., 2003). High BP causes the heart to work harder and contributes to atherosclerosis, the term for the hardening of the arteries (Chobanian et al., 2003). *Hypertension*, the medical term for high BP, is defined as a systolic BP (SBP) greater than or equal to 140 millimeters of mercury (mmHg), and/ or a diastolic BP (DBP) greater than or equal to 90 mmHg (e.g., Chobanian et al., 2003; Lloyd-Jones et al., 2010; Roger et al., 2012; Yoon et al., 2010). Hypertension is also indicated when an individual is prescribed antihypertensive medication to lower BP or has been told by a physician or other health professional on at least two occasion that BP is high (e.g., Chobanian et al., 2003; Lloyd-Jones et al., 2010; Roger et al., 2012; Yoon et al., 2010). Hypertension is categorized as either primary (essential) hypertension or secondary hypertension; primary hypertension is the name given to high BP without a known cause, representing 90-95% of all cases of hypertension, whereas secondary hypertension is the result of an already existing medical condition, such as Cushing's syndrome or thyroid problems (Carretero & Oparil, 2000). High BP is further classified into Stage 1 hypertension (140-159 mmHg SBP or 90-99 mmHg DBP) or Stage 2 hypertension (greater than or equal to 160 mmHg SBP or greater than or equal to 100 mmHg DBP); for those with diabetes or chronic kidney disease (CKD), high BP is defined as 130/80 or higher (e.g., Chobanian et al., 2003).

1.1.2. Prevalence: According to data from the National Health and Nutrition Examination Survey (NHANES) 2011-2012, high BP affects approximately 29.1% adults in the U.S. (Nwankwo et al., 2013). Projections for the year 2030 show rising prevalence estimates of hypertension, with an

expected increase of 9.9%, an additional 27 million Americans (Heidenreich et al., 2011). The prevalence of hypertension is nearly equal between men and women, though age-adjusted estimates vary (Roger et al., 2012).

1.1.3. High blood pressure control: In 2012, when the eligibility criteria for this study were established, BP control guidelines from the *Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure* (JNC 7) were used to operationally define what constituted BP goals, which at the time was achieved with a BP of <140/90 mmHg, or <130/80 mmHg for patients with diabetes or CKD (Chobanian et al., 2003). Since that time, targeted goals for BP in patients 60 years or older have continued to be debated; the American College of Cardiology (ACC) and the American Heart Association (AHA) recommend a goal of BP below 140/90 mmHg, whereas the most recent guidelines from the *Eight Report of the JNC* (JNC 8) suggest a goal of 150/90 mmHg or below. Of the approximately 30% of adults in the U.S. with hypertension, about 20% are unaware of having the condition, partly due to the lack of symptoms; control has been achieved in about 44% of those aware of their high BP (Chobanian et al., 2003; Egan et al., 2010; Roger et al., 2012).

1.1.4. Minority health disparities: Prevalence rates of high BP are the highest in the world for African Americans and it is on the rise in this population (Roger et al., 2012). The average BP for African Americans is higher than that of any other ethnicity and they tend to develop high BP earlier in life; additionally, African Americans are less likely to reach BP control, with rates of control 27% lower in Blacks than Whites (Roger et al., 2012). Biological differences (e.g., genetic traits, higher retention of salt) and environmental and behavioral characteristics (e.g., medication adherence, dietary habits, stress) have been delineated in proposed explanations of higher prevalence in a Black population (Fuchs, 2011). Particularly relevant to this study,

researchers have identified various factors that influence medication adherence in this population, including the mistrust of health care providers, perceived discrimination in health care partly based upon historical events (e.g., the Tuskegee Study), low health education, and beliefs that medication is harmful and/or ineffective (Flack et al., 2010, Fongwa et al., 2008; Forsyth, Schoenthaler, Chaplin, & Ogedegbe, 2014; Lukoschek, 2003; Yancey, Ortega, & Kumanyika, 2006).

1.1.5. Morbidity: Hypertension is a major risk factor for heart disease and stroke, the first and third leading causes of death in the U.S., respectively (e.g., Roger et al., 2012). Evidence suggests the relationship between BP and CVD events is continuous, consistent, and independent of other risk factors (e.g., smoking, high-density lipoprotein or left ventricular hypertrophy), down to at least 115/75 mmHg; the higher the BP, the greater the risk of other conditions, including heart failure, myocardial infarction, stroke and kidney disease (e.g., Chobanian et al., 2003; Lewington, Clarke, Qizilbash, Peto, & Collins, 2002; Roger et al., 2012). According to Gu and colleagues (2008), SBP, compared to DBP, is considered a more important risk factor for CVD.

1.1.6. Mortality: High BP has been called the "silent killer," referring to the typical absence of symptoms until vital organs (e.g., heart, brain, kidneys) are damaged (Lukoschek, 2003). The age-adjusted hypertension-related mortality rate (i.e., any mention of hypertension on the death certificate) has risen 23.1% from 2000 to 2013 (i.e., from 255.1 per 100,000 in 2000 to 314.1 in 2013), whilst the rate for all other causes of death combined decreased 21.0%; rates were highest among the non-Hispanic Black population compared with the non-Hispanic White and Hispanic populations (Kung & Xu, 2015). Kung and Xu (2015) reported the top five underlying causes of hypertension-related deaths were heart disease, hypertension, stroke, cancer and diabetes.

1.1.7. Cost: The direct and indirect cost of high BP in 2008 was about 50.6 billion (Roger et al., 2012). According to Roger and colleagues (2012), the number of medical visit for hypertension in 2009 was estimated to be slightly greater than 55 million (i.e., slightly less than 50 million physician office visits, about 1 million emergency department visits, and slightly more than 4 million outpatient department visits) and hypertension was listed as either a primary or secondary diagnosis slightly more than 9 million times for hospitalized inpatients.

1.1.8. Summary: High BP is a chronic condition that is present at an alarmingly high rate, with considerable impact on public health. Research has shown a strong, continuous, graded, consistent, independent and predictive relationship between high BP and vascular disease (IOM, 2010). High BP has significant health sequelae at present and prevalence is projected to increase, indicating a significant need to prioritize the effective implementation of efficacious prevention, treatment, and control programs (IOM, 2010).

1.2. Psychosocial stress: Stress is ubiquitous and those in the U.S. experience higher levels of stress than they believe to be healthy (American Psychological Association, 2012). Evidence suggests that psychosocial stress plays an important role in contributing to the development and prognosis of CVD in general and, specifically, in hypertension, such that some proponents have called for the standard evaluation and treatment of psychosocial stress and depression for patients with these conditions (e.g., Bosworth & Oddone, 2002; Chobanian, et al., 2003; Krantz, Sheps, Carney, & Natelson, 2000; Linden, 2003; Lloyd-Jones et al., 2010; Nezu, et al., 2011; Sparrenberger et al., 2009; Spruill, 2010). Recognizing the impact of psychosocial factors on blood pressure, various treatments (e.g., behavioral therapies, meditation including Transcendental Meditation, yoga, relaxation therapies, biofeedback approaches) have been developed to reduce arousal in response to stress and/ or the presence of stress, but the evidence-

base of such treatments has been considered inadequate or inconsistent (Bosworth et al., 2011; Blumenthal, et al., 2002; IOM, 2010; Linden, Stossel, & Maurice, 1996; Rainforth et al., 2007).

1.2.1. Psychosocial factors: A host of psychosocial factors (e.g., chronic stressors, perceived stress, emotional factors, motivation, avoidant coping, self-efficacy, functional social support, health literacy) contribute to uncontrolled high BP (e.g., Bosworth & Oddone, 2002; Magrin et al., 2014; Rozanski, Blumenthal, Davidson, Saab, & Kubzansky, 2005; Rod et al., 2009; Rutledge & Hogan, 2002; Sparrenberger, et al., 2009). Common chronic stressors include work stress, marital stress, caregiver strain, low socioeconomic status, and low social support (e.g., Rozanski et al., 2005). Although acute life events have been associated with hypertension, chronic stress has been identified as more likely to contribute to sustained BP elevation (Sparrenberger et al., 2009). Stressful events may lead to negative cognitive-affective coping responses, which may maintain physiological arousal whether or not the stressor is actually present; examples of this are worry and rumination, or anticipating future stress or dealing with past stress, respectively (e.g., Krantz et al., 2000). Common emotional factors include depression, anxiety, hostility and anger; of these, depression has been most widely studied in recent years, with findings suggesting depression increases the risk of adverse cardiac events (e.g., Krantz et al., 2000; Larzelere & Jones, 2008; Rozanski et al., 2005). Worry has also established affecting high BP and high BP control, particularly in African Americans (Bosworth, et al., 2008). Disconcertingly, compared to lifestyle behaviors (e.g., diet and physical activity), health care providers are less likely to assess and treat psychosocial risk factors possibly due to limited familiarity with effective strategies and recommendations (e.g., Rozanski et al., 2005).

1.2.2. Pathophysiology: Psychosocial stress is associated with the activation of the hypothalamic-pituitary-adrenal (HPA) axis and sympathetic nervous systems (SNS); catecholamines and

corticosteroids are released, which lead to increased heart rate, cardiac output, and BP (e.g., Krantz & Manuck, 1984; Lambert & Lambert, 2011; Spruill, 2010). The HPA and SNS response to acute stress appears well documented but the process through which stress contributes to prolonged elevation of BP over time is not as well understood; repeated activation, failure to return to resting levels after a stressful event, dysregulation of control and/or an excessive level of circulating cortisol and catecholamines, down-regulation in cortisol receptors leading to deficits in proinflammatory cytokine regulation, failure to habituate to a repeated stressor, or some amalgamation of these mechanisms may impair physiological and metabolic functions and be responsible for the development of hypertension (e.g., Lambert & Lambert, 2011; Larzelere & Jones, 2008; McEwen, 1998; Spruill, 2010).

1.2.3. Behavioral impact: Stress, including situational and cognitive-affective forms, indirectly impacts high BP through unhealthy lifestyle behaviors. Stress promotes poor diet, smoking, physical inactivity, and nonadherence to medical regimens (e.g., Claar & Blumenthal, 2003; Larzelere & Jones, 2008). In turn, these behaviors alter physiological processes thereby resulting in further development and progression of high BP and heart disease (Claar & Blumenthal, 2003). Rod and colleagues (2009) demonstrated the effect of stress on health behaviors, finding that individuals with high levels of perceived stress were less likely to quit smoking, more likely to become physically inactive, less likely to refrain from drinking alcohol above sensible limits, and more likely to be overweight compared to those with low levels of stress. Nonadherence to antihypertensive medication and lifestyle recommendations commonly interferes with high BP control; depression has been identified as impacting the likelihood of nonadherence with treatment recommendations, threefold and self-efficacy has been positive associated with medication adherence among African Americans (DiMatteo, Lepper, & Croghan, 2000; Warren-

Findlow, Seymour, Brunner Huber, 2011). Although psychosocial factors also influence lifestyle behaviors (e.g., medication adherence), thereby contributing to poorer high BP control, health care providers are more likely to assess lifestyle behaviors themselves, rather than psychosocial factor that may serve as barriers (e.g., Rod, Gronbaek, Schnohr, Prescott, & Kristensen, 2009; Rozanski et al., 2005; Warren-Findlow, Seymour & Brunner Huber, 2011).

1.2.4. Stress management: Stress reduction strategies consist of techniques that reduce excessive arousal to stress by changing cognitive, emotional, and/or physiological reactions to stress; this may occur by enhancing the ability to minimize the negative impact of stress on physical or emotional responses, cope effectively with situations leading to a negative stress response, and minimize the occurrence of stressors (e.g., Nezu, et al., 2011). Thus far, the evidence for stress-reduction interventions to reduce high BP has largely been considered inadequate (e.g., Brook et al., 2013; IOM, 2010); however, the National Institute for Health and Clinical Excellence (2011) recognized relaxation therapies, including stress management, meditation, and cognitive therapies, can serve as adjunctive lifestyle interventions that can reduce high BP, citing modest and varied reductions. Although research is limited and treatment components may vary, meta-analyses suggest that stress reduction approaches, particularly meditation and individualized multi-component cognitive behavioral stress management therapies (CBSM), may significantly reduce high BP (Blumenthal, Sherwood, Gullette, Georgiades, & Tweedy, 2002; Rainforth et al., 2007).

1.2.5. Summary: Extensive research has revealed the effects of psychosocial stress on high BP and further CVD; direct and indirect effects of psychosocial stress indicate the potential benefit of targeting psychosocial stress through intervention. Thus far, psychosocial interventions aimed at reducing high BP, including stress management/ reduction and behavioral interventions, have

yielded inconsistent and modestly efficacious findings, emphasizing the need for identifying an effective, multicomponent, standardized cognitive and behavioral stress management intervention to supplement established treatments (e.g., antihypertensive medication).

1.3. Problem-Solving Therapy:

1.3.1. Social Problem-Solving Theory: Social problem solving (SPS), on which Problem-Solving Therapy (PST) based, represents the multidimensional meta-process of ideographically determining and selecting coping responses to address the unique features of a given stressful situation at a given time (e.g., Nezu, 2004; Nezu & Nezu, 2012; Nezu, Nezu, & D'Zurilla, 2013). Contemporary SPS theory consists of two main dimensions, problem orientation and problem-solving style. Problem orientation, comprised of two orthogonal (positive and negative) types, refers to the relatively stable cognitive-affective schemas that characterize an individual's beliefs, attitudes, and emotional reactions regarding problems in living and one's ability to cope with such problems (Nezu & Nezu, 2012). Problem-solving style (i.e., rational problem solving, avoidant problem solving, and impulsive-careless problem solving) represents the core cognitive-behavioral activities that individuals engage in when attempting to solve stressful problems (Nezu & Nezu, 2012).

1.3.2. Therapeutic intervention: The premise of PST is based on a model demonstrating the relationship between SPS and distress (Nezu & Nezu, 2012; Nezu, et al., 2013). The overall goal of this psychosocial intervention is to foster the adoption and effective implementation of adaptive problem-solving attitudes (i.e., optimism, enhanced self-efficacy) and behaviors (i.e., adaptive emotional regulation, planful problem solving) to improve physical and mental health (Nezu, et al., 2013). Effective coping involves learning skills geared toward successfully resolving stressful problems and/or learning to better manage negative emotional reactions to

stressors (Nezu & Nezu, 2012; Nezu, et al., 2011). According to Nezu and colleagues (2011), a key therapeutic target of PST is altering attitudes or beliefs that impede attempts to cope adaptively with stressful problems. This major objective is supplemented with other treatment components to help individuals better manage negative emotions and engage in effective rational problem-solving activities (e.g., setting realistic goals, identifying barriers to reaching such goals, creatively thinking of various alternative solutions, deciding which alternatives may lead to success, and monitoring and evaluating the solution action plan). For a review of SPS theory and PST application, see Nezu and Nezu (2012) and Nezu and colleagues (2011).

1.3.3. Evidence base: PST is an evidenced-based cognitive behavioral intervention used to promote the effective application of adaptive problem-solving attitudes and skills to solve stressful problems in everyday living (e.g., D'Zurilla & Goldfried, 1971; Nezu, 2004; Nezu & Nezu, 2012; Nezu et al., 2013; Nezu, Nezu, Houts, Friedman, & Faddis, 1999). Across multiple populations, when under similar levels of stress, individuals with poor SPS have been consistently found to experience significantly high levels of psychological distress as compared to individuals with effective SPS (Nezu & Nezu, 2012). PST has been found efficacious in reducing multiple types of distress and evidence suggests that ineffective SPS is associated with a variety of poor health outcomes (e.g., Hill-Briggs, et al., 2006; Malouff, Thorsteinsson, & Schutte, 2007). Malouff and colleagues (2007) conducted a meta-analysis of 32 studies, capturing nearly 3,000 participants, that evaluated the efficacy of PST across various mental and physical health problems; the researchers concluded that PST was equally as effective as other psychosocial treatment and significantly more effective that both no treatment and attention placebo conditions. Specifically within a population with hypertension, one study employed a multi-component stress management protocol, consisting of PST, education and relaxation

training and found that those who received the intervention showed significant reductions in BP compared to a wait list control condition at posttreatment and 4-month follow-up (García, Labrador, & Sanz, 1997). Additional correlational and mediational analyses indicated that improvements in SPS were responsible for the effects of the stress management protocol, suggesting that PST was at least an active treatment ingredient (García-Vera, Sanz, & Labrador, 1998; Nezu & Nezu, 2012).

1.3.4. Efficacy and acceptability in ethnic minority populations: Although low-income minority populations are underrepresented in randomized clinical trials of cognitive-behavior therapies (CBTs), there is indication that CBT may be preferred by ethnic minorities in that it is a concrete, didactic, directive and active type of intervention from an expert that targets current problems (Nezu, Greenberg, & Nezu). PST has been evaluated as a treatment for depression among Black and Hispanic persons, although available evidence is limited, findings thus far suggest PST is both acceptable and effective in these populations (Ell et al., 2009; Kasckow et al., 2010).

1.3.5. Treatment tailoring: As discussed by Nezu and Nezu (2012), contemporary PST is designed in such a way that it facilitates the tailoring of treatment to a given population; in this case, PST was modified with two major considerations: a) fit with high BP and b) relevance to a low-income African American population. Because prevalence rates of uncontrolled high BP are higher in Black people, and sampling was performed in the City of Philadelphia, of which the racial distribution of residents is 43.4% Black, the sample was expected to consist of mostly Black individuals (United States Census Bureau, 2010). The standardized treatment manual (see Appendix B) was adapted to include examples and common problems a low-income Black patient with high BP might experience (e.g., coping with disability, anger, financial problems, family problems). In addition to the evaluation of social problem-solving attitudes and beliefs,

the therapeutic process itself involves collaboration with patients to identify current real-life problems and goals as well as the generation, implementation, and evaluation of specific, concrete strategies for coping with stated problems to the identified goal. As with PST, and many other cognitive-behavioral treatments, one aim of PST was to teach patients the skills for coping with current and future problems, rather than attempts at solving problems for participants.

1.3.6. Summary: Grounded in stress-diathesis model, PST has been found efficacious in reducing stress and distress among various populations, including medical patients (e.g., Nezu & Nezu, 2012; Nezu, Nezu, & Xanthopoulos, 2011). Given the aforementioned links between high BP and psychosocial factors, including chronic stressors, cognitive-affective variables, and behavioral responses, it was surmised that PST would be particularly suitable for reducing uncontrolled high BP. Evidentiary support for multicomponent cognitive-behavioral stress management interventions, the impact of psychosocial stress on high BP and lifestyle behaviors, and barriers to medication adherence, a common problem in uncontrolled high BP, all align with the theory, clinical targets, and skills that comprise PST. Figure 1 illustrates the conceptualized role of SPS ability in the relationship between stress and health, showing that improved SPS ability may prevent or mitigate negative health consequences of stress.

1.4. Current study aims: In consideration of the importance of developing and testing interventions that translate to evidence-based practice, and the health disparities present in minority populations, this trial was designed to balance internal and external validity. It was conducted in a real-world setting with community restraints, while maintaining control over threats to validity through standardization and randomization. The overarching goals of this pilot study were: a) examining preliminary efficacy of PST for reducing high BP and improving various psychosocial outcomes, as compared to an educationally based enhanced treatment-as-

usual (ETAU) condition and b) evaluating the feasibility of a PST intervention in the context of an urban medical setting.

1.4.1. Preliminary efficacy hypotheses: A major objective of this study was to determine the preliminary efficacy of PST, compared to that of a telephone-delivered educationally based ETAU condition, in patients with high BP. A series of hypotheses extend from the limited efficacy testing, as discussed below; briefly, these include evaluating changes in SBP and DBP, SPS ability, medication adherence, mental and physical health-related quality of life (HRQOL), perceived stress and depressive symptoms between participants receiving either PST or ETAU from baseline to posttreatment.

Hypothesis 1(a&b): It was hypothesized that participants in the PST condition would, on average, show statistically significantly greater reductions in BP [a) systolic and b) diastolic], compared to those in the ETAU condition, from baseline to posttreatment (H_1: $\mu_{PST} > \mu_{ETAU}$).

Hypothesis 2: On average, those in the PST condition will show statistically significantly greater improvements in SPS ability as compared to those in the ETAU condition from baseline to posttreatment (H_2: $\mu_{PST} > \mu_{ETAU}$).

Hypothesis 3: On average, those in the PST condition will show statistically significantly greater improvements in medication adherence as compared to those in the ETAU condition from baseline to posttreatment (H_3: $\mu_{PST} > \mu_{ETAU}$).

Hypothesis 4: On average, those in the PST condition will show statistically significantly greater improvements in mental and physical HRQOL as compared to those in the ETAU condition from baseline to posttreatment (H_4: $\mu_{PST} > \mu_{ETAU}$).

Hypothesis 5: On average, those in the PST condition will show statistically significantly greater reductions in perceived stress as compared to those in the ETAU condition from baseline to posttreatment (H_5: $\mu_{PST} > \mu_{ETAU}$).

Hypothesis 6: On average, those in the PST condition will show statistically significantly greater reductions in depression as compared to those in the ETAU condition from baseline to posttreatment (H_6: $\mu_{PST} > \mu_{ETAU}$).

1.4.2. Treatment feasibility: PST is considered a successful intervention for various populations in various settings (Nezu & Nezu, 2012); the current study is an expansion of PST for patients with high BP in an urban area. In consideration of the possibility of a larger RCT, this investigation served as a pilot trial to test the feasibility of implementing a full scale RCT. Feasibility was assessed using data gathered through recruitment and enrollment processes, intervention implementation, and acceptability of treatment; feasibility included the number of patients assessed for eligibility and enrolled, average days to complete eight sessions of treatment, and completion rates, as defined by a minimum of 6 session (i.e., after major treatment components have been delivered, to bring out the desired effect) and patient feedback on the credibility and effectiveness of the treatment.

Hypothesis 7: It was hypothesized that 80% of participants would be retained in the PST treatment, as defined as having attended at least 6 sessions of PST. Additionally, it was expected that the overall attrition rate for this trial would be 20% of less (see JARS flow diagram, Figure 2).

Hypothesis 8a: Both the ETAU and PST conditions were standardized and, given the frequency of one session per week (i.e., eight weeks), were expected to be delivered over the course of eight (56 days) to eleven weeks (77 days) for the full treatment protocol.

Hypothesis 8b: With regard to time elapsed between eighth session and posttreatment assessment and between posttreatment assessment and 3-month follow-up assessment, it was hypothesized that the time elapsed would be 0-14 days and 90-105 days, respectively.

Hypothesis 9: It was hypothesized that a substantial majority, about 80% of participants, in the PST condition would find the treatment acceptable (i.e., credible, effective, and confidently recommend it), as indicated by a rating of 4 or above on a 5-point Likert scale (1 = completely disagree to 5 = completely agree) on items of the program evaluation questionnaire.

1.4.3. Exploration of maintained effects: In an effort to examine the maintenance of potential gains, outcome data was collected 3 months post treatment completion; due to the limited number of participants that completed this phase of the study, basic descriptive data is provided.

CHAPTER 2: METHODS

2.1. Participant characteristics

2.1.1. Eligibility Criteria: To be eligible to participate in this research study, individuals must have: (a) presented with persistently high BP (i.e., BP > 140/90 mmHg on two or more occasions) or have a current diagnosis of hypertension given or confirmed by a board certified (e.g., internal medicine or cardiology) physician; (b) uncontrolled high BP in which the BP goal (i.e., BP <140/90 mmHg or <130/80 mmHg for patients with diabetes or chronic kidney disease, according to JNC 7 guidelines) had not been met; (c) been between 18 and 75 years of age (d) be able to read and understand the consent form; and (e) been able and willing to provide informed consent, which includes access to medical records as it pertains to any current or previous cardiovascular problems or related diseases.

2.1.2. Exclusion Criteria: Given the impact on high BP, the following conditions excluded an individual from enrollment in this investigation: (a) a current state of decompensated heart failure or a diagnosis of heart failure requiring inotropic agents; (b) currently receiving chemotherapy or radiation therapy; (c) currently receiving dialysis; (d) a heart attack/myocardial infarction during the previous six months; (e) a current or planned pregnancy within six months of treatment initiation; (f) hospitalization in the past two months for hypertension-related or psychiatric reasons, as this may indicated instability of the condition and/ or affect receipt of medication over which the patient may not have control; (g) currently receiving psychotherapy/ counseling; (h) taking psychotropic medication that may impact outcomes (e.g., depression) without stable dosage and/or with planned change(s) in dosage within six months of treatment initiation.

2.1.3. Major demographic characteristics: This sample consisted of individuals from the Philadelphia metropolitan area who received health care in an urban academic medical setting. Table 2 contains the sample means, standard deviations, and percentages of socio-demographic variables as well as relevant medical information. The age of total participants ranged from 35-71 years, with an average age of 58.58 (*SD* = 10.58) years [M_{ETAU} = 56.17 (11.62), M_{PST} = 61.00 (9.86)]. The majority of participants were female (66.7%; n_{ETAU} = 4, n_{PST} = 4). The racial composition of the sample was predominantly Black non-Hispanic 75% (n_{ETAU} = 4, n_{PST} = 5), with only 12.5% (n_{ETAU} = 2) White non-Hispanic and 6.3% (n_{PST} = 1) Asian non-Hispanic participants. This sample was comprised of a preponderance of Black persons and females, even higher than the distribution of those two demographics in the City of Philadelphia (United States Census Bureau, 2010). In terms of socioeconomic status, the most commonly reported estimated yearly household income was less than $20,000 (41.7%; n_{ETAU} = 2; n_{PST} = 3) and the average years of education was 14.17 (*SD* = 2.17, range 12-18 years). Regarding job status, 33.3% of participants reported working full-time (n_{ETAU} = 2, n_{PST} = 2), 25% were retired (n_{ETAU} = 1, n_{PST} = 2), 25% receiving disability/ government subsidy (n_{ETAU} = 2, n_{PST} = 1), and 16.7% unemployed/ seeking work (n_{ETAU} = 1, n_{PST} = 1). In this sample, 41.7% of participants indicated marital status as divorced/ separated (n_{ETAU} = 3, n_{PST} = 2), 33.3% as single/ never married (n_{ETAU} = 1, n_{PST} = 3), and 25% as married/ living with partner (n_{ETAU} = 2, n_{PST} = 1). All participants indicated they considered themselves religious or spiritual. In addition to the aforementioned sociodemographic variables, Table 1 also reflects self-reported medical comorbidities (e.g., diabetes, chronic kidney disease, cancer, human immunodeficiency virus, stroke, heart failure, obesity, sleep apnea), with 66.7% reporting at least one medical comorbidity (n_{ETAU} = 4, n_{PST} = 4), the most common of which was diabetes (41.7%; n_{ETAU} = 2, n_{PST} = 3).

2.2. Sampling procedures/ Recruitment: At the inception of recruitment, the calculated pool of potential participants within the target population was 15 patients per week (an estimated 25% of the sixty medical outpatients seen per week in a nephrology clinic had uncontrolled high BP). Access to potential participants was influenced by environmental factors (e.g., canceled appointments due to weather, transportation problems) and collaboration with physicians and staff (e.g., relationships developed with multiple providers, a few of whom vacated their positions at the hospital during recruitment). In addition to access, the likelihood of participation was considered. Research by Lang and colleagues (2013) and Wendler and colleagues (2006) found 73% and 45.3% of African Americans were willing to participate in health-related research and clinical intervention studies, respectively. Based on this literature, and in consideration of exclusion criteria, it was anticipated that about 25% of those with uncontrolled high BP would express interest in and be eligible to participate in the study. Of the estimated three to four potentially eligible and interested patients, approximately 50% were expected to enroll (i.e., one to two patients per week). As suggested in past research, efforts were made to attract Black individuals into this study through monetary compensation, conveyance of respect, advertisements showing the potential benefits of participation, flexible scheduling of assessments and reminders of assessments via telephone calls; however, due to limited resources, community outreach and partnerships were not feasible (Lang et al., 2013; Lukoschek, 2003; Yancey et al., 2006). An attrition rate for this study was expected to be similar to rates found in treatment outcome studies for stress management and PST among medical populations, which generally ranged from 12-25% (Davis & Addis, 1999; Nezu, Nezu, Felgoise, McClure, & Houts, 2003; Oxman, Hegal, Hull, & Dietrich, 2008). Thus, an initial timeline for recruitment was about

twelve months; after about twenty months, only fourteen patients had been enrolled in the study; for detail analysis, see discussion on feasibility.

2.2.1. Sampling method: Participants included individuals referred by health care providers who, at the time of referral, met eligibility criteria by having (a) high BP that was (b) uncontrolled. Health care providers were given instruction to invite/ refer any individual that meets criteria (a) and (b) to participate in the study, unless ineligibility is known, and avoid selection bias; this served as an initial pre-screening of patients. For in-person recruitment in one clinic, a research assistant approached a pre-screened patient after a 'warm handoff' from a physician. When in-person recruitment was not an option, it was requested that physicians provide the pre-screened and potentially interested patient with a study brochure, or, with permission from the patient, confidentially relay the contact information of the pre-screened patient to study personnel. Once referred and/or contacted, potential participants were given information about the research study and, if still interested and seemingly eligible, an appointment was scheduled with a research assistant to review the consent form and possibly complete the baseline assessment. If the patient was not randomized due to ineligibility or other constraints, local referrals/resources were provided. Medical records were used to confirm eligibility.

2.2.2. Setting: Participants were recruited from outpatient medical clinics within Drexel University College of Medicine (DUCOM), a University-affiliated hospital network in Philadelphia. Recruitment began in hypertension and nephrology clinics, and was later expanded to the women's health clinic, endocrinology clinic, and finally an internal medicine clinic. The option for community referrals were also approved by the institutional IRB, but due to limited resources, no advertisement or outreach was conducted to elicit participation from members of the community. Individuals from the community were occasionally referred to the study by a

family member or friend; these individuals were required to provide the contact information of a physician who could confirm the presence of uncontrolled high BP, but none were interested and eligible.

2.2.4. Agreements and Payments: Participants were compensated for assessments as follows: $5 (baseline), $20 (posttreatment) and $20 (3-month follow up) for a total of $45 (payment per participant).

2.2.5. Institutional Review Board: The study protocol was approved by the Institutional Review Board of Drexel University.

2.3. Sample size, power, and precision: This study did not reach the sample size of 52, estimated for sufficient power given planned analyses (Cohen, 1992). Due to inadequate power to detect statistical significance at $p < 0.05$ without a large effect, and standard errors that indicated generally wide confidence intervals (CIs) poor precision, the primary focus was on effect size estimates. Fourteen participants were enrolled and randomized in this investigation, twelve of which initiated treatment (two unable to schedule a first session), and eleven of which completed treatment (one dropped out of treatment after two sessions; ten completed the full eight sessions of the program). Regarding 3-month follow-up assessment, seven participants completed the assessment ($n_{ETAU} = 4$; $n_{PST} = 3$, unable to reach one participant after posttreatment; $n = 3$ that had not yet completed the assessment). See Figure 2 for a depiction of this in a JARS flow diagram.

During the development of this research study, a priori power analysis indicated that a sample of 52 participants would allow researchers to detect mixed model interactions with a large effect size, $\alpha = 0.05$, and power of 0.80 (Cohen, 1992; Faul, Erdfelder, Lang, & Buchner, 2007). Although the efficacy of PST in this population had yet to be determined, results of a

meta-analysis conducted by Malouff and colleagues (2007) indicated that PST was statistically significantly more effective than treatment-as-usual and attention placebo across varying types of mental and physical health problems, with reportedly medium effect sizes (d = 0.54 compared to either condition). Additionally, these researchers also identified three factors associated with effect size, participation of PST developers, assigned homework, and training in problem orientation, all of which were present in this study (Malouff et al., 2007). Although the efficacy of PST has not been examined in a population with high BP before and therefore it cannot be assumed, there is indication that it may produce medium to large effect sizes.

2.4. Randomization: Random allocation was generated using a random numbers table, stratified by sex, with a randomly permuted block size of four and six. Block sizes of four and six were chosen to control the distribution of participants in each condition; block sized were small given the expectation of less than 30 participants enrolled in the study and randomly varied to increase the difficultly of guessing an assignment.

The sequence of random assignment was concealed from assessors. Randomly assigned conditions were sealed in envelopes and revealed only after a consenting participant completed his/ her baseline assessment. An individual experienced in generating random numbers tables and uninvolved in recruitment, assessment or intervention delivery, created the random numbers table prior to commencing any participant allocation. Research assistants were provided with standard, manualized training in study-related procedures, which included detailed consent and assessment procedures, as well as the steps involved in the allocation of a predetermined random assignment. The research assistant/ assessor that delivered the random assigned was documented so that person did not complete any future assessment of that given participant, ensuring every assessor was masked to the assigned treatment of the participant being assessed. After the

random assignment, participants received an explanation of the condition to which they were assigned, afforded opportunity to ask questions about the assignment, given treatment materials, and provided with information about contact with the participant's 'health coach' (i.e., interventionist).

2.5. Masking: Each participant's assessor was masked to the randomly assigned condition prior to the assessment. Participants were instructed to refrain from discussing any aspect of the study with the assessor at posttreatment and 3-month follow up assessments. Intervention deliverers and participants were not masked to the condition due to the differing content and delivery method of the two conditions; therefore, intervention deliverers were aware of the condition assignment, as were participants. All data collected during assessments were de-identified using a unique participant number. Intervention deliverers were masked from the participant's assessment data. The individual responsible for random assignment generation did not have access to the assessment data.

Assessors were masked to the assigned condition of individuals prior to conducting the assessment, and the interventionists were masked to individual assessment data through the use of password-protected databases. A select few research assistants were aware of the identification number associated with the consent and assessment data as necessary.

2.6. Measures: See Table 1 for a list of measures given at each timepoint and see Appendix D for employed measures.

2.6.1. Blood pressure: Three measures of BP contribute to the adverse effects of hypertension: average level, diurnal variation, and short term variability; the average level is considered to be the measure most clearly linked to morbid events and some evidence suggests BP variability may be a risk factor for cardiovascular morbidity in particular (e.g., Pickering, 2005). In this study,

the average level of BP was measured and designated as the primary BP outcome variable. A reduction of 5 mmHg was considered clinically meaningful (Whelton et al., 2002).

Trained personnel used an automatic BP monitor (Omron 3 series, BP710) to read each participant's SBP, DBP and pulse. According to the *Omron Instruction Manual for the Automatic Blood Pressure Monitor Model BP710 (HEM-7113-Z)*, the automatic BP monitors used in the study has been calibrated to ±3mmHg or 2% of the reading. The Omron automatic BP monitor has been tested in accordance with protocols of the Association for the Advancement of Medical Instruments (AAMI) and the European Society of Hypertension (Grim & Grim, 2010). This method of reading BP is commonly used in outpatient medical clinics. A mercury sphygmomanometer using the Korotkoff sound technique was not chosen for use in this investigation, despite having been the standard approach for clinic BP monitoring for decades (Pickering, 2005); due to concerns about reliability when performed by research assistants without experience in this method, feasibility, practicality and environmental safety of a mercury sphygmomanometer, an automatic BP monitor was preferable for use in this study.

Assessor competency was determined by observation and evaluation of the correct procedures according to the instruction manual. Trainees were required to watch an educational/training video (e.g., a web-based video on the Mayo clinic website). Retraining was conducted periodically or as needed.

To control for avoidable inaccuracies, competent assessors were provided with specific written instructions that described the procedures for properly measuring BP. Although BP is inherently variable, a standardized method has been recommended to facilitate accuracy. The pressure accuracy of the automatic BP monitor has been calibrated to ±3mmHg or 2% of the reading; this accuracy was confirmed using a mercury sphygmomanometer prior to its use. To

control for deviations in BP measurement, the room temperature, positioning of the arm, and background noise (i.e., in a quiet room) were held as consistent as possible. Individuals were asked to refrain from eating, bathing, exercise, alcohol, and caffeine or nicotine consumption for 30 minutes prior to the assessment, as recommended in the instruction manual for the device due to their impact of BP readings. Prior to the assessment, individuals were also told that, as part of the standard method of measuring BP, he/she may be asked to remove clothing, or not wear clothing, that covers the upper arm where the cuff is typically placed. After 3-5 minutes of quiet rest by the individual, the assessor placed the appropriately sized BP cuff on the upper arm about ½ above the elbow, and ensured that the tubing fell in the front center of the participant's arm. Prior to and during BP measurement, participants were be asked to sit comfortably, legs uncrossed, and with the back and arm supported (i.e., muscle tension in the arm was discouraged by supporting it) so that the middle of the cuff of the upper arm was at the level of the right atrium (i.e., mid-point of the sternum). The participant was reminded to rest quietly and refrain from talking and/or moving during BP measurement. A BP reading was taken in both right and left arms initially (baseline only), and an additional two readings were taken in the arm with the higher reading (use same 'highest" arm for following assessments). About 2-3 minute lapses were provided between measurements in the same arm. Average DBP and SBP were calculated for each arm (during baseline), and the arm with the higher average BP was used for posttreament and 3-month follow-up assessments. If the monitor did not record a reading (error, 'E'), the assessor repositioned the cuff and repeat the procedures for BP measurement, as is recommended in the instruction manual for the device.

2.6.2. Social problem-solving ability: *Social Problem-Solving Inventory-Revised: Short-Form*: (SPSI-R:SF; D'Zurilla, Nezu, & Maydeu-Olivares, 2002). This is the short, 25-item version of

the SPSI-R, which was derived from a factor analysis of the original theory-driven Social Problem-Solving Inventory (SPSI) developed by D'Zurilla and Nezu (1990). It measures SPS ability and is comprised of five scales: (a) positive problem orientation (view problems as challenges and as solvable, maintain good self-efficacy, accept problems as part of life, understand that problems take time and effort to solve) (b) negative problem orientation (view problem as threats and unsolvable, doubt one's ability to cope successfully with problems, become frustrated and upset when facing problems or negative emotions), (c) rational problem solving (planful attempts to cope with stressful problems), (d) impulsivity/carelessness style (tendency to engage in impulsive, hurried or incomplete attempts to solve problems), and (e) avoidance style (tendency to avoid problems, procrastinate, and depend on others to solve problems). The inventory provides both a total score of SPS ability and single scores for each of the five SPS scales. Higher scores on a given scale indicate higher levels of that particular dimension. Research suggests that the SPSI-R contains strong psychometric properties (i.e., internal consistency of $\alpha = 0.79$ to 0.95 across scales, test-retest reliability for the total score ranging from 0.89 to 0.93, and evidence of strong structural, concurrent, predictive, convergent and discriminant validity according to D'Zurilla and colleagues, 2002).

2.6.3. Stress: *Perceived Stress Scale* (PSS; Cohen, Kamarck, & Mermelstein, 1983). This widely used, valid and reliable measure of one's perception of stress and the degree to which situations in one's life are appraised as unpredictable, uncontrollable, and overloaded. It consists of ten items and uses a self-report format. Items and the response scale, ranging from never to very often, are easy to understand and the measure typically takes about five minutes to complete. Questions on the PSS asked about feelings and thoughts during the last month and respondents

rate how often they've felt a certain way. Perceived stress has been shown to influence high BP, and this commonly used measure served as a means of assessing it.

2.6.4. Quality of life: *Short Form Health Survey, Version 2* (SF-12v2; Ware, Kosinski, & Keller, 1996). This general, standardized health-based survey instrument consists of 12 items extracted from the Medical Outcomes Study 36-Item Short Form Health Survey (SF-36). This brief measure typically takes about two to three minutes to complete. The SF-12 is considered to be a valid and reliable assessment (e.g., Jenkinson et al., 1997; Ware, Kosinski, & Keller, 1996; Ware, Koslinki, Turner-Bowker, & Gandek, 2002). The measure assesses health-related quality of life (HRQOL) using eight scales that represent various health-related concepts (i.e., physical functioning, role limitations because of physical health problems, bodily pain, social functioning, general mental health, role limitations because of emotional problems, vitality and general health perceptions). The measure contains two summary scales, the physical component summary (PCS) and the mental component summary (MCS), representing physical health and mental health, respectively, both of which had reliability scores above 0.80 (Ware et al., 2002). Using scoring software by QualityMetric Incorporated, summary measures of mental and physical health are generated by aggregating information from the eight health domain scales, then recoding and transforming *z* and *T* scores on a 0-100 scale (Ware et al, 2010). Higher scores suggest better HRQOL, a *T* score 45 or greater represents average overall functioning in that dimension, and a 1 standard deviation below the mean indicates impaired functioning (Ware et al., 2010). This measure was included given the importance of HRQOL in general, and the finding of slightly poorer HRQOL for those with high BP compared to those without it (Trevisol, Moreira, Kerkhoff, Fuchs, & Fuchs, 2011).

2.6.5. Depression: *Patient Health Questionnaire, Nine-item* (PHQ-9; Spitzer, Kroenke & Williams, 1999). This is a brief, self-rated depression screening device adapted from the PRIME-ME TODAY and utilized across various medical conditions, including CVD (e.g., Kroenke, Spitzer, Williams, & Löwe, 2010; Spitzer et al., 1994). The PHQ-9 can be used as either a diagnostic algorithm for making a probable diagnosis of major depressive disorder (MDD) or as a continuous measure, with scores ranging from 0 to 27 (Kroenke et al., 2010). Responses range from "not at all = 0" to "nearly every day = 3;" cut points of 5, 10, 15, and 20 represent mild, moderate, moderately severe, and severe levels of depressive symptoms (Kroenke et al., 2010). A probable diagnosis of MDD may be considered if one of the first two symptoms (i.e., depressed mood or loss of interest) is endorsed and a respondent endorses at least five of nine symptoms as present "more than half the days" (the ninth item is counted is "several days" is endorsed; Kroenke et al., 2010). The PHQ-9 has been found be valid and reliable, as indicated by criterion validity and reliability estimates generally above 0.80; the PHQ-9 is sensitive to change and has been well-validated for detecting and monitoring depression (Kroenke et al., 2010). A five-point decline in the score is considered representative of a clinical significant improvement (Kroenke et al., 2010). Given the impact of depression on high BP and further health sequelae, this measure served as a means of exploring symptoms of depression as they relate to high BP.

2.6.6. Adherence: *Eight-Item Medication Adherence Scale* (MMAS-8; Morisky, Ang, Krousel-Wood, & Ward, 2008). This short self-report instrument was be used to measure adherence to (antihypertensive) medication. Morisky and colleagues (2008) employed primarily low-income, minority patients with hypertension and found this measure to be valid (i.e., good concurrent and predictive validity), reliable (α = 0.83) and scores significantly associated with BP control ($p <$

0.05). Medication adherence is a common barrier to high BP control, and was therefore important to assess.

2.6.7. Lifestyle behaviors: A self-report questionnaire was developed to gather basic information about participants' lifestyle behaviors generally, including diet, exercise, tobacco use, and alcohol consumption. Data gathered by the questionnaire served to determine differences between conditions on health behaviors that impact BP. The lifestyle behaviors questionnaire was intentionally brief, as compared to the use of standard comprehensive measures of health behaviors, to minimize participant burden. Items were based on empirically supported factors that impact BP.

In consideration of the time required a complete comprehensive measure of diet (e.g., the Food Frequency Questionnaire, which takes about 30 minutes to complete), and because diet was not a primary variable of interest, five items based on the Dietary Approaches to Stop Hypertension (DASH) recommendations were included in the lifestyle behavior questionnaire (Willett, 1998). Participants were asked to provide a response (i.e., "yes," "no," or "I don't know") to questions about whether they followed a DASH diet, both overall and specific to key eating recommendations (e.g., "Do you eat foods low in saturated fat, cholesterol and total fat?"). Note, for simplification, the questions did not contain specific information, such as servings or food content; therefore, the responses are limited to a self-reported general determination of a diet consistent with DASH.

Physical activity affects the ability of the heart to pump blood; regular physical activity allows the heart to pump more blood with less effort, resulting in less force against the arteries, thereby lowering BP (Simons-Morton, 2008). Participants were asked to report on the intensity of their physical activity, the frequency by which they engaged in at least thirty minutes of

physical activity (e.g., brisk walking), and how they would describe their activity level (i.e., vigorously, moderately, or seldom active). These questions were intended to assess the participant's physical activity in general and in comparison to recommendations for physical activity in adults by the American Heart Association (Eckel et al., 2014).

Tobacco use was measured because it affects BP by damaging arteries and increases risk of atherosclerosis, in addition to temporarily increasing BP (e.g., Mukamal, 2006). Participants were asked if they currently use tobacco products, how many tobacco products they smoke per day, and how soon after waking they use their first tobacco product.

Heavy consumption has been associated with hypertension, a link with several possible mechanisms (Husain, Ansari, & Ferder, 2014; Miller et al., 2005; Puddey & Beilin, 2006). Self-reported alcoholic beverage intake (e.g., average drinks per week, and number of alcohol binges per year) was measured (National Institute on Alcohol Abuse and Alcoholism, 2005).

2.6.8. Program Evaluation: This questionnaire was created to obtain feedback on participants' satisfaction with PST. Participants were asked to rate agreement with statements using a 5-point Likert scale, ranging from *completely disagree* (1) to *completely agree* (5). Items on the questionnaire were geared towards perceived credibility, effectiveness, and confidence in recommending the program to other patients with high BP.

2.6.9. Data Collection: Prior to the baseline assessment, potential participants were instructed to refrain from caffeine, alcohol or nicotine intake, eating or exercise at least 30 minutes prior to being assessed. Assessments were completed at timepoint 1, hereafter referred to as "baseline," timepoint 2, referred to as "posttreatment" (i.e., after eight sessions, about 8 weeks), and 3-month follow up (i.e., about three months after posttreatment assessment).

Assessors were masked to the treatment condition of the individual being assessed until after the assessment was completed. Those conducting the assessments were trained in standardized procedures for performing assessments validly and reliably. Assessors were instructed to follow a written protocol of assessment procedures.

When this study commenced, PST sessions were intended to be audio-recorded for quality assurance, with the participant's permission. Two evaluators were expected to independently rate treatment integrity (i.e., competence and adherence) for 15% of randomly selected sessions. Refusal to grant permission did not exclude an individual from participation in the study, and efforts were made to inform participants about confidentiality and address concerns. During this study, five of the six participants in PST were asked for permission (one was not due to error), two patients provided permission (with the same therapist) and the other three denied permission. Special attention was not initially devoted to the standardization or rehearsal of requesting permission, but given the authorization rate of 33.33%, a script for future use was developed in which the rational and confidentiality of recordings were emphasized.

Participants were asked to complete a brief questionnaire containing items that targeted comprehension, utilization, and credibility of the treatment. These forms were respondent friendly, easy to understand, and brief (i.e., less than 5 questions each in a checkbox format).

2.7. Research Design

2.7.1. Experimental Manipulation: This investigation was developed as a two (condition) by three (time) mixed factorial design. Participants were randomly allocated to the treatment condition (i.e., PST or ETAU). Assessments were completed at three timepoints (i.e., baseline, posttreatment, and 3-month follow up).

2.7.2. Problem-Solving Therapy (PST): In the PST condition, a manualized PST protocol adapted to this patient population was implemented. This protocol was derived from PST, the evidence-based psychosocial intervention that promotes the adoption and effective application of adaptive problem-solving attitudes and skills to solve stressful problems in everyday living (D'Zurilla & Nezu, 2007; Nezu, 2004). Based on recent revisions and updates by Nezu and Nezu (2012) and Nezu, Nezu, and D'Zurilla (2013), the PST intervention contained four "toolkits": (a) problem-solving multitasking (i.e., externalization, visualization, and simplification), (b) the "Stop, Slow Down, Think, and Act" (SSTA) method of approaching problems (i.e., emotional mindfulness and modulation), (c) healthy thinking and imagery (i.e., cognitive change techniques geared toward enhancing optimism self-efficacy and visualization to enhance motivation and decrease hopelessness), and (d) rational (or planful) problem solving (i.e., problem definition, generation of alternatives, decision making, and solution implementation and verification). Principles of SPS were integrated throughout treatment. The general PST protocol was adapted for a hypertensive population. The intervention contained strategies for delivering a culturally sensitive treatment (e.g., recognition of cultural values, previous discrimination, and the importance of family).

The intervention was conducted using an individual format. Treatment manuals were detailed and user-friendly (Appendix B). Advanced clinical psychology graduate students served as therapists. Each therapist provided the PST intervention to no more than four individuals at a given time. PST interventionists received at least eight hours of training in PST by treatment developers and experts in PST, Arthur M. Nezu, Ph.D., ABPP and Christine Maguth Nezu, Ph.D., ABPP. Christine Maguth Nezu, Ph.D., ABPP, a licensed clinical psychologist provided weekly clinical supervision for study therapists. Graduate student interventionists practiced delivering

PST with an individual who was not randomized, and whose data was therefore not analyzed. These 'practice patients' were not used for the ETAU condition, given the educational nature of the condition, as well as the structure (i.e., a script and invitation to ask questions) and brevity of the content. The purpose of this was to familiarize the interventionist with the protocol in a real setting, rather than training or role-play exercise, to reduce errors in the protocol and intervention delivery. It is notable that, of the five practice patients, three did not complete treatment; reasons for dropout included scheduling conflicts, and problems with transportation.

Individual sessions were delivered in an office conveniently located proximal to the medical clinic from which participants were referred. Individual treatment sessions were intended to be held approximately weekly for about eight weeks and last approximately sixty minutes in duration.

2.7.3. Enhanced Treatment as Usual (ETAU): This condition served as the control condition and was enhanced with patient-friendly educational materials regarding high BP (i.e., a compilation of patient materials on the DASH eating plan and other materials developed by the National Heart, Lung, and Blood Institute and other health organizations).

The ETAU condition entailed a manualized weekly telephone check-in to address questions about the delivered educational materials. Efforts were made to culturally adapt the content of this condition (e.g., culturally-sensitive examples). Patient-friendly educational materials consisted of information about high BP and guidance for lowering BP (e.g., steps to controlling high BP and recipes for heart health). Participants were asked to read a section for homework, typically one to three pages of information in the handbook.

Once randomized to this condition, participants received a handbook of patient-friendly educational materials (e.g., materials developed by governmental agencies to promote BP

control). A weekly session was performed via the telephone using a written script and protocol. Trained graduate students reviewed the materials, which included strategies for reducing high BP and an opportunity to ask questions about the information delivered. A standardized manual for delivering health education to participants was provided to interventionists. The weekly sessions were conducted over the telephone during a time convenient to the participant, preferably at a time and location with limited distraction. A patient-friendly handbook was given to each participant after he/ she was randomization to the ETAU condition. The frequency of sessions was intended to be about once per week and duration was estimated to be about 30 minutes.

2.8. Ethical considerations

2.8.1. Confidentiality: Confidential and its limits were discussed with potential participants as part of informed consent, in accordance with APA standards and IRB regulation (American Psychological Association, 2010; Drexel University, 2015). Data was physically and electronically locked and password-protected, respectively. All study personnel received training on data security and confidentiality. In compliance with the Drexel University Investigator Manual (2015), research records are kept for at least three years after completion of research.

2.8.2. Diversity: Given the health disparities affecting African Americans, as well as the high prevalence rates of high BP among African Americans and the expected predominance of this ethnic minority in the sample, it was important to tailor recruitment and treatments to this population. Informed by past research, drawing interest in participation from Black individuals during recruitment and providing culturally sensitive treatments were addressed through assessor and interventionist trainings (e.g., conveying respect in the delivery of treatment, understanding the important of family in this population), advertisements and manuals that included culture-specific preferences (e.g., depicting Black individuals engaging in health behaviors, recognizing

the structure and value of families in treatment examples), explaining the potential direct and indirect benefits of participation, being flexible in scheduling assessments and treatment sessions for participant convenience, and providing compensation, though only a small amount due to budget constraints (Lukoschek, 2003; Yancey et al., 2006).

2.8.3. Safety: There were no adverse events to report to the IRB according to its policies (Drexel University, 2015). Documentation of circumstances in which concerns for safety arose (e.g., dangerously high BP) was kept with other locked study documents.

Training in suicide risk assessment and the safety protocol was established in case a response greater than "0" on item number 9 of the PHQ-9 (i.e., "thoughts that you would be better off dead, or of hurting yourself" with a frequency greater than "not at all") was provided during an assessment, or if indication of suicidal ideation, intent or plan was verbally stated or otherwise perceived by interventionists and/or supervisors. The suicide safety protocol included instructions for contacting a clinical supervisor, providing telephone numbers for those in crisis, and, if deemed appropriate (i.e., high risk), escorting the participant to the nearest emergency room and alerting pertinent personnel.

A protocol for responding to dangerously high BP during an assessment was established and training was provided to study personnel. After consultation with a collaborating physician, dangerously high BP was operationally defined as a SBP reading ≥ 180 mmHg or DBP reading ≥ 110 mmHg (Chobanian et al., 2003). In cases of dangerously high BP during an assessment, participants were asked to contact his/ her physician directly or provide permission for the assessor to contact the participant's physician or a physician consulting on the study, or be willing to be escorted to the nearest emergency room.

2.8.4. Reporting: Reports derived from this study comply with Journal Article Reporting Standards (American Psychological Association Publications and Communications Board Working Group, 2008).

CHAPTER 3: RESULTS

3.1. Statistical Analyses: Analyses were performed using SPSS Version 22 software. Outlined hypotheses were determined a-priori, but planned analyses were necessarily modified due to small sample size, few participants with completed 3-month follow up assessment due to timing of analyses, as well as the distribution and dispersion of variables. The preferred method of testing this two-by-two (treatment-by-time) mixed factorial design was repeated-measures Analysis of Variance (RM ANOVA) with assessment point (baseline and posttreatment) as the within-participants variable and treatment condition (ETAU versus PST) as the between-participants variable. When homogeneity of variance was violated, as indicated by a statistically significant Levene's test, the best alternative was determined to be an independent samples *t*-test using change scores (i.e., baseline scores subtracted from posttreatment scores to account for change over time). Effect sizes were estimated and described as small, medium or large according to the standards set forth by Cohen (1992). In consideration of the inflation of type I error due to multiple tests, a conservative Bonferroni correction was considered for *t*-tests and the more powerful Sidek correction for ANOVAs, although no inferential tests yielded statistically significant results for interaction effects at $p < 0.05$ (Fields, 2005). Due to the influence of low sample size on power to detect statistical significant, effect size are of primary interest. Table 3 contains the means and standard deviations for each condition at baseline and posttreatment, as well as the results of *t*-tests and estimated effects sizes for outcome variables in which change scores were used. Table 4 contains means and standard deviations for each condition at baseline and posttreatment, as well as the *F*-ratio, level of statistically significance, and effect size estimate (i.e., partial eta-squared) for outcome variables in which a RM ANOVA was conducted.

3.1.1. Missing data: Efforts to minimize attrition were made (e.g., compensation for time and travel, flexibility in scheduling sessions and phone call appointment reminders). Intent-to-treat analysis was used to minimize the effects of attrition on study findings; however, imputation was used only for participants who initiated treatment (i.e., a dropout was operationally defined as a participant who ceased treatment after the first session) rather than any participant who was randomized. Although not superior to multiple imputation, means imputation was used rather than last observation carried forward (LOFC), in consideration of the effects of time on outcome variables. For other missing data, imputation was used in accordance with guidelines provided for each measure, most frequently the mean of a given scale or subscale of that case. Two cases, one randomized to each condition, were excluded from analyses. One case randomly assigned to the ETAU condition dropped out of the study after 2 sessions due to "family issues;" for this case, the ETAU means across variables at posttreatment were imputed as part of intent-to-treat (ITT) analyses ($N_{total} = 12$, $n_{ETAU} = 6$, $n_{PST} = 6$).

3.1.2. Assumptions of statistical tests: Prior to conducting analyses, the distributions of variables within each condition were inspected to determine whether assumptions of parametric tests were met, including normality, lack of significant outliers, and homogeneity of variance using descriptive statistics, graphical representations of data and established tests (e.g., Fields, 2009). The Shapiro-Wilk test indicated that the distribution of DBP was non-normal, as were the distributions of a few demographic variables and health behavior variables. Transformations were used for distributions that were non-normal and contained outliers.

3.1.3. Determination of covariates: Baseline data were examined for between-condition differences using *t*-tests with equal variance not assumed for variables yielding a significant Levene's test, the nonparametric Mann-Whitney U for non-normally distributed continuous

variables, Pearson's Chi-Square test for categorical variables, or Fisher's Exact when the expected cell count was less than five. As expected with random assignment, there were no statistically significant between-condition differences across variables at baseline.

3.1.4. Preliminary efficacy: A major objective of this study was to determine the preliminary efficacy of PST as compared to ETAU, in patients with high BP. A series of hypotheses extend from this aim, as discussed below; these include evaluating changes in SBP and DBP, SPS ability, medication adherence, mental and physical HRQOL, and depressive symptoms between treatment conditions from baseline to posttreatment.

A change/ gain score approach was used to examine the mean differences in SBP between ETAU and PST from baseline to posttreatment, rather than the preferred mixed RM ANOVA, because the assumption of homogeneity of variance was violated (i.e., Levene's test indicated that variances between conditions were statistically significantly different at posttreatment). On average, participants in both the ETAU (M = -8.27, SD = 15.87) and PST (M = -10.11, SD = 9.34) conditions showed reductions in SBP from baseline to posttreatment but the mean differences between conditions over time were not statistically significant [$t(10) = 0.25$, $p = 0.81$], and the effect size (d = 0.14) was small. As would be expected given the small sample size, the 95% confidence interval was large (-14.91 to 18.59), indicating the estimate of the population mean was not precise.

The distribution of baseline DBP was non-normal, and transformations did not significantly improve normality; therefore, a change/ gain score approach was employed to examine mean differences in DBP between conditions from baseline to posttreatment. On average, participants in both the ETAU (M = -7.73, SD = 11.77) and PST (M = -1.61, SD = 9.31) conditions showed reductions in DBP from baseline to posttreatment. The difference between

mean change scores of the two conditions was not statistically significant [$t(10)= 0.99$, $p = 0.34$, 95% CI = -19.77 to 7.53), so the null hypothesis was not rejected. Results indicated a medium-sized effect ($d = 0.58$) of ETAU compared to PST.

To test the hypothesis that the PST condition would have statistically significant improvements in SPS ability, compared to ETAU, from baseline to posttreatment, a RM ANOVA was used. Results showed a large main effect of time that was not statistically significant [F (1, 10) = 3.74, $p = 0.08$, $\eta_p^2 = 0.27$]. The interaction of time and condition on SPS ability was also not statistically significant [F (1, 10) = 0.02, $p = 0.89$]. The magnitude of the difference between conditions ($\eta_p^2 = 0.002$) indicated a trivial 0.2% of the variance in SPSI-R: SF scores accounted for by treatment condition.

A RM ANOVA showed a main effect of time that was not statistically significant, with a very small effect size [F (1, 10) = 0.004, $p = 0.950$, $\eta_p^2 < 0.001$]. An examination of the time-by-treatment interaction showed a large effect of PST compared to ETAU [F (1, 10) = 2.54; $p =$ 0.14; $\eta_p^2 = 0.20$]. Figure 3 illustrates the increase in average medication adherence over time for those in the PST condition, while those in the ETAU condition decreased in adherence.

Due to a violation of homogeneity of variance according to Levene's test, a change/ gain score approach was utilized to examine mean differences in mental HRQOL between conditions across timepoints. Contrary to the stated hypothesis, no statistically significant differences were found between conditions [$t(6.40)= 1.14$, $p = 0.30$, 95% CI = -6.69 to 18.72)] and those in the ETAU condition showed greater improvements (medium effect, $d = 0.66$) in mental HRQOL.

To test the hypothesis that the PST condition would show statistically significant improvements in the physical dimension of HRQOL, compared to ETAU, a RM ANOVA was used. Results for the main effect of time were not significant and the magnitude of the effect was

small [F (1, 10) = 0.27, p = 0.61, η_p^2 = 0.03]. The time-by-condition interaction indicated that, on average, physical HRQOL of those in the ETAU decreased over time, whereas those in the PST condition showed improvement in physical HRQOL that was large in magnitude (F(1,10) = 2.54, p = 0.14, η_p^2 = 0.20; Figure 4).

A RM ANOVA yielded a statistically significant main effect of time on perceived stress [F (1, 10) = 12.303, p = 0.006], with a large effect size (η_p^2 = 0.55). The interaction of time and treatment condition did not show a statistically significant effect [F (1, 10) = 0.25; p = 0.63], and the effect size that was revealed was small (η_p^2 = 0.03).

To test the hypothesis that the PST condition would demonstrate statistically significant improvements in depression from baseline to posttreatment, compared to ETAU, a RM ANOVA was used. Results suggested a main effect that was large in magnitude, but not statistically significant [F (1, 10) = 2.21, p = 0.17, η_p^2 = 0.18]. The interaction of time and condition on depression was not statistically significant [F (1, 10) = 0.05, p = 0.82, η_p^2 = 0.005].

3.1.5. Feasibility: This aim examined the feasibility of conducting an RCT in this population as the study is designed, which includes the acceptability of the treatments by patients with uncontrolled high BP. Figure 2 shows the flow of participants according to JARS.

It was hypothesized that 80% of participants would be retained in treatment, as defined as having attended at least 6 sessions of PST or ETAU (i.e., an attrition rate of 20% or less). Completion was constituted by a minimum of 6 sessions. The completion rate of participants in the PST was 100% for those who initiated PST and 85.7% for those who were randomized to PST. For the ETAU condition, the rate of completion was 83.3% for those who initiated treatment (one participant dropped out after 2 sessions due to stated “family issues”) and 71.4% of those who were randomized to ETAU. Of particular interest, the high completion rate of PST

was consistent with other studies involving PST. Of note, attempts were made to contact the two participants who were randomized but never initiated treatment to ascertain reasons for not showing to a first session; one patient was unable to be reached and the other was unable to attend after multiple attempts due to scheduling conflicts.

To determine the feasibility of delivering treatment over the course of eight weeks, data was collected on time number of days from session one to session eight. The average number of days to complete eight sessions of treatment was M_{ETAU} = 55.40 (*SD* = 7.99) and M_{PST} = 63.17 (*SD* = 14.13). These averages indicate that it is feasible to conduct the treatment within eight to eleven weeks. Data collected on the time elapsed from session eight to posttreatment assessment was consistent with the estimated hypothesized for the PST condition, but not the ETAU condition [M_{ETAU} = 16.00 days (*SD* = 10.08); M_{PST} = 13.83 days (*SD* = 12.73). The average number of days from posttreatment assessment to 3-month follow up assessment was within the hypothesized range [M_{ETAU}= 102.50 days (*SD* = 7.77); M_{PST} = 100 days (*SD*= 2.65)]. Because of barriers to attendance (e.g., medical appointments, transportation, adequate funds, and family obligations) made it difficult to attend sessions on a consistent weekly basis, attempts were made to be flexible in scheduling treatment and assessment sessions. This led to slight adaptations to the preferred timing of treatment and assessment sessions, including one instance in which two treatment sessions were scheduled in one week to compensate for a missed session, as well as times when participants were seen on a biweekly basis for a brief period of time.

As hypothesized, the percentage of participants who found this treatment acceptable (i.e., average ratings of 4 out of 5 or higher on items targeting credibility, effectiveness and confidence in recommending the treatment) was about 80% (M_{ETAU}= 80%; M_{PST} = 83.3%). It should be noted that this estimate reflects the satisfaction of participants who completed a

posttreatment assessment, all of whom completed treatment, and does not capture the opinions of participants who did not received a first session or who dropped out prior to completion.

3.1.6. Exploration of follow up: Only very limited 3-month follow-up data was available (n_{ETAU} = 4, n_{PST} = 3); basic inspection of means and graphs seemed to indicate limited maintenance of treatment gains. For inferential testing and more valid comparison of treatments over time, it is necessary to gather more data.

CHAPTER 4: DISCUSSION

High BP is present in an alarmingly high rate of adults in the U.S. (i.e., it affects approximately one in three adults), disproportionately impacts African Americans, is a major risk factor for heart disease and stroke, and costs the U.S. billions of dollars each year (Chobanian et al., 2003; IOM, 2010; Lloyd-Jones et al., 2010; Nwankwo, Yoon, Burt, & Gu, 2013; Roger et al., 2012). Although high BP is preventable and modifiable, the prevalence of high BP continues to rise, and control remains relatively poor (IOM, 2010). Controlling high BP remains challenging, particularly in African Americans, due to a host of biological, environmental, and behavioral factors (Fuchs, 2011). Psychosocial factors, including chronic stress and health behaviors, have been recognized as important in the development and treatment of high BP, having both direct and indirect effects. However the evidence base for psychosocial treatments has largely been considered inadequate or inconsistent (Bosworth et al., 2011; Blumenthal, et al., 2002; IOM, 2010; Linden, et al., 1996; Rainforth et al., 2007).

There remains a need to establish an intervention that is effective in reducing high BP in the real world, particularly for African Americans. PST is an evidence-based CBT that promotes the adoption and effective application of adaptive problem-solving attitudes and skills for dealing

with stressful problems in living. Before examining the effectiveness of PST in this context, it was first necessary to conduct this pilot RCT to determine preliminary efficacy and feasibility.

The current study investigated the preliminary efficacy and feasibility of a PST intervention compared to an educationally-based ETAU condition, aimed at reducing BP, stress, and depression, while improving SPS ability, HRQOL, medication adherence. Main objectives were twofold: compare the effects of PST and ETAU from baseline to posttreatment, and assess the feasibility of implementing a full scale RCT in a predominantly Black, urban outpatient medical population.

4.1. Preliminary Findings:

4.1.1. Efficacy: A series of hypotheses were tested to determine preliminary efficacy of PST compared to ETAU across biopsychosocial outcomes. No statistically significant time-by-treatment interactions were found; this is not surprising given the small sample size ($n_{ETAU} = 6$, $n_{PST} = 6$). Rather than focusing on statistically significant effects, attention was placed on the magnitude and clinical significance of effects. RM ANOVAs yielded a large effect of time on outcome for SPS ability, perceived stress, and depression. Although these effects are notable, with a number of possible explanations (e.g., improved health education; experimental artifact), the primary focus was on the efficacy of PST compared to ETAU and clinically significant changes in outcomes.

Regarding blood pressure, participants showed reductions over time that were not statistically significant or differential between conditions; the main effect of time may be attributed to a number of factors, including treatment effects and medication effects. Those in the PST condition showed slight greater reductions in SBP on average, and those in the ETAU condition had greater reductions in DBP on average. A greater number participants ($n_{PST} = 4$) in

the PST condition showed clinically significance reductions in SBP (i.e., ≥ 5mmHg) compared to the ETAU condition (n_{ETAU} = 2) and half of those in either condition show clinical reductions in DBP. The results provide small preliminary indication that PST may produce meaningful reductions in high BP; however, as discussed in the limitations sections, the generalizability of such findings is limited given the low sample size, as well as concerns about confounding variables (e.g., medication effects) and threats to validity and reliability.

Regarding medication adherence, results showed a trend toward greater efficacy of PST compared to ETAU (η_p^2 = 0.20) and one participant in the PST condition showed a clinically significant improvement in medication adherence. Given the significant problem nonadherence poses to health outcomes, this finding highlights the potential value of PST. Medication adherence was not specifically targeted in the PST manual, but may have been identified by participants as a problem to target. It may be possible to amplify the effect of PST on medication adherence by standardizing it as a problem to target within the treatment.

PST and ETAU had differential effects on HRQOL compared to one another, with a greater effect of ETAU on the mental health component of HRQOL (d = 0.66), and a larger effect (η_p^2 = 0.20) of PST shown on the physical component of quality of life. At first glance, given PST is an evidence-based mental health treatment, these findings were surprising; however, upon close inspection of the clinical significance of changes from baseline to posttreatment, the mental component summary data shows two participants from the PST condition showed clinically significant improvements compared to only one participant in the ETAU condition. These findings are consistent with literature supporting the benefits of PST on improving mental health. Of note, one participant in the PST condition showed a clinically significant decline in this dimension. In examining the physical component of HRQOL (e.g., physical functioning and

role limitations because of health problems), there was a trend towards greater improvement for those receiving PST; however, none of these changes represented clinical significance.

It was hypothesized that those in the PST condition would show greater improvement in SPS ability, perceived stress, and depression, given the cognitive-behavioral roots, clinical targets and evidentiary support of the PST related to these constructs. Surprisingly, there were virtually no meaningful differences between PST and ETAU across these variables. Possible explanations for the lack of mean differences include threats to validity, namely restricted range of scores (e.g., SPS ability generally fell in the normal range, depression scores were, on average in the minimal to mild range) and demand characteristics, compromised integrity of the treatment (e.g., an interventionist used PST unintentionally in the delivery of ETAU), and overlap between the treatments (e.g., both treatments use a problem-solving approach). Notably, one participant in the PST condition showed a clinically significant reduction in depression.

Overall, preliminary evidence, ranging in magnitude and type (i.e., efficacy versus clinical significance), suggest a possible trend toward the efficacy of PST for uncontrolled high BP. Specifically, compared to ETAU, PST showed a greater preliminary effects on SBP, medication adherence, physical functioning, SBP, as well as a greater percentage of clinically significant improvements in mental HRQOL. This evidence is preliminary, with a number of limitations to consider; as such, it is necessary to further evaluate efficacy.

4.1.2. Feasibility: Not only was it important to determine the preliminary efficacy of PST compared to ETAU, it was also imperative to assess whether conducting a larger RCT would be feasible, given real-world constraints (e.g., access to participants).

As shown in Figure 2, 13.0% ($N = 14$) of the 108 patients recruited across multiple medical outpatient clinics over about 20 months were enrolled; of those who did not enroll,

43.6% did not meet inclusion criteria, 4.3% were excluded, 25.5% refused to participate, and 25.5% were unable to be fully assessed. The challenge of obtaining an adequate sample size is expected given the financial and environment constraints of an urban setting that serves primarily patients of low SES; with an awareness of such constraints, efforts were made to enhance recruitment, but these appeared insufficient. Perhaps prioritization of community outreach/ partnership (e.g., through already established university networks) or utilization of strategies effective in similarly difficult to enroll populations (e.g., motivational interviewing, health education) during recruitment would have improved enrollment.

Completion rates for both PST and ETAU indicated strong retention of participants once treatment was initiated; for participants who were randomized, the percentage was slightly lower, but still acceptable at about 20%. Treatment was completed in a reasonable timeframe, about eight to nine weeks and assessments were typically completed within three weeks of the expected time; this may have been impacted by efforts to make participation more accessible to patient's including attempts were made to make both treatment sessions and assessment as convenient as possible, given barriers to attendance (e.g., medical appointments, transportation, adequate funds, and family obligations). Fidelity was not assessed due to a lack of adequate audio-recordings.

The majority of participants who completed treatment rated it as acceptable in terms of credibility and effectiveness (i.e., greater than provided ratings ≥ 4 out of 5). Data on those who did not complete treatment is not available; therefore, this estimate is biased because it is unknown how acceptable the treatments were to all randomized participants.

4.3. Limitations: Findings of this study must be interpreted with caution, as there are a number of factors that threaten validity and reliability. The limitations are expected when attempting to

conduct research in a real-world context, with its accompanying restraints (e.g., not using highly restrictive inclusion criteria, modest financial and practical resources). Analyses were performed with a small sample size insufficient in reflecting the population, although the demographic make-up does reflect the high rates of high BP among Black women. The small sample size negatively impacted the power to detect statistically significant differences, hence the primary focus on effect sizes. Involvement in the community, rather than medical outpatient clinics as a main source of recruitment, has been shown to assist in engaging minority populations and would likely increase the rate of participant accrual, though this was not feasible given a lack of adequate resources. This may be especially true for patients with high BP, in that many are unaware of the condition and have little education about its effects, so they may not seek medical care (Chobanian, et al., 2003).

The data collected thus far, and analyzed contained non-normal distributions, heterogeneous variance, and outliers, thereby violating assumptions of inferential tests and limiting the types of statistical analyses possible. Regression to the mean and measurement error (e.g., inaccurate BP readings) may have impacted changes scores, which were necessary to use for a few variables.

Although intent-to-treat analysis was used to minimize the effects of attrition on study findings, imputation was performed only on cases that were considered dropouts (i.e., participants who ceased treatment after at least one session) and two cases that were randomized but not considered dropouts were deleted. A single participant from each study condition did not attend a first session after random assignment (e.g., unable to be reached via telephone or mail after multiple attempts or unable to attend a first session via telephone or in person); therefore, two cases were excluded from analyses (see Figure 2). Because these participants were unable to

be reached, no data beyond baseline was collected. Although attrition was not differential between groups in this regard, it is unknown whether participants who did not attend a first session differ from those who attended at least one session, and as such, serves as another limitation generalizability of findings.

With the aim of evaluating feasibility, sampling was intentionally performed in the context of a real-world medical setting; thus, it was necessary to balance methodological ideals within a limiting real-world environment. Additionally, due to limited resources, the study sample was drawn from medical outpatient clinics in one urban hospital network, and consisted of patients who showed for appointments, volunteered to participate and had the resources to attend assessments and treatment sessions (e.g., access to transportation). The small amount of compensation was, in some cases, not enough to cover the cost of public transportation to attend the PST sessions.

Regarding BP in particular, a number of other factors may have influenced findings, such as unreported changes in medication, reliance on self-report (e.g., for medication adherence), and unmeasured factors (e.g., weight changes). The majority of patients referred to the study came from a hypertension clinic; medication was often prescribed or changed during the appointment. As such, it is possible that the effects of that medication occurred after baseline and before posttreatment, thereby confounding change observed over time. Although participants were asked to report changes in medication, it is possible that changes were not reported.

4.4. Future Directions: This pilot investigation was the first randomized controlled trial to examine the efficacy and feasibility of PST compared to ETAU across various outcomes in a sample of individuals with uncontrolled high BP. There are a number of recommendations to improve the validity and generalizability of findings. First, continued data collection is needed to

increase the sample size, which should lead to more precise parameter estimates and the ability to use hierarchical modeling to examine effects longitudinally, including 3-month follow up data and mediators/ moderators of outcomes. Second, recruitment should be expanded to include community outreach in the form of building relationships with community leaders, creating a presence at community events/ activities (e.g., church services), and utilizing already established pathways between the university and the community. Third, increase compensation, if possible, and other means to reduce barriers to participation and increase interest. Fourth, examine weight as a possible covariate by measuring it at each assessment timepoint, given the association between weight loss and reductions in high BP (e.g., Brook et al., 2013; Harsha & Bray, 2008). Fifth, re-evaluate the device used to measure BP and consider an ambulatory blood pressure monitor, or other accurate methods, if funding is available. Sixth, examine fidelity in the delivery of PST; this may involve efforts to increase the likelihood of receiving permission to record sessions (e.g., as mentioned, a script for interventionists to use). Seventh, gather data from interventionists on the implementation of PST; this should include, for example, acceptability of the treatment, comprehension, ease of delivery, and feasibility given time restrictions. Eighth, conduct qualitative and quantitative analyses of participant utilization of PST strategies, including rate of homework completion, comprehension and utilization outside of and after treatment as well as preferences for treatment modality (e.g., in person, telephone, web-based options). Ninth, collect data from dropouts, if possible. And lastly, revise the PST treatment manual to be better adapted to patients with high BP after gather feedback from participants and interventionists on this (e.g., target specific problems like adhering to medication, meeting dietary restrictions). Given the preliminary trend towards the efficacy of PST, it is recommended that the aforementioned enhancements be used to further improve feasibility and evaluate PST

for reducing uncontrolled high BP and depression, and improving SPS ability, medication adherence, and HRQOL within a predominantly Black population.

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APPENDIX A: Tables and Figures

Table 1
List of Measures at Each Timepoint, Range of Possible Scores, and Clinical Significance

	Pre	Post	3-mo. FU	Estimate of Time (minutes) to Complete	Range of Scores	CS
Descriptive Measures						
Demographics Form	X			5		
Lifestyle Behaviors Questionnaire (LBQ)	X	X	X	5		
Feasibility Measures						
Treatment Expectations/ Acceptability (completed after the first session)	X	X		5		
Outcome Measures						
Blood Pressure (mmHg) (average of 3 readings) - Systolic Blood Pressure - Diastolic Blood Pressure	X	X	X	10-20	0-299	**Δ** -5
Social Problem Solving Inventory- Revised: Short Form (SPSI-R: SF)	X	X	X	10	0-20	
Morisky Medication Adherence Scale (MMAS-8)	X	X	X	5	0-8	**Δ** ≥2
Short Form Health Survey 12 (SF-12) - Mental Component Summary (MCS) - Physical Component Summary (PCS)	X	X	X	2-3	0-100	±10
Perceived Stress Scale (PSS)	X	X	X	5-10	0-40	
Patient Health Questionnaire (PHQ-9)	X	X	X	5	0-27	≤9 and **Δ** -50%

Note: Pre, baseline timepoint; Post, posttreatment timepoint; 3-mo. FU, 3-month follow-up timepoint; CS, clinical significance for that measure; Δ, change.

Table 2
Characteristics of Sample- Self-Reported Socio-demographic Information

Variable	Category	*Mean* (*SD*) or % (*n*)		
		Total	ETAU	PST
*Age (years)		58.6 (10.6)	56.2 (11.6)	61.0 (9.9)
Sex	Female	66.7% (8)	66.7% (4)	66.7% (4)
	Male	33.3% (4)	33.3% (2)	33.3% (2)
Race	Black	75.0% (9)	66.7% (4)	83.3% (5)
	White	16.7% (2)	33.3% (2)	0.0% (0)
	Asian	8.3% (1)	0.0% (0)	16.7% (1)
*Education (years)		14.2 (2.2)	13.7 (2.0)	14.7 (2.4)
**Household Members		2.5 (1.6)	2.0 (0.7)	2.8 (2.1)
Household Income	< $20,000	41.7% (5)	33.3% (2)	50.0% (3)
	$20,000-$40,000	8.3% (1)	16.7% (1)	0.00% (0)
	$40,000-$60,000	33.3% (4)	16.7% (1)	50.0% (3)
	$60,000-$80,000	8.3% (1)	16.7% (1)	0.0% (0)
	$80,000-$100,000	8.3% (1)	16.7% (1)	0.0% (0)
Marital Status	Divorced/ Separated	41.7% (5)	50.0% (3)	33.3% (2)
	Single/ Never Married	33.3% (4)	16.7% (1)	50.0% (3)
	Married/ Partnered	25.0% (3)	33.3% (3)	16.7% (1)
Religious/ Spiritual	Yes	100% (12)	100% (12)	100% (12)
	No	0.0% (0)	0.0% (0)	0.0% (0)
Current Job Status	Working Full Time	33.3% (4)	33.3% (2)	33.3% (2)
	Retired	25.0% (3)	16.7% (1)	33.3% (2)
	Disability/ Subsidy	25.0% (3)	33.3% (2)	16.7% (1)
	Unemployed	16.7% (2)	16.7% (1)	16.7% (1)
***Years since diagnosis		12.6 (9.2)	13.7 (9.8)	11.4 (9.4)
≥1 medical comorbidity	Yes	67.7% (8)	67.7% (4)	67.7% (4)
	No	33.3% (4)	33.3% (2)	33.3% (2)
≥2 medical comorbidities	Yes	16.7% (2)	33.3% (2)	0.0% (0)
	No	83.3% (10)	66.7% (4)	100% (6)
Family History of high BP	Yes	91.7% (11)	100% (6)	83.3% (5)
	No	8.3% (1)	0.0% (0)	16.7% (1)
Treatment Completer	Yes	91.7% (11)	83.3% (5)	100% (6)
	No	8.3% (1)	16.7% (1)	0.0% (0)
**Medication Change during study	Yes	27.3% (3)	60.0% (3)	0.0% (0)
	No	72.7% (8)	40.0% (2)	100% (6)
**Hospitalized during study	Yes	9.1% (1)	0.0% (0)	16.7% (1)
	No	90.9% (10)	100% (5)	83.3% (5)
**Other Service during study	Yes	27.3% (3)	40.0% (2)	16.7% (1)
	No	72.7% (8)	60.0% (3)	83.3% (5)

Note: * denotes N_{total}=12, n_{ETAU}=6, n_{PST}=6; ** denotes N_{total}=11, n_{ETAU}=5, n_{PST}=6; *** denotes N_{total}=11, n_{ETAU}=6, n_{PST}=5.

Table 3

Means ±SDs for ETAU and PST at Baseline and Posttreatment, and t-Test Results and Effect Sizes using Change Scores

	ETAU Mean ± SD		PST Mean ± SD				
Measure	Pre	Post	Pre	Post	*t*	*p*	Cohen's *d*
SBP	153.61 ±17.29	143.07 ± 8.93	162.11 ±22.17	152.00 ±21.99	0.25 [a]	0.81	0.14
DBP	88.56 ±9.67	81.74 ±8.25	93.83 ±6.77	92.22 ±15.26	0.99 [a]	0.34	0.58
$SF12_{MCS}$	45.49 ±3.73	51.96 ±4.25	47.38 ±9.06	47.87 ±12.85	1.14 [b]	0.30	0.66

Note: ETAU, enhanced treatment as usual; PST, Problem-Solving Therapy; Pre, baseline timepoint; Post, posttreatment timepoint.

[a] $df = 10$

[b] $df = 6.40$

Table 4

Means ±SDs for ETAU and PST at Baseline and Posttreatment, and Time-by-Treatment Interactions with Effect Size Estimates using RM ANOVA

	ETAU Mean ± SD		PST Mean ± SD				
Measure	Pre	Post	Pre	Post	F (1, 10)	p	η_p^2
SPSI-R	14.57 ±3.33	15.83 ±3.43	13.57 ±1.33	14.66 ±2.20	0.02	0.89	0.002
MMAS	6.04 ±1.86	5.50 ±2.14	6.25 ±1.20	6.75 ±1.57	2.54	0.14	0.20
$SF12_{PCS}$	46.04 ±10.20	42.14 ±8.80	37.67 ±10.31	39.66 ±11.56	2.54	0.14	0.20
PSS	19.33 ±3.50	13.20 ±6.24	19.33 ±5.28	14.50 ±7.15	0.25	0.63	0.03
PHQ-9	5.00 ±2.76	4.40 ±4.08	8.50 ±7.99	5.50 ±7.69	0.05	0.82	0.005

Note: ETAU, enhanced treatment as usual; PST, Problem-Solving Therapy; Pre, baseline timepoint; Post, posttreatment timepoint.

Figure 1

Hypothesized model of social problem solving in relation to distress, health behaviors, and medical disease among patients with high BP.

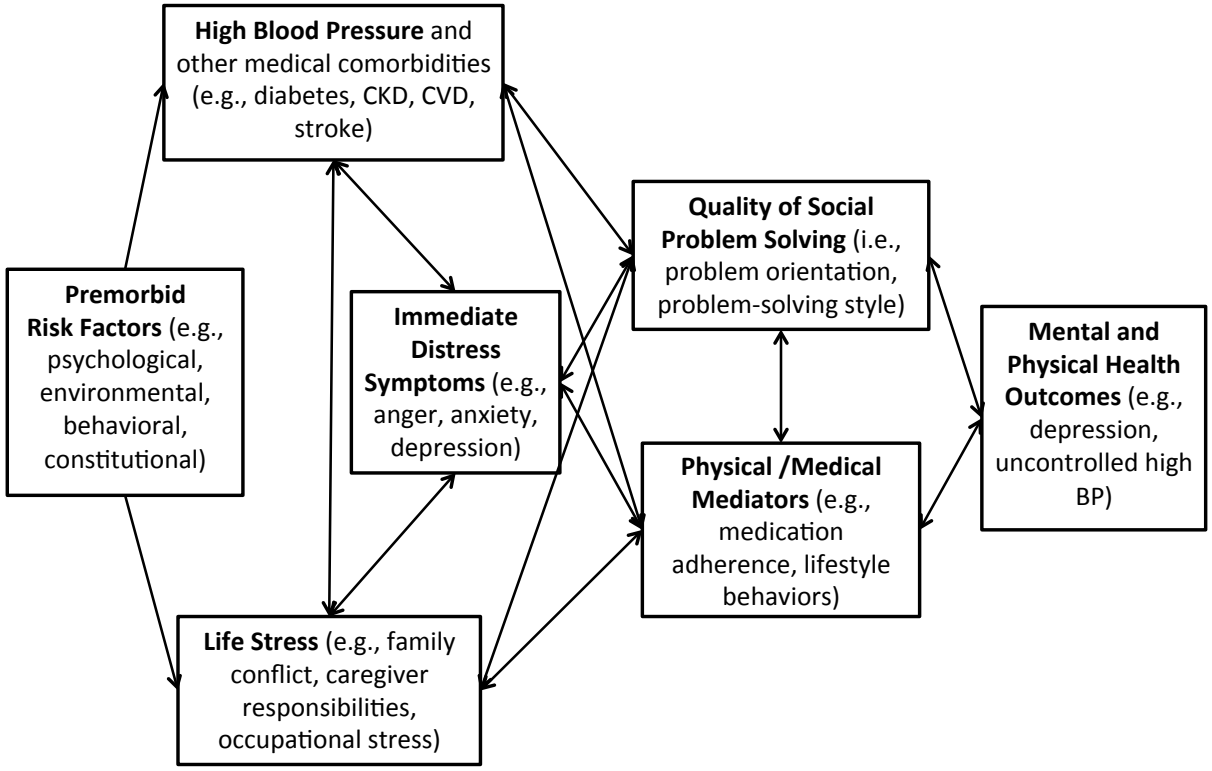


Figure 2

JARS Participant Flow Diagram

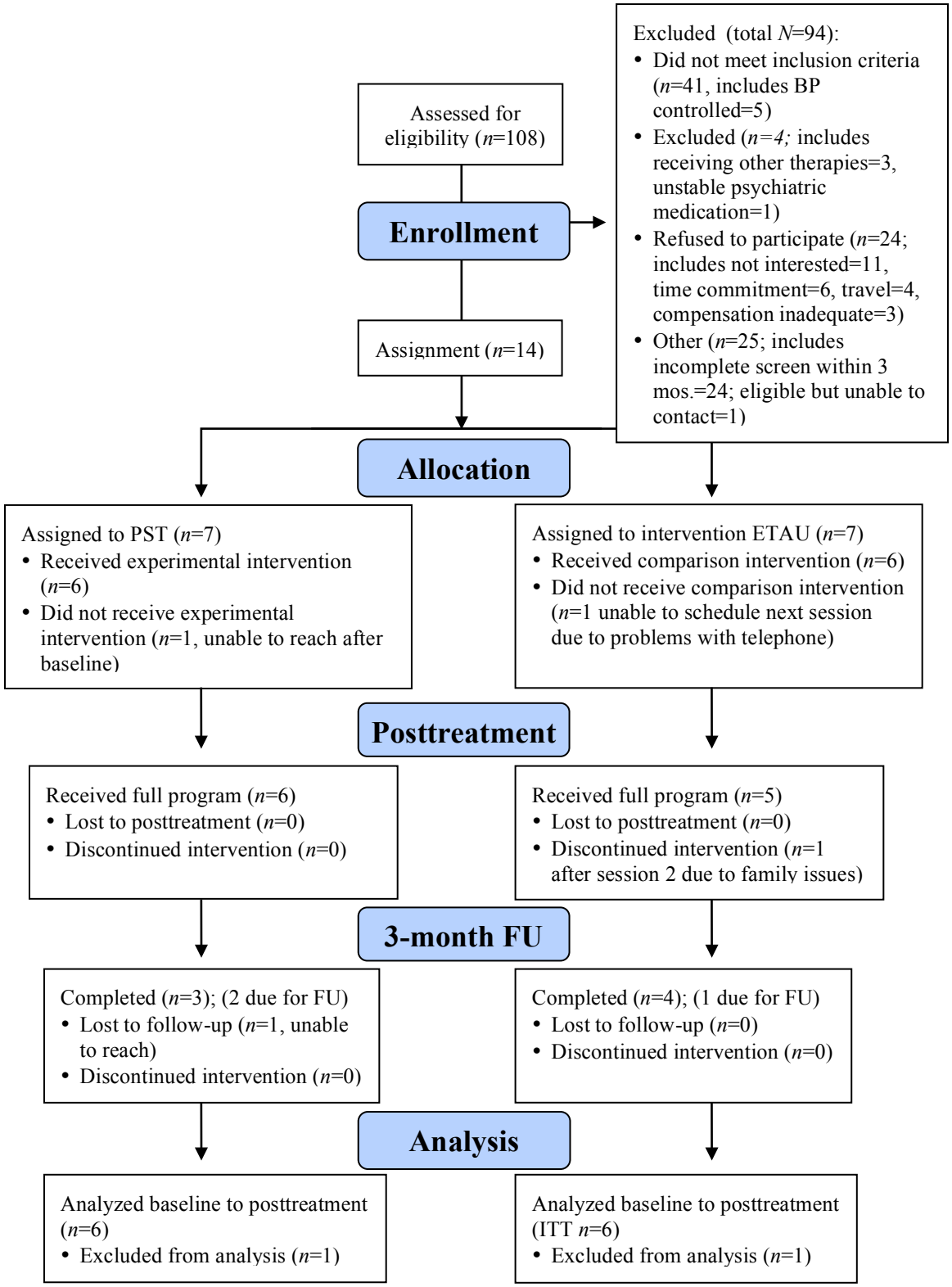
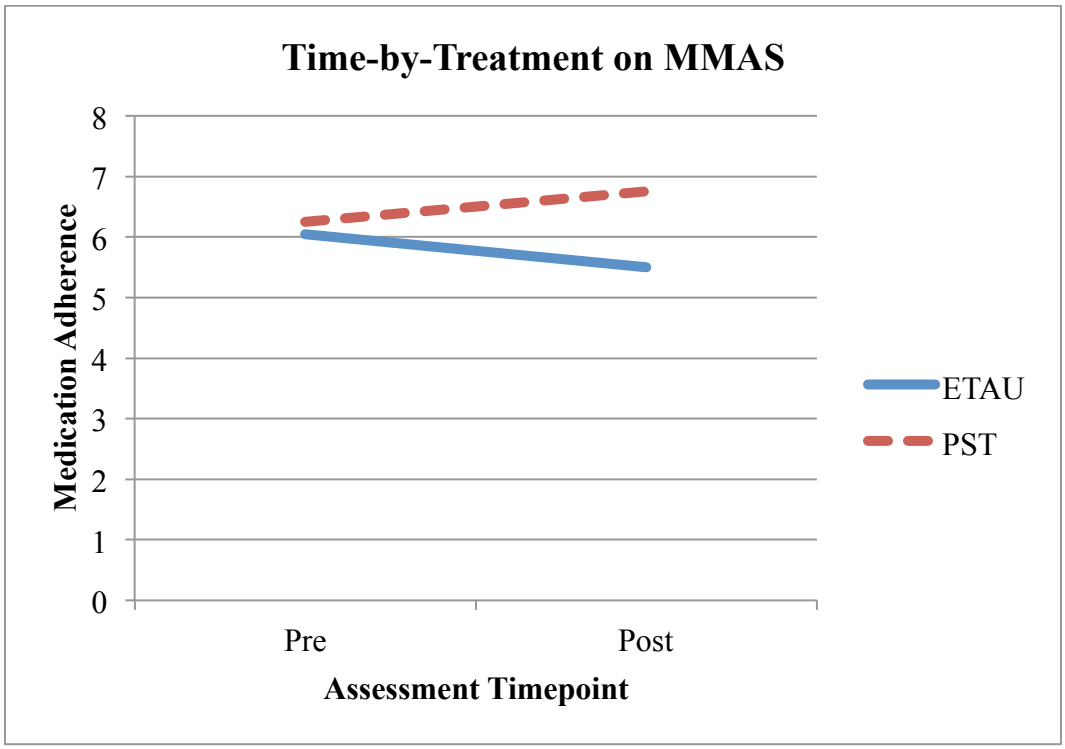


Figure 3

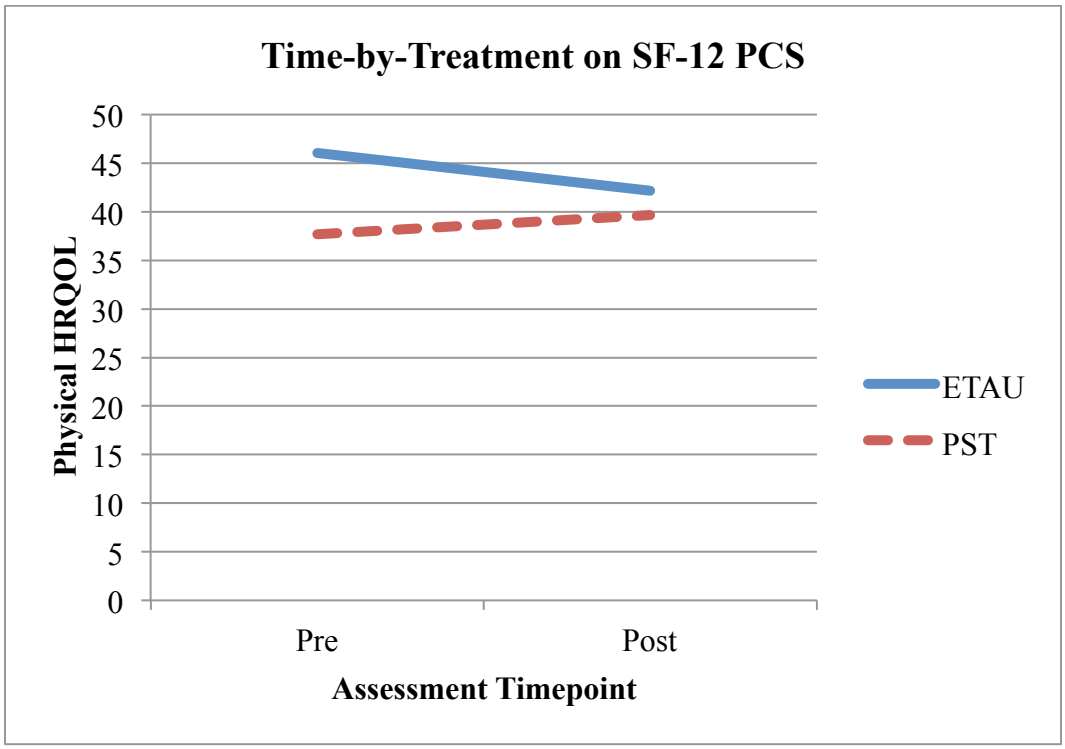
Interaction of Time and Condition on Medication Adherence



Note: MMAS, Morisky Medication Adherence Scale; ETAU, enhanced treatment as usual; PST, Problem-Solving Therapy; Pre, baseline timepoint; Post, posttreatment timepoint.

Figure 4

Interaction of Time and Condition on Physical HRQOL



Note: SF-12 PCS, Short Form Health Survey Physical Component Summary; ETAU, enhanced treatment as usual; PST, Problem-Solving Therapy; Pre, baseline timepoint; Post, posttreatment timepoint.

APPENDIX B: Intervention Manual Outlines

PST Treatment Manual Session Outline

Session 1:

- Introduction to the program and the therapist
- Education about the relationship between stress and HBP
- Education about problem solving as a mediator of stress and HBP; PST as a coping mechanism to effectively manage stress
- Education about PST
- Evaluation of SPS abilities

Sessions 2-6:

- Brief review of PST-HBP
- Guided practice of PST-HBP applied to current stressful problems
- Training in multi-tasking tools for cognitive overload (i.e., externalize, visualize simplify), the S-S-T-A method for overcoming emotion dysregulation (i.e., stop, slow down, think, act), healthy thinking and positive imagery for overcoming negative thinking (i.e., ABC model of thinking, healthy thinking rules), and planful problem-solving skills (i.e., define the problem, generating alternatives, decision making, action plan)

Session 7-8:

- Review of PST-HBP
- Forecast possible future problems
- Teach the use of PST skills as a means of preventing increased levels of stress
- Wrap-up

ETAU Treatment Manual Session Outline

Session 1:

- Introduction to the program and the therapist
- Orientation to the patient handbook

Sessions 2-7:

- What is High Blood Pressure?
- What Causes High Blood Pressure?
- Why is High Blood Pressure Bad?
- Lifestyle Changes Can Help Reduce your HBP
- Healthy Weight
- Eating Right
- Being Active
- Blood Pressure Medications
- Quit Smoking
- Chronic Stress and the Heart
- DASH details
-

Session 8:

- Ask your Doctor
- Wrap-up

APPENDIX C: Consent Form

1. Title of research study: A Pilot Randomized Controlled Trial Comparing the Efficacy of Problem Solving Therapy to Enhanced Treatment as Usual for Reducing High Blood Pressure, Protocol #1206001351

2. Researcher: Arthur M. Nezu, Ph.D., ABPP

3. Why you are being invited to take part in a research study
We invite you to take part in a research study because:

- You have presented with persistently high blood pressure or have a current diagnosis of hypertension given or confirmed by a board certified physician
- You have uncontrolled high blood pressure
- You are between 18-75 years old
- You are willing to give us permission to obtain information regarding your medical history as it pertains to any current or previous cardiovascular problems or related diseases
- You are able to read and understand this consent form
- You are not be in a current state of decompensated heart failure or a diagnosis of heart failure requiring inotrope agents
- You are not be currently receiving chemotherapy, radiation therapy, or dialysis
- You have not had a heart attack/ myocardial infarction in the previous six months
- You are not currently pregnant or planning to become pregnant within six months of treatment initiation
- You have not been hospitalized in the past two months for hypertension-related or psychiatric reasons
- You are not currently receiving psychotherapy/counseling
- You are not currently taking psychotropic medication that may impact outcomes (e.g., depression) without stable dosage and/or with planned change in dosage within six months of treatment initiation. Psychotropic medications are medications that have been prescribed by a physician to treat a diagnosed mental health disorder.

4. What you should know about a research study

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part now and later change your mind.
- Whatever you decide it will not be held against you.
- Feel free to ask all the questions you want before you decide.

5. Who can I talk to?
If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at (215) 553-7123.

This research has been reviewed and approved by an Institutional Review Board. You may talk to them at (215) 255-7857 or email HRPP@drexel.edu for any of the following:

- Your questions, concerns, or complaints are not being answered by the research team. You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

6. Why are we doing this research?
The purpose of this study is to evaluate the effect of a treatment, problem-solving therapy, compared to an enhanced treatment-as-usual condition in reducing stress and high blood pressure, and improve quality of life. This research project is being done in partial fulfillment to obtain a doctorate of philosophy in clinical psychology.

7. How long will the research last?
We expect that you will be in this research study for approximately 195 minutes (3 hours and 15 minutes) for the 3 assessments (blood pressure measurements and completion of inventories), plus up to about 8 hours of treatment; that is, your overall involvement will entail up to about 11.25 hours of direct contact over about 5 months.

8. How many people will be studied?
We expect about 60 people here will be in this research study out of 60 people in the entire study nationally.

9. What happens if I say yes, I want to be in this research?

a. You will be asked to participate in 3 assessments (a baseline assessment prior to treatment initiation, a posttreatment assessment after treatment is completed or 2 months, and a follow up assessment 3 months after treatment is completed or 2 months). There will be two parts to each of these 3 assessments:
  - A measure of blood pressure using an automatic blood pressure monitor by a trained research assistant.
  - Completion of a series of self-report questionnaires that ask you to respond to brief questions about your ability to solve real-life problems, your level of stress, your quality of life related to your health, symptoms of depression, list of prescribed medication and adherence to medications, and lifestyle behaviors like physical activity, diet, smoking and alcohol consumption.
  - Overall, each assessment will require approximately 65 minutes of your time.

b. This pilot investigation involves random assignment to one of two treatments:
  - The problem-solving therapy involves eight (8) 1-hour sessions that will be roughly scheduled about once a week. You will be asked to report any changes in prescribed medication while enrolled in the study and blood pressure will be assessed approximately every two sessions. This program is geared to help you

(a) better identify those situations that are particularly stressful for you, and (b) to help you cope better with them by learning strategies to manage stressful situations and emotional reactions. An trained clinical psychology doctoral student will provide the eight counseling sessions and will be supervised by a licensed clinical psychologist with expertise in delivering this treatment. In an effort to ensure the competence and adherence in the delivery of treatment, participants will be asked, but not required, to provide permission for the treatment sessions to be audio recorded.

- The enhanced treatment-as-usual condition will involve education material about lifestyle changes to reduce high blood pressure and weekly telephone check-ins once per week for eight weeks. You will be asked to report any changes prescribed medication while enrolled in the study.

c. Please note that no additional medical tests will be conducted as part of this study.

d. In order to best understand how effective the treatments are, we ask permission to obtain information from your medical records with regard to your medical history only as it pertains to your diagnosis and other medical problems. Specifically, this involves details about your high blood pressure/ hypertension diagnosis, such as your height, weight, antihypertensive medication changes, blood pressure, heart rate, the presence of other cardiovascular problems, and the presence of other common comorbid conditions. Such information will need to be contained both prior to, and after, your participation in the actual program.

e. Please note that participating in this study will not interfere with your medical procedures at this clinic at any time. The dosage of your anti-hypertensive medication may be adjusted by your physician during participation in this study.

f. Please note that if a blood pressure reading shows that your systolic blood pressure is elevated to >/=180 mmHg or diastolic blood pressure is elevated to >/=100 mmHg, the referring physician, or a proxy, will be contacted and 911 may be called.

g. All study-related visits will take place at the 'Stress and Coping' Lab offices (3141 Chestnut St., Stratton Hall, Room 265/229, Philadelphia, PA 19104 or 123 S. Broad St., Suite 2040, Philadelphia, PA 19107).

The treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what treatment you get. You will have a one in two chance of being given each treatment.

10. What are my responsibilities if I take part in this research?

If you take part in this research, it is very important that you:

- Follow your physician's or researcher's instructions.
- Tell your study physician or researcher right away if you have a complication or injury.

11. What happens if I do not want to be in this research?

You may decide not to take part in the research and it will not be held against you.

12. What happens if I say yes, but I change my mind later?

You agree to take part in the research now and stop at any time it will not be held against you.

If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the researcher can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

13. Is there any way being in this study could be bad for me?
The following are risks associated with participating in this study:

a. Mild distress may occur during or after responding to questionnaires, participating in interviews and/or counseling sessions that ask you about the stress you are experiencing.
b. We predict that even mild distress as a consequence of these activities is rare. In the event that participating in this study leads to some distress, you should remember that you can stop at any time without any adverse effects regarding your medical treatment at this facility.

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

14. Do I have to pay for anything while I am on this study?
There is no cost to you for participating in this study.

15. Will being in this study help me any way?
We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include better-controlled blood pressure, but there is no guarantee of this. There may be no direct benefits to you from participating in this study.

16. What happens to the information we collect?
Efforts will be made to limit your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

Limitation on confidentiality include if the research team uncovers intent/plan to harm oneself, or another, abuse, neglect, or reportable diseases, which may be disclosed to appropriate authorities.

The monitors, auditors, the IRB, the Food and Drug Administration will be granted direct access to your medical records for verification of the research procedures and date. By signing this document you are authorizing this access.

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

17. Can I be removed from the research without my OK?
The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include:

a) A change in your medical condition;
b) Discontinuation of all or part of the study; or
c) Other reasons, including new information available to the investigator or harmful reasons experienced by you or other subjects in this study.

If you leave the study before the final assessment, the study research assistant may ask you to make a final visit for some of the end of study procedures.

18. What else do I need to know?

This research study is being done by Drexel University.

If you agree to take part in this research study, we will pay you a total of $45 for your time and effort in completing the study. If you do not complete the study, you will be paid $5 for completion of the first (baseline) assessment, $20 for completion of the second (post-treatment) assessment, and $20 for completion of the third assessment (3-month follow up).

Federal law provides additional protections of your personal information that are described here.

Individually Identifiable Health Information That Will Be Collected

The following personal health information about you will be collected and used during the research study and may be given out to others:

- Your name, address, telephone number, date of birth;
- Personal and family medical history;
- Information from laboratory tests, blood and urine tests, x-rays, physical exams and other tests or procedures described in this consent form.
- Information learned during telephone calls, surveys, questionnaires and office visits done as part of this research study;
- Information in medical records located in your doctor's office or at other medical facilities you may have received treatment.
- Information about financial and social circumstances, or educational level.

Who Will See and Use Your Health Information within Drexel University

The researcher and other authorized individuals involved in the research study at Drexel University will see your health information during and may give out your health information during the research study. These include the researcher and the research staff, the institutional review board and their staff, legal counsel, research office and compliance staff, officers of the organization and other people who need to see the information in order to conduct the research study or make sure it is being done properly. Your health information may be disclosed or transmitted electronically.

Who Else May See and Use your Health Information

Other persons and organizations outside of Drexel University may see and use your health information during this research study. These include:

- Governmental entities that have the right to see or review your health information, such as The Office for Human Research Protections, and the Food and Drug Administration
- Doctors and staff at the hospital where this research study will take place.
- A data safety monitoring board.

If your health information is given to someone not required by law to keep it confidential, then that information may no longer be protected, and may be used or given out without your permission.

Why your health information will be used and given out
Your information may also be used to meet the reporting requirements of governmental agencies.

If you do not want to give authorization to use your health information
You do not have to give your authorization to use or give out your health information. However, if you do not give authorization, you cannot participate in this research study.

How to cancel your authorization
At any time you may cancel your authorization to allow your health information to be used or given out by sending a written notice to Human Research Protection at 1601 Cherry Street, 3 Parkway Bldg., Mail Stop 10-444, Philadelphia, Pennsylvania, 19102. If you leave this research study, no new health information about you will be gathered after you leave. However, information gathered before that date may be used or given out if it is needed for the research study or any follow-up.

When your authorization ends
Your authorization to use and give out your health information will end when the research study is finished.

After the research study is finished, your health information will be maintained in a research database. Drexel University shall not re-use or re-disclose the health information in this database for other purposes unless you give written authorization to do so. However, the Drexel University Institutional Review Board may permit other researchers to see and use your health information under adequate privacy safeguards.

Your right to inspect your medical and research records
You will not be able to look at your research records while you are taking part in this research study. Your personal information will be made available in an emergency if doctors need this information to treat you. You can have access to your medical record and any research study information when the study is over. However, the researcher does not have to release research information to you if it is not part of your medical record.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

DO NOT SIGN THIS FORM AFTER THIS DATE →

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date

Printed name of person obtaining consent	Form Date

APPENDIX D: Measures

Demographic Information Questionnaire

Please provide the following information. ***All information will be kept confidential***.

Sex: ❑ Female ❑ Male

Age: _____

Race/Ethnicity: ❑ Asian ❑ Black (non Hispanic) ❑ Hispanic/Latino
❑ Pacific Islander ❑ Native American/Alaskan ❑ White

❑ Other _____

Marital status: ❑ Married/ Living with Partner ❑ Widowed

❑ Divorced/ Separated ❑ Single/ Never Married

❑ Other _____

# of Household Members: _____

Are you currently pregnant? ❑ Yes ❑ No ❑ N/A (Male or post menopausal)

Do you consider yourself religious?: ❑ Yes ❑ No

Years of Education: _____ years (e.g., high school diploma or GED = 12 years)

Current Job Status: ❑ Working full time ❑ Working part time

❑ Unemployed/ Seeking work ❑ Volunteering ❑ Retired

❑ Receiving disability/ government subsidy

Estimated Yearly Household Income: ❑ less than $20,000 ❑ $20-40,000

❑ $40-60,000 ❑ $60-80,000 ❑ $80-100,000 ❑ more than $100,000

When were you first told that you have high blood pressure?: _____ years ago

Additional medical diagnoses: ❑ Cancer ❑ Chronic Kidney Disease

❑ Diabetes ❑ Heart Failure ❑ Stroke

❑ Other: _____

Is there a history of high blood pressure in your family members?:

❑ Yes ❑ No

Are there any services you are receiving related to changing behaviors (e.g., weight loss, smoking, alcohol, such as AA) or psychological problems (e.g., depression, anxiety)?

❑ Yes ❑ No

If yes, please describe:

_____

_____

Lifestyle Behavior Questionnaire

1) Do you follow the Dietary Approaches to Stop Hypertension (DASH) diet?
❑ Yes ❑ No ❑ I don't know

2) Do you eat foods low in saturated fat, cholesterol and total fat?
❑ Yes ❑ No ❑ I don't know

3) Do you eat fruits, vegetables, and fat-free or low-fat dairy products?
❑ Yes ❑ No ❑ I don't know

4) Do you eat foods rich in whole grains, fish, poultry, beans, seeds, and nuts?
❑ Yes ❑ No ❑ I don't know

5) Do you eat fewer sweets, added sugar or sugary beverages, and red meats than the typical American diet?
❑ Yes ❑ No ❑ I don't know

6) Indicate your level of physical activity in the past week (circle one number):

1 2 3 4 5 6 7 8 9 10
Light Intensity Moderate Intensity Vigorous Intensity
(e.g., brisk walking, dancing, gardening) (e.g., running, fast cycling, aerobics)

7) *In the past week*, on how many days have you done a total for *30 minutes or more* of physical activity, which was enough to raise your breathing rate. *This may include sport, exercise, and brisk walking or cycling for recreation or to get to and from places, but should not include housework or physical activity that may be part of your job.* __ days

8) What best describes your activity level? Place a check next to one response below:
_____ *Vigorously active for at least 30 min, 3 times per week*
_____ *Moderately active at least 3 times per week*
_____ *Seldom active, preferring sedentary activities*

9) Do you currently use tobacco products (e.g., cigarette, cigar, pipe, etc.)?:
❑ Yes ❑ No

If yes: How soon *after you wake up* do you use the tobacco product? :

_____ After 60 minutes _____ 31-60 minutes _____ 6-30 minutes
_____ within 5 minutes or more

On average, how many tobacco products do you use *per day* (e.g., cigarettes smoked)?

_____ 10 or fewer _____ 11-20 _____ 21-30
_____ 31 or more

10) Do you drink alcoholic beverages (e.g., beer, wine, liquor)? ❑ Yes ❑ No

If yes: How many alcoholic drinks do you consume, on average, per week?: _____

❑ None ❑ 1-3 ❑ 4-6 ❑ 7-9 ❑ 10-13 ❑ 13-16 ❑ 16-19 ❑ 20 or more

How many times in the past year have you had 5 (*if male*) or 4 (*if female*) or more drinks in a day? _____ times

Social Problem Solving Inventory-Revised: Short Form (SPSI-R:SF)

D'Zurilla, T.J., Nezu, A.M., and Maydeu-Olivares, A. (2002). Social Problem Solving Inventory Revised: Technical Manual. North Tonawanda, N.Y.: Multi-Health Systems.

Morisky Medication Adherence Scale (MMAS-8-Item)

This measure is copyrighted and therefore excluded from print here. Use of the ©MMAS is protected by US copyright laws. Permission for use is required. A license agreement is available from: Donald E. Morisky, ScD, ScM, MSPH, Professor, Department of Community Health Sciences, UCLA School of Public Health, 650 Charles E. Young Drive South, Los Angeles, CA 90095-1772. Please see the following reference for additional information regarding the MMAS-8:

Morisky, D. E., Ang, A., Krousel-Wood, M., & Ward, H. J. (2008). Predictive validity of a medication adherence measure in an outpatient setting. *Journal of Clinical Hypertension*, 10, 348-354.

Patient Health Questionnaire (PHQ-9)

This measure is copyrighted and therefore excluded from print here. PHQ9 Copyright © Pfizer Inc. All rights reserved. Please see the following reference for additional information regarding the PHQ-9:

Spitzer, R. L., Kroenke, K., & Williams, J. B. W. (1999). Validation and utility of a self-report version of PRIME-MD- The PHQ primary care study. *Journal of the American Medical Association*, 282, 1737-1744.

SF-12v2 Health Survey (SF-12)

Ware, J. E., Kosinski, M., & Keller, S. D. (1996). A 12-Item Short-Form Health Survey: Construction of Scales and Preliminary Tests of Reliability and Validity. *Medical Care*, 34, 220-233. DOI: 10.1097/00005650-199603000-00003

Perceived Stress Questionnaire (PSS)

This measure is copyrighted and therefore excluded from print here. PSS Copyright ©1994 by Sheldon Cohen. Please see the following reference for additional information regarding the PSS:

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

Program Evaluation

Reducing High Blood Pressure and Stress
Evaluation of Program

Remembering that all information is confidential, please answer the following questions as honestly as possible. Thank you.

A. Using the scale below, from 1 to 5, rate the extent to which you agree with each of the statements below by circling the number that best represents your response.

1 Completely	**2** Somewhat	**3** Agree	**4** Agree	**5** Completely Disagree

1. I believe that this program has helped me to better manage my high blood pressure.	1	2	3	4	5
2. I believe that this program has helped me to better manage my stress.	1	2	3	4	5
3. I believe that my health coach was competent and has been effective in helping me deal better with my problems.	1	2	3	4	5
4. I believe that my health coach was competent and has been effective in helping me make healthy lifestyle changes.	1	2	3	4	5
5. I agree with the ideas that this program is based upon.	1	2	3	4	5
6. Based upon this program, I am better able to manage my stress.	1	2	3	4	5
7. Based upon this program, I made healthy lifestyle changes.	1	2	3	4	5
8. I really *feel* that the program helped me to better control my high blood pressure.	1	2	3	4	5

9. I really *feel* that the program helped me to reduce my stress. 1 2 3 4 5

10. I would confidently recommend this program to other patients with high blood pressure. 1 2 3 4 5

PLEASE GO TO THE NEXT PAGE

B. Please indicate which elements of the program you found particularly helpful.

_____

_____

_____

_____

C. Is there anything that you would change in the program to make it better or more effective?

_____

_____

_____

_____

Thank you for your answers.

Vita

Lauren Miriam Greenberg

Drexel University, Philadelphia, PA (2015)
Doctorate of Philosophy in Clinical Psychology (APA-accredited)
Dissertation: *A Pilot Randomized Controlled Trial Comparing the Efficacy of Problem-Solving Therapy to Enhanced Treatment as Usual for Reducing High Blood Pressure*
Dissertation Chair: Dr. Arthur Nezu, Ph.D., ABPP
Dissertation Committee: Christine Maguth Nezu, Ph.D., ABPP, David DeMatteo, J.D., Ph.D., ABPP, Pamela Geller, Ph.D. & Diwaker Jain, M.D., F.A.C.C., F.R.C.P., F.A.S.C.N.

Veterans Affairs Palo Alto Health Care System, Palo Alto, CA (2014)
Predoctoral Internship in Clinical Psychology (APA-accredited)
Behavioral Medicine Track

Drexel University, Philadelphia, PA (2008)
Masters of Science in Psychology
Thesis: *Negative Problem Orientation as a Moderator of the Relation between Negative Life Events and Negative Affect in Collegiate Athletes*
Chair: Dr. Christine Maguth Nezu, Ph.D., ABPP

Drexel University, Philadelphia, PA (2006)
Bachelor of Science in Psychology
Bachelor of Science in Teacher Education

2013 Division 38 Graduate Student Research Award, APA ($1500)
2011 Basic Psychological Science Research Grant, APA ($1000)
2011 1st Place Graduate Humanities/ Social Sciences Research Day Award ($100)
2011 International Travel Award, Drexel University ($300)

Nezu, A. M. & **Greenberg, L. M.** (2015). Journal of Consulting and Clinical Psychology. In R. Cautin & S. Lilienfeld (Eds.), The Encyclopedia of Clinical Psychology (pp. 1-2). R. Klepec, Section Ed. New York: Wiley.

Nezu, A. M., Nezu, C. M., **Greenberg, L. M.**, & Salber, K. S. (2014). Cancer and depression. In C. S. Richards & M. O'Hara (Eds.). The Oxford Handbook of Depression and Comorbidity (pp. 302-318). New York: Oxford University Press.

Nezu, A. M., **Greenberg, L. M.**, & Nezu, C. M. (2013). Cognitive and Behavioral Therapies. In F. T. L. Leong, L. Comas-Diaz, G. N. Hall, V. McLoyd, and J. Trimble (Eds.). *APA Handbook of Multicultural Psychology: Applications and Training* (Vol. 2), Washington, DC: American Psychological Association.

Nezu, A. M., Nezu, C. M., Felgoise, S. H., & **Greenberg, L. M.** (2012). Psychosocial Oncology. In A. M. Nezu, C. M. Nezu, & P. Geller (Eds.). *Comprehensive Handbook of Health Psychology*. New York: Wiley