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Evaluating The Effects of an Educational Lifestyle Modification Intervention on Blood Pressure in Adults With Prehypertension

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EVALUATING THE EFECTS OF AN EDUCATIONAL LIFESTYLE MODIFICATION INTERVENTION ON BLOOD PRESSURE IN ADULTS WITH PREHYPERTENSION

by

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Abstract

The purpose of this project was to evaluate the effectiveness of an educational lifestyle modification (LM) intervention on blood pressure (BP) among adults with prehypertension. Prehypertension is a precursor to hypertension (HTN) and is a public epidemic in the United States. Approximately 68 million (31%) U.S. adult's aged ≥18 years have hypertension. Hypertension can cause significant target organ damage, lead to coronary heart disease, heart failure, stroke, and kidney failure. Early identification and the primary treatment of persons with prehypertension with LM have the potential to minimize the progression and delay the onset of comorbidities associated with hypertension. This quality improvement project retrospectively reviewed changes in blood pressure for a small sample (n=5) of patients diagnosed with prehypertension who received education about modifying lifestyle behaviors according to nationally accepted clinical practice guidelines. Blood pressure measurements were extracted from the medical record beginning at the time of the education through a three month period. Descriptive data indicates that all five patients had a decrease in systolic and diastolic blood pressure. The median systolic blood pressure at baseline was 129 mmHg decreasing to 121 mmHg at end of study period. The median diastolic blood pressure was 86 mmHg decreasing to 76 mmHg. Integration of lifestyle modification education and subsequent blood pressure monitoring during a routine primary care visit is feasible and may help motivate patients to implement changes and subsequently reduce blood pressure. Future studies should include identifying strategies for improving patient participation.

Chapter One: Introduction

Prehypertension (preHTN), if untreated, can progress to hypertension (HTN), which is a significant risk factor for cardiovascular disease (CVD). Lifestyle modification (LM) such as changes in diet, physical activity, and weight loss is the recommended treatment to lower blood pressure (BP). Chapter one will discuss the clinical problem of HTN and preHTN, present an abbreviated literature review of the affect of lifestyle modification on blood pressure, and describe the clinical practice guidelines for primary care treatment. The purpose of this quality improvement project, the study questions, and definition of terms are also discussed.

Hypertension & PreHypertension

Hypertension, a precursor to cardiovascular disease, is defined as the force of blood pushing against the walls of the arteries as the heart pumps blood. HTN can cause significant target organ damage. It can lead to coronary heart disease, heart failure, stroke, kidney failure, and other health problems. The prevalence of HTN tends to be higher in the fifth and sixth decade of life in men and higher in Non-Hispanic blacks or African American populations (Buttaro, Trybulski, Bailey, & Sandberg-Cook, 2008). In the U.S., HTN is responsible for one out of every seven deaths annually, has no signs or symptoms, and is known as the silent killer (NHLBI, 2012). HTN contributes to nearly half of all cardiovascular disease-related deaths in the United States (MMWR, 2011). Approximately 68 million (31%) U.S. adult's aged ≥18 years have HTN. Of these, 48 million (70%) were receiving pharmacologic treatment and 31 million (46%) had their condition controlled. Control prevalence is low among young adults (31%) and Mexican Americans (37%). Prevention and treatment guidelines are available to guide both

providers and their patients but patients sometimes fail to adhere to provider recommended lifestyle modifications. As a result, risk factors for CVD, kidney disease, and hypertension are increased (Svetky et al., 2009).

Slightly elevated blood pressure is known as preHTN representing a systolic blood pressure of 120-139 mmHg and/or diastolic blood pressure of 80-89 mmHg (USDHHS, 2004). A population-based survey reported that approximately one-third the US adult population has preHTN, a risk factor for HTN and eventual CVD (Gadddam, Ventura, & Lavie 2012). The National Health and Nutrition Examination Survey (NHANES) 1999-2000 data showed that 64% of individuals with preHTN had at least one other cardiovascular risk factor and the percentage increased to 94% in those aged 60 years or older (Zhang & Li, 2011). A 10-year cumulative incidence of CVD in persons between 35 and 64 years of age who had high normal BP was 4% women and 8% men; in older adults 65-90 the incidence was 18% women and 25% for men. Persons with preHTN can benefit with reduction in BP, blood glucose, lipid levels, weight loss, stress, healthy diet, increased physical activity, and smoking cessation. These risk factors for CVD also affect overall health status, health care use, and costs of health care.

The economic burden of HTN was estimated at $76.7 billion in 2010 (Brill, 2011). A randomized study by Milani and Lavie (2009), and a cross-sectional study conducted by Mendez-Hernandez et al. (2012), both concluded that wellness intervention and physical activity had a considerable effect on lowering health care costs. In any case, preventing the progression of preHTN to HTN is an important individual patient and health care system goal.

Clinical Practice Guideline JNC7

The *Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure,* commonly referred to as the JNC7, is the evidenced-based clinical practice guideline for the prevention and management of HTN (USDHHS, 2004). Originally published in 1976, the JNC7 guideline has been revised seven times with the eighth revision in development. The new classification for preHTN is contained in the JNC7 along with recommendations for treatment through lifestyle modification and pharmacotherapeutics.

Prehypertension Classification

The increased risk that HTN poses related to cardiovascular disease is the reason for the revised blood pressure classifications. HTN is classified as a systolic blood pressure (SBP) ≥ 140 mmHg or diastolic blood pressure (DBP) ≥ 90 mmHg. PreHTN is classified as a SBP 120-139 mmHg and/or DBP 80-89 mmHg. Furthermore, the measures classifying HTN among persons with diabetes have been lowered to <130/80 mmHg. Table 1 compares the blood pressure classifications between the JNC6 and the JNC7.

Table 1

Comparison of Blood Pressure Classifications, JNC-6 & JNC-7

JNC- 6 Classification	Blood Pressure Measures Systolic/diastolic	JNC 7 Classification
Optimal	<120/80	Normal
Normal	120-129 / 80-84	Prehypertension
Borderline	130-139 / 85-89	Prehypertension
Hypertension Stage 1 Stage 2 Stage 3	≥140/90 140-159 / 90-99 160-179 / 100-109 ≥180 / 110	Hypertension Stage 1 Stage 2 Stage 2

Source: (USDHHS, 2004, p. 11)

PreHTN is not designated as a disease category or a diagnosis; rather it is designed to identify those individuals at risk of developing HTN. The United States Department of Health and Human Services (USDHHS, 2004) based changes on new data on the lifetime risk of HTN and the increased risk of cardiovascular complications associated with BP levels that were previously considered normal. Reducing blood pressure through lifestyle modifications reduces the rate of progression to HTN with age and may prevent HTN altogether. Therefore patients should make lifestyle adjustments; and providers need to be more vigilant in monitoring, counseling, and adjusting their management of blood pressure, recognizing preHTN.

Lifestyle Modification Treatment

Lifestyle modifications (LM's) treatment regimen is presented in Table 2. LM's consist of weight reduction, Dietary Approach to Stop Hypertension (DASH) diet, dietary sodium reduction, increase in physical activity, moderation of alcohol consumption, and cessation of tobacco use. These strategies have been found to reduce systolic blood pressure.

Weight reduction relies on a combination of physical activity and dietary modifications. Replacing sweets with fruits and vegetables can reduce calories thus helping to reach weight loss goals. The DASH diet is rich in fruits, vegetables, whole-grain, high fiber foods, fat-free, and low-fat dairy products, beans, nuts, skinless poultry and lean meats as well as fish containing omega 3 fatty acids. Reducing dietary sodium to no more than 2.4 grams (1 teaspoon) of sodium a day and adhering to the DASH diet has been shown to reduce systolic blood pressure (Sacks et al., 2001; Vollmer, Stevens, Svetkey, Lien, & Champagne, 2008).

Several organizations recommend at least 30 minutes of regular aerobic physical activity most days of the week (USDHHS, 2004; The American Diabetes Association, 2012; & American Heart Association, 2012). Physical activity reduces systolic blood pressure by 4-9

mmHg (USDHHS, 2004). Physical activity can include walking, aerobic exercise, swimming, dancing, using stairs, and flexibility exercises. Losing weight may require more than 30 minutes a day. Benefits of physical activity reach further than reduction in BP; it reduces stress, strengthens the heart and lowers risk for pre-diabetes, heart disease and stroke. Increasing the awareness of the long-term benefits of lifestyle changes can have a positive long lasting effect on BP without the use of drugs.

Table 2

Lifestyle Modifications to Manage Hypertension

Modification	Recommendation	Approximate Systolic Blood Pressure Reduction (Range)
Weight reduction	Maintain normal body weight (body mass index 18.5–24.9 kg/m^2)	5–20 mmHg/10 kg weight loss
Adopt DASH eating plan	Consume a diet rich in fruits, vegetables, and low fat dairy products with a reduced content of saturated and total fat.	8–14 mmHg
Dietary sodium reduction	Reduce dietary sodium intake to no more than 100 mmol per day (2.4 g sodium or 6 g sodium chloride).	2-8 mmHg
Physical activity	Engage in regular aerobic physical activity such as brisk walking (at least 30 min per day, most days of the week).	4–9 mmHg
Moderation of alcohol consumption	Limit consumption to no more than 2 drinks (1 oz or 30 mL ethanol; e.g., 24 oz beer, 10 oz wine, or 3 oz 80-proof whiskey) per day in most men and to no more than 1 drink per day in women and lighter weight persons.	2–4 mmHg

Source: (USDHHS, 2004, p. 26)

Pharmacotherapeutics

It is common practice to implement lifestyle modifications before prescribing drug therapy (Pettman, Buckley, Misan, Coates & Howe, 2009). Treating preHTN and HTN with pharmacotherapeutic therapy usually occurs if LMs have failed. The goal for individuals with preHTN, without any co-morbidity is to reduce BP to normal levels, and to 139/89 mmHg or less for individuals with HTN. JNC7 (USDHHS, 2004) states that greater emphasis should be placed on managing systolic hypertension because of increased cardiovascular and renal disease, and stroke, as the population gets older. Drug therapy therefore would consist of one of the several different classes of drugs such as diuretics, angiotensin converting enzyme inhibitors, angiotensin receptor blockers, beta blockers, and calcium channel blockers. Two or more of these antihypertensive may be required to control blood pressure.

Hypertension Treatment Outcomes

Studies cited in the JNC7 (USDHHS, 2004) document that LM treatment produces a decrease in BP. Implementing the LM of weight reduction yields a 5-20 mmHg/10kg of weight loss. An individual usually achieves weight loss through physical activity and that produces an additional 4-9 mmHg decrease in BP. Replacing unhealthy foods with fruits and vegetables brings us to the second biggest reduction with the adaption of the DASH diet that yields an 8-14 mmHg decrease in BP. Dietary sodium restriction and moderate alcohol intake reduces BP by approximately 2-8 mmHg. Studies report that implementing more than one LM has a greater impact on lowering BP. In 2005 Aldana et al. conducted a study that assessed the impact of healthful eating and physical activity after attending a 40-hour educational course. BP improved within only six weeks. Consistent with the JNC7 (USDHHS, 2004), a combination of two or more lifestyle changes can produce better results.

Studies published after the JNC7 (USDHHS, 2004) continue to substantiate the impact of LMs on BP. Elmer et al. (2006) concluded that the established recommendations known as LM, plus the DASH diet, does lower BP. In 2008 Fleming and Godwin studied the effect of physical activity and healthy eating on BP and reported a positive result. Svetkey et al. (2009) conducted a study using physicians as control and intervention group as well as the patients in a control and intervention group. For the physicians, the interventions were online training modules, evaluation and treatment algorithm, and quality improvement procedure that assessed clinical performance measures. The interventions for the patients included 20 weekly group sessions. In this study the outcome was greatly improved with the combination physician intervention combined with patient intervention demonstrating a 9.7 ± 12.7 mmHg decrease in BP.

Clinical Problem

Individuals may be unaware that they have preHTN due to the reclassification of previously identified “normal” systolic and diastolic blood pressure levels. Consequently, they may not realize their risk for developing HTN and the associated risk for poor health outcomes. Several patients attending a primary care clinic in rural North Florida have been observed to have preHTN. A subsequent record review found that some patients also have additional risk factors such as hyperlipidemia, high blood glucose, and/or are overweight.

Demographic characteristics such as age, minority status, income, education, and rural residence may be factors that create barriers to HTN prevention (USDHHS, 2004) Access to exercise programs in school, availability of healthy food choices in school, places of work and restaurants, coupled with the higher cost of healthy food products is a major barrier. Individuals have to overcome barriers such as insufficient exercise facilities and access to food stores. It is difficult for individuals to change lifetime habits. Everyday traditions identified to a particular

culture, such as high salt diets in the African American and other minority population can be considered known barriers to adherence (USDHHS, 2004). Patients living in a rural area that are low income, under or non-insured, unemployed, and have limited access to transportation may be particularly challenged to adhere to lifestyle modifications.

According to the evidence, making patients aware of their preHTN and guiding them toward making lifestyle modifications should produce a positive result in lowering their BP as well as decreasing other CVD risk factors (Johnson et al., 2011). It is essential that Primary Care Providers (PCP's) discuss preHTN with patients and counsel them on lifestyle modifications. Primary Care Providers are well suited to educating patients. Finding ways to motivate an individual can be done if there is a relationship of trust and respect, which is developed and or built during patient visits. Good customer service, access to the provider and decreased waiting time, often leads to patient adherence and the desire to engage in their own care (USDHHS, 2004).

Whittemore et al. (2010) reported a mixed-method clinical trial implementing a lifestyle program to prevent type II diabetes implemented by nurse practitioners (NPs) in their primary care facilities. The NPs first completed a questionnaire on confidence of preparedness and effectiveness in providing LM education and received a two-hour training session on the Diabetes Prevention Program protocol for enhanced standard care sessions and documentation. The program provided an adult population at risk for type II diabetes with education, behavioral and psychological strategies to promote lifestyle change. The enhanced standard care NP group received 1.5 hours of professional support while the lifestyle change NP group received 4.1 hours of professional support. At the end of the study a survey was sent to participants and a sub-sample were interviewed to evaluate their satisfaction with the program. Participants reported

knowing the NP, wanting more information on healthy eating, concern about risk of type II diabetes, and not wanting to take medicine, as motivating factors for change.

Project Purpose

The purpose of this quality improvement project was to evaluate outcomes of an educational lifestyle modification program delivered to adults with preHTN in a primary care rural setting. The study question was: Among adults with preHTN, does an educational lifestyle modification program implemented in a primary care setting lower blood pressure?

Definition of Terms

Prehypertension

Blood pressure ranging from 120-139 mmHg systolic and/or 80-89 mmHg diastolic (USDHHS 2004, 7, p. xiv.).

Hypertension

The condition in which a person displays a systolic blood pressure of 140 mmHg or higher and/or a diastolic blood pressure of 90 mmHg or higher, or is current user of antihypertensive medication (Rigsby, 2011, p.1).

Lifestyle Modification

Includes weight loss, physical activity, lowering dietary salt intake, smoking cessation, reducing stress and lowering alcohol consumption (Ebrahim & Smith, 1998, p. 1).

Blood Pressure

That force in arterial structures created by interplay of flow, volume, and constriction (Buttarro, et al., 2008, p. 572).

Summary

PreHTN is an important medical issue. Untreated, it can progress to hypertension, which increases risk for morbidity and mortality associated with CVD. The JNC7 (USDHHS, 2004) offers treatment approaches including LM and pharmacological therapy. LM interventions such as weight loss, DASH diet, physical activity, dietary sodium reduction and reduction in alcohol consumption have been shown to lower BP. Individuals with preHTN may not recognize the seriousness of this condition and may not be actively engaging in LM that could prevent the development of HTN. The classification of preHTN prompts providers and patients to actively intervene and prevent the progression to HTN. The purpose of this project is to assist adult patients in a primary care setting to lower their BP through LM.

Chapter Two: Review of Literature

This chapter will describe the search process, assess the JNC7 (USDHHS, 2004), and discuss the results of the review of literature. A critical appraisal of the JNC7 (USDHHS, 2004) was conducted using the Appraisal of Guidelines for Research and Evaluation II (AGREE) instrument (Brouwers et al., 2010). Systematic reviews, meta-analyses, and randomized controlled trials (RCTs) focused on effect of lifestyle modification on blood pressure in adults with prehypertension were appraised.

Search Process

A literature search was conducted using The Cochrane Library, EBSCO Host, CINAHL, Science Direct, ProQuest, and Medline databases. Keywords employed in the search were: hypertension or prehypertension or blood pressure; and lifestyle modification or behavioral modification; and African American, diet, physical activity, weight loss, systematic review, meta-analysis, and RCTs. The search focused on studies published since the JNC7 (USDHHS, 2004) that included publication dates between 1998 and 2012. Inclusion criteria were: diagnosis of hypertension or preHTN, adults aged 18 years of age or older, with lifestyle modification treatment. The search revealed 21 research studies of which 13 did not meet inclusion criteria, for example, studies of treatment with pharmacologic agents. Eight studies met the inclusion criteria and were used in the analysis (Table 3). The strength of the research evidence was assessed as well as applicability of methods for primary care practice.

Clinical Practice Guideline Evaluation

The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure, JNC7 (USDHHS, 2004), submitted November 2004 to the journal *Hypertension* is the clinical practice guideline that drives practice on hypertension. The JNC7 (USDHHS, 2004) was evaluated using the AGREE II (Brouwers et al., 2010) instrument to evaluate the quality and applicability of a guideline. It uses the basis of six domains separated into 23 questions to accomplish an evaluation. The six domains consist of: scope and purpose, stakeholder involvement, rigor of development, clarity of presentation, applicability, and editorial independence.

Scope and Purpose

The rationale and purpose for this guideline is explicitly described in the abstract and then again in the introduction. Their purpose was to increase the awareness, prevention, treatment, and control of hypertension. In the forward they state that the guidelines are a synthesis of scientific evidence and guidance geared to busy PCPs. Many key messages can also be found in the abstract. Identified in this guideline are people with HTN and preHTN. It identifies treatment with LM, and pharmacotherapy (USDHHS, 2004).

Stakeholder Involvement

The guideline development group dedicated to the management of, and the prevention of morbidity and mortality, and the consequences of uncontrolled hypertension include a conglomerate of organizations from all relevant groups. The views of the target population were sought and the target users are clearly defined. The National Heart, Lung, and Blood Institute have administered the National High Blood Pressure Education Coordinating Committee, consisting of 39 major professional, public, and voluntary organizations that participated. The

federal agencies that also participated were: Agency for Health Care Research and Quality, Centers for Medicare & Medicaid Services, Department of Veterans Affairs, Health Resources and Services Administration, National Center for Health Statistics, National Heart, Lung, and Blood Institute, and the National Institute of Diabetes and Digestive and Kidney Diseases (USDHHS, 2004).

Rigor of Development

The need to update the guideline was based on the overwhelming publications of new hypertension observational studies and clinical trials; the need for new, clear and concise guidelines useful to clinicians; the simplification of BP classification; and the need to get enhanced public benefit results. Using peer-reviewed, scientific literature that spanned from January 1997 through April 2003 they developed two versions. The succinct version was launched in May 2003. The more in depth version also offered justification for the committee's recommendation. The committee continued their efforts to stay abreast of the studies being conducted on hypertension by investigating on four different levels that cover science; long-range planning; professional, patient, and public education; and program organization, thus being clear and concise in their methods.

The guideline outlined the health benefits and the possible consequence for non-adherence. The committee considered evidence that showed pertinent outcomes of concern to patients that was of such magnitude it warranted changes in practice. The studies show an unambiguous link between heart disease, stroke, and renal disease to hypertension. Thirty-three national hypertension leaders externally reviewed the JNC7 Express and the complete JNC7 (USDHHS, 2004).

Clarity of Presentation

The key recommendations from this guideline are descriptive in that it is appropriate for the population and situation in which it addresses. It gives a precise definition of prehypertension and hypertension and the two stages. The guideline clearly outlines the different classes of antihypertensive therapy, combinations, and that it may take two or more to meet goal. They also outline the different classes that work better with other co-morbidities such as diabetes and heart failure. They include that a combination of LMs such as diet, exercise, weight loss, and physical activity enhance the positive affect on BP.

Applicability

The JNC7 (USDHHS, 2004) lists facilitators that assist with the reinforcement of LM and BP control. Those facilitators include but are not limited to nurse managers, pharmacists, managed care organizations, licensed nutritionists, optometrists and worksite occupational health departments. Incorporating a LM and BP regimen should be individualized to the patient and include the patient in the decision making process. Recommendations indicate how the guidelines can be applied in practice.

The barriers to guideline application were also identified and solutions to those barriers were described. The primary reason for non-adherence to treatment guidelines related to medication costs. The patient and primary care provider must agree upon a BP goal, time frame of achievement and monitoring frequency. The guideline acknowledges that social services or someone to assist individuals with special needs programs and other resources can help with adherence (USDHHS, 2004).

Editorial Independence

This guideline provides the parameters for the different levels and stages of hypertension including the new category of prehypertension. The recommended approach the guideline suggests is appropriate for use in the primary care clinical setting. The National Heart Lung and Blood Institute Health Information Center serves the health professional, and the recommendations are applicable to patients, and the public as well on things such as prevention, diagnosis, and treatment.

The JNC7 (USDHHS, 2004) has a perfect score in all domains using the AGREE II tool. The objectivity of the guideline were clearly written and met, and the overwhelming strength of the guideline has clearly been justified. The work was supported entirely by the National Heart Lung and Blood Institute. The Executive Committee and team of reviewers, and writers assisted as volunteers without remuneration.

Literature Review

Systematic Reviews

The two systematic reviews conducted by Ebrahim & Smith (1998); and Fleming & Godwin (2008) reviewed a total of 40 RCTs. Ebrahim & Smith (1998) presented studies of 33 RCTs that looked at the effects on systolic BP from different aspects of lifestyle modifications. Thirty-two studies included LM's of weight reduction, salt restriction, stress management and exercise. One study included alcohol reduction. All studies were of six months duration or longer and reported a reduction of systolic BP in all areas studied with the greatest affect of -5.2 mmHg with a 95% CI (-8.3, -2.0) from weight reduction. Ebrahim & Smith (1998) determined that although weight reduction and salt restriction seem to have the greatest effect on systolic BP, a

larger study is needed, and methodological constraints make it difficult to test LM's compared to pharmacological interventions.

Fleming & Godwin (2008), compared studies in primary care, by PCP's with a control group using usual care. They measured cardiovascular risk scores, blood pressure, lipid levels, weight or body mass index (BMI), and morbidity and mortality as outcomes. Three of the six studies that used BP as an outcome found that there was small but significant benefit to LM intervention. Of the seven RCTs compared, four found significant positive effect on the outcomes of interest and two found consistent effects across the several outcomes. Although statistically significant, and showing that the main effects were on blood pressure and lipid levels, they were rather small. The authors concluded that PCP's time might best be spent counseling patients at highest risk of disease given the small improvement in BP among lower risk groups.

Meta-Analyses

Two meta-analyses reviewed 51 articles, all of which studied BP and BMI. Some articles reviewed waist circumference, dyslipidemia, fasting plasma glucose, and smoking and drinking as well. One study by Guo et al. (2011) was conducted after the guideline was released. Between all studies a total of 255,615 participants were included. Both analyses conclude that LM has a positive effect on decreasing blood pressure.

Neter, Stam, Kok, Grobbee, & Geleijnse (2003) conducted a meta-analysis reviewing studies published on the influence of weight reduction on blood pressure. This meta-analysis documents the improvement in BP by the reduction in weight gain in hypertensive patients, especially those taking antihypertensive medications. They identified 25 articles that met their criteria, especially non-pharmacological weight reduction. Energy or calorie restriction,

increased physical activity and sometimes a combination of both were used in the meta-analysis of the RCTs. Whelton, Chin, Xin & He (2002), concluded that BP was considerably reduced with minimal overall weight loss, implying that exercise alone lowers BP freely of changes in body weight.

In 2011, Guo et al. (2011) reviewed 26 studies of which 20 were cross-sectional and six were longitudinal studies with a combined sample size of 250,741 individuals. Their outcome measures were the predictors of preHTN; BMI, and waist circumferences, dyslipidemia, fasting plasma glucose, smoking and drinking, and predictors of progression from preHTN to HTN (increased age, male sex, low education status and C-reactive protein).

Guo et al. (2011) also found significant association of fasting plasma glucose, total cholesterol, and LDL-C with HTN. Eight studies done on fasting plasma glucose were included in this meta-analysis. With 10 studies investigating the correlation between smoking and drinking eight of which reported drinking met with conflicting results. Although they report their limitations as only searching PubMed and The Cochrane Library and admit there needs to be further study, both meta-analyses conclude by saying many of the risk factors mentioned preclude the progression of preHTN to HTN.

Randomized Control Trials

Four randomized control trials reported on outcomes of blood pressure from any form of lifestyle modifications. A total of 2,133 individuals participated in these trials. One study by Aldana et al. (2005) also measured knowledge, nutrition, physical activity and other chronic disease risk factors. Overall the studies compared usual care or no intervention to at least one lifestyle modification. Three of the four studies held an educational intervention course of some kind. One study however assigned the control group a typical United States diet and the DASH

diet was assigned to the intervention group (Sacks et al., 2001). Another study included the physicians as part of the study and used internet-based training, self-monitoring and quarterly feedback reports as the intervention (Svetkey et al., 2009). The latter two studies both showed significant positive effect of the interventions used.

Elmer et al. (2006) is continuation of a prior study at 18 months, however their measured outcomes were the individual components of lifestyle modification. They used weight, cardiorespiratory fitness, and physical activity assessed at baseline, six months, and 18 months. The results after 18 months showed an increase in fitness measured by heart rate for all groups. After 18 months, all three groups showed a decrease in absolute blood pressure. Their conclusion, individuals with preHTN and stage 1 HTN can implement LM and sustain them for an extended period, control their BP, and reduce their risk for CVD.

After Aldana et al. (2005) conducted the last RCT reviewed, their conclusion support the RCTs presented earlier. They used the Coronary Health Improvement Project intervention to which is focused on participants' improvement in cognitive understanding of the importance of a healthy lifestyle, improvement in nutrition and physical activity, and improvements in variables that affect diabetes, HTN, CVD and cancer. They held a 40-hour educational course delivered over a four-week period, meeting four times a week for two hours. The reported dramatic change in BP among the participants in the intervention group was that prevalence of HTN decreased from 18.5 % to 7.5% at follow up, supporting lifestyle modification.

Strength of the Evidence

The purpose of the literature review was to appraise the evidence of the effectiveness of an educational intervention of LM changes on BP in adults with preHTN. There is a broad scope of evidence that has been steadily and methodically reviewed. The systematic reviews are

considered the most rigorous and the strongest level (Level 1) of evidence and approach to minimization of bias in summarizing research (Melynk & Fineout-Overholt, 2011). The five randomized control trials reviewed are considered to be Level II evidence. They are generated from at least one well-designed randomized clinical trial (Melynk & Fineout-Overholt, 2011).

Conclusion

This literature review supports that lifestyle modification has a positive effect on lowering blood pressure in adults. This suggests that educational intervention creates awareness of the many risk factors leading to CVD and that those risk factors can be changed. As shown in the study done by Svetkey et al. (2009), primary care providers can also benefit from educational intervention. It seems to be the consensus of most of the studies reviewed that some participants fail to continue with behavioral changes once the study is completed. It would be ideal to see individuals adopt healthy lifestyle behaviors and maintain them for life. Based on the findings in this literature review, LM's should be implemented. Evidence shows that this implementation can reduce BP, thereby preventing the progression from preHTN to hypertension. The interventions in these studies, some being complex, are applicable to practice. In the primary care setting these very same standards of care can be implemented for the type of population that is unique to a rural area.

Table 3

Literature Analysis of Lifestyle Modifications Effect on Blood Pressure

Author (Date)	Design	Sample	Outcome Measures	Intervention	Results	Limitations
Ebrahim & Smith (1998)	Level I Systematic Review	25 articles-from 1966-1995	BP	Salt restriction, weight reduction, stress management, exercise, & alcohol reduction	Control group: 95% CI: salt restriction -2.9 (-5.8,0.0); weight loss -5.2(-8.3,-2.0); stress control -1.0(-2.3,+0.3); & exercise -0.2(-2.8,+2.4). Normotensive: salt restriction -1.3(-2.7,+0.1); weight loss -2.8(-3.9,-1.8); exercise -0.2(-2.8,+2.4), & alcohol reduction -2.1(-4.1,-0.1). Weak evidence except for weight loss.	Some low methodological quality and not well controlled. Findings may be overestimates of effect.
Fleming & Goodwin (2008)	Level I Systematic Review	7 RCTs	BP, lipids, BMI, cardiovascular risk scores,	Physical activity, healthy-eating	2 studies showed positive results in BP (2 mm Hg), as compared to control group with size of effects small.	Meta-analysis not possible due to non-homogeneity of study populations.
Guo et al. (2011)	Level I Meta-Analysis	26 articles; 20 cross-sectional; 6 longitudinal. Sample of 250,741 individuals	BMI and waist circumference, dyslipidemia, Fasting Plasma Glucose, smoking and drinking	None. Assessing epidemiology of preHTN.	Overall pooled prevalence-36%; males>females at (40% vs 33%). Standardized mean difference for BMI was 1.37(95% [CI], 1.20-1.55); total cholesterol, 8.08(95% CI, 6.71-9.46) for LDL 5.14(95% CI, 3.09-7.18); and for FPG, 4.23 (95% CI, 3.28-5.18) all showed more significant in females. Pooled OR was 1.13 (95% CI, 0.93-1.37) for smoking; 0.98 (95% CI, 0.69-1.39) for drinking. Findings identify modifiable risk factors amendable to intervention.	Search databases limited to PubMed, Cochrane, English and Chinese. Potential for measurement error of outcomes. Time delay between search and publication.
Neter et al. (2003)	Level I Meta-Analysis	25 RCTs; 4874 participants	BP, BMI	N/A	Net weight reduction of -5.1kg (95% CI, -4.88—2.25) by energy restriction, increased physical activity or both reduced SBP by -4.44 mmHg (95% CI, -5.93—2.95); DBP -3.57 mmHg (95% CI, -4.88—2.25); Significantly lower BP reductions with avg weight loss >5 kg (-6.63 mmHg [95% CI, -8.43—4.82] vs -2.70 mmHg [95% CI, -4.59—0.81]) and DBP (-5.12 mmHg	Not specified. RCT's used in analyses were noted to have high internal validity.

Author (Date)	Design	Sample	Outcome Measures	Intervention	Results	Limitations
					[95% CI, -6.48—3.75] vs -2.01 mmHg [95% CI, -3.47—0.54]). Strong evidence for weight loss.	
Aldana et al. (2005)	Level II RCT	337 volunteers. Age 43-81.	Change in health knowledge, nutrition, physical activity, risk factors including BP	40-hour educational course over 4 weeks, 4 times per week for 2 hours..	Beneficial mean changes in scores tended to be significant for the intervention group. Variables improved scores: health knowledge, % body fat, total steps/week and most nutrition variables. Improvement in resting heart rate, total cholesterol, LDL cholesterol, and SBP and DBP. Control group-small but significant improvements in health knowledge, SBP and DBP, glucose, and some nutrition variables.	Participants highly motivated and had higher ed level compared to community. Short intervention (4 wks) with short follow (6 mos)
Elmer et al. (2006)	Level II RCT PREMIER 18 month results	810 adults with preHTN or stage 1 HTN	BP	1.Behavioral intervention, 2.Behavioral plus Dash diet 3.Advise only	Blood pressure decreased in all three groups. Reduction was greater for participants in groups 1 and 2 but not significantly different compared to the advice only group. Participants were able to sustain lifestyle changes over time.	Multi-site comprehensive RCT with population heterogeneity. Volunteers randomized.
Sacks et al. (2001)	Level II RCT, Multi-site	412 adults with BP >120/80	BP	30 day salt reduction + DASH diet	DASH diet with low sodium level reduced BP by 7.1 mmHg ($p<0.001$) in participants without HTN; by 11.5 mmHg ($P=0.03$) in participants with HTN. Combination had greater effect.	Multi-site trial with population heterogeneity. Volunteer randomized.
Svetkey et al. (2009)	Level II RCT	8 primary care practices; 32 MD's, 574 patients	Change in SBP at 6 months. Change in DBP at 6 & 18 months. Height, weight, intake, physical activity, medications, lab measures.	1. Trained MD 18 mos. Intervention. 2. Control MD, usual care. 3.Patient 20 week LM group session 4. Patient control usual care advice for BP control office visit.	MD control + Patient control, blood pressure fell by mean 6.7 ± 12.8 mmHg at 6 mos; MD intervention + Patient control, blood pressure fell by 5.3 ± 12.1 mmHg Pt intervention + MD control, blood pressure fell by 7.1 ± 12.1 mmHg. MD intervention + Patient intervention, blood pressure fell by 9.7 ± 12.7 mmHg significant compared to other groups, p=.0072 At 6 months there was a significant interaction effect for MD + Patient intervention.	Patient completion at 6 months was 91% and at 18 months was 88%. Only 10% of patients were randomized therefore not generalizable.

Chapter Three: Methods

This chapter describes design, source, sample, collection, measures and analysis of the data. The design is a retrospective review of existing data obtained from patient records pre and post education about lifestyle modification. The answer to the project question, "In adults with prehypertension does education on lifestyle modification affect blood pressure," was explored.

Procedure, Sample, and Data Collection

An educational intervention on lifestyle modification for adults with preHTN was implemented in a rural primary care practice following recommendations of the JNC7 (USDHHS, 2004) and approval of the Primary Care Physician of the clinic. The educational lifestyle modification program was delivered by the Nurse Practitioner to adult patients 18 years of age and older who were identified as being prehypertensive during a non-related scheduled office visit beginning in February 2013. For intervention details and script See Appendix A. Appendix B includes a color brochure designed and distributed by the NP regarding blood pressure and lifestyle modification. A web link to a 1.32-minute educational video was also shown during the visit. The LM intervention included counseling related to physical activity, weight loss, diet, sodium intake, alcohol intake, and smoking cessation.

Data collected during the visit per customary clinical practice was BP, height, weight, and BMI, and was recorded in the patient electronic health record (EHR). Patients identified as prehypertensive were scheduled for free monthly blood pressure checks in the primary care office. A medical assistance trained in BP measurement protocols conducted the blood pressure follow-up checks. The medical assistant also received 30 minutes of training on how to maintain

a separate paper log of patients referred for blood pressure. Following standard practice the medical assistant recorded blood pressure, height and weight, and BMI into the electronic health record (EHR). Once the quality improvement project was completed the medical assistant was instructed on how to extract that information from the EHR, assign a code to the individuals in order to de-identify the data and enter it into an Excel spreadsheet. Once verified and analyzed, the medical assistant used the office shredder to destroy all project-related documents.

Measures

Descriptive Variables

Descriptive variables extracted from the EHR on patients who were prehypertensive included age in years, gender, as well as clinical measures of BP, height, weight, and BMI. Age and gender were used to describe the population sample. Coding of these variables is described in Table 4.

Outcome Variables

Blood pressure was the outcome of interest. Actual blood pressure readings were extracted from the EHR. The first BP measurement was the baseline and used to compare and categorize subsequent measures. A categorical variable indicating decrease in BP was generated and coded as yes decrease, no decrease, or no change in BP for subsequent measures. Participants who did not return for monitoring were coded as “lost to follow-up” in blood pressure.

Table 4

Variables Used for Project and Their Coding

Descriptive Variables	**Coding**
Age in years	18-99
Gender	1=male, 2=female
Weight in pounds	00.0-000.0
Decrease in weight	No=0, Yes=1, No need=2
Height in inches	00
Body Mass Index (BMI)	00.0
BMI category	1=Underweight = Below 18.5 2=Normal = 18.5-24.9 3=Overweight = 25.0-29.9 4=Obese = 30.0 and above
Improved BMI	No=0, Yes=1, No need=2
Outcome Variable	
Blood pressure measured in mmHG	000 systolic 00-000 diastolic
Decrease in blood pressure	No=0, Yes=1, Lost to follow-up=2

Data Analysis

Data was obtained from the EHR and entered into an excel file by the medical assistant. A statistician was consulted. The data was analyzed using SPSS® statistical software (Version 21.0, 2013, Excel, 2010). Categorical variables were described using counts and percentages. Continuous variables were described using median, means, standard deviations (SD), and ranges (minimum, maximum). The change in systolic and diastolic blood pressure from baseline to end

of study was explored using descriptive analysis. Bar charts were used to show relationships between variables.

Feasibility

The project was feasible and additional resources were not required. The regular office visit was used to implement the project using customarily collected data. The educational lifestyle modification program was part of the regular office visit taking less than 20 minutes of time. The use of available office supplies such as copy paper and copy machine was used to make copies of BP Fact Sheet and DASH diet plan.

Protection of Human Subjects

This quality improvement project commenced upon approval from the Institutional Review Board (IRB) of the University of North Florida (UNF) and Baptist Medical Center (see Appendix C and D). The UNF IRB deemed the project “not research involving human subjects” and therefore not necessary to be reviewed or approved by the UNF IRB. Baptist Medical Center IRB reviewed and approved the project via expedited review process. A retrospective chart review was conducted to extract de-identified patient descriptive and outcome variables among patient’s categorized as prehypertensive by an employee in the primary care practice. The risk to patients was considered to be minimal and individual patient informed consent was not required.

Chapter Four: Results

This chapter reports results that answer the quality improvement project question: Does an educational lifestyle modification program implemented in a primary care setting lower blood pressure among adults with preHTN? Data was collected from established patients in the primary care setting between February 1, 2013 and June 30, 2013. Results describe the sample, the intervention, and report the project outcomes.

Project Sample

The quality improvement project was conducted at a rural primary care clinic affiliated with a large network of clinics and hospital network. There were five participants in total. The participants mean age was 36.4 years (SD=6.9 years), with a range from 26 years to 43 years. Three (60%) of the five patients were female. The patients had a mean height of 67.6 inches (SD=3.4 inches), with a range from 64 inches to 72 inches. At the beginning of the study the mean weight was 204.6 pounds (SD=56.6 pounds), with a range from 158 pounds to 299 pounds. Their BMI decreased from baseline to end of study on average by .87 (SD=1.0), with a range from -1 (increase) to 2 (decrease). With respect to their heart rate the mean rate was 81 (SD=12.7), with a range from a heart rate of 63 to 96 beats per minute. The demographic information related to the patients is listed in Table 5. In this case, each baseline reading is matched with the reading at 3 months (end of study). For each patient, the difference between baseline and 3 months was calculated using descriptive analysis to determine change in blood pressure readings pre and post program.

Intervention and Follow-Up

On initial visit all identified prehypertensive adult patients were counseled by the PI about LMs, they viewed an educational video that gave a basic description of hypertension, and received a PI developed brochure. During the interactive time with the patient, the PI discussed lifestyle modification interventions such as weight loss, DASH diet, physical activity, dietary sodium reduction and reduction in alcohol consumption with each patient. All patients were instructed to return for monthly follow-up visits for 3 months. Each visit included BP, height and weight, heart rate and BMI checks.

Table 5

Description of Patient Characteristics

	N	Minimum	Maximum	Mean	Std. Deviation	Median
Age	5	26	43	36.40	6.914	39.00
BMI change from Baseline to End	5	-1	2	.87	.951	1.10
BMI Baseline	5	26.30	40.50	31.0600	5.55050	29.90
BMI End of study	5	27.00	39.15	30.1900	5.11669	28.10
Heart rate change from Baseline to End of study	5	-3	20	5.00	9.434	2.00
Heart Rate Baseline	5	63	96	81.00	12.728	86.00
Heart Rate End of study	5	66	88	76.00	8.124	76.00
Weight change from Baseline to End of study	5	-3	10	3.80	4.764	5.00
Weight Baseline	5	158	299	204.60	56.602	178.00
Weight End of study	5	161	297	200.80	57.081	173.00
Height (Inches)	5	64	72	67.60	3.362	67.00
Valid N	5					

Outcomes

The study began with SBP baseline median of 129 mmHg, with a range from 126 mmHg to 137 mmHg. The DBP baseline had a median of 86 mmHg, and a range of 82 mmHg to 90 mmHg. At the end of the study all five patients had a decrease in SBP and DBP, respectively. After participants incorporated one or more LMs, the median SBP decreased to 121 mmHg, and ranged from 108 mmHg to 128 mmHg. The end of study median DBP was decreased to 78 mmHg, and ranged from 77 mmHg to 83 mmHg. The outcome BP from baseline to end of study for SBP and DBP is presented in Table 6 and Figure 1. Patients who engaged in LMs had a clinically significant decrease in BP.

Table 6

Outcome Blood Pressure

	N	Minimum	Maximum	Mean	Std. Deviation	Median
SBP change from Baseline to End	5	3	18	9.80	5.450	9
DPB change from Baseline to End	5	3	9	6.40	2.408	7
SBP Baseline	5	126	137	130.00	4.183	129
DBP Baseline	5	82	90	85.40	3.130	86
SBP End of study	5	108	128	120.20	7.662	121
DBP End of study	5	77	83	79.00	2.550	78
Valid N	5					

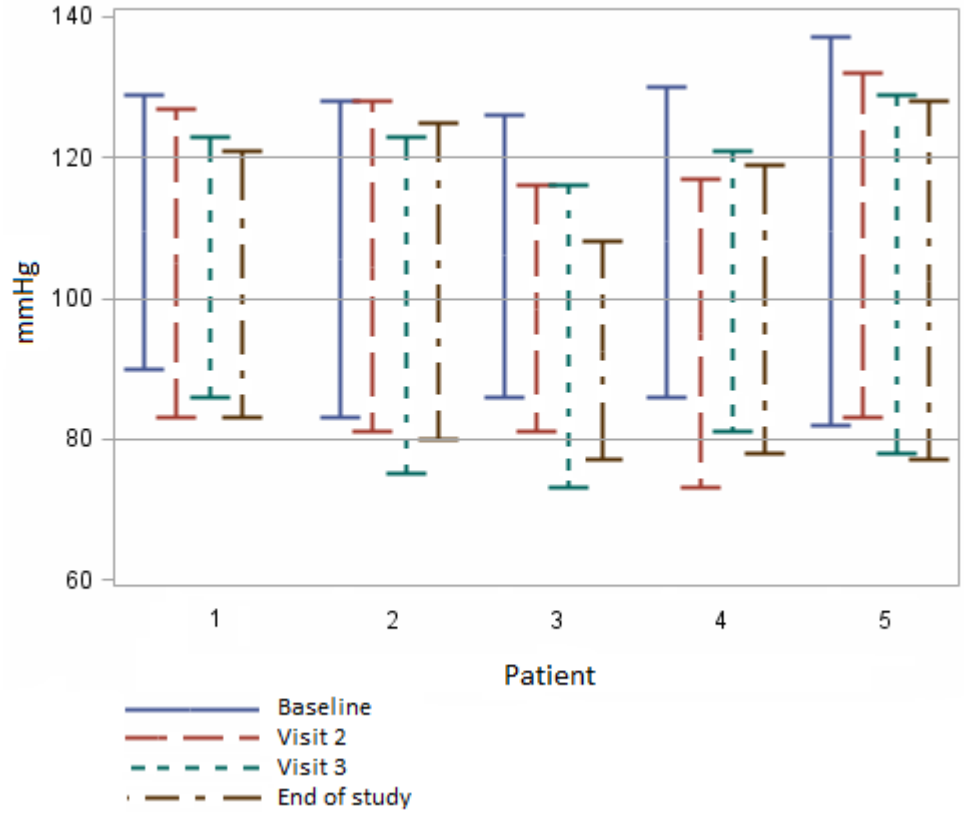

Figure1. Blood pressure: Systolic Pressure and Diastolic Pressure

Summary

The results of this quality improvement project indicate that implementing lifestyle modification and blood pressure monitoring in primary care is feasible. All patients received a minimum of one LM education intervention through initial contact. Findings indicate that blood pressure among this small sample was lowered at the end of the three month monitoring period. Statistical significance cannot be inferred due to small sample size; however, lower blood pressure would be significant for the individuals.

Chapter Five: Discussion

This chapter provides a discussion of the major findings of this quality improvement lifestyle modification project. The following will be discussed: the major findings and a comparison to the findings of similar studies, the clinical relevance to nursing practice, the study's limitations, and suggestions for future research.

Major Findings

An educational lifestyle modification program implemented in a primary care setting can lower blood pressure among adults with preHTN. The results are consistent with first line therapy found in current clinical practice guidelines for adults with prehypertension (USDHHS, 2004). Lifestyle modification is an important part of treating preHTN and preventing progression to HTN. This finding is consistent with the two systematic reviews findings of Ebrahim and Smith (1998) and Fleming and Godwin (2008). Incorporating one or more interventions of lifestyle modification can reduce adult prehypertension. In the Svetkey et al. (2009) study, the physicians received training on JNC7 (USDHHS, 2004) guidelines, LM for BP control, treatment algorithms, a decision tree on a pocket sized card, and quarterly feedback reports. The patient intervention consisted of 20 weekly group sessions over six months on LMs. The combination of physician and patient intervention yielded a total decrease of 9.7 mmHg ± 12.7 mmHg in systolic blood pressure.

Clinical Relevance

As a chronic disease, hypertension is one of the most prevalent conditions in the United States. It is responsible for $76.6 billion in health care costs, medications, missed days from

work not to mention a risk factor for stroke, heart and kidney disease (Johnson et al., 2011). There were many risk factors for preHTN observed in some patients including weight, high cholesterol, diabetes and other diseases. The justification for concern of cardiovascular disease is more likely to influence clinical practice. To implement this practice change into the clinical setting is not only feasible for all providers to accomplish but recommended. Lowering one's blood pressure can also reduce cholesterol levels and blood glucose. Aldana et al. (2005) states improvements in nutrition and physical activity, LMs that also lower BP, improves whole body glucose tolerance, increases insulin sensitivity, and amount of glucose transporter.

Lifetime risk of HTN increases as the general population ages. This study examined the effectiveness of incorporating a practice change as delineated by the JNC7 (USDHHS, 2004) regarding blood pressure. Implementing LMs in the clinical setting can be a challenge. Not all patients are receptive to changing behaviors. Therefore, the approach and presentation is crucial. Educating patients of diseases that HTN is associated with (heart –LV hypertrophy, angina, heart failure; brain – stroke or transient ischemic attack; chronic kidney disease; peripheral arterial disease; retinopathy), and that modifiable LMs play a vital role in lowering BP, is therapeutic and follows along with current JNC7 (USDHHS, 2004) guidelines.

Once prehypertenive patients are identified, it takes a few extra minutes to discuss the progression to HTN, the diseases HTN is associated with, showing the short video, and/or providing educational materials and answering questions to help guide patients on implementing the different LMs that can decrease blood pressure. At the end of data collection all participants had a lower BP reading compared to the baseline BP. The lower BP suggest that the participants followed some or all of the recommended LM practices such as diet rich in whole grains, fruits and vegetables, and low-fat diary products (DASH diet) (can reduce BP by 8-14 mmHg), eating

less sodium (can reduce BP by 2-8 mmHg), limiting alcoholic beverages can reduce BP by 2-4 mmHg), engaging in exercise (can reduce BP by 4-9 mmHg), losing weight (can reduce BP by 5-20 mmHg/kg), and smoking cessation (can reduce overall risk for cardiovascular disease) (USDHHS 2004).

The JNC7 (USDHHS, 2004), calls for providers to begin prompt implementation of LMs for adults with preHTN to stop the progression to HTN. Because of the known effectiveness of LMs modifications, Guo et al. (2011) suggests providers also be aware of individuals at an increased risk for cardiovascular disease. Once identified, providers should encourage patients to incorporate as many LMs to reduce modifiable risk factors for a greater benefit. From a clinical perspective it is crucial that providers begin this intervention as the standard of care.

As early as two months ago the USDHHS released the Eighth Joint National Committee (JNC 8) recommending nine new guidelines on the management of adult hypertension. The greatest change is in patient's aged ≥60 years to initiate pharmacologic treatment at SBP ≥ 150 mmHg or DBP ≥90 mmHg to a goal of SBP ≤150 mmHg and DBP ≤90 mmHg. The new JNC 8 has not changed the parameters for the new PreHTN classification and LM remains the recommended treatment so the results of this project are not affected by the update of the guidelines. Providers should be aware that guidelines change and are revised and updated periodically as new evidence emerges.

Limitations

This quality improvement project targeted adults with preHTN in a rural setting. The main limitation to this project was the limited number of patients with prehypertension. In many cases, patients were either already diagnosed with HTN or were already being treated with medication therapy. Therefore sample size became the major limitation to this study. Secondly,

due to administrative security settings on the computers, in the office, a personal electronic device had to be used to show the short video on basic HTN. Had access to the Internet been possible on clinic computers, the process would have been shorter and the provider could have spent more time with the patient on the educational program. Third, even though the clinical setting allowed participants to schedule follow-up BP readings freely and at their convenience, there were participants lost to follow up. The main reason stated for this was time off from work. Many participants were unable or unwilling to take the time off from work during clinic hours. Offering extended hours for a specific day of the month for return visits could have provided for a lower loss to follow up rate. Also, individuals may have returned for clinic visits if they received reminders.

Implication for Future Study

Future study should include identifying strategies to increase patient participation and improve sample size. This can be achieved by increasing patient awareness of guidelines, consequences of HTN, and benefits of incorporating one or more lifestyle modifications into their daily lives. Finally, more study is needed and would be beneficial if long-term benefits of LMs that reduce disease morbidity and mortality are studied.

Conclusion

This study suggests that an educational lifestyle modification program implemented in a primary care setting is feasible and can have a positive effect on lowering blood pressure among adults with preHTN. Providers can confidently promote LMs to reduce BP using JNC7 (USDHHS, 2004) guidelines and available educational materials and resources. Whittmore et al. (2010) reports that the implementation becomes easier over time. The significance to patients includes positive health outcomes and reduced reliance on pharmaceutical measures to control

HTN. Consequently, patients with their providers can impact healthcare costs, prevent the progression of preHTN to HTN, and reduce stroke, heart, kidney, and other diseases.

Appendix A
Lifestyle Modification (LM) Intervention
Intervention and First Line Treatment of Prehypertension in Primary Care

During an office visit the primary care provider addresses blood pressure with the patient using the 5 A's Behavior Change Model (Assess, Advise, Agree, Assist and Arrange) as a guide.

Ask and Assess about lifestyle behaviors:

NP might say
"Good morning/afternoon, in looking at your vital signs, I notice your blood pressure is slightly elevated". "Can we talk about that for a minute?"[Asking permission]
"Did you know that what was once considered normal BP, 120's/80's, is now considered prehypertension by the new JNC 7 guidelines?" "Although your blood pressure is not classified as high blood pressure, it could progress to it"
"The new guidelines now want providers to intervene at this time to prevent the progression to hypertension." This is done with what is called Lifestyle modifications; do you know what those are?"
[Assessing basic knowledge of HTN and assessing lifestyle]

Information provided includes: Explain prehypertension to patient. Show short 1:32 second educational video about the basics of HTN. The video is completely on the layperson's level of understanding. It demonstrates blood flow, factors affecting it, and the dangers resulting from HTN.

After the video is shown the NP then uses motivational interviewing techniques to advise the patient about changing the behaviors that are applicable. Ask permission to talk about LM, this shows respect and caring for patient.
"What is your daily diet like?" "Do you exercise regularly?"
If they smoke, are overweight, and/or drink alcohol the NP might say:
"I see that you are a daily smoker, how much do you smoke?" "Any thoughts on quitting?"
"What kind of alcohol do you drink and how much?" "Any thoughts on quitting or limiting intake?"

Advise and Agree to change LM: Motivational interviewing:

NP might say
"Would you be interested in learning how you can reduce your blood pressure?"
"Let's talk about changing your daily diet and incorporating an exercise regimen?"
"Did you know that cutting your sodium intake down to 2400 grams a day, 1 teaspoon, can reduce you BP by approximately 2-8 points", and that brisk walking 30 minutes a day for most days of the week reduces your BP by 4-9 points?"

Information provided includes: Patients that are interested in reducing BP the *NP might say*, "I am glad you recognize the potential benefits of lifestyle changes." A LM brochure is then handed

and reviewed with the patient. This leads to in depth counseling on benefits of LM, harms of HTN, and short and long-term goal setting.

For the prehypertenive patient unsure of using LM to reduce BP the *NP might say* "what concerns you most about reducing your BP?" This might introduce barriers and challenges that need to be addressed and overcome. The patient may not perceive a need to change if they are not experiencing any apparent problems at this time. Giving this patient brief advice on BP reduction may lead to future interest in LM changes when those challenges and barriers are reduced or removed. The *NP might say,* "Perhaps we can address this again at your next visit."

Assist and Arrange LM incorporation: The patient who desires to make LM changes and set a goal date.

Information provided includes: The NP provides counseling based on the JNC7 (USDHHS, 2004) and on individual assessments of patient's lifestyle. The NP helps the patient devise a Self-Management Action Plan. The plan addresses barriers and concerns, and strategies that will encourage and increase the chance of successful LM incorporation. A handout on the Dietary Approach to Stop Hypertension (DASH) diet is given to assist the patient in knowing the proper foods to eat. The LM brochure also has links to websites the patient can access at their own convenience to aid in their knowledge and success of these changes.

Arrange for follow-up:

Information provided includes: At monthly intervals the patient will visit the office for routine height and weight, and BP measurements. The patient may also call the office or schedule an appointment with the NP for any questions or concerns.

Appendix B
Lifestyle Modification (LM) Intervention Brochure

Healthy Living and Awareness

Making lifestyle changes can have a positive long lasting effect on blood pressure and help keep you off medications.

A lifestyle change not only lowers your blood pressure but also can lower blood lipids (fats) and blood glucose (sugar).

Information on the Internet

High Blood Pressure Basics Video
http://youtu.be/a3aC9BDpdAo

Treating High Blood Pressure Video
http://youtu.be/XbLmIoyDJuE

Physical Activity
www.cdc.gov/physicalactivity/

My Plate
http://www.choosemyplate.gov/

ANDREA M. PATTERSON
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Baptist Primary Care, Family Practice
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Callahan, Fl. 32011
904 879-4544

LIFESTYLE MODIFICATION

Lower your Blood Pressure!

Eat healthy
Limit salt
Limit alcohol
Move more
Lose weight
Stop smoking

This brochure is based on findings from research and national guidelines

- Hypertension or high blood pressure is a SERIOUS health problem.
- It can lead to heart disease, stroke, kidney failure and other problems.
- The DANGER is you can't FEEL high blood pressure.
- YOU can keep track of your blood pressure.
- YOU can do something!

		Top Number		Bottom Number
Normal		<120	and	<80
Pre-High Blood Pressure		120-139	or	80-89
High Blood Pressure	1	140-159	or	90-99
Very High Blood Pressure	2	>160	or	>100

What YOU Can Do

Eat Healthy

Vegetables, fruits, whole grains, high fiber foods, nuts, beans, lean meats, fish containing omega 3 fatty acids, skinless poultry, low fat dairy products.

Less cholesterol & fat. Try the American Heart Association DASH diet.

Eat less Salt

Eat less than 2.4 grams a day (1 teaspoon) or 1.5 grams a day if you are diabetic. Read labels carefully as salt is in lots of foods – not just in your salt shaker.

Drink less Alcoholic beverages

No more than 2 drinks per day. One drink = 12 oz of beer, 5 oz of wine, and 1.5 oz of 80 proof liquor.

Move More

Walk, swim, bike, dance, use the stairs, etc., at least 30 minutes a day.

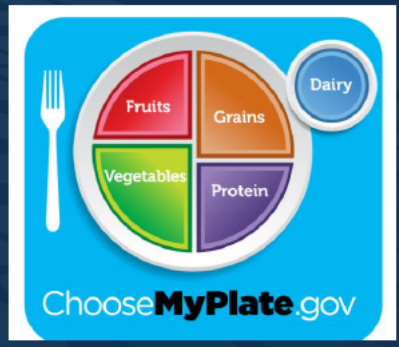
Lose Weight

Weight loss means moving even more and eating fewer empty calories like alcohol.

Stop Smoking

Smoking is linked to blood pressure, stroke, and heart disease. Try to stop.

Ask me for Help



Appendix C
IRB Approval Documents

UNF
UNIVERSITY of NORTH FLORIDA.

Office of Research and Sponsored Programs
1 UNF Drive
Jacksonville, FL 32224-2665
904-620-2455 FAX 904-620-2457
Equal Opportunity/Equal Access/Affirmative Action Institution

MEMORANDUM

DATE: October 11, 2013

TO: Ms. Andrea Patterson

VIA: Dr. Barbara Kruger
Nursing

FROM: Dr. Krista Paulsen, Chairperson
On behalf of the UNF Institutional Review Board

RE: Review of New Project by the UNF Institutional Review Board IRB#501110-1:
"Evaluating the Effects of an Educational Lifestyle Modification Intervention on Blood Pressure in Adults with Prehypertension"

This is to advise you that your project, "Evaluating the Effects of an Educational Lifestyle Modification Intervention on Blood Pressure in Adults with Prehypertension" was reviewed on behalf of the UNF Institutional Review Board. You are receiving this waiver because you will not be obtaining individually identifiable data about human subjects so this project was declared "not research involving human subjects" based on the federal definition of research involving human subjects as stated in the U.S. Department of Health and Human Services Code of Federal Regulations 46.102. Therefore, it is not necessary for this project to be reviewed and approved by the UNF IRB.

Thank you for submitting your work for IRB review. We appreciate that you understand the value of IRB review of research and projects conducted at UNF. Any unanticipated problems involving risk and any occurrence of serious harm to subjects and others shall be reported promptly to the IRB. This waiver should be kept for your records and applies to your project in the form and content as submitted to the IRB for review. Any variations or modifications to this waived project as related to dealing with human subjects must be cleared with the IRB prior to implementing such changes.

Should you have questions regarding your project or any other IRB issues, please contact the research integrity unit of the Office of Research and Sponsored Programs by emailing IRB@unf.edu or calling .
This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within UNF's records.

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MEMORANDUM

TO: Andrea M. Patterson, MSN, FNP-BC

FROM: Michael Joyce, MD, PhD Signature Deleted

DATE: November 11, 2013

RE: **Expedited Review – Initial Approval**

The Institutional Review Board (IRB) of Baptist Medical Center (BMC) met on October 17, 2013 and the following new protocol was reviewed and approved via expedited review for a period of one year:

> **#13-66, Baptist, "Evaluating The Effects of an Educational Lifestyle Modification Intervention on Blood Pressure in Adults with Hypertension"** -Introductory Questionnaire; Protocol Submission Checklist; Protocol Version 1 dated 12 July 2013; HIPAA Waiver; UNF IRB Waiver dated 11 October 2013

The anniversary date for this study is October 16, 2014. At that time, please submit a report of your experiences with this protocol.

Should you have any questions, please contact the IRB office. The BMC IRB meets the requirements in 21 CFR 56 (Rev.), 45 CFR 46 (Rev.) and ICH (E6) GCP guidelines. Good luck with this endeavor.

Appendix D

BAPTIST Primary Care

January 13, 2013

University of North Florida
1 UNF Drive
Jacksonville, FL 32216

Dear Institutional Review Board:

I give Andrea Patterson permission to conduct her study entitled Evaluating The Effects of an Educational Lifestyle Modification Intervention on Blood Pressure in Adults with Prehypertension. Andrea is a doctoral student at the University of North Florida (UNF). Pending UNF IRB approval the Study is estimated to start February 2013.

If you should have any questions I can be reached from 9:00 am to 5:00 pm Monday thru Friday

Sincerely,

Signature Deleted

Warren S. Groff, M.D.

45465 Fifth Avenue • Callahan, Florida 32011
Phone: 904/879-4544 • Fax: 904/879-4411 • Website: www.e-baptisthealth.com

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Vita

Andrea M. Patterson was born and came to the United States with her family in 1971. She grew up in Brooklyn, New York, moved to Ft. Lauderdale, Florida where she joined the United States Navy and retired in 2006. During her service to country she attended and graduated from Florida Community College at Jacksonville with an Associate in Arts (1998) and Associate of Science in Nursing (2000), and Jacksonville University with a Bachelor of Science in Nursing (2006). She completed her Masters of Science in Nursing in 2012 at University of North Florida, Jacksonville, Florida. She is currently enrolled in the Doctor of Nursing program at University of North Florida, Jacksonville, Florida.

Ms. Patterson is currently working as a Board Certified Family Nurse Practitioner at Baptist Primary Care, Callahan where she has worked since October 2012. Her previous work experience includes 12 years as a staff nurse in various areas such as Telemetry, Neuro Intensive Care Unit (ICU) and Medical ICU.

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