Prevent and manage high blood pressure using theory-based comprehensive nonpharmacological approaches

by

Yanli Wang

B.S., Tianjin University, 2007
M.S., Tianjin University, 2009

AN ABSTRACT OF A DISSERTATION

submitted in partial fulfillment of the requirements for the degree

DOCTOR OF PHILOSOPHY

Department of Food, Nutrition, Dietetics, and Health
College of Health and Human Sciences

KANSAS STATE UNIVERSITY
Manhattan, Kansas

2024

Abstract

High blood pressure (HBP), also known as hypertension (HTN), is a major health problem worldwide. The prevalence of HTN is a public health concern because it increases the risk for cardiovascular diseases worldwide.

Primary prevention in the general population to prevent the risk of HTN and associated complications later in life is beneficial. Proper management in the hypertensive population could substantially reduce healthcare costs and improve quality of life.

We conducted focus groups and one-on-one interviews to explore understanding, perceptions, and knowledge among adults on how to prevent and manage hypertension using nonpharmacological approaches and to identify nutrition education gaps for educational interventions. Our qualitative study revealed four underlying themes, which set the tone for education needs and knowledge gaps for educational interventions. The four underlying themes that emerged from the qualitative study were: (1) HTN and associated risk factors, (2) underestimated HTN complications, especially organ damage caused by HTN, (3) nutrition and HTN, and (4) integration of nonpharmacological approaches as part of a healthy lifestyle. The qualitative study provides a strong basis for developing effective nutrition education programs to prevent and manage HTN in adults.

A randomized controlled trial was applied to investigate the effects of a four-week educational intervention on knowledge, perceptions, and behavior change in preventing and managing HBP among adults based on the Protection Motivation Theory (PMT) as a theoretical framework. Significant differences were observed between control and intervention groups in knowledge level ($p=0.04$), perceived severity ($p=0.00$), and response efficacy ($p=0.01$) after controlling for pre-survey data. Fruit and vegetable consumption increased compared to the

baseline but was still below the dietary recommendation. Dietary potassium consumption increased in the intervention group compared to the control group. No significant difference was observed between the control and intervention groups in quality of life after controlling for pre-survey data. The findings of the study indicated that a short-term educational intervention promoting nonpharmacological approaches had positive effects on HBP prevention and management.

Our study underscores the potential of educational interventions using PMT as a theoretical framework in the short-term prevention and management of HBP among adults. By intensively focusing on nonpharmaceutical approaches, we significantly enhanced knowledge, perceived severity, response efficacy, and protection motivation. Moreover, our findings demonstrate that a brief educational intervention promoting nonpharmacological approaches can effectively induce behavior change in HTN prevention and management.

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Approved by:

Major Professor
Dr. Tandalayo Kidd

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Acknowledgements

Too much to be thankful for as I stand at the end of the journey, looking back at the past few years. Nothing could have been possible without the wonderful and special people who have crossed my path or walked along the journey.

Thank you Dr. Tandalayo Kidd for being an advisor, a mentor, a cheerleader, and an ever-present friend. I could not have been who I am today without you. You helped me grow in so many ways, academically, mentally, and spiritually. I have learned so much from you and have received so much support and love from you. You started my dream of being a nutrition educator and I saw how you carried me through to fulfill the dream.

I also want to thank my committee members, Dr. Mark Haub, Dr. Richard Rosenkranz, and Dr. Nancy Muturi. I could not have done this dissertation without your comments, suggestions, questions, and invaluable feedback on my Ph.D. study. Thank you for helping me to design, write, and finalize every detail to make it a better project.

My sincere gratitude goes to my beloved husband and daughter, Wei and Hannah. Thanks for being so supportive as I completed a very important chapter of my life. Your every single word of encouragement, sweet smile, and deep-felt hugs gave me the strength to make progress in this journey!

A big thanks goes to my family in China, who have been very supportive throughout this journey. Although they were far away on the other side of the world for most of this journey, they have always been in my heart all the time! Their love has supported me through this eventful journey at various challenging times.

In addition to my family, the support groups, the International Friday Night group, and the Manhattan Chinese Christian Fellowship have given me support beyond what I can ask. Your

deep love helped me through hard times while pursuing a degree abroad. Your presence in need of help makes my journey of pursuing a Ph.D. not only an academic journey but also a journey full of hope, love, and encouragement.

My special thanks go to the 249ers, who are also Kidd's kids. I love you all dearly, Erika Lindshield, Yijing Li, Audrey Opoku-Acheampong, and Corey Miller! I cherish the time we spent together, discussing, chatting, laughing, sharing tears, and prayers. The memories we shared added a very sweet sense to my Ph.D. journey!

Thank you, Kathleen Hoss-Cruz and Zaw Wai Htoo, for your encouragement and support along the journey as peers. It is not easy to complete this journey alone, but your presence made it more manageable and pleasant knowing the fact that I am not alone on this journey.

We thank all the participants in the study, especially those who participated in both the qualitative and workshop sessions. My sincere thanks go to those who participated in the focus group or one-on-one interviews for their insights and comments to help me design the educational workshops. I deeply appreciate those 30 participants in the intervention study. I would not have been able to collect valuable data for my dissertation without your time, presence, support, persistence, and feedback.

The financial support I received from the Dissertation Award from the College of Health and Human Sciences ($1000) and the Graduate School AHSS Small Grant Fund ($1000) made this study less stressful. Thanks to the donors and the scholarship program.

I also thank the Seek magazine at Kansas State University and K-State Research and Extension for promoting my study throughout the university and throughout Kansas. Knowing that this study is making an impact in the community greatly encouraged me.

Lastly, I want to give myself a round of applause as I eventually finish up this challenging chapter of my life. In this journey, I enjoyed being a wife, a mom, and a student at the same time as I see myself and my family striving in different ways. Although there were storms of life I had to go through, I am glad I made it to the end of the journey and I am now ready to embrace a brand new chapter of life!

Dedication

I dedicate my dissertation to my dad who is in heaven now, as well as my family and friends who supported me all through this Ph.D. journey.

Chapter 1 - Introduction

High blood pressure (HBP), also known as hypertension (HTN), is a major health problem worldwide. The prevalence of HTN is a public health concern because it increases the risk for cardiovascular diseases (CVDs) worldwide. In 2023, The World Health Organization (WHO) released its first report on HTN and indicated that the number of people with HTN has doubled between 1990 and 2019, from 650 million to 1.3 billion (WHO, 2023). HTN was defined as blood pressure of 140/90 mmHg or higher or taking medication for HTN. WHO even projected the number of patients with HTN in the adult population in some areas will be higher by 2040 (Boateng & Ampofo, 2023).

In the United States, the data from the Behavioral Risk Factor Surveillance System showed that the age-standardized, self-reported diagnosed HTN was approximately 30% during 2017–2021 (Sekkarie et al., 2024), which indicated that HTN remains a significant public health concern across the States. The prevalence of antihypertensive medication use, single medication or a combination of several medicines, increased by approximately three percentage points, from 59.8% to 62.9% (Sekkarie et al., 2024). In 2017, the American College of Cardiology and the American Heart Association (ACC/AHA) updated HTN guidelines by increasing the threshold for diagnosis of HTN in adults. Under the 2017 ACC/AHA guidelines, HTN is when blood pressure is constantly higher than 120 mmHg systolic and 80 mmHg diastolic (Boateng & Ampofo, 2023; Whelton et al., 2018a). As a result of the current guidelines, the prevalence rate of HTN would increase from 31.7% based on the National Health and Nutrition Examination Survey 2017–2018 to 45.6% with the previous guidelines (Rana et al., 2020). This can also be translated as nearly half of American adults in the United States are considered to have HTN (Whelton et al., 2018a). The potential increase in the hypertensive population showed the

urgency for continuous efforts to reduce the incidence of HTN and promote overall cardiovascular health.

Problem statement

HTN, if left untreated, is associated with a high risk for the development of heart disease, stroke, and chronic kidney disease (Zhou et al., 2018). According to the most recent 2017 ACC/AHA HBP guidelines, a substantial increase in adults with HTN is expected. Consequentially, this will lead to an increase in the overall burden of HTN, which therefore highlights the importance of prevention and management of HTN in the US general population (Colantonio et al., 2018; Dorans et al., 2018).

Adverse health outcomes of HTN in adults

HTN is one of the most important public health problems and the number one modifiable risk factor for the development of CVDs and other chronic diseases (Zhou et al., 2018). Despite increased awareness of the importance of blood pressure control, research still showed about half of HTN patients remained undetected (Cheung et al., 2006). One of the reasons for the low diagnosis rate is the asymptomatic characteristic of HTN. In most cases, people with HTN may not show any symptoms. However, when blood pressure elevates, even with no apparent symptoms, the damage to the body has already started. In addition, it increases the risk of developing other life-threatening diseases, such as heart disease and stroke (Wang & Vasan, 2005; Zhou et al., 2018). Therefore, HTN is often called the “silent killer” (Pokharel et al., 2022).

HTN is also a major cause of clinical and pre-clinical damage to different body organs, such as the heart, brain, eyes, and kidneys (Celik et al., 2010; Schmieder, 2010). In many patients, the damage to blood vessels and, thus, to the organs begins soon after blood pressure is

elevated and, in some cases, even before HTN is diagnosed. Since HTN does not normally show symptoms, the need to manage blood pressure (BP) levels and keep BP levels within the normal range is necessary and important for overall well-being. The ultimate goal of managing HTN is to reduce the incidence of organ damage and prevent CVDs (Mancia & Parati, 2003).

In addition to the damage to the body, HTN also presents a substantial economic burden both at an individual and a societal level. Treatment of HTN requires an investment over many years to prolong disease-free quality of life. The AHA estimated that the national annual direct and indirect costs of HTN were $47.3 billion and $3.9 billion, respectively (Tsao et al., 2023). Compared to people without HTN, the healthcare cost of people with HTN is estimated to be $2500 per capita higher annually. A total of $131 to $198 billion is spent each year on HTN treatment, including the cost of healthcare services, medications to treat HTN, and loss of productivity from premature death (Kirkland et al., 2018). Prevention and treatment of HTN can effectively reduce healthcare costs and improve overall quality of life (Tsao et al., 2023).

Pharmacological approach vs. nonpharmacological approach to prevent and manage HTN

Pharmacological and nonpharmacological approaches are the two primary ways to manage HTN (Muntner, Whelton, et al., 2018). The ACC/AHA HTN guidelines outline a nonpharmacological approach as the recommended first-line treatment for people with elevated blood pressure levels. For hypertensive patients, proper management of HTN may involve both pharmacological and nonpharmacological approaches (Carey & Whelton, 2018).

Pharmacological approach

Pharmacological treatment plays a vital role in managing HTN. It refers to treating HTN using medication to manage blood pressure within the recommended range (Moick et al., 2023).

Reduction of BP levels using antihypertensive medication is normally recommended by physicians to patients with a clear diagnosis of HTN in a clinical setting (Al-Makki et al., 2022).

Although antihypertensive medications have been proven to be effective in lowering blood pressure and reducing the risk of CVDs and related complications, concerns about risk versus benefits have led to low adherence rates to prescribed medication. In addition, once the treatment starts, it can be a life-long process that increases the financial burden and challenges medication adherence (Dzau & Balatbat, 2019). Approximately 40%–60% of patients with HTN do not follow the prescribed treatment (Jankowska-Polanska et al., 2017). Patient nonadherence is a major factor associated with poor blood pressure control.

HTN is often asymptomatic, but treatment may result in side effects like dry cough, dizziness, nausea, and headache, depending on the drug administered. The decision to use antihypertensive drugs involves weighing the potential benefits against any adverse effects. Patients fail to follow the instructions to take prescribed HTN medication because of the potential side effects after taking the medication, which will also lead to a low adherence rate (Hunter et al., 2021).

Nonpharmacological approach

Nonpharmacological management of HTN involves a wide range of strategies that encourage individuals to adopt a healthy lifestyle to prevent and manage HTN (Dhungana et al., 2022). This approach has gained popularity worldwide due to its benefits and positive impact on the overall health of individuals, with little or no side effects and reducing the financial burden of medication expenses (Kodela et al., 2023).

Nonpharmacological approaches in the prevention and management of HTN is a dynamic process that involves a single or a combination of several interventions, such as being physically

active, attaining a healthy weight, following dietary interventions like dietary approaches to stop hypertension (DASH) diet, staying on a low-sodium diet, limiting alcohol consumption, smoking cessation, and adequately managing stress (Mahmood et al., 2019; Verma et al., 2021).

Compared to pharmacological approaches, nonpharmacological approaches have shown benefits in HTN prevention and management, especially among those with elevated blood pressure levels. The adoption of nonpharmacological approaches could potentially slow down the progression from being evaluated to different stages of HTN.

For hypertensive patients, the benefits of using nonpharmacological approaches are substantial in addition to the pharmacological treatment. Interventions involving nonpharmacological approaches could help reduce the daily dose of antihypertensive medication (Verma et al., 2021). Research also showed that some nonpharmacological approaches are more effective than commonly prescribed medications when pre-treatment blood pressure levels are accounted for (Mahmood et al., 2019). In addition, nonpharmacological treatment provides an additional effective method for improving medication adherence and long-term BP control (Hong & Shan, 2021),

In the hypertensive population, nonpharmacological interventions can be applied either as an initial treatment before drug therapy or as a complementary approach (Verma et al., 2021). In hypertensive patients on pharmacological treatment, lifestyle changes that can be adopted permanently may reduce the use of antihypertensive medication. Nonpharmacological management of HTN has been an attractive approach for dealing with HTN and promoting overall cardiovascular health worldwide due to its cost-effectiveness and additional health benefits with few or almost no side effects (Dorans et al., 2018).

Theoretical application in HTN prevention and management

Protection Motivation Theory (PMT) has been widely used in preventing several health-related issues, including cancer and weight management (Daddario, 2007; Li et al., 2020). The main constructs of PMT theory have been adopted and shown to be effective in influential in healthy behavior prediction. However, to our best knowledge, PMT has not been used to prevent and manage HTN with a special emphasis on organ damage which is the construct of perceived severity in the PMT theory.

Justification

National guidelines recommend five nonpharmacological approaches to preventing HTN: (1) reduction of sodium intake; (2) an eating plan that is rich in fruits, vegetables, and low-fat dairy products and reduced in saturated fat, total fat, and cholesterol; (3) prevention and reduction of excess body weight; (4) regular physical activity; and (5) moderation of alcohol intake (Bundy et al., 2018). In addition to these recommendations, smoking cessation, stress management, and monitoring BP levels have also gained substantial attention in preventing and managing HTN (Verma et al., 2021).

Prevention and management of HTN will increase cardiovascular health and reduce the economic burden associated with this prevalent disease (Zhou et al., 2020). Nonpharmacological strategies as the first-line treatment are successful primary and adjunctive treatment options for lowering blood pressure. Moreover, the benefits of many of these approaches extend to and promote overall health and well-being (Verma et al., 2021).

The study was designed with the guidance of protection motivation theory (PMT), which was created to explain the effect of fear appeals on health attitudes and behaviors (Rippetoe & Rogers, 1987). PMT also attempts to explain and predict what motivates people to change their

behavior (Li et al., 2020). Using PMT to design interventions to promote healthy behaviors helps to motivate an individual to initiate and maintain healthy behaviors to prevent health problems.

Purpose of study

Given the potential negative health outcomes and high healthcare burden of HTN in adults in the United States, nutrition intervention programs using nonpharmacological approaches to prevent and manage HTN in adults may be beneficial. Prevention plays a major role before the onset of HTN, while management, which involves a comprehensive approach to controlling HBP, is crucial once diagnosed with HTN. Although nonpharmacological approaches are effective in preventing and managing HTN, studies investigating both the severity of organ damage caused by HTN and the beneficial aspects of using nonpharmacological approaches to HTN prevention and management are rare.

Therefore, the purpose of this study is two-fold. First, to assess nutrition education needs and identify knowledge gaps related to using nonpharmacological approaches in HTN prevention and management. Second, to test the effectiveness of a four-module nutrition education resource, designed based on the focus group needs assessment for the adult population using nonpharmacological approaches to promote healthy lifestyles to prevent and manage HTN among adults.

Based on the PMT framework, this project will focus on answering the following research questions: (1) Will there be a statistically significant difference in knowledge between control and intervention groups after controlling for pre-survey data? (2) Will there be a statistically significant difference in various constructs of PMT theory between control and intervention groups after controlling for pre-survey data? (3) Will there be an improvement in lifestyle behaviors to prevent and manage HTN after the educational intervention? (4) Will there

be an increase in dietary sodium consumption and potassium consumption after the educational intervention? (5) Will there be an improvement in health-related quality of life after the educational intervention?

Chapter 2 - Literature review

Hypertension (HTN) is one of the leading public health problems and the number one modifiable risk factor for the development of cardiovascular diseases (CVD) and other chronic diseases (Zhou et al., 2018). HTN does not usually show signs of illness that the human body can see or feel, so it is often called the "silent killer"(Kalehoff & Oparil, 2020). Primary prevention in the general population to prevent the risk of HTN and associated complications later in life is beneficial. Proper management in the hypertensive population could substantially reduce healthcare costs and improve quality of life (Tsai et al., 2004).

Current 2017 HTN guidelines

The 2017 American College of Cardiology/American Heart Association (ACC/AHA) guidelines for the prevention, detection, evaluation, and management of HTN in adults provide recommendations for the definition, prevention, and treatment of HTN (Colantonio et al., 2018). This guideline was an update of the Joint National Committee (JNC7), published in 2003 (Chobanian et al., 2003).

In the 2017 ACC/AHA guidelines, normal blood pressure is defined as lower than 120 mm Hg systolic and 80 mm Hg diastolic, whereas in JNC7, normal BP was considered with a systolic BP lower than 140 mm Hg and diastolic BP lower than 90. According to JNC7, about 1 in 3 U.S. adults (32%) are considered to have HTN; however, with the definition of the new guidelines, a substantial increase in the HTN population is observed (Muntner, Carey, et al., 2018a, 2018b). The age-adjusted prevalence of HTN among US adults ≥20 years of age was estimated to be 46.7% in NHANES from 2017 to 2020 (50.4% for males and 43.0% for females). This equates to an estimated 122.4 million adults ≥20 years of age who have HTN (62.8 million males and 59.6 million females) (Tsao et al., 2023).

What used to be called “prehypertension” in JNC7 now is defined as “elevated blood pressure” (without a diagnosis of HTN), which means systolic blood pressure (SBP) is between 120 mm Hg and 129 mm Hg while the diastolic blood pressure (DBP) remains less than 80 mm Hg. Stage 1 HTN is now between 130 and 139 systolic or between 80 and 89 diastolic. Stage 2 HTN is now over 140 systolic or 90 diastolic. HTN categories according to 2017 ACC/AHA guidelines are shown in Table 2.1.

Table 2.1. Blood pressure categories according to 2017 ACC/AHA guidelines

Blood pressure category	Systolic mm Hg (top number)		Diastolic mm Hg (bottom number)
Normal	Less than 120	and	Less than 80
Elevated	120-129	and	Less than 80
HTN stage 1	130-139	or	80-89
HTN stage 2	140 or higher	or	90 or higher
Hypertensive crisis	Higher than 180	and/or	Higher than 120

The guidelines also clearly outline a diet-and-lifestyle approach as the recommended first-line treatment to prevent and manage HTN. This also explains why the increase in the prevalence rate does not indicate a significant increase in the population that needs medication treatment according to this guideline (Muntner, Carey, et al., 2018a). For people with elevated BP levels, medication treatments are not recommended right away; instead, evidence-based nonpharmacological approaches are highly recommended (Dhungana et al., 2022; Vamvakis et al., 2017). According to present guidelines, the first-line treatment for all hypertensive patients should be nonpharmacologic means and, if necessary, with pharmacological antihypertensive therapy.

Risk factors of HTN

Elevated BP is a major risk factor for heart disease, ischemic and hemorrhagic stroke, and renal failure. It also causes significant morbidity and mortality worldwide. In the U.S., heart disease is the leading cause of death (Webster & Heeley, 2010). Unfortunately, despite the increases in understanding and treating HTN, its prevalence continues to rise and remains high (Kearney et al., 2005).

Risk factors that could lead to HTN generally come from two different categories: unmodifiable and modifiable behavioral risk factors. Unmodifiable risk factors are those that are unavoidable and relate to who we are, such as age, sex, race and ethnicity, and family history (Lathrop & Soubrier, 1994; Padmanabhan et al., 2012). Modifiable behavioral risk factors relate to what we do, such as unhealthy eating habits, lack of physical activity, being overweight or obese, stress, alcohol overconsumption, and smoking (Sesso et al., 2008; Yan et al., 2003).

Unmodifiable risk factors

Age

Aging is a natural and continual process in the human race. This unavoidable process will eventually cause decreased body functions in all the organ systems. Over time, aging will lead to increased vulnerability and disease in older adults. HTN is a highly prevalent condition among adults 65 and over (Buford, 2016). Recent data from the NHANES indicate that 7 out of 10 older adults aged 65+ have HTN (Virani et al., 2020). Even though aging is unmodifiable, HTN seems to be the most prevalent and potentially modifiable factor in reducing CVD risks among older adults and, in the meanwhile, improving quality of life.

In recent years, HTN has become increasingly recognized as a critical risk factor for the development of cognitive decline and dementia (Buford, 2016). The capacity to perform basic

physical functions is a central aspect of health-related quality of life. Declines in basic physical functions such as walking also strongly predict future cardiovascular events (Heckman & McKelvie, 2008). Compared to their normotensive counterparts, older adults with HTN experience accelerated declines in physical function and increased incidence of disability. However, the mechanisms are yet to be fully elucidated (Buford, 2016).

Sex

The prevalence of HTN differs between sexes in the U.S. During early adulthood, women have lower SBP levels than men, while the opposite is true after they turn 60. DBP tends to be slightly lower in women than men, regardless of age.

The mechanisms responsible for age-related sex differences in BP are not fully understood. Still, they are attributable at least partially to the rapid decrease in sex hormones (e.g., estrogen) accompanying menopause. Other factors associated with a menopause-related increase in BP are overproduction of pituitary hormones, weight gain, or a combination of these and other undefined influences (Coylewright et al., 2008).

Even though sex difference exists in the development of HTN, whether sex should be a significant consideration in the choice of individual antihypertensive drugs continues to be a topic of intense interest and debate.

Race and ethnicity

The racial disparity in HTN and HTN-related outcomes has been recognized for decades. The prevalence of HTN in African Americans is higher than in other races or ethnicities in the U.S. (Lackland, 2014). The onset of HTN among African Americans is also earlier compared with other races or ethnicities.

Non-Hispanic (NH) black men and women were the most likely to have HTN compared with adults in other racial and ethnic groups (Go et al., 2014). According to NHANES 2017 to 2020 data, the age-adjusted prevalence of HTN among the NH Black population was 55.8% among males and 56.9% among females. In contrast, the prevalence rates for NH whites and Hispanics are 50.0% and 41.9%, respectively (Chobufo et al., 2020).

The reasons for the racial disparities in elevated BP and HTN-related outcomes risk remain unclear. However, the implications of the disparities of HTN for prevention and clinical management are substantial, identifying African American men and women with increased HTN risk and warranting interventions focused on these differences (Lackland, 2014).

Family history

Family history is a major predictor of HTN. One study screened a cohort with 9914 individuals to determine whether a family history of HTN is quantitatively associated with the prevalence of HTN. The results showed that an increase in the number of direct family members with HTN was associated with an increasing prevalence of HTN and elevated BP in the probands, independent of conventional risk factors for HTN (Tozawa et al., 2001). Similarly, several large-scale clinical trials (e.g., Dietary Approaches to Stop Hypertension, also known as DASH) have also identified genetic factors that determine responsiveness to dietary interventions (Bazzano et al., 2013). Consideration of a hypertensive patient's genetic profile seems important when caring for the patients.

Modifiable behavioral risk factors

Unhealthy diet

Eating an unhealthy or poor-quality diet has been associated with a high risk of HTN in all ages (Colantonio et al., 2018). These unhealthy eating patterns normally feature overconsumption of salt/sodium and low consumption of fruits and vegetables.

Based on data from NHANES 2017 to 2018, less than 10% of American adults met the dietary consumption requirement for sodium, which was less than 2300 mg per day. The estimated mean sodium intake by 24-hour urinary excretion was 4205 mg/d for males and 3039 mg/d for females from 2013 to 2014 (Tsao et al., 2023).

Consumption of high-sodium foods contributes to most of the dietary sodium consumption. These foods included prepared foods with added sodium, such as frozen dinners, boxed macaroni and cheese, canned soups, smoked meats, and sausages (Calliope & Samman, 2019; Dong, 2018). Research also showed that more than 70% of sodium consumed came from restaurants and processed food (Payne Riches et al., 2019). These foods are typically high in sodium, fat, and added sugar, which are the top three unhealthy nutrients commonly seen in the Western diet. Overconsumption of these unhealthy nutrients, especially sodium, could substantially increase the risk for HTN, obesity, and other cardiovascular events (Mohan & Campbell, 2009; Payne Riches et al., 2019).

Inadequate consumption of fruits and vegetables, especially fresh fruits and vegetables, also significantly contributes to the HTN risk. Other forms of fruits and vegetables, such as frozen, dried, canned, and 100% juice, may provide similar BP-lowering effects but should be consumed cautiously due to added salt and sugar and nutrient loss, e.g., fiber, during preparation. Based on data from NHANES 2017 to 2018, less than 10% of American adults meet the guidelines for consuming at least 2 cups of fruits and 2.5 cups of vegetables per day (Hoy et al., 2020).

Higher intake of fruits and vegetables, as a part of a healthy dietary pattern, was associated with a lower risk of HTN (John et al., 2002; Miura et al., 2004; Wang et al., 2012). Fruits and vegetables contain healthy nutrients, such as vitamins and minerals, and they tend to be low in calories, which will also help to reduce the chance of gaining excess weight and thus reduce the risk of HTN (Tsao et al., 2023).

Lack of physical activity

Physical inactivity is an important modifiable risk factor in the development of HTN. According to a self-report in 2018, the age-adjusted proportion of adults who reported meeting the aerobic PA guidelines for Americans (≥150 min/week of moderate PA, or ≥75 min/week of vigorous PA, or an equivalent combination of the two) through leisure-time activities was 54.2% (Gan et al., 2024). In addition, a lack of physical activity is likely to cause unwanted weight gain, contributing to elevated BP levels (Sobngwi et al., 2002).

Several studies consistently demonstrate the beneficial effects of physical activity on HTN with reductions in both SBP and DBP with as much as 5-7 mmHg reductions in those with HTN (Diaz & Shimbo, 2013; Kokkinos et al., 2009; Tsai et al., 2004). However, more evidence is needed to determine whether associations between physical activity and BP vary by frequency, intensity, time, or duration.

Being overweight or obese

Being overweight or obese remains among the most neglected public health issues worldwide. "Globesity" has been defined as a worldwide epidemic of obesity that is currently on the increase (Carneiro, 2021). Obesity can result in serious health issues that are potentially life-threatening, including HTN (Jiang et al., 2016) .

According to data from NHANES from 2017 until March 2020, the age-adjusted prevalence of overweight or obesity among adults ≥20 years of age in the United States was 71.2%, and the prevalence of obesity was 41.4% (Tsao et al., 2023). The high prevalence rate of overweight or obesity is one of the reasons that explain why the HTN rate remains high (Papathanasiou et al., 2015).

Although the relationship between obesity and HTN is well established in adults (Jiang et al., 2016), the mechanism by which obesity directly causes HTN remains unclear. One possible mechanism is that excess energy intake leads to an expansion of adipose tissue, which is the hallmark of obesity. This unusual adipose tissue may, in turn, induce activation of the sympathetic nervous system and the renin–angiotensin–aldosterone system and oxidative stress and, hence, promote the development of obesity-associated HTN (Pausova, 2006).

Alcohol overconsumption

The association between alcohol consumption and BP levels has been established in previous literature through observational studies and clinical trials.

In a study aimed at examining the association between alcohol intake and the risk of developing HTN, two large prospective cohorts of women and men were investigated (Sesso et al., 2008). The results confirmed that heavier alcohol consumption exceeding two drinks per day increased the risk of developing HTN, regardless of sex. Another study explored the impact of the drinking behavior of 8334 Americans between the ages of 45 to 64 years. The study found that higher levels of consumption of all types of alcoholic beverages are associated with a higher risk of HTN for all races and sexes (Fuchs et al., 2001).

The association between alcohol consumption and HTN was shown to be independent of a variety of potential confounding factors, including age, relative body weight, exercise, and

smoking status (Husain et al., 2014). The maximum contribution to the prevalence of HTN of alcohol consumption greater than two drinks per day is approximately 5%–7%, as shown in a study conducted in Russia (Akhmedjonov & Suvankulov, 2013).

Even though the association between alcohol overconsumption and elevated BP levels is established, the mechanisms remain unclear. Several potential mechanisms have been proposed, including directly influencing the heart (Fuchs et al., 2001), increasing plasma cortisol levels, and imbalance of the central nervous system (Roerecke et al., 2017).

Smoking

It is well-documented that smoking is a major risk factor for CVD and could cause serious damage to the lungs (Erhardt, 2009). However, less is known about the impact smoking has on BP levels. A higher BP level among smokers has been observed in epidemiology studies compared to nonsmokers (Al-Safi, 2005; Tesfaye et al., 2008). The rise in BP among smokers is due both to an increase in cardiac output and total peripheral vascular resistance caused by smoking (Omvik, 1996).

In addition to traditional cigarette smoking, modified-risk tobacco products, such as electronic vaping cigarettes and heat-not-burn cigarettes, also have an impact on BP. The use of e-cigarettes with nicotine may result in short-term elevations of both SBP and DBP and thus potentially increase cardiovascular events risk (Martinez-Morata et al., 2020).

Psychological stress

It has been suggested that chronic exposure to psychological stress can cause increased BP and lead to HTN development. A cohort study of over 3,000 young adults showed that urgency/impatience behavior and hostility assessed during young adulthood were strongly associated with a higher risk of developing HTN later in their lives (Yan et al., 2003). In a 3-year

longitudinal study conducted among 160 adults aged 47 to 59 years to assess the association between chronic stress and BP, the results showed that favorable changes in chronic stress are associated with reduced BP and CVD during the three years (Steptoe et al., 2005).

Psychological stress, depression, or anxiety could potentially lead to inadequate sleep. A cross-sectional and longitudinal association was observed between inadequate sleep duration and increased BP levels in the Coronary Artery Risk Development in Young Adults (CARDIA) cohort study (Knutson et al., 2009). In the U.S., the proportion of adults reporting insufficient sleep (<7 hours) in 2020 was 32.8% (Tsao et al., 2023). This indicates that it is necessary to identify ways to reduce stress, improve sleep, and prevent and manage HTN.

Adverse health outcomes of HTN in adults

HTN is one of the most common public health problems in the U.S. and the number one modifiable risk factor for the development of CVD and other chronic diseases (Zhou et al., 2018). Most people with HTN are unaware of the problem because of the asymptomatic feature, but untreated HTN can cause severe health problems. In many patients, the damage to blood vessels starts soon after BP is elevated, typically before HTN is diagnosed (Schmieder, 2010).

HTN-related structural or functional changes happen in major organ systems, i.e., the heart, the brain, the eyes, the kidneys, the arteries, the bones, the ears, and the reproductive organs (Oh et al., 2020; Vasan et al., 2022). This damage to the organs is common in severe HTN patients but is also prevalent in less severe HTN conditions, including asymptomatic people with elevated BP. Unless treated, target organ disease gradually progresses from asymptomatic to symptomatic, ultimately leading to severe health problems. The goal when treating HTN is to reduce the incidence of end-organ damage and prevent CVD, thus decreasing the incidence of premature death (Mancia & Parati, 2003).

Arteries

HTN causes extra force against the artery walls, leading to damage to the inside walls of the arteries. The damage could cause scar tissue to build inside the artery walls, thus causing the arteries to become even narrower over time, leading BP levels to increase even more (Schmieder, 2010).

The damage to arteries can also be associated with atherosclerotic materials along the arterial walls. These materials form plaques inside the artery wall, narrowing the artery and forming blood clots that can cause complete blockage, leading to severe health situations (Cohuet & Struijker-Boudier, 2006).

Heart

Left ventricular hypertrophy (LVH) is a condition wherein the cardiac muscle gets enlarged while adapting to an increased resistance in blood circulation. LVH is a strong independent predictor of cardiovascular morbidity and mortality. In the case of HTN, the increased BP levels will cause elevated myocardial stress. Over time, the cardiac muscle will enlarge and get thicker to compensate for the overwork of the heart. If left untreated or undiscovered, the fibers of the hypertrophied heart muscle become thickened and shortened and consequently less able to relax. Even at an early stage, a diastolic filling disorder can exist because of delayed left ventricular relaxation. In the late stages, reduced left ventricular compliance ensues, leading to diastolic heart failure (Schmieder, 2010).

Brain

HTN is one of the principal risk factors for cerebrovascular diseases. HTN is commonly present in stroke cases, and the risk of stroke increases with the increase in BP (Flack & Adekola, 2020). In most cases, an underlying ischemic infarction is the cause of stroke.

In addition to increasing stroke risk, HTN also has been recognized as a critical risk factor for the development of dementia and cognitive decline. The possible explanation for cognitive decline caused by HTN is the increased risk for stroke and subsequential complications (Buford, 2016).

Kidneys

The kidneys play a major role in filtering toxins and keeping the liquid balance inside the body. HTN is the second most common cause of chronic kidney disease and is a strong predictor of kidney failure when accompanying other complications (Hamrahian & Falkner, 2017).

HTN and chronic kidney disease are closely intertwined conditions, as HTN can lead to deteriorating renal function, and progressive chronic kidney disease can contribute to worsening HTN (Hall et al., 2014). Poorly or untreated controlled HTN can accelerate the progression to end-stage kidney disease (De Bhailis & Kalra, 2022).

Hypertensive nephropathy is a medical condition referring to the damage to the kidney due to chronic elevated BP levels and often results in chronic renal failure. This process usually happens without clinical symptoms (Schmieder, 2010). The decline in renal function mirrors the structural changes that take place in the heart and small blood vessels.

Eyes

HTN, if not controlled, causes alterations in the retinal microcirculation. Classically, elevated BP results in a series of retinal microvascular changes called hypertensive retinopathy (Bhargava et al., 2012). Advanced retinopathy is nowadays confirmed as HTN-induced target organ damage (Cohuet & Struijker-Boudier, 2006).

The damage to the eyes is different from ocular HTN, which occurs when the pressure inside the eye is higher than normal. Higher than normal eye pressure can cause glaucoma, a disease where eye pressure damages the optic nerve, causing vision loss (Bhargava et al., 2012).

Ears

Recently, the role of HTN in the development of hearing impairment/loss has received great attention. In a cross-sectional study conducted among 104 participants, 52 were hypertensive and had elevated hearing thresholds compared to the non-hypertensive control group (Yikawe et al., 2019). A retrospective cohort study conducted among Japanese adults aged 20–59 years investigated the association between measured systolic BP levels and objective hearing impairment at a medical center hospital in Japan. The results showed that higher SBP levels were associated with an increased risk of objective hearing loss (Miyata et al., 2022).

Even though more human studies are needed to better understand the relationship between hearing loss and HTN, incorporating regular audiological assessment for hypertensive patients could be one of the early disability prevention strategies and thus improve the quality of life for hypertensive patients.

Reproductive organs

HTN is associated with impaired sexual health in both men and women. HTN could lead to erectile dysfunction and a decrease in semen volume in men. Similarly, hypertensive females exhibit decreased vaginal lubrication, low sex drive, and several complications in pregnancy, leading to fetal and maternal morbidity and mortality. The adverse effect of HTN on male and female fertility is attributed to hormonal imbalance and changes in the gonadal vasculature (Nilsson et al., 2020). However, more research is needed to investigate the impact of HTN on gonads in more detail.

Bones

Adults with HTN experience accelerated declines in physical function and increased incidence of disability and osteoporosis due to bone loss compared to normotensive counterparts (Buford, 2016). Prior studies have demonstrated that bone loss is positively associated with elevated BP levels (Metz et al., 1999). Persons with HTN have increased urinary calcium excretion and increased absorption of calcium from the bones (Cappuccio, 1999; Metz et al., 1999). There are two explanations for these changes. First, sodium intake is positively associated with calcium excretion (Cappuccio et al., 1999). Therefore, the increased blood volume under HTN conditions could lead to excess calcium excretion. Second, the disorder within the kidney tubule potentially caused by HTN could cause extra calcium loss (Ilic et al., 2013).

HTN and other chronic diseases

It is well established that HTN causes body organ damage, which could lead to severe health conditions. Nevertheless, HTN is also associated with other chronic diseases, such as obesity, diabetes, cancer, etc. (Benghanem Gharbi et al., 2016).

Obesity is a major risk factor for HTN. Obesity raises BP by increasing renal tubular sodium reabsorption and causing volume to increase via activation of the sympathetic nervous system and renin–angiotensin–aldosterone system (Benghanem Gharbi et al., 2016; Hall et al., 2014). Increased liquid volume and visceral adiposity will also cause extra pressure against the kidneys. Body weight reduction via caloric restriction and increased physical activity is an important first step in managing HTN.

Diabetes can be both the result and the cause of HTN. In other words, diabetes can lead to HTN, or it can be a complication of HTN. On one hand, people who have diabetes tend to have hardened arteries, which eventually lead to atherosclerosis due to the damage to arteries

(Yen et al., 2022). This hardening process could cause BP levels to increase. On the other hand, people with HTN usually have impaired glucose metabolism, which leads to insulin resistance and an increased risk of developing diabetes compared to those with normal BP levels (Benghanem Gharbi et al., 2016).

HTN and cancer are associated in two ways. In one way, some types of cancers, such as breast cancer, are associated with HTN. And this is more prevalent among postmenopausal hypertensive women (Han et al., 2017). Another possible way is through therapies used to treat cancer, which can directly or indirectly increase the risk of HTN (Dolmatova et al., 2023). HTN is also the most commonly observed comorbidity among cancer survivors. Given the increased cardiovascular and mortality risk related to HTN, it is important to screen for and treat HTN to promote cardiovascular health, particularly in the population of vulnerable cancer patients.

Increased healthcare burden

In addition to the impact on the body's organs, HTN also shows a substantial economic burden—a "hidden" cost. Compared with people without HTN, the healthcare cost of people with HTN is estimated to be $2000 higher annually (Park et al., 2020). Antihypertensive medication costs account for about half of the total medical expenses for the treatment of HTN (Tsao et al., 2023). In addition, HTN is a modifiable independent risk factor for other costly diseases, such as heart disease and stroke.

Nonpharmacological approach to prevent and manage HTN

Although there is clear evidence that pharmacologic approaches to manage THN through administering antihypertensive medications are useful and effective in controlling HTN and reducing the incidence of stroke and infarction, long-term drug treatment can be expensive, and side effects can cause low prescription adherence rates among patients (Krousel-Wood et al.,

2004). Identifying non-pharmacological methods to prevent or significantly delay the onset of HTN would represent an important aspect of preventing CVD.

Extensive published evidence supports the concept that non-pharmacological interventions, more recently referred to as lifestyle modifications, are highly recommended for the prevention of HTN in adults with normal and elevated BP and also for the management of HTN in adults with mild forms of HTN (Mellen & Goff, 2007; Vamvakis et al., 2017). It can also be administered in combination with pharmacological therapy to patients with severe HTN conditions to obtain better health outcomes.

The primary purposes of non-pharmacological therapy are threefold: 1) to prevent the development of HTN in normotensive individuals who are at higher risk for HTN due to unmodifiable risk factors, such as age and sex; 2) to prevent patients with elevated BP levels from developing HTN and improve BP control and reduce CVD risk; 3) and to reduce the amount of pharmacological treatment required for those hypertensive patients who need medical treatment (Vamvakis et al., 2017).

BP management in hypertensive patients and primary prevention in the general population to prevent mortality risk later in life is beneficial (Zhou et al., 2018). Changes in the lifestyle of the general population would result in a lower prevalence of HTN (Kearney et al., 2005). These evidence-proven lifestyle interventions include adopting healthy eating behaviors (Strilchuk et al., 2020), being physically active (Barone Gibbs et al., 2021), limiting excessive alcohol consumption (Klatsky & Gunderson, 2008), managing body weight (Jiang et al., 2016), smoking cessation (Minami et al., 1999), self-monitoring BP (Aekplakorn et al., 2016; Kawano, 2002), as well as stress management (Irvine et al., 1986).

Adopting healthy eating behaviors

Adopting healthy eating behaviors plays a significant role in HTN prevention and management. The 2020 US Dietary Guidelines Advisory Committee highlighted that the core elements of a healthy dietary pattern are (1) vegetables of all types; (2) fruits, especially whole fruit; (3) grains, of which at least half are whole grains; (4) dairy, including fat-free or low-fat milk, yogurt, and cheese, or lactose-free versions and fortified soy beverages and yogurt as alternatives; (5) protein foods, including lean meats, poultry and eggs, seafood, beans, peas, lentils, nuts, seeds, and soy products; and (6) oils, including vegetable oils and oils in food such as seafood and nuts. A healthy dietary pattern also limits foods and beverages high in added sugars, saturated fat, sodium, and alcoholic beverages (Bailey et al., 2022). It is important to note that higher consumption of fruits and vegetables is associated with a lower prevalence of hypertension and reduced cardiovascular risk (John et al., 2002). A study conducted among healthy female professionals aged 39 years and older showed an increased intake of fruits and vegetables as part of a healthy dietary pattern may contribute to the blood pressure prevention effect through improvement in body weight regulation (Wang et al., 2012).

In line with the dietary recommendations, a BP-friendly diet provides substantial benefits to prevent and manage HTN and promotes overall health. A BP-friendly diet has the following features: high in fruits and vegetables (such as the DASH diet, which is naturally high in potassium but low in sodium) and decreased consumption of salt and unhealthy fats.

DASH diet

The DASH diet, which stands for dietary approaches to stop hypertension, is promoted by the National Heart, Lung, and Blood Institute to manage or prevent HTN. It is a plant-based dietary pattern that emphasizes the consumption of fruits and vegetables, whole grains, lean

protein, and low-fat dairy. This dietary pattern is also high in BP-deflating nutrients like potassium and calcium. DASH also discourages foods high in saturated fat, such as fatty meats, full-fat dairy foods, tropical oils, sugar-sweetened beverages, and sweets. The DASH diet has been recognized as a highly recommended dietary pattern for reducing BP in adults with or without HTN (Saneei et al., 2014).

In the most recent Heart Disease and Stroke Statistics 2023, the DASH diet showed great potential in reducing BP levels (Tsao et al., 2023). Compared with a typical Western diet, a DASH-type diet with low sodium reduced systolic BP greatly from 5 to 9 mm Hg in adults with elevated BP or even different stages of HTN at baseline (Tsao et al., 2023). The DASH diet also shows the effect of lowering BP equally effectively or even more significantly than some antihypertensive drugs (Strilchuk et al., 2020). In addition, the DASH diet is also associated with a 10% CVD risk reduction (Chiavaroli et al., 2019).

The DASH diet and modifications to the DASH diet, coupled with reduced sodium intake, show a dose-dependent decrease in BP (Ozemek et al., 2018). These diets are more effective in older and hypertensive adults (Aljuraiban et al., 2023). The DASH diet should be promoted, along with other lifestyle modifications, to lower BP and reduce the risk of CVD.

Sodium

Dietary sodium consumption is associated with BP levels. There has been a major increase in sodium content of the human diet because of salt use in food preservation and preparation in the past few decades. Excessive dietary sodium consumption (>2300 mg daily) is associated with increased BP levels, whereas sodium restriction has a BP-lowering effect. A reduction in dietary sodium not only decreases the BP and the incidence of HTN but is also associated with a reduction in morbidity and mortality from CVD (Grillo et al., 2019).

Potassium

Aside from sodium, potassium is the second most important electrolyte for the nonpharmacologic control of BP. Contrary to increased BP levels with increased sodium consumption, an inverse relationship between potassium intake and blood pressure status has been shown in the literature (Houston, 2013). The BP-lowering effects of potassium are greater in subjects with high sodium intake. Therefore, to keep BP levels in the optimal range, it is necessary to consume adequate dietary potassium and limit sodium consumption. The interaction between sodium and potassium is a key aspect of the BP-lowering effects of potassium. The sodium-to-potassium ratio is a better indicator than either sodium or potassium alone in the incidence of HTN (Perez & Chang, 2014). A high sodium-potassium ratio can potentially be associated with elevated BP. In contrast, a diet with a low sodium-potassium ratio is associated with potential blood-pressure-lowering effects.

Magnesium

Dietary magnesium is also associated with BP levels. An inverse relationship between dietary magnesium intake and BP has also been indicated in a previous study (Houston, 2011). The possible mechanism of the magnesium-lowering effect is that magnesium acts like a natural calcium channel blocker that competes with sodium for binding sites. The BP-lowering effect of magnesium seems to be additive to the effect of high potassium and low sodium, both in treated and untreated hypertensive subjects (Houston, 2011). In addition, magnesium lowers BP by increasing the effectiveness of all antihypertensive drug classes (Sontia & Touyz, 2007).

Calcium

Dietary calcium has been shown to influence blood pressure through several physiological mechanisms. These hypothesized mechanisms include the activation of calcium-

regulating hormones, modulation of the sympathetic nervous system (Hatton & McCarron, 1994), and increasing vascular volume through the renin–angiotensin–aldosterone system (Villa-Etchegoyen et al., 2019). Increased calcium intake reduces blood pressure. The impact is more noticeable in individuals with low calcium intake. In addition, increased dietary calcium consumption could compensate for the lost calcium caused by HTN.

Mineral combinations

The combination of increased magnesium, potassium, and possibly calcium, coupled with reduced sodium intake, is more effective in lowering BP than single mineral intake and is often as effective as one antihypertensive drug in treating HTN (Houston, 2013). Eating a diet that includes these nutrients is also important for people with normal BP to prevent HTN and major health problems.

Antioxidants

The dietary intake of antioxidants, such as exogenous antioxidant vitamin C, has shown protective effects against BP increase (Juraschek et al., 2012; Rodrigo et al., 2011). The vitamin C or plasma ascorbate concentration in humans is inversely correlated with BP and CVD risk (Block et al., 2008). However, the role of antioxidant therapy remains an open question; these interventions are expected to be more efficient in preventing rather than reducing established HTN.

Beetroot juice has also shown a BP-lowering effect among adults on both a low nitrate diet and a normal diet (Bonilla Ocampo et al., 2018; Coles & Clifton, 2012). A randomized controlled trial was conducted with disease-free adults on a normal diet to investigate if beetroot juice supplementation could reduce BP among subjects on a normal diet. The results showed that beetroot juice could lower BP in adults when consumed as part of a normal diet (Coles &

Clifton, 2012). Furthermore, a systematic review of randomized controlled trials also concluded that beetroot juice supplementation should be promoted as a key component of a healthy lifestyle to control blood pressure in both healthy and hypertensive individuals (Bonilla Ocampo et al., 2018).

Being physically active

Being physically active has extensive benefits, including improving both SBP and DBP levels (Kokkinos et al., 2009). A consistent, temporal, and dose-dependent relationship between physical activity and the development of HTN has been established through epidemiologic studies. Physical activity has been associated with immediate significant reductions in SBP. This immediate reduction in BP after physical activity can persist for almost 24 hours and is most effective in those with higher baseline BP and sedentary individuals (Tsai et al., 2004). The volume of exercise required to reduce BP may be relatively small but reasonably attainable by a sedentary hypertensive population. The dose-dependent BP-lowering effect could reach a plateau beyond which no further benefits are foreseen (Frisoli et al., 2011).

Even though the beneficial effects of physical activity are clear, the underlying mechanisms responsible for the reduction in BP remain elusive. The prevailing current opinion is that exercise training must act upon several mechanisms, resulting in a decrease in total peripheral resistance, cardiac output, or both (Hegde & Solomon, 2015; Tsai et al., 2004). The changes in BP may be independent of or associated with changes in body weight, body composition, and dietary influences (Kokkinos et al., 2009).

The current Physical Activity Guidelines for Americans recommend that adults do at least 150 minutes of moderate-intensity physical activity, or 75 minutes of vigorous-intensity aerobic physical activity a week, or an equivalent combination of moderate- and vigorous-

intensity aerobic activity. It is also recommended that adults do muscle-strengthening activities on two or more days a week. Adults with chronic conditions or disabilities, such as HTN, should follow the key guidelines and do aerobic and muscle-strengthening activities if the health condition allows. Recommendations emphasize that moving more and sitting less is the standard rule for everyone to gain health benefits (Piercy & Troiano, 2018).

Given the clear health benefits of physical activity, it is highly recommended to incorporate physical activity as part of a healthy lifestyle. Physical activity promotion is an excellent approach for primary prevention and treatment options for all patients, including those with elevated BP and cardiovascular events (Barone Gibbs et al., 2021). However, the optimal prescription for the prevention of HTN remains elusive. More conclusive evidence is needed regarding the appropriate mode, intensity, and duration of physical activity for hypertensive individuals. In addition, promoting physical activity to patients with stage 2 or greater HTN can be challenging due to other morbidities associated with HTN, thus interfering with the patient's ability to perform physical activity.

Keeping a healthy body weight

Being overweight and obese increases the chances of many chronic diseases, such as HTN, heart disease, diabetes, and some types of cancers (Hall et al., 2014; Jiang et al., 2016). Thus, keeping a healthy body weight is important for overall health and improved quality of life.

Different ways of losing weight may cause different results in BP reduction. Among the possible means of reducing body weight are lifestyle modifications, pharmacological interventions, and invasive or surgical interventions. Of all the above-mentioned means, sustainable lifestyle modifications could lead to a larger decrease in BP levels compared to other methods (Frisoli et al., 2011).

Moderate or no alcohol consumption

The association between alcohol consumption and HTN and related CVD is complicated. Alcohol intake has paradoxically divergent effects on BP. Heavy drinking is associated with a higher prevalence of HTN, whereas moderate drinking is associated with a lower prevalence of HTN and other associated CVDs (Roerecke et al., 2017).

To delay the development of HTN and decrease cardiovascular risk, alcohol intake should be limited to two drinks daily in men and one drink daily in women (one drink constitutes 12 ounces of beer, 5 ounces of wine, or 1.5 ounces of 80-proof liquor) (Zaidi Touis et al., 2018). The cardioprotective effects of moderate consumption are greatest when the consumption is spread out evenly over a week.

Smoking cessation

It is a paradox that while smoking acutely increases BP, a slightly lower BP level has been found among smokers than non-smokers. In a study conducted among a cohort of 8,170 healthy Korean men with a 4-year follow-up to test the effects of smoking cessation on changes in BP and incidence of HTN, progressive increases in BP were observed among smokers after smoking cessation during the four-year period. This indicates that the cessation of smoking may increase BP (Lee et al., 2001).

Even though the impact of smoking on BP levels is inconclusive, it has been shown that smoking is associated with greater pulse pressure. Pulse pressure measures the difference between SBP and DBP, which strongly predicts CVD risk after middle age (Luehrs et al., 2021). Coronary Artery Risk Development in Young Adults study showed that compared to adults who never smoked, adults who regularly smoked had greater pulse pressure. The slightly increased pulse pressure may contribute to a greater CVD risk (Diez Roux et al., 2003).

Although smoking cessation is not recommended as the best-proven lifestyle treatment due to its inclusive impact on BP, smoking cessation is still prudent because smoking has well-documented adverse cardiovascular effects, including an interaction with HTN that increases the risk of cardiovascular events (Omvik, 1996).

Stress management

Proper stress management could help patients with HTN lower BP levels and improve their quality of life (Clemow et al., 2018; Dusek et al., 2008). External stressors and blood pressure levels might be mediated or confounded by coping mechanisms influencing lifestyle factors that directly affect blood pressure. In addition, stress management may have beneficial effects on more than just HTN-related aspects of the CVD process (Johnston, 1991). Therefore, selective, integrated, continuous, and stimulating stress management strategies should be promoted to help better BP control and improve the quality of life.

Self-monitoring BP levels

Self-monitoring is beneficial to prevent and manage HTN in addition to the above-mentioned ways. Self-monitoring BP provides immediate feedback to individuals and may motivate them to be active in self-care and medication adherence (Aekplakorn et al., 2016). Self-monitoring could also motivate patients to recognize the monitoring of BP as a tool in self-care to attain a better quality of life.

Theories on risk perception and health behavior change

Risk perception is an individual's process of decision-making based on the overall evaluation of the characteristics and severity of a risk. It is an important determinant of protective behavior, and a key component of many health behavior change theories. Accurate risk perceptions can help people make appropriate decisions about actions to avoid

illness or injury. Higher risk perceptions can motivate people to engage in healthier behaviors. Interventions that are designed to engage and change risk perceptions are more likely to be successful in producing subsequent increases in health behaviors (Ferrer & Klein, 2015).

Motivation is also an important determinant of behavior change. People with strong motivation are more likely to adopt healthy behavior compared to individuals with weak motivation (Prentice-Dunn & Rogers, 1986). Multiple theoretical models focus on motivation to prompt health behaviors. The Health Belief Model (HBM) and Protection Motivation Theory (PMT) emphasize the importance of risk perception and motivation in behavior change.

Health Belief Model

The Health Belief Model (HBM) was originally developed to help understand why people did or did not use preventive services offered by U.S. Public Health Services (Janz & Becker, 1984). Later, HBM was applied to predict a wide variety of health-related behaviors (e.g., mammography screening) (Janz & Becker, 1984). Up till now, the model has been widely used to understand lifestyle behaviors related to chronic diseases (Daddario, 2007; Deshpande et al., 2009).

The original HBM model has four constructs (i.e., perceived susceptibility, perceived severity, perceived benefits, and perceived barriers). The model proposes that to take actions to avoid a certain disease, an individual has to believe that (1) the individual is personally susceptible to the condition or disease, (2) the occurrence of the disease is severe in some way which will lead to serious health consequences, (3) taking a particular action would be beneficial either by reducing the susceptibility or the severity of the condition, and (4) the anticipated barriers to take action, such as convenience and cost are outweighed by its benefits (Janz & Becker, 1984). The susceptibility and perceived severity together mobilize an individual to take

an action, whereas the cost-benefit analysis of perceived benefits and perceived barriers explains why an individual takes a preferred action. An individual is more likely to take a health-related action when a cue to action is present. Psychological variables, such as self-efficacy, may affect the likelihood of a self-protective action (Janz & Becker, 1984; Rosenstock et al., 1988).

The current HBM includes three main constructs: individual perceptions, modifying factors, and the likelihood of an action occurring. For individual perception, it examines both perceived susceptibility and perceived severity. Modifying factors include an individual's demographics, perceived threat, and cues to action. The Likelihood of action results from the combination of perceived benefits compared to perceived barriers and self-efficacy.

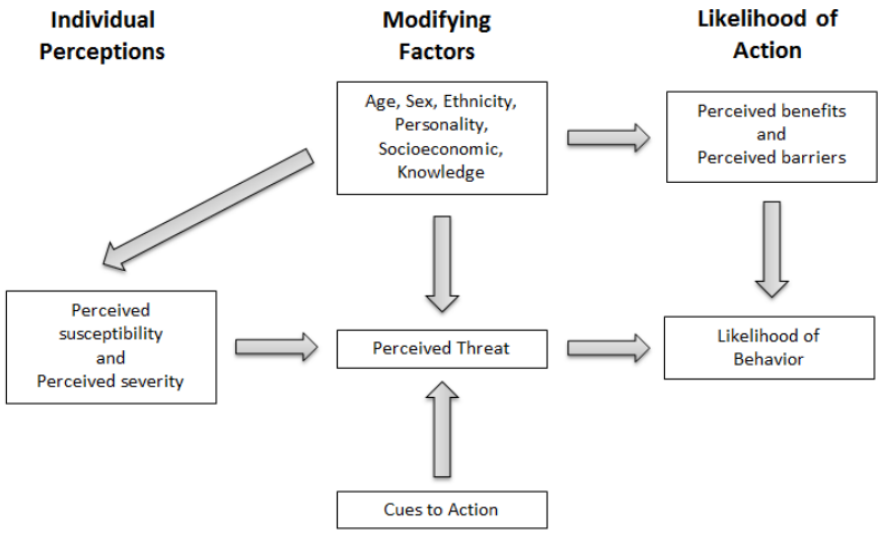


Figure 2.1. The adapted Health Belief Model (Rosenstock et al., 1988)

Individual perceptions include perceived susceptibility and perceived severity. Perceived susceptibility refers to the degree to which a person feels at risk for a health condition. When looking into a person's perceived susceptibility, knowledge, and education level should be considered. Besides susceptibility, perceived severity addresses feelings concerning the

seriousness of contracting an illness if left untreated. Previous experiences can affect how an individual perceives severities, which can differ from one another.

It is imperative to examine the three distinct components of the modifying factors: demographics, perceived threat, and cues to action. Demographics include age, sex, ethnicity, personality, socioeconomic status, and education. Perceived susceptibility and perceived severity lead to the perceived threat level, which looks more into the cause and outcome of having a health problem. Cues to action refers to the factors that serve as a cue, or a trigger, to appropriate action. Cues to action can be internal (e.g., symptoms) and external (e.g., interpersonal interactions or receiving reminder information from healthcare providers).

The likelihood of action is influenced by perceived benefits, perceived barriers, and self-efficacy. Perceived benefits are the positive outcomes an individual believes if an action is taken to reduce or prevent a disease. Perceived barriers are the potential negative aspects of a particular health action, such as cost or inconvenience. People make health decisions based on the perceived benefits compared to the perceived barriers. Self-efficacy refers to a person's confidence in one's ability to take an action. Higher self-efficacy increases the likelihood of taking a certain health action.

HBM helps explain the change and maintenance of health behavior and is a guiding framework for health behavior interventions. Successful health interventions should be designed to alert the susceptibility and severity, emphasize the benefits, and reduce the barriers by providing dietary monitoring, practical advice, and action tips. Since self-efficacy is a strong predictor for many health-related behaviors, it is preferable to focus on promoting self-efficacy for more favorable intervention accomplishments.

Protection Motivation Theory

Protection motivation theory (PMT) was created to explain the effect of fear appeals on health attitudes and behaviors. In the original formulation of PMT, a fear appeal communication initiates a cognitive appraisal process including (1) the severity of the threat, (2) the probability of the occurrence of the event, and (3) the efficacy of a recommended coping response (Rogers, 1975). Self-efficacy expectancy was added as a fourth component of PMT later. Self-efficacy has a direct influence on protection motivation and could interact with other variables of PMT (Rippetoe & Rogers, 1987).

PMT hypothesizes that the motivation to protect oneself from danger is the function of four cognitive beliefs. These are as follows: (1) the threat is severe; (2) one is personally vulnerable to the threat; (3) the coping response is effective in averting the threat; and (4) one can perform the coping response. The main constructs of PMT and their definition are shown in Table 2.2.

Table 2.2. Main constructs of PMT and their definition

PMT main constructs	Definition
Perceived severity	A person's perception of the personal impact of contracting the illness.
Perceived vulnerability	A person's perceived risk of contracting an illness or health condition.
Response efficacy	A person's perception of the good things that could happen from undertaking specific behaviors, especially regarding reducing the threat of the disease or illness.
Self-efficacy	A person's belief or confidence that he or she can perform a specific behavior.
Intention	A person's intention in adopting a specific behavior.

PMT is premised on expectancy-value theory and contains cost-benefit analyses (Rogers, 1975). PMT proposes that information from different sources, environmental or intrapersonal,

could initiate the cognitive process to deal with the received information. This cognitive process includes two aspects: threat appraisal and coping appraisal.

Threat appraisal assesses the severity of the situation and examines how serious the situation is. This process is done by evaluating the factors that affect the possibility of making a maladaptive response. Intrinsic rewards (e.g., personal satisfaction) and extrinsic rewards (e.g., social approval) could increase the likelihood of a maladaptive response. Factors such as the perceived severity of the threat and perceived vulnerability to the threat could affect the maladaptive response. A complete evaluation of variables that increase and decrease the likelihood of maladaptive behavior determines the maladaptive response.

An individual makes a coping appraisal in response to the potential threat in addition to the threat evaluation. Coping appraisal evaluates the various factors that are relevant to an individual's evaluation of the recommended coping response to the current threat. Coping appraisal consists of both response efficacy and self-efficacy. In the original model, response efficacy was the main determinant of coping appraisal. Response efficacy is the individual's belief that taking action can remove the perceived threat and produce benefits. Self-efficacy is the belief in one's ability to successfully initiate and complete the adaptive response. Self-efficacy is the key factor for an individual to successfully avoid a threatening situation. Response efficacy and self-efficacy evaluations could potentially increase an individual's possibility of making an adaptive response. Factors such as inconvenience, cost, and side effects are response costs that could decrease the likelihood of adapting response. The likelihood of adaptive response is the result of the response efficacy and self-efficacy compared to response costs. Higher response efficacy and self-efficacy could produce a positive main effect on intentions regardless of levels of severity and vulnerability.

The combination of the threat appraisal and the coping appraisal forms the protection motivation, which then either stimulates (e.g., increasing fruit and vegetable consumption) or inhibits (e.g., quitting smoking) an action. Protection motivation serves as a key mediator between behavior and threat. Protection motivation is similar to the intention to perform a behavior.

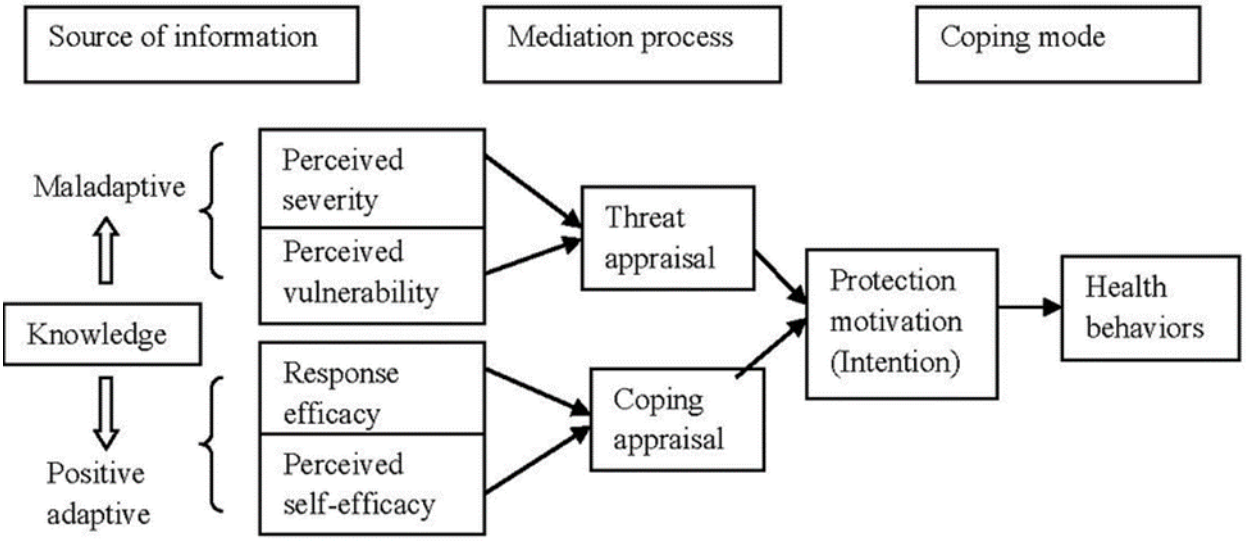


Figure 2.2. Modified model of PMT (Rogers, 1975)

PMT has been widely adopted as a framework for predicting and intervening in health-related behavior. Studies using PTM to predict physical activity intention and behaviors in different groups of people have shown inconsistent results. In a study using PMT to predict the intention of doing regular physical exercise in obese and overweight women (Mirkarimi et al., 2017), results showed that perceived response efficacy and attitude were the strongest predictors. However, another study used PMT to explain physical activity in an adult population with type 1 diabetes (T1D) and type 2 diabetes (T2D). Results show that self-efficacy was a stronger predictor of intention than response efficacy in individuals with T1D or T2D. Self-efficacy and intention were significantly associated with physical activity behavior (Plotnikoff et al., 2010). A

systematic review looked at the use of PMT in the physical activity domain among general populations in prediction, experimental, and intervention studies. The prediction studies suggested that self-efficacy might be the strongest predictor of physical activity participation. Among experimental manipulation studies, increasing the coping appraisal generally facilitated physical activity intentions and behavior. Intervention findings showed a positive effect on intentions using PMT for intervention guidance (Bui et al., 2013).

PMT attempts to explain and predict what motivates people to change their behavior. In general, increases in threat severity, threat vulnerability, response efficacy, and self-efficacy facilitated adaptive intentions or behaviors. Conversely, decreases in maladaptive response rewards and adaptive response costs increased adaptive intentions or behaviors. PMT also emphasizes that more than knowledge of an effective behavior is needed; the individual must perceive themselves to be able to carry it out (Mirkarimi et al., 2017). PMT also proposes that perceptions of response efficacy and self-efficacy can better predict intention formation and subsequent behavior change. Increasing coping appraisal generally facilitated healthy behavior adaptation (Bui et al., 2013; Plotnikoff et al., 2010). Using PMT to design interventions to promote healthy behaviors should mainly focus on improving coping appraisal, especially promoting self-efficacy, to motivate an individual to initiate and maintain healthy behaviors to prevent health problems.

Chapter 3 - Nutrition education needs assessment in adults to prevent and manage hypertension: a qualitative study

Abstract

Objective: To assess understanding, perceptions, and knowledge among adults on how to prevent and manage hypertension (HTN) using nonpharmacological approaches and to identify nutrition education gaps for educational interventions. **Methods**: A qualitative method with focus group and one-on-one interviews was used to assess knowledge of HTN and associated risk factors, the severity and vulnerability of HTN (threat appraisal), and the potential health benefits of nonpharmacological approaches in preventing and managing HTN (copying appraisal). This study used the Protection Motivation Theory to guide the design of the qualitative questions. Thematic analyses were conducted to analyze the qualitative information generated by the participants. **Results:** Four focus groups and two one-on-one interviews were conducted with 20 participants. Four underlying themes emerged from the qualitative study: (1) HTN and associated risk factors, (2) underestimated HTN complications, especially organ damage caused by HTN, (3) nutrition and HTN, and (4) integration of nonpharmacological approaches as part of a healthy lifestyle. **Conclusion:** Knowledge gaps among participants were found, emphasizing the need for nutrition education on these main themes. Nutrition education needs were identified, which could potentially provide valuable information for future interventions. The lack of self-efficacy in incorporating nonpharmacological approaches indicates the benefit of developing nutrition education to facilitate practical lifestyle modifications to target HTN prevention and management.

Background

High blood pressure (HBP), also known as hypertension (HTN), is a major health problem worldwide. The prevalence of HTN is a public health concern because it is the number one modifiable risk factor for the development of cardiovascular diseases (CVDs) and other chronic diseases (Zhou et al., 2018).

According to the American College of Cardiology and American Heart Association (ACC/AHA) in 2017, in adults, HTN is when blood pressure is constantly higher than 120 mm Hg systolic and 80 mm Hg diastolic. According to the guidelines, nearly half of American adults in the United States are considered to have HTN (Whelton et al., 2018b). If left untreated, HTN increases the risk of CVDs, such as heart disease and stroke, which are the two leading causes of death in the United States (Wang & Vasan, 2005).

The guidelines also clearly outline nonpharmacological approaches as the recommended first-line treatment, especially for people with elevated blood pressure levels. In the hypertensive population (HTN stages 1 and 2), nonpharmacological interventions can be applied either as an initial treatment before drug therapy or in combination with the drug treatments. Nonpharmacological intervention that can be adopted permanently may reduce the use of antihypertensive medication in hypertensive patients.

Despite increased awareness of the importance of blood pressure control and the availability of an ever-increasing range of antihypertensive treatments, research shows that HTN remains undetected in about half of patients (Yoon et al., 2015). One of the reasons for the low diagnosis rate is the asymptomatic characteristic of HTN (Levy & Cline, 2009). In most cases, people with HTN may not show any symptoms and thus remain undetected for years. Because there are no visible symptoms associated with high BP but the damage to the body started right

away after the blood pressure is elevated, HTN is often called the “silent killer.” Elevated blood pressure is a serious warning sign that causes severe damage to different parts of the body, such as the heart, eyes, brain, kidneys, arteries, and reproductive organs (Kearney et al., 2005). To reduce the damage caused by HTN, people first need to be alerted to the organ damage caused by elevated blood pressure levels, and secondly, they need to know how to take steps to reduce blood pressure levels to normal ranges. In addition to that, individuals also need to know that raised blood pressure and other chronic diseases, such as diabetes, often are associated.

Both focus groups and interviews are qualitative research methods. As a means of qualitative data collection, the focus group has gained popularity among health and social care professionals (Deliens et al., 2015; Stewart et al., 2005). Using focus groups as a qualitative research method could allow people to interact in a discussion of different topics, opinions, or questions (Leung & Savithiri, 2009). The focus group discussion also helps to form an interactive atmosphere where participants are free to share their thoughts under the guidance of the moderator. As a tool, focus groups help researchers generate data quickly, interacting directly with the participant, asking for clarification of opinions, observing non-verbal responses, and/or uncovering new and different data or ideas. Interviews, on the other hand, differ from focus groups because they lack interaction between participants. However, interviews provide flexibility and allow for deep conversations on the selected topic with the guidance of open-ended questions.

Protection Motivation Theory (PMT) was created to explain the effect of fear appeals on health attitudes and behaviors (Rogers, 1975). PMT assumes that the motivation for people to take protective action is the threat of suffering. According to PMT, an individual’s knowledge of a certain health-related problem (HTN, in this case) affects the decision-making process. The

knowledge of HTN will initiate the cognitive process. However, whether an individual practices health behavior or not is affected by two factors: threat appraisal and coping appraisal. Threat appraisal is influenced by 1) specific beliefs about the vulnerability to HTN, and 2) beliefs about the consequences or the severity of HTN. For example, an individual may decide they should increase their fruits and vegetables consumption to prevent and manage HTN if they feel the threat of developing CVD and perceive the threat of CVD to be serious. The belief that one can cope with HTN also breaks down into two parts: 1) beliefs about the effectiveness of particular health practices (nonpharmacological approaches), and 2) beliefs about the ability to perform the recommended health behaviors.

Therefore, the objective of this qualitative study is two-fold: first, to assess understanding, perceptions, and knowledge among adults on how to prevent and manage HTN using nonpharmacological approaches; second, to identify nutrition education needs to promote HTN prevention and management through nonpharmacological approaches among adults.

Methods

Aim

This study aimed to access understanding, perceptions, and knowledge on preventing and managing HTN in adults living in Riley County, KS.

Design

This study used focus groups and one-on-one interviews to determine topics of interest. The focus groups and one-on-one interviews were conducted via Zoom – a video conferencing platform, from May 1 to June 25, 2021.

Two pilot interviews were conducted and transcribed, after which the interview guide was refined, and then the remaining focus groups were conducted. The pilot interviews were included in the data analysis. One-on-one interviews were 30–60 minutes, and focus groups were 60–90 minutes. The semi-structured discussion was designed to elicit participants' perspectives using open-ended questions to trigger responses and prompts/probes as necessary for clarification purposes.

Participants

The participants were recruited by word of mouth and snowball sampling method. A recruitment flyer was created and distributed in the local extension office, WIC office, Riley County Health Department, blessing boxes, food distribution events, churches, local recreational centers, and doctors' offices in Riley County, Kansas. The exclusion criteria were: 1) under age 18; 2) not an American citizen or a permanent resident; 3) having language difficulties in understanding and reading English, as this would cause communication problems during focus groups or interviews.

The sample size was determined by data saturation across focus groups. Data saturation is reached when there is enough information to replicate the study, the ability to obtain additional information has been attained, and further coding is no longer feasible (Hennink et al., 2019).

Focus group questions

The focus group/one-on-one interview questions were selected with the guidance of PMT and previous literature (Espejo et al., 2019; Jolles et al., 2013). The questions are listed in Table 3.1. A semi-structured focus group procedural protocol of open-ended interview questions related to HTN prevention and management was developed. The questions aligned with the following principles for creating focus group questions: (1) relative semi-structured open-ended

questions using “How do you feel about?” “What do you think about?” “Do you think?” and (2) avoiding ‘yes’ or ‘no’ answers. Probe questions were asked for clarification during the focus group/interview.

Theory guidance

PMT proposes that people protect themselves based on four factors: perceived severity, perceived vulnerability, response efficacy, and self-efficacy. The focus group questions were designed in line with PMT's main constructs. Table 3.1 lists questions discussed in the focus groups relevant to the PMT framework.

Table 3.1. Focus group questions and the corresponding theory components

Focus group questions	PMT constructs
1. When you hear high blood pressure, what comes to mind? Probe 1: In general, what do you think the general population knows about high blood pressure?	Knowledge
2. What are some reasons that would put a person at risk for high blood pressure? Probe: How do the following conditions affect your chances of getting high blood pressure? • Physical inactivity • Being obese or overweight • Unhealthy diet • Alcohol consumption • Smoking	Perceived vulnerability
3. How do you think high blood pressure affects your body? Probe 1: How do you think high blood pressure will affect your heart? Kidney? Arteries/blood vessels? Eyes? Other organs? Probe 2: How do you think high blood pressure will increase your risk of developing other chronic diseases, such as heart disease?	Perceived severity
4. What can you do to decrease the damage to the organs caused by high blood pressure besides taking medication? Probe 1: How do you think the food you eat will affect your body?	Response efficacy and self-efficacy

Probe 2: Please share your thoughts on some nutrients that can be beneficial to regulate blood pressure levels.
5. If a program could be developed for adults in KS to prevent and manage high blood pressure, what would it look like?
Probe 1: What would you want to know about high blood pressure?
Probe 2: What would make a program good to prevent and manage high blood pressure?

Program design

Focus groups were moderated by trained research members. Informed consent was obtained from all individual participants included in the study before the start of the focus group discussion. Participants were not identified by their names during the recorded focus group session. Each participant was identified by a code number for confidentiality. Before the focus group discussion, the moderator briefly introduced the study goals for this focus group discussion. Participants were questioned on various topics that ranged from perception, knowledge, and behaviors related to the prevention and management of HTN. If participants did not elaborate on the initial question, a probe question was asked as a follow-up to encourage all participants to join the discussion actively. To achieve the objective of focus group discussion, the participants were encouraged to interact with each other, exchange ideas, and share their experiences or points of view. Every participant had the opportunity to contribute additional thoughts on preventing and managing HTN. Upon completion, participants received a $25 electronic gift card for attending a 60–90-minute focus group session.

Data collection and analysis

Participants completed a brief survey on socio-demographic information at the end of the focus group discussion. Demographic variables collected included age, sex, race, income level, and insurance status.

Focus groups and interviews were audio-recorded and transcribed verbatim. The field notes were referred to during the transcribing process. Two researchers coded transcripts independently, and then data were further reviewed by a third coder for content validity. This stepwise replication was helpful to ensure the dependability of the study. Numerous codes were identified, and relevant quotes were categorized under each code. Thematic analyses were performed to gather information for developing nutrition educational modules. The thematic analysis is a method of qualitative data analysis that follows a six-step process: familiarization, coding, generating themes, reviewing themes, defining and naming themes, and writing up (Braun & Clarke, 2023). The focus group transcripts were coded using Microsoft Word © without assistance from qualitative data analysis software. The research questions served as an input and basis for the initial codebook. After systematically coding all qualitative data from participants, the researcher began to organize the codes, based on similarity, into larger categories that lead to a hierarchical structure of code -> subtheme -> theme.

Ethical considerations

Ethical approval for this study was obtained by the Kansas State University Institutional Review Board (IRB) in December 2020 with approval #10334.

Results

Four focus groups and two pilot one-on-one interviews with 20 participants were completed before the saturation point was achieved. Of the 20 participants, 12 were female and 8 were male. The majority of the participants (n=15) were non-Hispanic white, with 3 being Asian and 2 being Hispanic, Latino, or Spanish origin. More than half of the participants (n=13) had completed a bachelor's or higher education, with the remaining receiving degrees from GED, trade/technical/vocational training, and associate degrees.

Table 3.2. Focus group participants' characteristics

Participants' characteristics	n
Age	
18-35	3
36-49	2
50-64	7
65+	8
Sex	
Male	8
Female	12
Race	
Asian	3
Black or African American	
Hispanic, Latino, or Spanish origin	2
White	15
Education level	
High school graduate, diploma or the equivalent (GED)	1
Trade/technical/vocational training	3
Associate degree	3
Bachelor's degree	6
Master's degree	5
Doctorate	2

Data were analyzed to identify major themes and nutrition topics of interest, which were then used to determine the topics for the nutrition education sessions. The grouping of the participants' answers into common themes used to develop the modules can be found in Appendix A.

Four underlying themes emerged from the focus group discussion and interviews. The themes identified included: (1) HTN and associated risk factors, (2) underestimated HTN

complications, especially organ damage caused by HTN, (3) nutrition and HTN, and (4) integration of nonpharmacological approaches as part of a healthy lifestyle.

Theme 1 HTN and associated risk factors

When asked about HTN, the majority of the participants indicated that it is a serious public health problem that needs to be taken care of. However, many of the participants could not clearly identify HTN cutoff points or give an exact definition, which in some way indicates the knowledge gap in providing nutrition education with a clear definition of HTN. Even though participants generally recognized HTN as a health concern, only a few were aware of what HTN is other than a medical term.

Some participants indicated that HTN is commonly seen in the media, however, there were some misunderstandings or misconceptions about it. The misunderstandings came mainly from two categories: 1) the confusion of HTN with other health conditions, such as heart disease; and 2) the lack of a clear understanding of the risk factors associated with HTN. Some related comments are:

"I can't really tell you the difference between heart disease and high blood pressure. I thought high blood pressure was under heart disease."
"I think that a lot of people don't realize how common it is, and they don't think it's a big deal because it doesn't present symptoms in a lot of cases."
"And I think the general public thinks it's only for old people and obese people."
"To me, I was told that as old people our blood pressure can get up to 160 over 100 and that's perfect for old people."

Participants were also asked to identify possible risk factors of HTN. Some participants identified heredity, family history, and aging as significant contributors to HTN. It is well established that these risk factors play a role in the development of HTN. However, it is important to note that these factors are inherent aspects of our identity, and we have little to no

control over them. As a result, they are categorized as unmodifiable risk factors. Participants also identified modifiable risk factors related to lifestyle choices. These included unhealthy eating, especially high dietary salt consumption, lack of physical activity, overweight or obesity, and poor stress management. While these risk factors are well-documented in the literature, it is worth noting that certain risk factors, such as smoking and excessive alcohol consumption, were not mentioned at all by any participants across all focus groups or interviews.

The participants showed a general but limited understanding of HTN throughout the discussion. More information regarding what HTN is, current HTN guidelines, and associated risk factors are needed for the general audience to gain a comprehensive understanding of HTN. Nutrition education addressing these elements would greatly help adults understand HTN at a deeper level. In addition, it is necessary to explain to the general audience what HTN is in layperson's terms so they can correctly understand this commonly seen health problem.

"I would like to know what high blood pressure even really means."
"one aspect of it I think would be food preparation, so guide somebody to walk alongside me with that give me some pointers dips what I think recipes that would be helpful."

Theme 2 Underestimated HTN complications

The results from the focus group and one-on-one interviews showed that the severity of HTN, especially organ damage caused by HTN, was underestimated by participants. Many participants indicated that HTN is a health condition that needs to be taken care of but did not know how exactly HTN affects the body. And in most cases, the damage is underestimated before severe conditions happen. One female participant shared the experience of one of her relatives who suffered from HTN:

"I know, in the case of my relatives, it took a heart attack and a trip to the ER to get on high blood pressure medication."

Out of the comments, some participants mentioned that HTN left untreated could cause damage to the heart, which could lead to heart disease. Damage to the brain potentially leading to stroke was also identified by participants. Even most participants agreed that HTN negatively impacts the body; however, less is known about how HTN affects other body organs, such as the brain, kidneys, eyes, and ears. Another thing worth noting is that participants misunderstood how HTN affects the eyes. To be specific, a few participants agreed that HTN affects the eyes and would cause glaucoma. However, glaucoma happens when eye pressure is higher than normal, but it does not necessarily indicate a higher body blood pressure (Bhargava et al., 2012). In the organs mentioned above by participants, little to nothing is known about how these effects happen. Some related comments are:

"I don't understand all of it, but I know it's really hard on the heart because your heart has to work harder, but I can't tell you exactly what it does."
"Well, I would suspect that it would potentially harm all your organs as the blood supply and the vessels inside the organs".
"What's so called glaucoma? I just wanted to know if there would be a connection between the two [high blood pressure and glaucoma]."

Most of the participants underestimated the relationship between HTN and other chronic diseases. Some participants indicated that HTN is a warning sign for other diseases but could only list one or two diseases associated with HTN. When asked how the appointed disease is connected to HTN, participants admitted a lack of understanding of the mechanisms behind the connection. As one male participant commented:

"I'm thinking things like diabetes and I'm not necessarily seeing a connection so I'm trying to think of other diseases and see if I can think of a connection, but I think I am not coming up with any right now."
"I would think it would have some effect but I couldn't tell you tangibly what you know [about] other diseases."

Theme 3 Nutrition and HTN

Most participants acknowledged that nutrition played a role in HTN prevention and management. However, when probed to identify specific BP-related nutrients or food items, participants had very little knowledge on this matter but showed great desire to know how nutrition is related to BP levels. As one female participant commented:

"We don't really understand the food that we're eating and the benefits that they have."

Participants mentioned that consuming salty food water consumption, and other sugary drinks increase BP levels. They also believed many foods contain hidden salt, which we consume regularly, in addition to high-sodium condiments, such as soy sauce, as contributors to high-sodium consumption.

"We know and don't use regular table salt in our cooking but use a lot of soy sauce so it kind of shocked me how high the sodium content in soy sauce was. There are a lot of foods we're eating that would increase sodium consumption that we didn't realize, for example, soy sauce."

Another aspect of BP-related nutrients mentioned among participants was potassium supplements. Some participants indicated they took potassium supplements, either in over-the-counter form or prescribed dose, to reduce BP levels. Other participants showed interest in knowing whether taking potassium supplements is beneficial in reducing BP levels. This aspect was included in the later-developed nutrition workshops to address participants' questions.

"I know people who are on potassium pills, I mean potassium supplement. I was told that you can't eat enough bananas or whatever to get enough potassium if you need to be prescribed potassium."

Even though very little is known about BP-related nutrients, the participants showed great interest in finding out more information on how nutrition is related to BP levels. When probed about a nutrition education program to introduce BP-related nutrients, participants showed great interest in learning more about healthy eating, cooking recipes, and nutrients that

are associated with BP levels. To potentially improve the overall eating behaviors, especially on salt consumption, participants indicated the need to look for salt substitutes or alternative ways to make their food taste better without overconsuming salt. Nutrition education featuring this aspect should be helpful for hypertensive patients on medication in understanding how food items and specific nutrients affect BP levels instead of relying on medication only to manage BP levels.

"If I was better educated nutritionally, I wouldn't have to go to the store and go buy a pill."

Theme 4 Integration of nonpharmacological approaches as part of a healthy lifestyle

The results also indicated a lack of knowledge of nonpharmacological approaches to prevent and manage HTN among participants. As indicated by participants, a healthy lifestyle was important in HTN prevention and management. However, in real life, it is not uncommon to see patients taking medications to offset unhealthy lifestyles. Several aspects of a healthy lifestyle, but not all, were identified by participants through the discussion, such as healthy eating behaviors, being physically active, and proper stress management strategies. When probed about the details of each lifestyle approach, facilitators noticed misconceptions and misunderstandings in some of the commonly known concepts. One participant shared her opinion on healthy eating:

"And to me, healthy eating means to try and eat things as close to their original form as possible so cooking from scratch, is how I would describe it: buying the vegetables and then meat separately and using seasonings."

A lack of self-efficacy in taking these actions is also observed among participants. When probed about a nutrition intervention to prevent and manage HTN, participants showed interest in knowing how to adopt the recommendations in a step-by-step guide. Another aspect regarding

these lifestyle approaches is that the recommendations must be tailored to each individual as it is not a one-size-fits-all thing.

Regarding the program's design, participants endorsed nutrition educational workshops to prevent and manage HTN in a community setting. The group setting would help participants hold each other accountable during the program and possibly after the program ends. A small portion of participants believed offering incentives would motivate people to attend community outreach programs. Participants also pointed out that practical advice with incremental and achievable steps is more likely to be successful in helping participants incorporate these modifications into their daily lives.

Discussion

This study explored knowledge, risk factors, perceptions, and behaviors associated with HTN prevention and management from the general adults' perspective by using semi-structured questions in a focus group or one-on-one interview setting. Thematic analysis revealed four recurrent themes: (1) HTN and associated risk factors, (2) underestimated HTN complications, especially organ damage caused by HTN, (3) Nutrition and HTN, and (4) integration of nonpharmacological approaches as part of a healthy lifestyle.

The qualitative study method was beneficial in exploring participants' knowledge, perceptions, values, and beliefs. In this study, the participants were able to identify some but not all the risk factors of HTN. Interestingly, none of the participants in all focus groups or interviews identified smoking or alcohol overconsumption as risk factors for HTN. This finding aligns with a qualitative study conducted among African Americans in an urban city near New York to assess knowledge, perception, and behavior related to HTN and cardiovascular diseases (Espejo et al., 2019). It is shown in this study that smoking and alcohol consumption were the

least-discussed topics in preventing HTN and CVDs. This indicates that the public is aware of the risk factors of HTN, but only to some extent. There is limited knowledge of the associated risk factors that could potentially increase the risk of developing HTN if exposed to smoking or alcohol overconsumption.

A small number of participants showed their concern about the role genetics plays in HTN development. They perceived that they were more vulnerable to developing HNT but less able to change their blood pressure diagnosis. Those participants who stated HTN as being inherited felt it was inevitable that they would eventually have HTN in their lives, sooner or later. This perception can be changed if participants have increased knowledge of HTN and improved self-efficacy in adopting lifestyle modifications to at least delay the onset of HTN.

Interestingly, a few participants from the focus groups showed particular interest in knowing whether taking potassium supplements is beneficial in reducing BP levels. It is worth noting that participants were aware of the BP-lowering effects of potassium but lacked knowledge of the amount needed and good dietary sources of potassium. Not surprisingly, potassium supplements had gained attention among participants, given the BP-lowering effect of potassium. However, the answer to that question is quite complicated. In the US, the FDA has strict rules on potassium supplementation because potassium is a critical nutrient, especially for those with kidney disease. As is recommended, the combination of a low sodium and high potassium intake is associated with the lowest blood pressure levels and the lowest frequency of stroke in individuals and populations. Vegetables and fruits are good sources of potassium; thus, potassium supplements are neither necessary nor recommended for the general population (FDA, 2022).

Appropriate sample size is important as a large sample offers thick and rich data while a small sample takes the risk of missing key elements or lacking enough diversity to show important influences. In this study, four focus groups and two one-on-one interviews were sufficient to identify a range of issues without providing too much repetitive information. The number of participants ranged from three to seven. The groups were small enough for all members to talk and share their thoughts yet large enough to create a diverse group.

The clinical term "high blood pressure" instead of "hypertension" was used during the focus group and one-on-one interviews. The reason is that the public may not understand the clinical meaning of "hypertension" and/or cannot equate it to "high blood pressure." Meanwhile, it is important to keep it consistent even though these terms are used interchangeably in clinic settings. The same holds for nutrition workshops developed based on this qualitative study.

Due to technology challenges, some older participants had problems using the Zoom conference tool to join the group discussion. The moderator was able to help guide them in navigating the tool. Participants who were from a family were allowed to use one Zoom account to join the meeting to avoid any background noise, but their responses were recorded and analyzed separately.

PMT is a disease prevention and health promotion model that has been widely used in previous research (Bui et al., 2013; Li et al., 2020; Mirkarimi et al., 2017). This study adds to the growing literature on the PMT to prevent health problems. The use of PMT in nutrition interventions is commonly seen; however, it is less common to apply PMT in a qualitative study. To our knowledge, this is the first time PMT has been used as a theory guide to conduct qualitative research regarding HTN. The use of PMT theory is beneficial in guiding the design of the qualitative study, especially with the setup of the open-ended questions.

Even though focus groups and one-on-one interviews are both formats of qualitative study, each has its advantages in collecting data. One-on-one interviews are more flexible since only the facilitator and participant are involved, but they are also limited in providing information. On the other hand, a focus group as a tool helped provide thick data since a group of participants was involved. Not only that, but the interaction among participants can also trigger new thoughts through the exchange of information. Using both focus groups and one-on-one interviews in this study to gain a comprehensive understanding of the subject is a strength.

The study has some limitations that must be highlighted. First, the participants were recruited in Riley County, KS, thus, may not be a good representation of the general population across the country, which might affect the transferability of the study. Second, the credibility of the study was limited due to a lack of member checking. Nevertheless, the researcher had prolonged and continuous communication with the participants throughout the study to help ensure credibility. In addition to that, the researcher also sought support from a team of researchers who were willing to provide scholarly guidance in conducting focus group research. This peer debriefing process could also help to improve the quality of the findings. Third, over half of the participants have received at least a bachelor's degree, indicating that they are fairly educated. This also explains why the participants were able to identify most of the risk factors. However, receiving higher education does not necessarily mean they are well-educated about nutrition. This also supports the fact that some risk factors were hardly mentioned across the four focus groups. Despite the limitations, this study is an excellent start to understanding nutrition education needs in preventing and managing HTN using a theory-based qualitative method.

Conclusion

This qualitative research study of adults regarding their knowledge, perceptions, and behaviors of HTN risk resulted in the identification of four main themes. The identified themes laid a solid foundation for future research to provide nutrition education information for the adult population to prevent and manage HTN. The nutrition education needs assessment is critical as it helps the researcher understand the real nutrition needs of the adult population from the participants' perspective.

Chapter 4 - Educational intervention based on Protection Motivation Theory to improve knowledge and promote nonpharmacological approaches to prevent and manage hypertension among adults: a pilot RCT study

Abstract

Objective: To investigate the effects of an educational intervention on knowledge, perceptions, and behavior change in preventing and managing high blood pressure (HBP) among adults based on the Protection Motivation Theory (PMT) as a theoretical framework. **Methods:** A total of 30 participants were recruited and randomly divided into control (n=15) and intervention groups (n=15). All participants completed the self-administered survey instrument composed of knowledge, PMT constructs, lifestyle behaviors, quality of life, and demographic variables. The survey was administered at baseline and then after the education sessions were completed in the intervention group. ASA24 was used to collect data on fruit and vegetable consumption and dietary potassium consumption at baseline, two weeks into the program, and after the intervention was completed for all participants. SPSS was used for data analyses. **Results:** Significant differences were observed between control and intervention groups in knowledge level (p=0.04), perceived severity (p=0.00), and response efficacy (p=0.01). Fruit and vegetable consumption increased compared to the baseline but was still below the dietary recommendation. Dietary potassium consumption increased in the intervention group compared to the control group. No significant difference was observed between the control and intervention groups in quality of life. **Conclusion:** The findings of the study indicated that a short-term

educational intervention promoting nonpharmacological approaches had positive effects on HBP prevention and management.

Introduction

High blood pressure (HBP), which is also clinically known as hypertension (HTN), is a common and complex health condition that is prevalent worldwide. Across the globe, 26% of the adult population experiences HTN, which could reach 29% by 2025 (Boateng & Ampofo, 2023). HTN remains the leading cause of noncommunicable disease deaths worldwide and also could lead to significant morbidity and mortality worldwide (Fuchs, 2020). In addition, HTN is a major risk factor for cardiovascular diseases and stroke, and a life-long treatment is needed once diagnosed (Riley et al., 2019). To achieve the global target of reducing the prevalence of HTN by 25% by 2025, the World Health Organization (WHO) and the United States Centers for Disease Control and Prevention (CDC) launched the Global Hearts Initiative in 2016. Unfortunately, despite recent advances in understanding and treating HTN, its prevalence continues to rise. According to the American Heart Association, in 2017, about half of the adult population was hypertensive (Carey & Whelton, 2018).

HTN causes severe impact on the body, and organ damage (e.g., the heart, arteries, kidneys, eyes, heart, bones, and reproductive organs) often occurs before the onset of HTN due to elevated blood pressure levels. In addition to the impact on the body's organs, HTN also shows a substantial economic burden—a "hidden" cost. Compared with people without HTN, the healthcare cost of people with HTN is estimated to be $2000 higher annually (Park et al., 2020). The estimated direct and indirect cost of HBP for 2018 to 2019 (annual average) was $52.2 billion (Tsao et al., 2023). Antihypertensive medication costs account for about half of the total medical expenses for the treatment of HTN (Sokol et al., 2005). When dealing with HTN, in

most cases, more than one type of medication is needed, which is associated with heavy socio-economic burdens both on individuals and health systems (Birabaharan et al., 2021). Let alone antihypertensive medications can be costly, and low adherence rates often occur (Abegaz et al., 2017). Moreover, almost all antihypertensive medications carry the potential for adverse effects. In addition, HTN is a modifiable risk factor for other costly diseases, such as heart disease and stroke.

Health-related quality of life (HRQoL) is an important outcome measure for non-communicable chronic diseases, including HTN (Chatzinikolaou et al., 2021; Wimmelmann et al., 2021). SF-36, also known as the Medical Outcomes Study Short Form Health Survey questionnaire, is a self-administered questionnaire that has been widely used in the field of HRQoL study (Germanova et al., 2023). The essential components of health-related life quality assessments include physical health, mental health, social function, and overall health perception (Riley et al., 2019)

Given the rising prevalence of HTN in adults, properly designed population-wide reductions in blood pressure strategies must be implemented to create a system of better general health practices. Such measures may greatly impact cardiovascular morbidity and mortality and subsequently reduce healthcare costs. From this standpoint, going upstream to prevent the onset of HTN is beneficial and provides a great opportunity to intervene before the start of the costly cycle of managing HTN and its complications. Adoption of healthy lifestyles by all individuals is critical for the prevention of high blood pressure and is an important component of managing HTN. These nonpharmacological approaches to preventing and managing HTN include: (1) reduction of dietary sodium intake; (2) a balanced eating plan that is rich in fruits, vegetables, and low-fat dairy products and reduced in saturated fat, total fat, and cholesterol; (3) prevention

and reduction of being overweight or obese; (4) regular physical activity; (5) moderation of alcohol intake; (6) proper stress management; (7) regular blood pressure monitoring; (8) no smoking; and (9) get adequate sleep. These approaches are also effective in the first place in preventing the onset of HTN, treating HTN, and potentially reducing the need for medications (Havas et al., 2004). Nonpharmacological approaches combined with the proper pharmacological treatment will best achieve optimal goals for blood pressure levels, reduce cardiovascular risk factors, improve vascular biology and vascular health, reduce cardiovascular target organ damage, improve quality of life, and reduce health care expenditures.

It is widely accepted that educational intervention can be beneficial in treating long-term disease. HTN is a common long-term disease and public health problem affecting adults of all ages (Chen et al., 2020; Ho et al., 2016). Theory-based educational intervention can potentially improve intervention efficacy to promote healthy behaviors. Previous studies that used theory-guided educational interventions to promote healthy behaviors and reduce risk factors have been effective (Azadi et al., 2021; Hoseini et al., 2014; Khorsandi et al., 2017).

The Protection Motivation Theory (PMT) provides an understanding of why an individual's attitudes and behavior can change when confronted with threats (Rogers, 1975). As a theory, PMT is applied as a general framework for predicting health behaviors and health-associated interventions (Morowatisharifabad et al., 2021; Rakhshani et al., 2023; Vasli et al., 2023). In general, increases in threat severity, threat vulnerability, response efficacy, and self-efficacy facilitated adaptive intentions or behaviors. Conversely, decreases in maladaptive response rewards and adaptive response costs increased adaptive intentions or behaviors (Wurtele & Maddux, 1987). PMT also emphasizes that knowledge of an effective behavior is not sufficient; the individual must perceive themselves to be able to carry it out. PMT also proposes

that perceptions of response efficacy and self-efficacy can better predict intention formation and subsequent behavior change. Increasing coping appraisal generally facilitated healthy behavior adaption (Plotnikoff et al., 2010; Preissner et al., 2023). Using PMT to design interventions to promote healthy behaviors should mainly focus on increasing coping appraisal, especially promoting self-efficacy, to motivate an individual to initiate and maintain healthy behaviors to prevent health problems.

High blood pressure is one of the top risk factors for heart disease and stroke, which are the leading causes of death in the United States. A theory-guided and evidence-based educational intervention can be helpful to motivate participants to adopt healthy behaviors. These educational modules use the PMT to help participants increase their knowledge, alert them to threats, promote self-efficacy, and empower the ability to take healthy actions by providing dietary monitoring, practical advice, and action tips.

Methods

Aim

The study aims to increase nutrition knowledge, promote nonpharmacological approaches, and improve the quality of life among adults through a theory-based educational intervention to prevent and manage HTN.

Participants

Participants were recruited through various channels, such as word of mouth and snowball sampling. A recruitment flyer was created and distributed at different highly accessed locations in Riley County, Manhattan, KS. These places include restaurants, grocery stores, the Riley County Health Department, doctors' offices, fitness centers, etc. The inclusion criteria

include being 18 years old or older, currently residing in Riley County, Kansas, being a US citizen, or a permanent resident, and proficient in English.

The smallest effect sample size was determined based on previous research to be scientifically meaningful (Aekplakorn et al., 2016; Saneei et al., 2014). To ensure that the final analysis had enough participants, we also accounted for potential dropout. Finally, the sample size was adjusted according to the study protocol, taking into account practical constraints such as time, budget, and availability of participants.

Program design

The educational intervention was a randomized controlled trial in which participants were randomly divided into control and intervention groups. The study was registered on ClinicalTrails.gov with an identifier number NCT06490575. Participants in the intervention group attended four face-to-face workshops (one session per week). Each session took about 30 minutes and consisted of lectures with PowerPoint presentations, discussion, questions and answers, and the distribution of educational pamphlets and booklets. Education sessions (led by a public health nutrition doctoral student and a nutrition expert) focused primarily on increasing knowledge and promoting nonpharmacological approaches to prevent and manage HTN. Sessions also concentrated on changing related beliefs of response efficacy, self-efficacy, perceived vulnerability, perceived severity, and intention, which are key components of PMT. Participants in the control group received no educational or counseling sessions until the final post-survey questionnaires were administered. All the educational pamphlets and booklets were given to the participants in the control group with a brief overview of the contents after the interventional sessions were implemented. The study flowchart is shown in Figure 4.1.

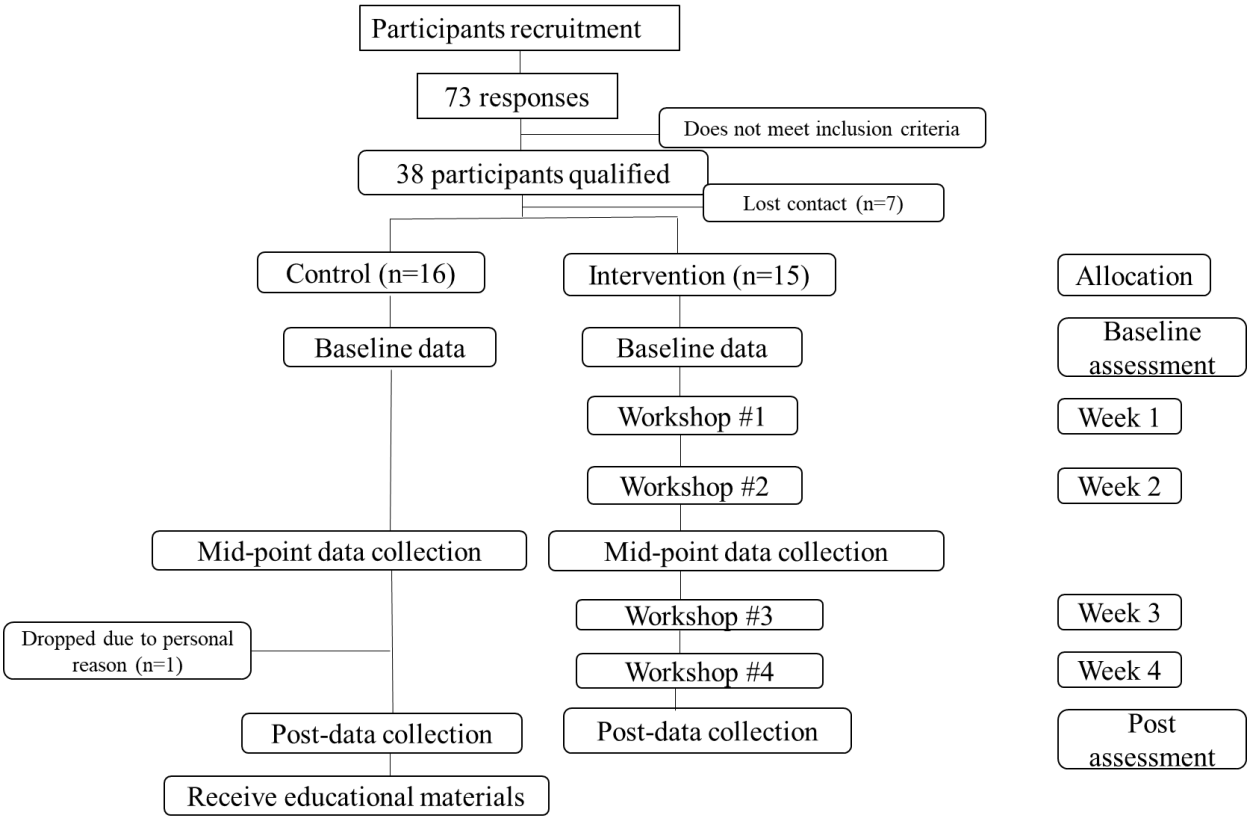


Figure 4.1. RCT flowchart

Module outline and theoretical application

Based on the nutrition education needs assessment from a previous qualitative study, this nutritional intervention was designed to test the effectiveness of the program. Four identified themes are: (1) HTN and associated risk factors, (2) underestimated HTN complications, especially organ damage caused by HTN, (3) Nutrition and HTN, and (4) integration of nonpharmacological approaches as part of a healthy lifestyle.

According to PMT, an individual's knowledge of a certain health-related problem, such as HTN, affects the decision-making process. Knowledge of a potential health threat (HTN in this case) will initiate the cognitive process. However, whether an individual practices health behavior or not is affected by two factors: threat appraisal and coping appraisal. Threat appraisal is influenced by specific beliefs about the vulnerability to HTN and beliefs about the

consequences or the severity of HTN. For example, an individual may decide they should increase their fruit and vegetable consumption to prevent and manage HTN if they feel the threat of developing cardiovascular disease (CVD) and perceive the threat of CVD to be serious. The belief that one can cope with a specific health threat (HTN in this case) also breaks down into two parts: 1) beliefs about the effectiveness of health practice (nonpharmacological approaches) and 2) beliefs about the ability to perform the recommended health behaviors.

Using PMT to design an educational intervention to prevent and manage HTN includes 1) introducing knowledge about HTN (e.g., HTN fact sheet), 2) highlighting perceived vulnerability (e.g., nearly half of American have HTN according to 2017 ACC/AHA guidelines) and perceived severity (e.g., HTN is one of the risk factors for CVD and stroke, which are the leading causes of death in the U.S., HTN could cause severe damage to different organs of the body), and 3) emphasizing response efficacy (e.g., nonpharmacological approaches are effective in preventing HTN and managing HP) and self-efficacy (e.g., practical advice and action tips to adopt healthy behavior to lower BP, such as a healthy meal planner).

This study also applied a 26-item taxonomy of behavior change techniques (BCTs) to optimize the reporting and scientific study of behavior change interventions (Abraham & Michie, 2008; Michie et al., 2011; West et al., 2011).

Table 4.1. Module outline, goals, main focus, the corresponding theoretical constructs from PMT, and related BCTs

Module	Theoretical constructs	Goals and main focus	Michie's BCTs
Module 1	Knowledge and perceived vulnerability	This lesson mainly focuses on increasing knowledge about blood pressure. This includes: What is blood pressure? Understand blood pressure readings Know factors that affect blood pressure readings Understand current blood pressure guidelines Risk factors associated with HTN (vulnerability) Unmodifiable risk factors Modifiable risk factors Common myths on HBP	Provide information on the consequences of behavior in general (technique #1) Provide information on the consequences of behavior to the individual (technique #2) Outcome goal setting (technique #6) Prompt self-monitoring of behavior (technique #16) Prompt self-monitoring of behavioral outcome (technique #17) Provide feedback on performance (technique #19) Fear arousal (technique #32) Prompt use of imagery (technique #34)
Module 2	Perceived severity	This lesson is built based on the information given from the previous lesson. This lesson is designed to alert the severity of HTN by introducing the damage to different organs caused by HTN. The main points are: High blood pressure damages different organs of the body How does high blood pressure affect the function of damaged organs? How is HBP associated with other chronic diseases?	Provide information on the consequences of behavior in general (technique #1) Provide information on the consequences of behavior to the individual (technique #2) Model/Demonstrate the behavior (technique #22) Fear arousal (technique #32) Prompt use of imagery (technique #34) Stimulate anticipation of future rewards (technique #40)
Module 3	Response efficacy	Response efficacy is the main focus of this lesson. This lesson is designed to help participants	Provide instruction on how to perform the behavior (technique #21)

		understand how different BP-related vitamins and minerals regulate body blood pressure levels. This lesson covers: BP-related vitamins and minerals Dietary recommendations for BP-related vitamins and minerals Dietary sources of BP-related vitamins and minerals	Prompt practice (technique #26) Prompt use of imagery (technique #34) Stimulate anticipation of future rewards (technique #40)
Module 4	Response efficacy and self-efficacy	This lesson is designed to help participants increase their expectancy that taking action can remove the threat by emphasizing the benefits of different nonpharmacological approaches. Evidence-based nonpharmacological approaches are proven to help prevent and manage high blood pressure. This lesson also focuses on increasing the participants' confidence in the ability to take action to prevent and manage high blood pressure by providing practical advice and action tips. These are: o Eat a healthy diet o Keep a healthy body weight o Be physically active o Do not smoke o Limit alcohol consumption o Get enough sleep o Stress management o Monitor blood pressure	Behavior goal setting (technique #5) Outcome goal setting (technique #6) Action planning (technique #7) Barriers identification/problem solving (technique #8) Provide information on where and when to perform the behavior (technique #20) Provide instruction on how to perform the behavior (technique #21) Prompt practice (technique #26) Stimulate anticipation of future rewards (technique #40)

Module development

Module 1 High blood pressure, what do you need to know?

Module 1 was developed according to comments such as "*I think the general public thinks high blood pressure is only for old people and obese people." "Most people think that hypertension is bad, but they might not know exactly what that is,"* and *"I can't really tell you the difference between heart disease and high blood pressure. I thought high blood pressure was under heart disease"*. These comments indicate a need to understand HBP from a correct scientific perspective yet in layperson's terms. Therefore, Module 1 was developed to address these matters, including what blood pressure is, what the current HBP guidelines are, what affects BP readings, risk factors (modifiable and unmodifiable risk factors) of HBP, and common myths about HBP.

This module included a demonstration to illustrate blood pressure to participants during the workshop. Handouts on smoking and HBP were created to illustrate how HBP affects the vascular system. Common myths on HBP were made into flashcards for participants to take home.

After lesson 1, participants should be able to:

- define blood pressure.
- understand their blood pressure readings.
- identify factors that could potentially affect blood pressure readings.
- explain the most current blood pressure guidelines by ACC/AHA.
- identify risk factors, modifiable and unmodifiable, that are associated with high blood pressure.
- correctly understand the common myths about high blood pressure.

- increase their overall knowledge of blood pressure.

Module 2 What does high blood pressure do to your body? Nothing good.

Module 2 was developed in response to the following comments: "*I don't think they know much, only that it's bad for you, but I don't think they can explain why," "I would think heart disease. But I have no idea how."* and *"Well, I would suspect that it would potentially harm all your organs as the blood supply and the vessels in the inside the organs*." These comments reflect the need to explain what parts of the body HBP affects and how. Module 2 was developed to explain how HBP affects the different organs, including arteries, heart, brain, kidneys, eyes, ears, bone, and reproductive organs. Module 2 also highlights the association between HBP and other chronic diseases.

A "Pass Tunnel" demonstration was designed to illustrate how HBP damages the arteries and other organs. Pictures were used to support the information. The healthcare burden of having HBP and other associated chronic diseases was explained as a "hidden cost" to highlight the severity of HBP.

A group activity was planned to reinforce the information shared in this session. At the beginning of this session, participants sitting at a table worked as a group, 3–5 in each group, to identify the organs that could be damaged by HTN. During the workshop session, participants had a chance to look at their responses, which were recorded at the beginning. At the end of the session, participants reviewed their answers again, which provided an opportunity to review the shared content.

After lesson 2, participants should be able to:

- understand the severity of high blood pressure.
- discuss how high blood pressure affects the functions of damaged organs.

- understand the relationship between HBP and other chronic diseases, such as diabetes, chronic kidney disease, and obesity.

Module 3 Blood pressure, fuel it up or down?

Comments such as "*I don't know how the food actually will decrease blood pressure. I just heard that certain foods…can help lower BP," "I don't know the specific nutrients that increase or decrease BP levels," "I don't understand the nutrition, but I do know that when I'm eating a well-balanced food choice. You know good carbohydrates, good fats, good vegetables…I feel better,"* and *"Something with recipes should be included,"* show a need to introduce vitamins and minerals that could potentially affect blood pressure levels. Module 3 was designed to help participants understand how these BP-related vitamins and minerals affect blood pressure levels and identify food sources of these nutrients.

Module 3 was designed with handouts to understand the facts about sodium/salt, identify salt alternatives, and sample a BP-friendly recipe (a sample was made for participants in the intervention group to try). This module also included dietary recommendations on BP-related vitamins and minerals and dietary sources of these nutrients.

After lesson 3, participants should be able to:

- recognize major BP-related vitamins and minerals.
- understand the association between BP-related vitamins and minerals and blood pressure levels.
- know the dietary guidelines on BP-related vitamins and minerals.
- identify salt alternatives and apply them in cooking.
- identify dietary sources of BP-related vitamins and minerals.

Module 4 Live to lower your BP levels! Lifestyle choices matter!

This module was designed regarding these comments: "*I wonder if people really know what to look for to make better choices," "I want to learn how to just avoid it in the first place,"* and *"Many times we take medication to offset bad lifestyle."* These comments indicate the participants' desire to learn practical tips they could incorporate into their daily lives that could help prevent the onset of HBP or lower blood pressure levels if they have elevated BP levels currently. Therefore, the idea of the nonpharmacological approach to prevent and manage HTN was introduced to participants during this session.

Handouts were created to assist participants in understanding the information in Module 4. These handouts include a processed foods spectrum, a healthy meal planner, and DE-STREES—fighting stress with healthy habits. Guidelines were given on the flip side of the healthy meal planner handout to help participants plan a healthy meal on their own. A "DASHED IN/OUT" activity was created to help participants understand the key elements of a Dietary Approaches to Stop Hypertension (DASH) diet. Several food items were listed for the participants to identify as DASHED IN or DASHED OUT.

After lesson 4, participants should be able to:

- understand the importance of eating a healthy diet for blood pressure management.
- know what a DASH eating plan recommends and limits.
- discuss different ways of being physically active and review the Physical Activity Guidelines for Americans.
- identify ways to manage stress.
- identify processed foods from the processed food spectrum.
- create a healthy meal according to the recommendations in different food groups given in the healthy meal planner.

- create an action plan to prevent and manage high blood pressure and incorporate it into daily life.
- identify helpful nonpharmacological approaches to prevent and manage high blood pressure.
- explain the benefits of different nonpharmacological approaches.
- recognize an approach that works best for an individual.

Data collection

The data were collected through the following tools:

(1) Demographic and lifestyle pre- and post-survey instrument

The survey includes items on knowledge, risk perceptions, assessment of response efficacy and self-efficacy, intention for behavior change, and lifestyle behaviors. The survey items were adopted from different sources (Schapira et al., 2012). The survey was self-administered to participants at baseline and after the intervention to collect pre- and post-intervention data. A full list of the questionnaire is in Appendix B.

Demographic factors included age, sex, race, education level, marital status, self-reported height and weight, total household income, health insurance status, and whether taking HTN medication.

HTN knowledge was measured using ten items aimed at assessing knowledge about HTN. The questions from the self-administered questionnaires have been included in Appendix B. The questions were designed to convey key concepts of HTN in a simple format that participants with low literacy levels easily understood. Based on the qualitative study conducted before the educational workshops, the issues to be addressed during the educational intervention were determined.

If the participant answered the questions correctly, it is coded as 1; otherwise, 0. The knowledge variable was computed by adding the number of correct answers, with a possible total of 10 points.

The perceived severity of HBP was assessed with eight questions, which measured participants' perception of the severity of HTN, including damaged organs, using a 5-Likert scale with (1) strongly disagree, (2) disagree, (3) neutral, (5) agree, and (5) strongly agree. Response efficacy was assessed with seven questions to determine how beneficial it is of each nonpharmacological approach using a 5-Likert scale with (1) not beneficial at all, (2) a little beneficial, (3) somewhat beneficial, (4) quite beneficial, and (5) very beneficial.

Self-efficacy was measured with seven questions to assess how confident to adopt each behavior using a 5-Likert scale with (1) not confident at all, (2) a little confident, (3) somewhat confident, (4) quite confident, and (5) very confident.

Intention to behavior change was assessed with seven questions to determine the intention to which degree to adopt each nonpharmacological approach in the next 30 days. The 5-Likert scale was applied with (1) strongly disagree, (2) disagree, (3) neutral, (5) agree, and (5) strongly agree.

The survey was primarily administered through Qualtrics, which is an online survey software. For participants who had trouble accessing the tool, a hard copy was provided, and the data were entered by the researcher afterward.

Lifestyle behaviors assessment:

- Consumption of fruits and vegetables was assessed using one item. "In total, how many servings of fruits and vegetables do you eat daily? Examples explaining the serving of

fruits and vegetables were included as a note. The participants reported their consumption in the following categories: “I do not eat fruits and vegetables,” “1–3”, “4–5”, and “5 or more”.

- Physical activity was assessed with one item. “How many of the past 7 days did you do at least 30 minutes total of physical activity?” A brief definition of physical activity was attached to help guide participants in answering this question. The responses ranged from “0” to “7” days.

- Smoking status was assessed with one item, “How many of the past 7 days did you smoke a cigarette or cigar, even just one puff?” The responses ranged from “0” to “7” days.

- Alcohol intake was assessed using an existing measure, the 2-item National Institute on Alcohol Abuse and Alcoholism (NIAAA) Quantity and Frequency Questionnaire (NIH, 1995). “How many of the past 7 days did you drink alcohol or have any kind of drinking containing alcohol?” and the answer options ranged from “0” to “7” days. “How much did you drink on the days you had any kind of drink containing alcohol?” What a drink means was attached as a note. The participants were asked to answer from “0” to “5 or more”.

- Dietary sodium consumption was assessed with two items. “On average, how much sodium do you think you consume every day?” and “During the past month, how often did you consume processed foods such as processed meats (deli or lunch meats, sausages, bacon, hot dogs, smoked or canned meats), frozen and microwavable meals, frozen pizzas, instant or flavored rice and pasta dishes, and canned soups or broths, sauces, or gravies?”

(2) Automated self-administered 24-hour food recall (ASA24)

This tool is based upon the validated Automated Multiple-Pass Method (AMPM) to collect dietary data using the 24-hour food recall. The ASA24 system was developed by the National Cancer Institute and was first released in 2009. Previous studies have demonstrated

that 24-hour dietary recalls provide high-quality dietary intake data with minimal bias, making them the preferred tool for monitoring the diets of populations and, increasingly, for studying diet and disease associations (Ettienne-Gittens et al., 2013; Kupis et al., 2019; Subar et al., 2012). Participants were asked to complete three 24-hour food recalls during the study, one at baseline, one at mid-point, and one after the intervention. Participants could report as many meals as they had in the past 24 hours, including snacks. For each meal, participants were asked to include all the food items. A nutrition report was generated after each participant completed the 24-hour food recall each time and was sent to participants for their records. The nutrition report included an overview of the food items consumed on the day reported, total calorie consumption (including breakdown from carbohydrate, fat, protein, and alcohol), daily food group consumption compared to the recommendations, nutrients, and foods to limit (e.g., added sugars, saturated fat, alcohol, and sodium), and nutrient intake from food and drinks (including macronutrients, fiber, vitamins, and minerals). In this ASA24 edition, each individual's sleeping data was also collected but not reported due to incomplete data.

The ASA24 website is appropriate for people with at least a fifth-grade level and with respondents who are comfortable using computers, tablets, or mobile devices. Due to the study's design, for participants who had trouble completing the 24-hour food recall online, the data were collected either via phone call or face-to-face meetings so the data could be collected and entered into the ASA24 system.

(3) 36-item quality of life (SF-36)

This questionnaire is a general health-based survey of quality of life. It has been validated and is used widely to measure health-related quality of life in a variety of population groups with different health conditions (Barcones-Molero et al., 2018; Chatzinikolaou et al., 2021; Clause-

Verdreau et al., 2019). Quality of life is either defined as the subjective perception of one's well-being within the socio-cultural context or as the satisfaction of desires and pleasures and the accomplishment of the ideal to a standard of perfection. The questionnaire is attached in Appendix C.

The SF-36 questionnaire can provide a direct quantitative indication of an individual's health status. It has become one of the most widely used tools to evaluate quality of life in the world due to its convenience to administer. The SF-36 includes one multi-item scale that assesses four major components: general health, mental health, physical health, and social function (Patel, Alpesh A.; Donegan, Derek; Albert, 2007).

Self-rating of health was assessed with responses ranging from excellent (5) to poor (1). General health was assessed with six items for participants to self-report their health status. Limitations of activities were assessed with ten items asking participants how their health limited daily activities. The responses included "Yes, limited a lot (coded as 3)", "Yes, limited a little (coded as 2)", and "No, not limited at all (coded as 1)". Physical health problems in the past four weeks were assessed with four items with "yes (coded as 1)" and "no (coded as 0)" answers. These items aimed to determine if physical health caused any problems with work or other daily activities. Emotional health problems in the past four weeks were assessed with three items with "yes (coded as 1)" and "no (coded as 0)" answers. These items aimed to assess if emotional problems (e.g., feeling depressed or anxious) caused any issues with work or other regular daily activities.

Social activities in the past 4 weeks were assessed with 2 items. The first item assessed the extent to which emotional problems interfere with normal social activities with family, friends, neighbors, or groups with options "not at all (coded as 1)", "slightly (coded as 2)",

“moderately (coded as 3)”, “severe (coded as 4)”, and “very severe (coded as 5)”—the second item aimed to assess the frequency of physical health or emotional health interfered with social activities. The responses were “All of the time (coded as 5)”, “Most of the time (coded as 4)”, “Some of the time (coded as 3)”, “A little bit of the time (coded as 2)”, and “None of the time (coded as 1)”.

The pain was assessed with 2 items. The first item assessed how much pain the participants had in the past four weeks with responses “none (coded as 1)”, “very mild (coded as 2)”, “mild (coded as 3)”, “moderately severe (coded as 4)” and “very severe (coded as 5)”. The second item assessed how much pain interfered with normal work in the past four weeks. The responses were “not at all (coded as 1)”, “a little bit (coded as 2)”, “moderately (coded as 3)”, “quite a bit (coded as 4)”, and “extremely (coded as 5)”.

Energy and emotions were assessed with nine items to determine how participants felt and how things had been during the past four weeks.

(4) Daily BP tracker

The BP tracker was created for participants to record daily BP readings at home with the provided wrist blood pressure monitor. Brief instructions on how to use the wrist blood pressure monitor were included on the flip side of the tracker. Instructions on how to measure blood pressure correctly were also listed. The participants were asked to take their blood pressure once a day with two readings. The average of the two readings was obtained to get a more accurate reading. Participants were encouraged to take their blood pressure using the same wrist every time and keep it constant by measuring it at the same time every day.

(5) Workshop evaluation form (intervention group only, Appendix D)

Participants in the intervention group also filled out an evaluation form, which included information on the following aspects:

1. Which module is most helpful?
2. How was the module designed and delivered in terms of usefulness and length?
3. Do you have any other suggestions to better benefit audiences in the future?

Data analysis

Data gathered from all questionnaires and survey tools were analyzed and reported using descriptive statistics. Paired t-tests were performed to determine significant differences before and after the educational intervention. The average scores and differences of each variable were reported as mean ± SD. To control the effect of pre-survey data, assumptions of ANCOVA were checked and met before conducting the test. The intervention effect was determined using ANCOVAs for making between-group comparisons in post-survey data. Bonferroni correction was applied if the difference was significant. Categorical variables were presented as frequencies and percentages. Continuous variables were described with mean and standard deviation. p-Values less than 0.05 were considered statistically significant. Analysis was performed with statistical software SPSS 18.0 (IBM Corp., Chicago).

CONSORT checklist

The CONSORT checklist of the study is attached in Appendix E.

Results

Participants' characteristics

Seventy-three individuals expressed interest in this study and completed the screening survey. Out of the 73 responses, 38 were included to proceed as participants of the study. The rest (n=35) were excluded due to a lack of contact information or not meeting the inclusion

criteria. The selected 38 participants were divided into control and intervention groups, with 19 participants in each group. Due to the timeline of the study (the recruitment started in December 2022, and the study started in the second week of January), four participants in the control group and three in the intervention group lost contact before the study. A total of 31 individuals, including five from the previous focus groups, participated in the study. One participant in the intervention group dropped out due to personal reasons. The main characteristics of the participants in both control and intervention groups are listed in Table 4.2.

Table 4.2. Characteristics of participants in both control and intervention groups

Demographic variables	Total n=30		Control n=15		Intervention n=15	
	Number	Percent%	Number	Percent%	Number	Percent%
Age (yr)						
18-35	10	33.3	2	13.3	8	53.3
36-49	3	10	3	20	0	0
50-64	8	26.7	3	20	5	33.3
65+	9	30	7	46.7	2	13.3
Sex						
Male	9	30	5	33.3	4	26.7
Female	21	70	10	66.7	11	73.3
Race						
White	25	83.3	11	73.3	14	93.3
Black or African American	1	3.3	0	0	1	6.7
Asian	4	13.3	4	26.7	0	0
Marital status						
Divorce or widowed	6	20	4	26.7	2	13.3
Married	15	50	9	60	6	40
Single	9	30	2	13.3	7	46.7
Education						
High school or equivalent	1	3.3	1	6.7	0	0

Technical or occupational certificate	1	3.3	0	0	1	6.7
Associate degree	3	10	1	6.7	2	13.3
Some college coursework completed	7	23.3	2	13.3	5	33.3
Bachelor's degree	7	23.3	6	40	1	6.7
Master's degree	8	26.7	3	20	5	33.3
Doctorate	3	10	2	13.3	1	6.7
Annual income						
Less than $25,000	2	6.7	1	6.7	1	6.7
$25,000-$50,000	6	20	1	6.7	5	33.3
$50,000-$75,000	6	20	4	26.7	2	13.3
$75,000-$100,000	6	20	4	26.7	2	13.3
$100,000-$150,000	4	13.3	3	20	1	6.7
≥$150,000	3	6.7	1	6.7	2	13.3
Don't Know/Not sure	2	6.7	1	6.7	1	6.7
Choose not to answer	1	3.3			1	6.7
Health insurance						
Yes	29	96.7	15	100	14	93.3
No	1	3.3	0	0	1	6.7
HBP medication						
No	22	73.3	10	66.7	12	80
Yes	8	26.7	5	33.3	3	20
Types of HBP medication						
1	4	13.3	1	6.7	3	20
2	4	13.3	4	26.7	0	0

Comparison on knowledge, risk perceptions, response efficacy, self-efficacy, and intention to behavior change in control and intervention groups

The pre- and post-survey on knowledge, risk perceptions, response efficacy, self-efficacy, and intention to behavior change was administered at baseline and the end of the study. The

average scores for each category at baseline and post-survey were compared using a paired sample t-test. The average scores and differences of each variable were reported as mean ± SD. To control the effect of pre-survey data, assumptions of ANCOVA were checked and met before conducting the test. The intervention effect on knowledge, risk perceptions, response efficacy, self-efficacy, and intention to behavior change was determined using ANCOVAs for making between-group comparisons in post-survey data. Bonferroni correction was applied if the difference was significant. A detailed summary of ANCOVAs and related statistics comparing the control and intervention groups is presented in Table 4.3.

After the educational intervention, the average score for knowledge of HTN prevention and management had a greater increase in the intervention group (1.27±1.39) compared to that of the control group (0.6±1.55). A higher average score indicates better knowledge. When compared to the control group (1.87±6.46), the average score for the perceived severity of HTN increased greater in the intervention group (3.07±5.93). The increase in the perceived severity indicates a higher level of acknowledgment of the severity of HTN. The response efficacy shows how beneficial it is to perform particular behavior in preventing and managing HTN. Participants rate the perceived benefits of performing certain behaviors, and a higher score indicates a stronger belief in the benefits of these behaviors. A larger increase was observed in the intervention group (2.8±4.53), whereas a small increase was shown in the control group (0.2±4.44). Self-efficacy refers to an individual's level of confidence in performing a certain behavior. A higher self-efficacy indicates a higher level of confidence. The self-efficacy in the intervention group has increased (2.73±5.71) while a small decrease was observed in the control group (-0.47±4.97). The intention to change behavior shows how likely the participants are willing to perform a certain behavior. A higher intention indicates a higher likelihood of

adopting healthy behaviors. The intention in the intervention group increased (3.53±5.54), whereas the intention in the control group decreased (-0.93±5.28).

ANCOVA results showed that controlling for pre-survey data, participants in the intervention group reported statistically significant improved outcomes in knowledge [$F(1, 15) = 4.73$, $p = 0.04$, $\eta^2 = 0.15$], perceived severity [$F(1, 15) = 9.63$, $p = 0.00$, $\eta^2 = 0.26$], and response efficacy [$F(1, 15) = 6.85$, $p = 0.01$, $\eta^2 = 0.2$]. Post hoc comparisons using the Bonferroni test indicated that the intervention group significantly differed in knowledge (p=0.04), perceived severity (p=0), and response efficacy (p=0.01). Compared to the control group, the intervention group reported higher self-efficacy and intention to behavior change in the post-survey; however, the differences were not statistically significant (p>0.05). Therefore, the short-term educational intervention on HBP prevention and management could significantly improve knowledge, perceived severity, and response efficacy.

Table 4.3. Summary of ANCOVAs and related statistics comparing the control and intervention groups in pre- and post-survey

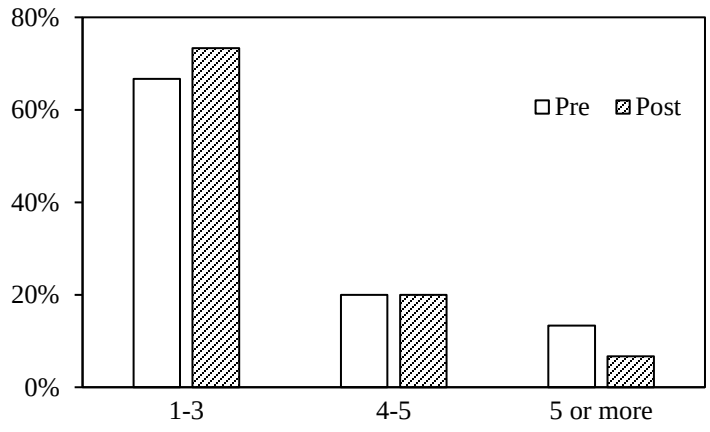
Variables	Control			Intervention			F	p	η^2
	Pre	Post	Difference	Pre	Post	Difference			
Knowledge	8.13±1.56	8.73±1.62	0.6±1.55	8.47±1.36	9.73±0.46	1.27±1.39	4.73	0.04*	0.15
Perceived severity	32.2±3.03	34.07±4.88	1.87±6.46	35.13±4.72	38.2±2.78	3.07±5.93	9.63	0.00*	0.26
Response efficacy	31.4±3.42	31.6±2.89	0.2±4.44	31.07±4.17	33.87±1.64	2.8±4.53	6.85	0.01*	0.20
Self-efficacy	28.8±3.77	28.33±3.77	-0.47±4.97	27±5.64	29.73±5.61	2.73±5.71	1.67	0.21	0.06
Intention	30.4±3.24	29.47±3.27	-0.93±5.28	27.8±4.68	31.33±3.90	3.53±5.54	1.73	0.2	0.06

*$p<0.05$ indicate values are significantly different

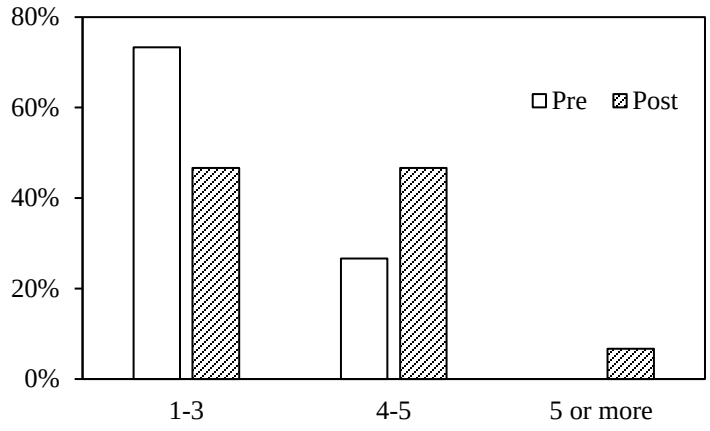
Comparison of lifestyle behaviors at baseline and after intervention

The self-reported fruit and vegetable consumption in both control and intervention groups are represented in Figure 4.2. There was very little change in fruit and vegetable consumption in the control group, which was shown as a minor decrease in the frequency of consuming more than 5 servings of fruits and vegetables and a minor increase in the frequency of consuming 1–3 servings. In other words, the overall consumption of fruits and vegetables in the control group had a minor decrease compared to the baseline. On the other hand, the intervention group showed a decrease in the frequency of 1–3 servings of fruits and vegetables, whereas an increase in the frequency of 4–5 servings and more than 5 servings was observed. This indicated an increase in the overall fruit and vegetable consumption in the intervention group after the educational intervention.

Since the data on fruit and vegetable consumption were self-reported, the increase in the overall consumption of fruits and vegetables could be partially due to the knowledge increase through the educational intervention, as Module 4 focused on promoting healthy eating habits and educating participants on appropriate serving sizes. This increase in knowledge may have led to changes in behavior, resulting in a higher consumption of fruits and vegetables. Additionally, the intervention may have helped participants understand serving sizes, which could potentially result in more accurate reporting of their fruit and vegetable consumption.



Control group



Intervention group

Figure 4.2. Fruit and vegetable consumption in control and intervention groups at baseline and after intervention

The self-reported sodium consumption in the control group has changed over the four weeks. In the control group, the percentage of participants reporting sodium consumption between 1,500 mg and 2,300 mg decreased from 46.67% to 33.33%, whereas the percentage of participants reporting consumption of more than 3,400 mg increased from 13.33% to 26.67%. Changes in sodium consumption in the intervention group have also changed. As for the intervention group, there was a decrease in the number of participants who reported “I don’t

know" compared to the baseline, from 26.67% to 13.33%. This led to an increase in the category of less than 1,500 mg of sodium from 20% to 26.67%. Additionally, there was a small increase in the category of consuming more than 3,400 mg of sodium from 6.67% to 13.33%. The data are presented in Figure 4.3.

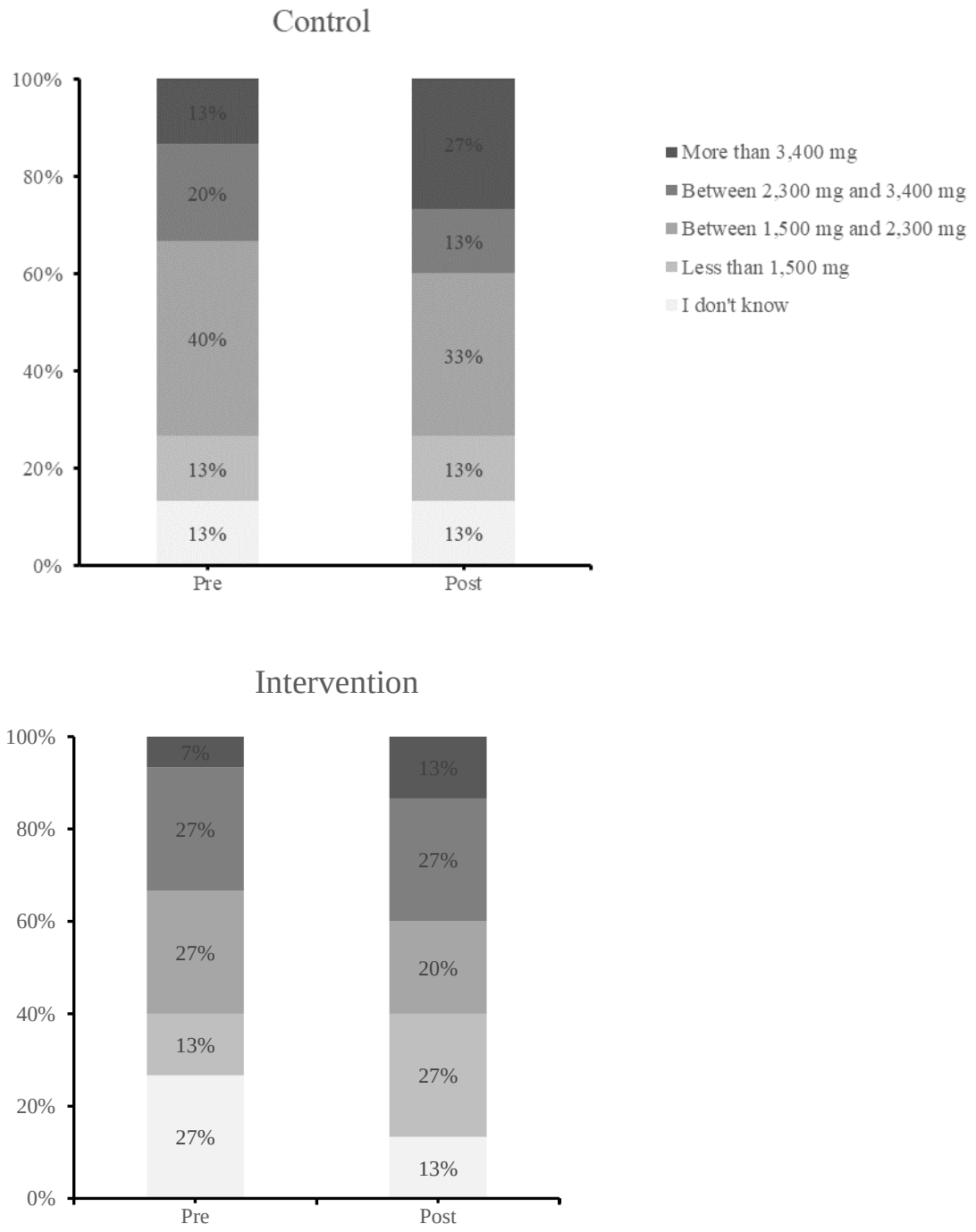


Figure 4.3. Sodium consumption in the control and intervention groups at baseline and after intervention

The data showed that there were no changes in smoking habits both in the control and intervention groups. Both the control and intervention groups showed a decrease in alcohol

consumption compared to the baseline data, with the control group showing a greater decrease (-0.73±2.19) than the intervention group (-0.33±1.35). Compared to baseline data, there was an increase in physical activity in the intervention group, but the increase was not significant (0.67±3.31), whereas the control group experienced a minor decrease in physical activity (-0.07±3.12).

To control the effect of pre-survey data, assumptions of ANCOVA were checked and met before conducting the test. The intervention effect on healthy behaviors related to HBP prevention and management was determined using ANCOVAs for making between-group comparisons in post-survey data. ANCOVA results showed that controlling for pre-survey data, participants in the intervention group did not report statistically significant improved outcomes in healthy behaviors related to HBP prevention and management ($p>0.05$). A detailed summary of ANCOVAs and related statistics comparing the control and intervention groups is presented in Table 4.4.

Table 4.4. Summary of ANCOVAs and related statistics comparing the behavior variables in control and intervention groups

Variables	Control			Intervention			F	p	η^2
	Pre	Post	Difference	Pre	Post	Difference			
Smoking	0.07±0.26	0.07±0.26	0±0.38	0.93±2.46	0.93±2.47	0±3.74	2.26	0.14	0.08
Alcohol consumption	1.4±2.06	0.67±1.68	-0.73±2.19	0.80±1.37	0.47±1.39	-0.33±1.35	0.01	0.93	0.03
Physical activity	4±2.20	3.93±2.43	-0.07±3.12	3.87±2.2	4.53±1.68	0.67±3.31	0.57	0.46	0.21

Changes in ASA24 24-hour food recall

The ASA24 24-hour food recall was collected repeatedly at baseline before the workshop (recorded as #1), two weeks into the program (recorded as #2), and after the final workshop (recorded as #3). One participant was excluded from the control group (n=14) because of inaccurate dietary recall. Similarly, two participants were excluded from the intervention group (n=13) due to incomplete dietary recall.

Dietary data on sodium, potassium, and fruit and vegetable consumption were collected from the participants. The mean and standard error were calculated and presented in Table 4.5. At the end of the program, the control group showed a decrease in dietary sodium consumption compared to the baseline. However, in the intervention group, there was a decrease in sodium consumption halfway through the program, followed by an increase at the end of the intervention (Figure 4.4). Although there were changes in the dietary sodium intake over the four weeks, the average minimum intake for participants in both the control and intervention groups was still higher than the recommended intake of 2,300 mg. During the study, the control group showed a decrease in dietary potassium consumption from the baseline. On the other hand, the intervention group showed a decrease in potassium consumption from the baseline to halfway through the program, followed by an increase (Figure 4.5). However, the maximum potassium consumption in both groups was less than the recommended 4,700 mg per day. Regarding fruit and vegetable consumption, both groups showed a similar trend. There was a decrease in consumption from the baseline to two weeks into the program, followed by an increase from halfway through the program. The intervention group showed a greater increase in consumption than the control group. However, the average total consumption of fruits and vegetables in both control and

intervention groups was below the recommended 4–4.5 servings per day for adults (Figure 4.6). The mean and standard error are presented in Table 4.5.

Table 4.5. Dietary sodium, dietary potassium, and fruit and vegetable consumption from ASA24

Sodium	Control (Mean±SE)	Intervention (Mean±SE)
#1	3878.89±452.25	3153.99±527.43
#2	3194.03±311.65	2592.52±295.41
#3	2790.68±261.28	3286.11±295.201
Potassium		
#1	2953.19±379.67	2685.33±380.78
#2	2726.68±301.19	2339.97±248.23
#3	2640.57±305.46	2882.24±229.58
Fruit and vegetable consumption		
#1	2.79±0.31	2.37±0.21
#2	2.52±0.41	2.28±0.26
#3	2.87±0.52	3.28±0.25

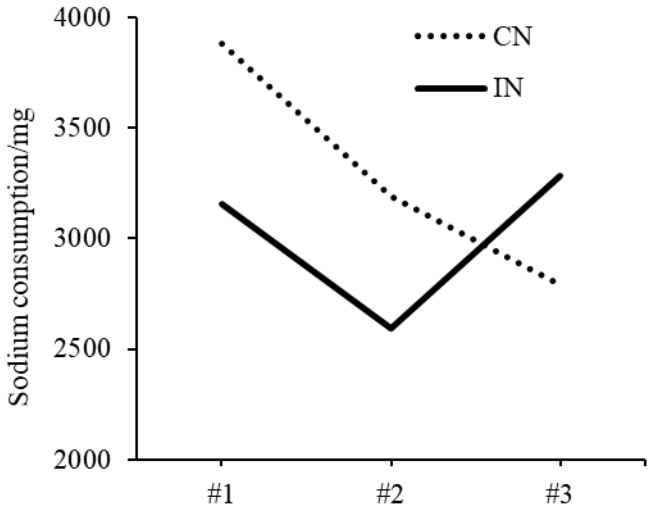


Figure 4.4. Dietary sodium consumption from baseline (#1), mid-point (#2), and after the intervention (#3) according to ASA24

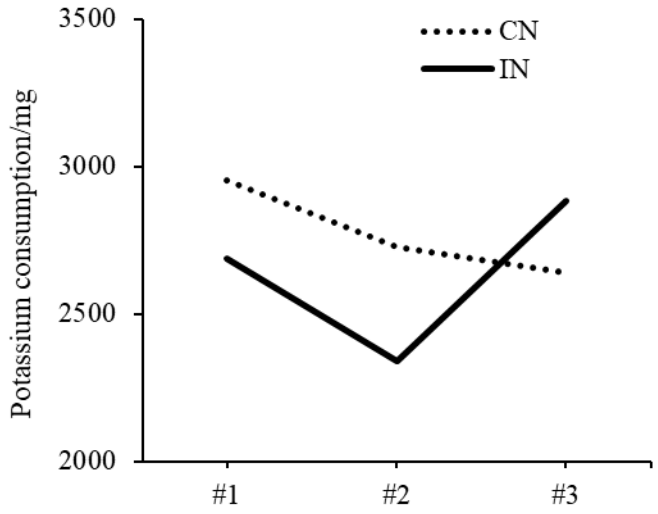


Figure 4.5. Dietary potassium consumption from baseline (#1), mid-point (#2), and after the intervention (#3) according to ASA24

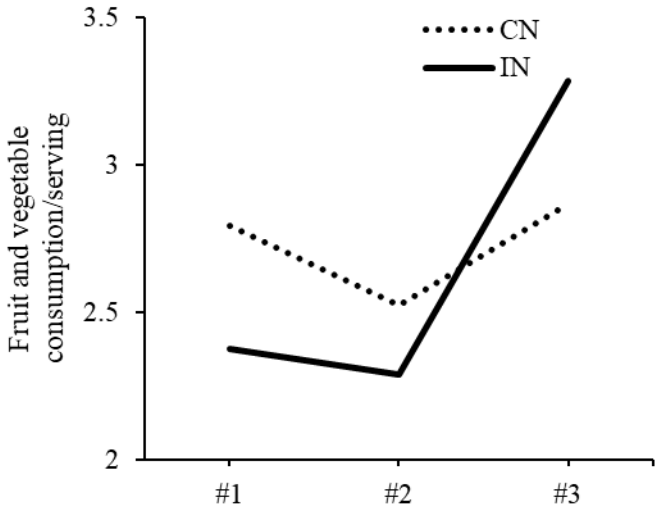


Figure 4.6. Total fruit and vegetable consumption from baseline (#1), mid-point (#2), and after the intervention (#3) according to ASA24

Comparison of HRQoL in control and intervention groups

The study assessed the general health of participants using six items in the HRQoL survey. Both the control (0.47±3.76) and intervention groups (2.13±5.33) showed an increase in general health, but the change in the intervention group was greater.

Greater limitations in activities indicate a more restricted ability to conduct daily tasks. Compared to the baseline, both the control (-0.4±4.85) and intervention group (-0.2±2.18) showed a decrease in limitations of activities. Moreover, the decrease in the control group was even greater than that observed in the intervention group.

Both the control group (-0.67±1.5) and intervention group (-0.13±1.13) showed a decrease in physical health problems compared to baseline data. A higher number of physical health problems can interfere with regular daily activities and work and may suggest poor physical health.

The control group experienced a reduction in emotional health problems (-0.27±1.28,), whereas no change was observed in the intervention group (0±1.65). A higher score in emotional health problems signifies greater difficulties with daily activities and work due to emotional concerns such as depression, anxiety, or other negative emotions.

A decrease in social activities was observed in both the control (-0.47±1.13) and intervention groups (-0.67±2.44) with a greater decrease being observed in the intervention group. A higher score in social activities indicated a higher level of impact on normal social activities.

The pain level and the impact on work and housework have decreased in both the control (-0.6±2.06) and intervention groups (-0.53±1.88) compared to baseline data. The pain level was measured on a scale where higher values indicated a greater degree of pain and disruption of normal work.

The energy and emotions have increased in both control (0.8±8.5) and intervention groups (1.53±15.95) with a greater increase in the intervention group. A higher score in energy and emotion is associated with a higher level of energy and positive emotions.

To control the effect of pre-survey data, assumptions of ANCOVA were checked and met before conducting the test. The intervention effect on different aspects of HRQoL was determined using ANCOVAs for making between-group comparisons in post-survey data. ANCOVA results showed that controlling for pre-survey data, participants in the intervention group did not report statistically significant improved outcomes in HRQoL ($p>0.05$). A detailed summary of ANCOVAs and related statistics comparing the control and intervention groups is presented in Table 4.6.

Table 4.6. Summary of ANCOVAs and related statistics comparing the HRQoL variables in control and intervention groups

Variables	Control			Intervention			F	P	η^2
	Pre	Post	Differences	Pre	Post	Differences			
General health	18.13±3.14	18.6±3.11	0.47±3.76	17.6±3.78	19.73±4.96	2.13±5.33	0.78	0.38	0.03
Limitations of activities	12.8±3.86	12.4±2.79	-0.4±4.85	11.87±2.53	11.67±2.41	-0.2±2.18	0.37	0.54	0.01
Physical health problems	1.27±1.75	0.6±1.24	-0.67±1.5	0.4±0.74	0.27±1.03	-0.13±1.13	0	0.98	0
Emotional health problems	0.67±1.23	0.4±0.91	-0.27±1.28	0.73±0.96	0.73±1.16	0±1.65	0.72	0.4	0.03
Social activities	3.13±1.51	2.67±1.11	-0.47±1.13	3.33±2.02	2.67±1.11	-0.67±2.44	0	0.95	0
Energy and emotions	40±6.73	40.8±6.55	0.8±8.5	37.87±9.12	39.4±9.95	1.53±15.95	0.36	0.55	0.01
Pain	4.4±1.68	3.8±1.21	-0.6±2.06	3.87±1.81	3.33±1.72	-0.53±1.88	0.42	0.52	0.02

Evaluation of educational workshops by participants in intervention group

As part of the study, participants in the intervention group were asked to evaluate the four modules and select the ones they found most helpful. They were allowed to choose more than one module. The results showed that more than half of the participants (53.3%, n=8) found Module 2 to be the most helpful. The second most helpful module was Module 1, which was chosen by 47% (n=7) of the participants. Module 3 and Module 4 were selected as helpful by 33.3% (n=5) and 40% (n=6) of participants, respectively.

Module 2 was designed to help participants understand the severity of HBP by explaining how HBP affects the different organs of the body. Participants found it eye-opening and very helpful in learning how HBP affects the body. Module 2 was considered the most helpful based on the participants' feedback. This aligns with the program's design with Module 2 being the highlight of the program. Module 1 provided essential information on HBP, and participants found it useful for various reasons. Firstly, the information on BP is beneficial, and the visual demonstration used in the workshop helps participants understand how the heart works and what BP is. Secondly, introducing the new HBP guidelines from ACC/AHA provides participants with a clear definition of normal blood pressure levels and recommendations for different levels of HBP. Thirdly, the risk factors help each participant identify risk factors in their cases and prepare them to seek solutions or make changes in the following workshops. Lastly, the common myths about HBP were made into flashcards, and they were very helpful in guiding participants in understanding HBP correctly and seeking scientific evidence for future occasions.

Participants were asked to evaluate the workshop based on its usefulness, hands-on activities and demonstrations, handouts, workshop length, presenter's knowledge, and the

program's overall design. Each variable was rated on a scale of 1 to 5, with 1 being the worst and 5 being the best. The evaluation details are listed in Table 4.7.

Table 4.7. Evaluation of educational workshops

Evaluation variables	Score
Usefulness	4.73/5
Hands-on activities and demo	4.5/5
Handouts	4.8/5
Workshop length	4.8/5
Presenter's knowledge	5/5
The program's overall design	4.8/5

Usefulness The participants were asked to evaluate the usefulness of the four workshops. The average score was 4.73 out of 5, with 4 being the lowest score. This indicates that the workshop was overall helpful for participants.

Hands-on activities and demonstrations During the workshop, a variety of interactive, hands-on activities and demonstrations were used to explain key topics and help participants in the intervention group understand concepts related to HBP prevention and management. The average score is 4.5 out of 5, with the lowest score being 3. These results indicate that the hands-on activities and demonstrations were highly effective and stimulating in fostering a positive learning environment.

Handouts Handouts were prepared along with the workshop to fit the topic and provide supplementary information to assist participants in comprehending the subject. The average rating of the handouts is 4.8 out of 5, indicating that they were well-designed and beneficial for participants to understand the information.

Length Participants were asked to evaluate the length of the workshop, and the average score is 4.8 out of 5. This implies that each workshop was properly delivered with the right amount of information, and the participants remained engaged without feeling overwhelmed.

Presenter's knowledge This question was designed to ask participants in the intervention group to evaluate the presenter's knowledge on this topic to ensure the delivery of evidence-based information. According to the participants' feedback, the average score for this question is 5 out of 5, which indicates that the presenter was well-prepared and had a good understanding of the topic discussed.

Overall design Participants in the intervention group evaluated the overall program design. The average score for this question is 4.8 out of 5, which indicates that the program was well-designed and perceived as helpful by the participants.

The participants in the intervention group also provided additional feedback to improve the program for future audiences, such as providing more healthy eating tips, recipes, and information about healthy fats. The feedback was evaluated after the program concluded, and additional details were included accordingly.

BP monitoring

Participants in both the control and intervention groups were provided with a wrist blood pressure monitor to track their blood pressure levels for four weeks. This duration was chosen to minimize the likelihood of high dropout rates. If a participant observed an abnormal blood pressure reading, they were instructed to record it and seek medical advice. The wrist blood pressure monitor was purchased using university funds allocated for research purposes.

The use of the wrist blood pressure monitors to record participants' blood pressure levels has three main goals: firstly, to help participants practice the correct method of measuring blood

pressure, whether in a medical setting or at home on their own. The back of the blood pressure tracker contained a brief set of instructions that served as a reminder for participants when they used the provided blood pressure monitor at home. The instructions on how to use the wrist blood pressure monitor were also explained during the first workshop with the participants in the intervention group and during the first meeting with participants in the control group. Upon being properly introduced to the correct way to measure blood pressure, many of the participants realized that previous BP measurements, either taken at home on their own or at a doctor's office, were often performed incorrectly. By monitoring their blood pressure levels on their own, participants were able to gain a better understanding of how to measure their blood pressure correctly. Secondly, to help participants understand how various factors can influence BP readings, such as arm position or food and drink intake less than 30 minutes before getting their blood pressure checked. This information can help participants better understand their BP readings. Thirdly, it is crucial to monitor blood pressure regularly, and this intervention serves to highlight its significance in maintaining good health.

Discussion

This pilot study aimed to investigate the effectiveness of a four-week educational program in preventing and managing HBP in adults with the guidance of PMT. The results demonstrated a significant difference in knowledge, perceived severity, and response efficacy between control and intervention groups after controlling for pre-survey data. Although the difference in self-efficacy and intention also appeared, it was not statistically significant. Based on the self-reported data, there was an improvement in fruit and vegetable consumption, and the ASA24 data showed an increase in dietary potassium consumption.

The educational intervention led to an increase in knowledge in the intervention group. A survey conducted before and after the intervention showed that the participants' consumption of fruits and vegetables had also increased. However, despite this increase, the daily consumption of fruits and vegetables remained below the recommended minimum of 4–5 servings per day. This suggests that increased knowledge did not necessarily translate into behavior change, as reported by the participants themselves. This was also observed in the data collected through the ASA24.

In the self-reported pre- and post-survey, the intervention group consumed less dietary sodium. However, the minimum sodium consumption was more than 2,500 mg, according to the data shown in ASA24, which was higher than the recommended 2,300 mg of sodium per day. This indicated that even though the dietary sodium consumption has been decreased through the educational intervention, the sodium consumption before the educational intervention was much higher than the recommendation. The same was observed in physical activity behavior. According to pre- and post-survey data, physical activity in both control and intervention groups is below the recommended 30 minutes of moderate physical activity for at least 5 days a week. Despite these positive changes, adequate time is required before anticipated behavioral changes happen, such as increased adherence, can be observed. Similarly, intensive nutritional intervention therapy (intense one-on-one educational sessions) for hypertensive patients increased knowledge but was not associated with improved dietary behavior (Mourouti et al., 2023). In summary, patient education can lead to increased knowledge about HTN; however, this is not necessarily reflected in behavioral adaptations. This indicates that patients are aware of the impact of lifestyle modifications; however, they failed to translate this into lifestyle application.

In some studies, knowledge has been shown to enhance behavior changes but only to a limited extent (Mooney & Franks, 2011).

The perceived severity construct in the PMT theory was a highlight component of the study. After controlling for the pre-test, the study results showed a significant difference in perceived severity between the control and intervention groups with the intervention group experiencing a greater increase. This indicates that the educational intervention was effective in increasing perceived severity among participants.

Findings from this study also indicated an increase in response efficacy both in the control and intervention groups after the intervention and the difference between the two groups was significant. Self-efficacy is an important component in nutrition interventions to promote healthy behaviors (Bakouei et al., 2018). In the present study, educational intervention increased the self-efficacy score from 27±5.64 to 29.73±5.61 in the intervention group, while in the control group, self-efficacy decreased slightly from 28.8±3.77 to 28.33±3.77. However, the difference between the control and intervention groups was not significant after controlling for the pre-test.

The present study findings revealed an increase in protection motivation (intention) scores in the intervention group, whereas a light decrease was observed in the control group. After controlling for the pre-test, the difference between the control and intervention groups was not significant. In summary, results showed significant changes in PMT constructs between control and intervention groups at post-intervention.

According to the data from ASA24, both the intervention and control groups showed changes in their dietary sodium consumption during the study. While there was a decrease in sodium consumption from the baseline to the end of the study, the consumption was still higher than the minimum recommended level. This was observed in both the intervention and control

groups. The intervention group showed a decrease in sodium consumption from baseline to the midpoint of the study, but there was a subsequent increase in the second half of the study. This could be attributed to the timing of the study, which coincided with the New Year holiday season when people tend to make resolutions related to healthy eating. This can lead to a decrease in dietary sodium consumption as they cut back on unhealthy foods high in sodium, fat, and added sugar. However, as the study progressed, participants were more likely to return to their normal diet. The survey data showed a decrease in sodium consumption, but this was not reflected in the ASA24, a more reliable representation of actual sodium intake.

The decrease in dietary sodium consumption observed in the control group may be due to the study's awareness. Although there was no intervention in the control group, participants were aware of the ongoing nutrition study, which may have increased their awareness of healthy eating habits. Additionally, based on the focus group results, adults are aware of the link between dietary sodium and hypertension. Therefore, keeping the HTN study in mind, the participants were likely to reduce their sodium intake, especially since they had to monitor their blood pressure levels twice a day for four weeks.

Module 3, which focused on BP-related nutrients, was introduced to the intervention group right before the second ASA24 data collection. The importance of potassium as one of the nutrients related to blood pressure was discussed. Data obtained from ASA24 revealed that the participants in the intervention group increased their dietary potassium consumption, particularly from the midpoint to the end of the study. The increase in dietary potassium consumption among the intervention group could be attributed to the information provided in Module 3.

In contrast, the control group did not receive any nutrition information until after all data was collected, and their dietary potassium consumption slightly decreased according to the

ASA24 data. Although all self-report dietary assessment tools have some degree of misreporting, ASA24 provides the best estimate of absolute dietary intakes for the nutrients (Park et al., 2018). Therefore, the study concludes that the educational intervention not only increased knowledge of BP-related nutrients but also led to changes in dietary behaviors.

HRQoL survey results indicate no significant changes in the key aspects of quality of life between control and intervention groups after controlling for pre-survey data. However, the overall health of the intervention group showed some improvement (2.13±5.33), although not significant. This pilot study was conducted over a period of just four weeks, which may have been too brief to see any substantial changes in HRQoL. Even though the educational intervention did not result in any significant changes in HRQoL, it is important to note that individuals with hypertension represent a vulnerable population that requires special attention from healthcare providers. Furthermore, just being aware of having hypertension can also have an impact on quality of life.

Several limitations of the study need to be considered. The data collected from the survey instrument and ASA24 are self-reported, which could introduce biased outcomes and limit the generalizability of the results. Therefore, it is recommended that similar studies be conducted on a larger scale among other groups. Additionally, due to the study design, this pilot study was conducted over a four-week period, which was not long enough to observe any anticipated behavior changes or evaluate the sustainability of the changed healthy behaviors.

Despite the limitations, there are some advantages that should be addressed. This is the first nutrition intervention study to highlight the perceived severity of HTN using PMT among adults to prevent and manage HTN. There were few or no earlier studies to refer to or rely upon

to predict an outcome. Furthermore, the study design, which used both control and intervention groups, provided a means of comparing the efficacy of the educational intervention.

Conclusion

The current pilot study suggests that implementing an educational intervention using PMT as the theoretical framework can be an effective strategy for preventing and managing HBP among adults in the short term. Intensive interventions that focus on nonpharmaceutical approaches through educational interventions are effective in increasing knowledge, perceived severity, response efficacy, and protection motivation. Using nonpharmacological approaches to prevent and manage HBP consists of several aspects of healthy living, which require a dynamic process that involves long-term interventions, adherence to the guidelines, and acceptance of the changes. All these require more than a simple and short-term approach, and the ultimate goal is to adopt a philosophy that leads to a better quality of life.

Chapter 5 - Conclusions, perspectives, and implications for future research and practice

Conclusion

We conducted focus groups and one-on-one interviews to explore the knowledge, perceptions, and behaviors of adults regarding their risk of HTN. Our findings revealed four underlying themes, which set the tone for education needs and knowledge gaps for educational interventions. The qualitative study provides a strong basis for developing effective nutrition education programs to prevent and manage HTN in adults.

Our study underscores the potential of educational interventions using PMT as a theoretical framework in the short-term prevention and management of HBP among adults. By intensively focusing on nonpharmaceutical approaches, we conclude the knowledge level, perceived severity, and response efficacy in the intervention group are significantly different from those of the control group. Moreover, our findings demonstrate that a brief educational intervention promoting nonpharmacological approaches can effectively induce behavior change, especially dietary sodium and potassium consumption in HTN prevention and management.

The strength of the study lies in its mixed-methods approach, which incorporates both qualitative and quantitative research methods. This comprehensive approach was designed to promote nonpharmacological approaches to preventing and managing HTN.

While our study was limited by a small sample size, which posed challenges in producing statistically significant changes, this pilot study contributed to the existing research on HBP prevention and management among adults using nonpharmacological approaches. It underscored the importance of comprehending the organ damage HBP inflicts on the body. Additionally, it

provided initial findings to develop meaningful and comprehensive education and support programs for adults in the spectrum of preventing and managing HBP.

Lessons learned

The overall design

This study is a combination of qualitative and quantitative methods. The use of combination methods challenges me to become familiar with both research methods; however, these challenges will be translated to be my strength upon completion of the research.

Focus group

The focus group started before COVID-19 when everyone was around, and things were preferred to be done in person. Suddenly, COVID-19 created a new norm that everybody has to adjust to. This unexpected change brought challenges in many ways, especially to this kind of research dealing with human subjects. Adaption is the lesson I learned as I tried to accommodate the focus group amid COVID even before I introduced adaption to the participants in the later workshops. Even though, when I said “adaption” in two different realms, it happens everywhere and can be and, in most cases, has to be part of life. What an interesting ‘chapter’!

As I mentioned before, the change in the environment leads to an adaptation in how we conduct research with human subjects. Conducting focus groups is one of the best examples of real adaptation. Focus groups involve facilitating group discussions and observing dynamics such as body language and eye contact. With the shift from in-person to online Zoom format, having the camera on is not required, but it is highly recommended. In most cases, participants remained ‘unseen,’ leading to a lack of results from observation compared to the in-person scenarios.

Interventional workshop

As one Confucius said, “I hear and I forget. I see and I remember. I do and I understand.” I have to say that by now, I have a better understanding of what I learned in class. What I have learned and trained to do was well applied and understood in this part of the study, as it involved many aspects, from research design, participant recruitment, workshop development, implementation, and evaluation. The knowledge I have learned laid the foundation for this study. I wouldn’t have gained such a clear understanding of the whole study if I hadn’t started from scratch and worked through every single step.

Conducting research with human subjects is challenging as a researcher has little to no control over the subjects. This has been a big transition for me since I came from a lab background where all the data were collected and controlled. However, studying human subjects while interacting with them is very rewarding. The way I treated them during the study will be reflected back and help me understand how I did. For example, the questions they asked related to the topic inspired me to be better prepared for the workshops.

Not only did I gain an understanding of what I have learned, but I also established relationships with the participants. From this standpoint, I consider conducting the study to be a “win-win.”

How to improve

I would not take a ‘break’ between recruiting and the actual start of the intervention part. Due to the holiday break, I lost 8 out of 39 participants as the recruitment started before the holiday, while the interventions did not begin until after the holiday.

Follow-up would be added as part of the study if time allows. Sustainable behavior changes are preferable in terms of lifestyle application. Although some changes were observed in the study, long-term changes would bring more beneficial results.

I would have completed the RCT registration sooner. Although this is not a clinical trial, it is highly recommended to register with an RCT.

As several participants commented on the importance of being in a supportive environment when making sustainable lifestyle changes, fostering supportive groups can be beneficial to hold each group member accountable, as making changes itself is challenging enough.

If it is possible, I would seek assistance in developing an APP to benefit the participants and, in the future, the public. The participants indicated the desire to have a trustworthy APP so they would not be confused when faced with mixed messaging from different resources. The APP will cover the main topics of the workshop and provide additional reliable information for participants to use when needed.

Implications for future research and practice

HTN is a highly prevalent condition worldwide, and it is also a chronic condition that takes time to progress. To better treat HTN, it is much easier to focus on treating symptoms or damaged organs. However, we leave the underlying causes behind, which will cause even more severe health problems if left unidentified. The risk factors associated with HTN, both modifiable and unmodifiable, are very complicated, but nonpharmacological approaches cover all the risk factors. Therefore, it is highly encouraged to initiate nonpharmacological approaches as early as possible to prevent or manage HTN from a long-term perspective.

Prevention and management of HTN involve a multi-component intervention, and these components are not standalone factors. The reason may be that it is hard to pursue one lifestyle intervention in isolation. When one is determined to lose weight, in most cases, it involves several aspects of lifestyle changes, such as healthier dietary behaviors, being more physically active, etc. And that is why the key principle to prevent and manage HTN is not about a single nutrient or a single component but rather the combination of several.

The literature highlights physical activity as a beneficial aspect of blood pressure control. However, lifestyle-related factors need to be considered regarding physical activity, especially for stage 2 HTN patients and senior adults.

The prevention and management of HTN requires the collaboration of several parties, including healthcare professionals. The close relationship between patients, healthcare professionals, and dietitians could ensure the necessary information is given to the patients to obtain the best care regarding prevention and management. For example, healthcare teams work with dietitians to provide consultation on diet, given that diet plays an important role in blood pressure control and management. Furthermore, healthcare providers must focus on adherence to behavior change to gain control of HTN in a larger population.

Our current pilot study has shown encouraging results in behavior change. However, the effectiveness of nonpharmacological approaches to prevent and manage HTN needs to be further established in population-wide groups, as implementation of healthier lifestyles is challenging. The recent program that started in Kansas extension networks, Hypertension Awareness & Prevention Program (HAPp) emphasizes the importance of population-wide interventions in HTN prevention and management. However, this program does not include the component of

organ damage, which is also the highlight of this pilot study. We genuinely believe that this pilot study could add a strong aspect to the HAPp program and, in the near future, to go nationwide.

According to PMT, the most immediate measure of the effectiveness of the communication is the intention to accept the recommendation. To maintain intentions may require additional interventions, such as relapse prevention training and booster treatments. Therefore, studies that include follow-up procedures could greatly support the conclusion that treatment interventions can be sustained over time and that decisions made become implemented. In addition, future researchers need to promote self-efficacy in adopting healthy lifestyle behaviors.

Chapter 6 - References

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Appendix A - Classification of participants' comments by identified themes

Themes	Quotes
HTN and associated risk factors	
• Lack of knowledge	• *High blood pressure, I think of as a medical disease that adversely affects your heart and potentially could lead to stroke as well that might affect your cognitive ability.* • *I can't really tell you the difference between heart disease and high blood pressure. I thought high blood pressure was under heart disease.* • *"Where I come from in rural Western Kansas, I know people who don't take it seriously at all they'll go into their doctor and they'll say oh your blood pressure's like 176 over 100 okay why you know still walking around that's fine we're good, … don't want medication doing just fine."* • *I think that a lot of people don't realize how common, it is, and they don't think it's a big deal because it doesn't present symptoms in a lot of cases.* • *And I think the general public thinks it's only for old people and obese people.* • *I don't think they know much only that it's bad for you, but I don't think they can explain why, what it does to you or have any details on how to prevent or reduce it.* • *To me, I was told that as old people our blood pressure can get up to 160 over 100 and that's perfect for old people.* • *I would like to know high blood pressure even really means.* • *started off with a definition what high blood pressure is and then secondly a cause and effect, so what creates high blood pressure, and why should we care, what's the effect of high blood pressure and then after you identify those things, I think, in the final part of that would be the process in which you could take an active role in controlling your own blood pressure, which might include monitoring and then we've talked about healthy diet, exercise, reducing stress, whatever those elements might be.*

	• *Maybe just with age as well as you get older and just the natural process of aging could put you high blood pressure.* • *I think of high blood pressure I'm thinking of something salty food know somebody is concerned to my salt.* • *I think if you're sedentary or you're not active. You don't exercise, I think that also will affect your high blood pressure.* • *What does that look like inside of a human's body.* • *And how that affects us on a real level.* • *I think the heavier you are, the more difficult it is to have even the motivation to go out and exercise or to do things and leads to more immobile sedentary life* • *to have a sedentary lifestyle in other words, just the complete lack of exercise if you simply sit or whether that be at work or at home and don't get out and do anything much. I think that could potentially lead to high blood pressure.* • *I don't know if i've thought about it in the correlation of high blood pressure.* • *I do think alcohol consumption would impact blood pressure levels, but I don't understand.*
Underestimated HTN complications	• *I know, in the case of my relatives, it took a heart attack and a trip to the ER to get on high blood pressure medication.* • *I don't understand all of it, but I know it's really hard on the heart, because your heart has to work harder, but I can't tell you exactly what it does.* • *Well, I would suspect that it would potentially harm all your organs as the blood supply and the vessels inside the organs.* • *I'm thinking things like diabetes and I'm not necessarily seeing a connection so I'm trying to think of other diseases and see if I can think of a connection, but I think I am not coming up with any right now.* • *I would think it would have some effect but I couldn't tell you tangibly what other diseases.* • *I'd say if your blood pressure got to the point where you had a heart attack or stroke, then that's a dramatic effect on your body and your physical well being paralysis or death or inability to function in any kind of normal way so that's kind of the ultimate bad news with HBP.* • *I do think high blood pressure, I mean over time can cause damage to kidneys and there's also some of the*

	things going on the kidneys that can actually then can adversely affect blood pressure to but then when you have kidney damage, I mean that's all starts a whole another thing, so I think blood pressures, very important. Preserving kidney function maintaining good blood pressure is very important to preserving kidney function, I think. • *I mean to manage the high blood pressure, you know it's meant to be within the normal range that's going to have more blood coming through and more pressure and it's just probably going to damage kidney and not healthy for you know. I don't know if that's reversible but the damage that's done.* • *if you do not treat it, it will damage your kidneys and eventually could lead to a need for dialysis.* • *I think if you would think about anything that's under pressure as that pressure expands what you worry about a pipe freezing it bursts, and so what I would think that high blood pressure it potentially lead to would be arteries or blood vessels that could be under the pressure to the point where they would either weakened or literally burst. And I guess that could potentially maybe be stroke or an aneurysm or something of that nature.* • *I think over time with chronic hypertension that's not managed well that I mean when your vessels are continually you know forced and have lots of pressure whether there's plaque buildup or for whatever reason, if your heart seven to do that, and I think there is risk of like micro tears so things like you know, having problems with bleeding or aneurisms, which is different. But do think there's damage to the arteries over time if it's not managed well.* • *I'm thinking things like diabetes and I'm not necessarily seeing a connection so I'm trying to think of other diseases and see if I can think of a connection, but I think I am not coming up with any right now.* • *I guess, maybe for me to thinking that if you have high blood pressure, and it is related to lifestyle choices, then those lifestyle choices probably affect other parts of your body and so I guess, to me, maybe it's kind of interconnected that if one area is unhealthy that so with high blood pressure and stress on your heart and stress in your body, then that would just yeah kind of open the door for other chronic things to kind of affect your heart or other body organs.*

	• *I have no idea. never think of high blood pressure effect. I know diabetic can make the eye bind possible but I never think or high blood pressure will affect eye.*
Nutrition and HTN	• *We don't really understand the food that we're eating and the benefits that they have.* • *I started to pay more attention to the salt intake you the foods that we eat like hamburgers. When I eat fast food or and things like soy sauce we use a lot of soy sauce in our food and cooking so just recently noticed that there's hot very high sodium content yeah so it really surprise me how hide yeah because we do take we use much salt, you know. We know and don't use regular table salt in our cooking but use a lot of soy sauce so it kind of shocked me how high the sodium content in soy sauce was so. There is a lot of foods that maybe we're eating that would for soy sauce in there, increase its highest sodium that we didn't realize.* • *I know people who are on potassium pills, I mean potassium supplement I on I don't know but nutrient. I was told that you can't eat enough bananas or whatever to get enough potassium if you need to be prescribed potassium.* • *If I was better educated nutritionally, I wouldn't have to go to the store and go buy a pill.* • *I don't know how the food actually will decrease blood pressure, I just heard that certain foods suggest to take can help lower BP.* • *I don't understand the nutrition, but I do know that when I'm eating a well-balanced food choices, you know good carbohydrates good fats good vegetables good that kind of thing there's I'm I feel better.* • *I was always told you take potassium or you know eat a bunch of bananas.* • *I think magnesium is supposed to be good for just relaxing vessels.* • *I would think that if you didn't have your iron stores weren't good and you're not clear enough oxygen that your blood you're gonna have to work a little bit harder to get the oxygen where it needs to go.* • *Banana also is good, because it has a good potassium content and I know avocado is good, but how does that help our body.* • *I don't know the specific nutrients.* • *Maybe educate people just on good nutrition. There's maybe a lot of confusion on what it means to eat healthy.*

	• *something with recipes should be included* • *I think, would be important would be substitutions* • *we don't really understand the food that we're eating and the benefits that they have.* • *I wonder if people really know what to look for to make better choices* • *what to look for in an ingredient list or if they even know what to look for in the nutrition, you know serving size or the different numbers.*
Integration of nonpharmacological approaches as part of a healthy lifestyle	• *And to me healthy eating means to try and eat things as close to their original form as possible, so cooking from scratch, is how I would describe it so buying the vegetables and then meat separately and using seasonings.* • *we talked about a good diet, but I mean what exactly does that mean.* • *Just lower fat diet, I would say a lot more fruits and vegetables.* • *Not very much sugar.* • *And that it's true that doctors, maybe give some medication to help with that, but I do kind of believe that a larger that can be treated through a better lifestyle eating healthier and more exercise.* • *I think it needs to come up in with some practical advice on how to incorporate the changes and into your lifestyle and that might be very individualistic.* • *helpful to know what those small decisions, whether negative or positive how they lead to the long term* • *I would think that sort of someone to walk aside incrementally would be really helpful.* • *I would wonder if accountability, would be a factor in there as well.* • *I think if there was avenue for just better education through accountability, a place where you could chat.* • *one aspect of it I think would be food preparation, so guide somebody to walk alongside me with that give me some pointers dips what I think recipes I think that would be helpful.* • *it would be nice to have a place to go with like minded people to get more one on one time, more education than what I just get with my doctor for 45 minutes every six months to a year.* • *I think there has to be in some kind of an incentive to make people pay attention because we get so much good advice from so many different areas.*

	• *even if people know something's good for them, sometimes they need a little bit more of an incentive and sometimes that money is helpful.* • *doing that in a practical way that it can fit into your lifestyle.* • *"I like your idea earlier of baby steps. Sometimes you know it is very overwhelming. I'll never be able to do that, so why would I even start you know, but if you can say well okay let's you're right here let's do this step first, step next and then incremental kind of thing."* • *what kind of food to eat and then maybe you will have a recipe* • *education and guidelines that in layman's term* • *I think something that's practical and small steps.*

Appendix B - Demographic and lifestyle survey instrument

High blood pressure knowledge and perception survey questionnaire

Thank you for supporting our research by completing the questionnaire. You must be an adult 18 years or older to participate. We understand that your time is valuable and we appreciate your participation. The purpose of this research is to measure the extent of knowledge related to high blood pressure (HBP), perceptions on HBP, current lifestyle behaviors related to HBP, and behavior change determinants of taking actions to prevent and manage HBP. The survey will take approximately 15-20 minutes of your time to complete.

Be assured that all answers you provide will be kept confidential. Participation in this research is anonymous and voluntary. You have the option of skipping any questions you do not feel comfortable answering, and you can withdraw from the study at any time. You may refuse to participate or quit at any time. If you quit or refuse to participate, the benefits or treatment to which you are entitled will not be affected. There is no foreseeable risk to the participants. You can freely respond to the questionnaire, as it bears no consequence of your participation.

This survey is part of research conducted by Kansas State University. If you have any questions, feel free to call Dr. Tandalayo Kidd at (785)532-0154 or you can call the University Research Compliance Office at Kansas State University – Lisa Rubin at (785)532-3224. This study has been reviewed by the Institutional Review Board and has received approval No. 10334.

You can contact the primary investigator, Dr. Tandalayo Kidd (martan@k-state.edu) or the graduate student in charge, Yanli Wang (yanliw@ksu.edu), if you have any questions or concerns about your participation.

Part I Knowledge on HTN

Please answer these questions to your best judgement.

	True	False	I don't know
1. A normal blood pressure range is <120/80 mm Hg.	o	o	o
2. Most of the time, people with high blood pressure don't feel it.	o	o	o
3. Most of the salt Americans eat is added with a saltshaker.	o	o	o

4. There is nothing you can do to prevent high blood pressure.	o	o	o
5. Being overweight or obese increases your risk of having high blood pressure.	o	o	o
6. Regular exercise can help reduce blood pressure levels.	o	o	o
7. Drinking alcohol lowers blood pressure levels.	o	o	o
8. Smoking does not affect your blood pressure levels.	o	o	o
9. If your mother or father has high blood pressure, your chance of getting it is higher.	o	o	o
10. Young adults do not get high blood pressure.	o	o	o

Part II Perceived severity on HTN

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
11. High blood pressure can be life-threatening.	o	o	o	o	o
12. Untreated high blood pressure may lead to other health complications.	o	o	o	o	o
13. If an individual does not have any symptoms, they do not have high blood pressure.	o	o	o	o	o
14. High blood pressure can lead to severe organ damage to the heart.	o	o	o	o	o
15. High blood pressure can lead to severe organ damage to brain.	o	o	o	o	o
16. High blood pressure can lead to severe organ damage to kidneys.	o	o	o	o	o
17. High blood pressure can lead to severe organ damage to eyes.	o	o	o	o	o
18. High blood pressure can lead to severe organ damage to ears.	o	o	o	o	o

Part III Assessment on response efficacy and self-efficacy

How beneficial is it for you to do the following to prevent or lower blood pressure levels?	Not beneficial at all	A little beneficial	Somewhat beneficial	Quite beneficial	Very beneficial
19. Eat at least 4-5 servings of fruits and vegetables a day.	o	o	o	o	o
20. Limit sodium consumption to 2,300 mg (that equals to one teaspoon of salt).	o	o	o	o	o
21. Be physically active for at least 30 minutes a day, at least 5 days a week.	o	o	o	o	o
22. Keep a healthy body weight.	o	o	o	o	o
23. Drink alcohol in moderation. (Moderate drinking is generally considered to be: Two drinks a day for men younger than age 65 One drink a day for men age 65 and older One drink a day for women of any age (Note: A drink is 12 ounces of beer, 5 ounces of wine or 1.5 ounces of 80-proof distilled spirits.)	o	o	o	o	o
24. Quit smoking.	o	o	o	o	o
25. Manage stress.	o	o	o	o	o

How confident are you that you could do the following to prevent or manage blood pressure levels?	Not confident at all	A little confident	Somewhat confident	Quite confident	Very confident
26. Eat at least 4-5 servings of fruits and vegetables a day.	o	o	o	o	o
27. Limit sodium consumption to 2,300 mg (that equals to one teaspoon of salt).	o	o	o	o	o
28. Be physically active for at least 30 minutes a day.	o	o	o	o	o
29. Keep a healthy body weight.	o	o	o	o	o
30. Drink alcohol in moderation. (Moderate drinking is generally considered to be: Two drinks a day for men younger than age 65 One drink a day for men age 65 and older One drink a day for women of any age (Note: A drink is 12 ounces of beer, 5 ounces of wine or 1.5 ounces of 80-proof distilled spirits.)	o	o	o	o	o
31. No smoking.	o	o	o	o	o
32. Stress management.	o	o	o	o	o

Part IV Intention to behavior change

Please indicate to which degree you agree with your intention to the following behaviors **in the next 30 days:**	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
33. I intend to eat 4-5 servings of fruits and vegetables.	o	o	o	o	o
34. I intend to keep my sodium consumption below 2,300 mg (equals to one teaspoon of salt).	o	o	o	o	o
35. I intend to be physically active for at least 30 minutes a day, 5 days a week.	o	o	o	o	o
36. I intend to keep a healthy body weight.	o	o	o	o	o
37. I intend to drink alcohol in moderation or not at all.	o	o	o	o	o
38. I intend to quit smoking or not smoking at all.	o	o	o	o	o
39. I intend to manage my stress levels.	o	o	o	o	o

Part V Lifestyle behaviors

40. In total, how many servings of fruits and vegetables do you eat daily?

(Note: A serving of fruit is one medium fruit, or ½ cup fresh, frozen or canned fruit, or ¼ cup dried fruit, or ¼ cup 100% fruit juice. A serving of vegetable is 1 cup raw leafy vegetable, or ½ cup fresh frozen or canned vegetable, or ½ cup vegetable juice.)

- o I do not eat fruits and vegetables
- o 1-3
- o 4-5
- o 5 or more

41. How many of the past 7 days did you do at least 30 minutes of physical activity?

(Think only about those physical activities that you did for at least 10 minutes at a time, such as brisk walking, bicycling, vacuuming, gardening, or anything else that causes some increase in breathing or heart rate.)

- 0
- 1
- 2
- 3
- 4
- 5
- 6
- 7

42. How many of the past 7 days did you smoke a cigarette or cigar, even just one puff?

- 0
- 1
- 2
- 3
- 4
- 5
- 6
- 7

43. How many of the past 7 days did you drink alcohol or have any kind of drink containing alcohol?

- 0
- 1
- 2
- 3
- 4
- 5
- 6
- 7

44. How much did you drink on the days you had any kind of drink containing alcohol?
(A drink is 12 ounce can or glass of beer or cooler, a 5 ounce glass of wine, or a drink containing 1 shot of liquor)

- I answered “0” in the previous question
- 1
- 2

- 3
- 4
- 5 or more

45. On average, how much sodium do you **think** you consume every day?
(Remember: the recommendation for sodium is 2,300 mg which equals to 1 teaspoon of salt. For people who are over age 50, have high or slightly elevated blood pressure, have diabetes, African Americans the recommendation is 1,500 mg. Americans consume more than 3,400 mg of sodium each day on average).

- Less than 1,500 mg
- Between 1,500 mg and 2,300 mg
- Between 2,300 mg and 3,400 mg
- More than 3,400 mg
- I don't know

46. During the past month, how often did you consume processed foods such as processed meats (deli or lunch meats, sausages, bacon, hot dogs, smoked or canned meats), frozen and microwavable meals, frozen pizzas, instant or flavored rice and pasta dishes, and canned soups or broths, sauces, or gravies?

- Never
- 1 time last month
- 2-3 times last month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

Part VI Sociodemographic information

Please answer these questions by filling in the blank area or giving a mark on the answer.

47. How old are you (in years)?
    - Younger than 18
    - 18-35
    - 36-49
    - 50-64
    - 65+

- Choose not to answer

48. What is your gender identity at birth?
    - Male
    - Female
    - Intersex
    - Choose not to answer
49. Which one or more of the following would you say is your race?
    - American Indian or Alaska Native
    - Asian
    - Black or African American
    - Hispanic, Latino, or Spanish origin
    - Native Hawaiian or Other Pacific Islander
    - White
    - Other
    - Choose not to answer
50. What is your marital status?
    - Single
    - Married
    - Divorce or widowed
    - Choose not to answer
51. What is your height (in inches)?

    _____ inches

52. How much do you weight (in pounds)?

    _____ lbs

53. What is your highest level of education you have completed?
    - Elementary/middle school
    - High school or equivalent
    - Technical or occupational certificate
    - Associate degree
    - Some college coursework completed
    - Bachelor's degree
    - Master's degree
    - Doctorate
    - Professional
    - Choose not to answer
54. How many people are in your household, including yourself?

    _____

55. Which of these categories best describes your total combined family income for your household for the past 12 months? This should include income (before taxes) from all sources, wages, rent from properties, social security, disability and/or veteran's benefits,

unemployment benefits, workman's compensation, help from relatives (including child payments and alimony), and so on.

- Less than $25,000
- $25,000-$50,000
- $50,000-$75,000
- $75,000-$100,000
- $100,000-$150,000
- ≥$150,000
- Don't Know/Not sure

56. Do you currently have health insurance?
    - Yes
    - No
57. Do you regularly get an annual physical check?
    - Yes
    - No
58. Are you currently taking high blood pressure medication?
    - Yes
    - No
59. How many medications are you taking to control your blood pressure levels?
    - I answered "no" in the previous question
    - 1
    - 2
    - 3
    - More than 3

Appendix C - SF-36 quality of life survey instrument

GENERAL HEALTH:

1. In general, would you say your health is:

Excellent Very Good Good Fair Poor

2. Compared to one year ago, how would you rate your health in general now?
   - o Much better now than one year ago
   - o Somewhat better now than one year ago
   - o About the same
   - o Somewhat worse now than one year ago
   - o Much worse than one year ago

LIMITATIONS OF ACTIVITIES:

The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

3. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports.

o Yes, limited a lot o Yes, limited a little o No, not limited at all

4. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf

o Yes, limited a lot o Yes, limited a little o No, not limited at all

5. Lifting or carrying groceries

o Yes, limited a lot o Yes, limited a little o No, not limited at all

6. Climbing several flights of stairs

o Yes, limited a lot o Yes, limited a little o No, not limited at all

7. Climbing one flight of stairs

o Yes, limited a lot o Yes, limited a little o No, not limited at all

8. Bending, kneeling, or stooping

o Yes, limited a lot o Yes, limited a little o No, not limited at all

9. Walking more than a mile

o Yes, limited a lot o Yes, limited a little o No, not limited at all

10. Walking several blocks

o Yes, limited a lot o Yes, limited a little o No, not limited at all

11. Walking one block

o Yes, limited a lot o Yes, limited a little o No, not limited at all

12. Bathing or dressing yourself

o Yes, limited a lot o Yes, limited a little o No, not limited at all

PHYSICAL HEALTH PROBLEMS:

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

13. Cut down the amount of time you spent on work or other activities

Yes No

14. Accomplished less than you would like

Yes No

15. Were limited in the kind of work or other activities

Yes No

16. Had difficulty performing the work or other activities (for example, it took extra effort)

Yes No

EMOTIONAL HEALTH PROBLEMS:

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

17. Cut down the amount of time you spent on work or other activities

Yes No

18. Accomplished less than you would like

Yes No

19. Didn't do work or other activities as carefully as usual

Yes No

SOCIAL ACTIVITIES:

20. Emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

o Not at all o Slightly o Moderately o Severe o Very severe

PAIN:

21. How much bodily pain have you had during the past 4 weeks?

o None o Very mild o Mild o Moderately severe o Very severe

22. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

o Not at all o A little bit o Moderately o Quite a bit o Extremely

ENERGY AND EMOTIONS:

These questions are about how you feel and how things have been with you during the last 4 weeks. For each question, please give the answer that comes closest to the way you have been feeling.

	All of the time	Most of the time	A good bit of the time	Some of the time	A little bit of the time	None of the Time
23. Did you feel full of pep?	o	o	o	o	o	o
24. Have you been a very nervous person?	o	o	o	o	o	o
25. Have you felt so down in the dumps that nothing could cheer you up?	o	o	o	o	o	o
26. Have you felt calm and peaceful?	o	o	o	o	o	o
27. Did you have a lot of energy?	o	o	o	o	o	o
28. Have you felt downhearted and blue?	o	o	o	o	o	o
29. Did you feel worn out?	o	o	o	o	o	o
30. Have you been a happy person?	o	o	o	o	o	o
31. Did you feel tired?	o	o	o	o	o	o

SOCIAL ACTIVITIES:

32. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

- o All of the time
- o Most of the time

- o Some of the time
- o A little bit of the time
- o None of the Time

GENERAL HEALTH:

How true or false is each of the following statements for you?

33. I seem to get sick a little easier than other people

o Definitely true o Mostly true o Don't know o Mostly false o Definitely false

34. I am as healthy as anybody I know

o Definitely true o Mostly true o Don't know o Mostly false o Definitely false

35. I expect my health to get worse

o Definitely true o Mostly true o Don't know o Mostly false o Definitely false

36. My health is excellent

o Definitely true o Mostly true o Don't know o Mostly false o Definitely false

Appendix D - Educational workshop evaluation form

1. **Which module do you find most helpful? Check all that apply.**

- ○ Module 1 High blood pressure, what you need to know?
- ○ Module 2 What does high blood pressure do to your body? Nothing good.
- ○ Module 3 High blood pressure, fuel it up or down?
- ○ Module 4 Live to lower your blood pressure levels! Life choices matter!

2. **What information do you find most helpful?**

_____

_____

3. **What information is least helpful for you?**

_____

_____

4. **How would you rate the workshop? ("1" being the worst, "5" being the best)**

How would you rate the usefulness of the content?	1	2	3	4	5
How would you rate the hands-on activities and demo in the workshop?	1	2	3	4	5
How would you rate the handouts distributed throughout the workshops?	1	2	3	4	5
How would you rate the length of the workshop?	1	2	3	4	5
How would you rate the presenter's knowledge in the subject?	1	2	3	4	5
How would you rate the overall design of the workshop?	1	2	3	4	5

5. **Is there any other information you want to learn regarding hypertension prevention and management?**

_____

_____

6. **Please provide any additional suggestions or comments you may have about the program. Thanks.**

_____

Thank you for your feedback! Your feedback will help us to make the program better for our future users!

Appendix E - CONSORT 2010 checklist of a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	P60
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	P60
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	P61-63
	2b	Specific objectives or hypotheses	P64
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	P65-66
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	P65
Participants	4a	Eligibility criteria for participants	P65
	4b	Settings and locations where the data were collected	P65
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	P65
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	P74-79
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NA
Sample size	7a	How sample size was determined	P65
	7b	When applicable, explanation of any interim analyses and stopping guidelines	P65
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	P65
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	P65
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	P65
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	P65
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	NA
	11b	If relevant, description of the similarity of interventions	NA

Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	P80
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	NA
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	P66
	13b	For each group, losses and exclusions after randomisation, together with reasons	NA
Recruitment	14a	Dates defining the periods of recruitment and follow-up	P65
	14b	Why the trial ended or was stopped	P65
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	P81
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	P80-85
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	NA
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	NA
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	NA
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NA
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	P101
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	P101
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	P99-102
Other information			
Registration	23	Registration number and name of trial registry	P65
Protocol	24	Where the full trial protocol can be accessed, if available	P65
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	NA

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.