

DASH 2 Wellness: Effects of A Multi-Component Lifestyle Modification Program
On Nutrition, Physical Activity, and Blood Pressure in Prehypertensive Middle-Aged
Adults
A Randomized Controlled Trial

Ashley E. Dorough

Dissertation submitted to the faculty of the Virginia Polytechnic Institute and State
University in partial fulfillment of the requirements for the degree of

Doctor of Philosophy

In

Psychology

Richard A. Winett
Eileen S. Anderson
George A. Clum
Brenda M. Davy

April 17, 2009
Blacksburg, Virginia

Keywords: prehypertension, hypertension, blood pressure, nutrition, physical activity,
lifestyle modification

DASH 2 Wellness: Effects of A Multi-Component Lifestyle Modification Program
On Nutrition, Physical Activity, and Blood Pressure in Prehypertensive Middle-Aged Adults
A Randomized Controlled Trial

Ashley E. Dorough

Abstract

The primary goal of this project was to develop, implement, and evaluate a lifestyle modification intervention that did not require extensive, ongoing personal contact to improve lifestyle behaviors shown to lower blood pressure (BP) in adults with prehypertension ($N=23$, *mean age*=54, *mean BP*=126.7/75.1). Incorporating clinical practices and psychological approaches to behavior change, this intervention used primarily the DASH Eating Plan, coupled with a low-sodium diet and a walking program; it applied social cognitive theory to health behavior change, specifically self-regulation for self-monitoring and management of BP, diet, exercise, and weight. The study compared two conditions, the *DASH 2 Wellness Only* standard of care condition to the *DASH 2 Wellness Plus* treatment condition on the primary outcome measures of fruit and vegetable (servings/day), sodium consumption (milligrams/day), physical activity (steps/day), weight (kgs), and blood pressure (primarily systolic BP).

Consistent with hypotheses, MANOVAs detected significant differences between the conditions with *D2W Plus* evidencing a larger increase in change of total daily steps ($M= 2900.14$, $SD= 1903.83$) than *D2W Only*, ($M= 636.39$, $SD= 1653.26$), a larger decrease in systolic BP change (mmHg) ($M= 15.14$, $SD= 4.33$) than *D2W Only*, ($M= 4.61$, $SD= 8.28$), and a larger decrease in weight change (kg) ($M= 4.78$, $SD= 3.81$) than *D2W Only*, ($M= 1.47$, $SD= 2.57$). While conditions did not significantly differ on daily sodium reduction or fruit and vegetable increase, *D2W Plus* evidenced a larger decrease in sodium (mg) ($M= 932.22$, $SD= 1019.22$) than *D2W Only*, ($M= 423.64$, $SD= 749.15$) and larger increase in fruit and vegetable increase, ($M= 2.10$, $SD= 1.73$) than *D2W Only*, ($M= 1.02$, $SD= 2.24$). It was also hypothesized that the *D2W Plus* condition would show greater improvements in nutrition-specific and PA-specific health beliefs of self-regulation, social support, self-efficacy, social support, and outcome-expectancy compared to those in the *D2W Only* condition. A MANOVA revealed significant group differences in PA-specific health beliefs primarily attributable to increased PA self-regulation in *D2W Plus* compared to *D2W Only*, ($M= 1.78$, $SD= 0.75$) and ($M= 0.55$, $SD= 0.57$), respectively. While no overall significant group differences were found for nutrition-specific health beliefs, analyses showed meaningful differences in nutrition-specific health beliefs attributable to increased nutrition self-regulation strategies in *D2W Plus* compared to *D2W Only*. Results provide preliminary support for the efficacy of an electronic delivery of an intervention aimed at improving lifestyle behaviors and lowering BP in middle-aged individuals with prehypertension.

Acknowledgements

To Brad, my family, & my committee:

The joy of life comes from our encounters with new experiences, and hence there is no greater joy than to have an endlessly changing horizon, for each day to have a new and different sun.
-Into the Wild

Thank you for accompanying me through this journey. You have invested in me, as I have invested in this pursuit. Your guidance, encouragement, and unfailing support nurtured the calling I committed myself to 6 years ago. While words fail in accurate expression, I am humbled and grateful to you all...and am very much looking forward to the next horizon.

in loving remembrance of Allie B

DASH 2 Wellness: Effects of A Multi-Component Lifestyle Modification Program
On Nutrition, Physical Activity, and Blood Pressure in Prehypertensive Middle-Aged Adults
A Randomized Controlled Trial

Table of Contents

Introduction.....	1
Methods.....	15
Results.....	34
References.....	46
Appendix A: Medical Oversight for Adverse Events.....	58
Appendix B: IRB Approval	59
Appendix C: Newspaper Advertisement.....	60
Appendix D: Telephone Eligibility Screening Form: Prehypertension Study.....	61
Appendix E: Information Sheet & Consent Document.....	62-66
Appendix F: Health History Questionnaire.....	67-74
Appendix G: Pedometer Instructions.....	75-76
Appendix H: Instructions for Keeping Your Food Intake Record.....	77
Appendix I: Food Intake Record.....	78
Appendix J: Dash 2 Wellness Tracker & Dash Diary.....	79-80
Appendix K: Physical Activity Enjoyment Scale (PACES).....	81
Appendix L: Health Beliefs Survey.....	81-99

DASH 2 Wellness: Effects of A Multi-Component Lifestyle Modification Program
On Nutrition, Physical Activity, and Blood Pressure in Prehypertensive Middle-Aged Adults
A Randomized Controlled Trial

List of Figures

Figure 1: The DASH 2 Wellness Program protocol was comprised of the following intervention components.....32

Figure 2. Minimal Detectable Differences: Predicted & Actual SDs and Differences.....34

Figure 3: Consort Diagram51

DASH 2 Wellness: Effects of A Multi-Component Lifestyle Modification Program
On Nutrition, Physical Activity, and Blood Pressure in Prehypertensive Middle-Aged Adults
A Randomized Controlled Trial

List of Tables

Table 1: Blood Pressure Classification.....	4
Table 2: Lifestyle Modification Recommendations.....	6
Table 3: Demographics.....	52
Table 4: Changes in Clinical Outcome Measures in Dash 2 Wellness.....	53
Table 5: Changes in Nutrition Health Beliefs in Dash 2 Wellness.....	54
Table 6: Changes in Physical Activity Health Beliefs in Dash 2 Wellness.....	55
Table 7: Lifestyle Behaviors and Health Beliefs Outcomes Correlations.....	56
Table 8. Baseline and Post Demographic and Outcomes Means and Standard Deviations Among Participants in Dash 2 Wellness Only and Dash 2 Wellness Plus.....	57

DASH 2 Wellness: Effects of A Multi-Component Lifestyle Modification Program
on Nutrition, Physical Activity, & Blood Pressure in Prehypertensive Middle-Aged Adults

INTRODUCTION

Suboptimal blood pressure is the number one attributable risk factor for premature death throughout the world (NIH, 2004 p. 1; World Health Report, 2002). Illustrated by its positive linear relationship to cardiac events, stroke, heart failure, and kidney diseases, chronic high blood pressure (BP), or *hypertension*, represents the leading cause of cardiovascular disease (CVD) worldwide (NIH, 2004; Hajjar, Kotchen, Kotchen, 2006). This is a reflection of an uncontrolled and quickly progressing disease state. What was previously considered ‘normal range’ BP now carries ominous reports of increased cardiovascular complications and event risks. This compelling evidence was recently brought together by the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure for release of their *Seventh Report (JNC 7)* (NIH, 2004). The critical message of the *JNC 7* report is two-fold: 1) effectively communicate the increased CVD risks associated with uncontrolled progression of high BP and hypertension over the lifespan as the basis for reclassification of BP and 2) target this new BP designation of *prehypertension* as the decisive juncture for the application of early interventions (i.e., lifestyle modifications) to prevent BP from progressing into hypertensive levels, or ‘stages’.

Seminal trials such as the DASH (Dietary Approaches to Stop Hypertension: DASH Collaborative Research Group, 1999) and PREMIER (PREMIER Collaborative Research Group, 2006) studies offer initial guidance for nonpharmacologic approaches to reduce BP. These trials highlight advances made thus far, demonstrating the impact of lifestyle modifications on BP

change. Both trials demonstrated BP reductions, DASH through a diet rich in fruits and vegetables and low in sodium, and PREMIER through multiple lifestyle behavior changes, primarily weight loss and implementation of the DASH Eating Plan. It is notable, however, that there was considerable personal contact needed for adherence to DASH. PREMIER also used high personal contact with individual and group sessions and suggests that important lifestyle behaviors may be more resistant to change. For example, despite the extensive personal contact, changes in physical activity were minimal. Overall, findings from these major trials suggested approaches are needed with these characteristics: 1) the delivery mode parallels the need for widespread dissemination, i.e. an efficacious intervention delivery system requiring less personal contact, and 2) lifestyle modification strategies parallel the need for improvement of identified risk factors, i.e. effectively targeting components for initial and sustained changes in weight, diet, and physical activity.

Blood Pressure: Mercury Rising

As blood circulates throughout the body, it exerts force on artery walls, and is referred to as one's blood pressure (BP). Blood pressure is commonly reported in a measurement reflecting the systolic pressure (when the heart beats and when the BP is at its highest) over the diastolic pressure (between heart beats and when BP is at its lowest) (United States Department of Health and Human Services: USDHHS, 2006). Normal BP is below 120/80 millimeters of mercury (MMHG). Because there are typically no discernable symptoms between normal and high levels, chronically high BP has been appropriately referred to as the *silent killer*. Now, even *high normal* BP (>115 MMHG) is considered *sub-optimal* and has been associated with increased risk of CVD events (Lawes, Hoorn, & Rodgers, 2008; Lawes et al., 2006). The BP/CVD relationship is continuous across factors, consistent over time and independent of other risk factors.

Essentially and undeniably, *the higher one's blood pressure, the greater one's chance of cardiac events, heart failure, stroke, and kidney diseases* (NIH, 2004, p. 12). Accumulating evidence now specifies systolic BP as the primary indicator, or risk factor, for CVD, particularly in those 50 years of age and older (NIH, 2004); after the age of 55, adults have a 90% lifetime risk of developing hypertension (Rosendorff et al., 2007).

Hypertension

While no official definition for *hypertension* exists, from a disease-state perspective, it is understood as a highly complex, progressive *syndrome*, characterized by a range of pathophysiologic abnormalities (Izzo, 2007). In a clinical context, it is *the level of BP at which the institution of therapy reduces BP-related morbidity and mortality* (Hajjar, Kotchen, Kotchen, 2006, p. 466). In 90-95% of cases, there is no one identifiable cause of high of BP, often called *essential* or *primary* hypertension (Mayo Foundation for Medical Education & Research: MFRMER, 2006). In late 2005, the American Society of Hypertension expanded its definition of hypertension to reflect the complex and gradual development of this syndrome:

Hypertension is a progressive cardiovascular syndrome arising from complex and interrelated etiologies. Early markers of the syndrome are often present before blood pressure elevation is observed; therefore, hypertension cannot be classified solely by discrete blood pressure thresholds. Progression is strongly associated with functional and structural cardiac and vascular abnormalities that damage the heart, kidneys, brain, vasculature, and other organs and lead to premature morbidity and death (Giles et al., 2005).

Thus, recognition of early stages of progression is imperative for hopes of attenuating the prevalence of prehypertension and preventing the advance to hypertension. Official recognition of these earlier stages of the syndrome itself will help identification and detection. Evidence on a unique set of risk factors, lifestyle behaviors, now provides an avenue for better and more focused treatment prescriptions for lifestyle behavior change.

Requisite Reclassification of Blood Pressure

Despite marked improvements in awareness of hypertension in the past 30 years, i.e., from 51%-70% from 1976 to 2000, increased awareness has yet to effectively or functionally improve control rates (Burt et al., 1995; NIH, 2004). In short, control rates are simply *unacceptable* as high BP is identified as the most commonly diagnosed condition within the clinical practice setting (*JNC 7*: NIH, 2004). This underscores the basis for *JNC 7* BP reclassification, designated as *prehypertension*. This term applies to those individuals whose SBP (systolic) is 120-139 mmHg or DBP (diastolic) is 80-89 mmHg (Table 1). Coupled with this new designation is the recognition that early interventions, namely lifestyle modifications, must predominate in preventing progression to hypertension.

Table 1. Blood Pressure Classification

Systolic/Diastolic Blood Pressure MM Hg	JNC 7 Category
< 120/ 80	Normal
120-139/ 80-89	Prehypertension
≥140/ 90	Hypertension
140-159/ 90-99	Stage 1
160-179 & ≥180/ 100-110	Stage 2

Currently, in the US there are approximately 59 million adults with hypertension and 70 million (37.4%) with prehypertension (Quereshi, Suri, Kirmani, & Divani, 2005; Burt et al., 1995). The increase in prehypertensive adults is rapid, 5.2% from 1988-1994 NHANES to 1999-2000 NHANES, and exceeds changes in all other categories of hypertension (Quereshi et al., 2005). Given such rates and that high BP remains a modifiable risk factor, the magnitude of this health issue cannot be overstated. Aggressive treatment of prehypertension is supported, as a potential 30% of new cardiovascular disease and stroke risks could be prevented if prehypertension was eliminated (Pacini, Patel, Bavikati, & Sperling, 2008; Kshirsagar, Carpenter, Bang, Wyatt, & Colindres, 2006).

The feasibility of diagnosing, treating, and managing this population then becomes of crucial concern. Improved guidance and understanding for the behavioral medical treatment of risk factors such as overweight and obesity, smoking, a sedentary lifestyle, and an unhealthy diet (e.g., increased sodium and alcohol intake) is a starting point. Then, delivery of such knowledge and programs becomes a central issue.

Prehypertension: Risk Factors & Treatment

Prehypertension: Risk Factors. A new study by the Agency for Healthcare Research and Quality (AHRQ) released age-specific estimates that roughly two-thirds of adults, ages 45 to 64, and 80% of adults, ages 65 to 74, might have prehypertension or residual hypertension (AHRQ, 2004). Additional studies confirm there are significant health risks associated with prehypertension, particularly in those ages 45 and above. For example, the Framingham Study (Quereshi et al., 2005) indicated increased risk of coronary heart disease, specifically, in prehypertensive individuals, ages 45-65 and above. In sum, the linear relationship between systolic BP and aging makes age a considerable risk factor (NIH, 2004; Hajjar, Kotchen, & Kotchen, 2006). Certain life style factors coupled with genetic and environmental factors also increase the risk for prehypertension. Identifying factors causally related to prehypertension has become more possible and important in recent years. Specific factors include 1) excess body weight, 2) decreased physical activity, and 3) unhealthy diet characterized by increased sodium and alcohol intake, and 4) inadequate fruit and vegetable consumption.

Prehypertension: Treatment Options. Understanding the impact of these risk factors on BP is particularly useful, allowing for more focused efforts in the management of prehypertension. Causal factors, in particular increased body weight, high sodium and alcohol intake, and decreased levels of physical activity are all highly prevalent in today's society.

Preventive measures in prehypertensive individuals can be best achieved through lifestyle modifications specifically targeting these factors (See Table 2) (NIH, 2004). Making multiple lifestyle modification changes may have additive effects and produce better results, effectively lowering systolic BP 7-11 mmHg using a combination of several interventions (PREMIER Collaborative Research Group 2006; NIH, 2004).

Table 2. Lifestyle Modification Recommendations

Modification	Recommendation	Average SBP Reduction Range*
Weight Reduction	Maintain normal body weight body mass index 18.5-24.9 kg/m ²	5-20 mmHg/ 10 kg
DASH Eating Plan	Adopt a diet rich in fruits, vegetables, & low fat dairy products with reduced content of saturated & total fat	8-14 mmHg
Dietary Sodium Reduction	Reduce dietary sodium intake to ≤100 mmol per day (2.4 g sodium or 6 g sodium chloride)	2-8 mmHg
Aerobic Physical Activity	Regular aerobic physical activity (e.g. brisk walking at least 30 minutes per day, most days of the week)	4-9 mmHg
Moderation of alcohol consumption**	Men: limit to ≤2 drinks per day Women & lighter weight persons: limit to ≤ 1 drink per day	2-4 mmHg

*effects are dose and time dependent (USDHHS, 2003) **will not be a focus in this current study

Weight Reduction: Being overweight is a primary risk factor. Based on the Body Mass Index (BMI), a measure indicating *healthy* weight based on a person's weight to height ratio, an estimated 66 percent of U.S. adults are either overweight (BMI of 25-29.9 lbs/in²) or obese (BMI ≥ 30 lbs/in²) (Centers for Disease Control (CDC), 2007). There is a positive linear association between body mass and the amount of blood required to supply necessary nutrients and oxygen to tissues. Therefore, as body mass increases, the volume of blood circulated through blood vessels also increases, and similarly the force on artery walls increases (MFRMER, 2006). For this reason, weight reduction helps considerably to reduce SBP by as much as 5-20 mmHg per 10 kg lost.

DASH (Dietary Approaches to Stop Hypertension): Well-known and widely accepted, the DASH dietary change plan is relatively low in saturated and total fats, cholesterol, and added sugars; it emphasizes fruits, vegetables, whole grains, lean meats, and low-fat dairy. Rich in potassium, magnesium, calcium, protein, and fiber, the DASH Eating Plan aims to increase intake of foods that are high in minerals (i.e. potassium) and nutrients known to lower BP. DASH and similar diets have been shown to be effective in lowering systolic BP in older individuals (Svetkey et al., 2005). An additional focus of the DASH eating plan specifically centers on reducing dietary sodium. DASH is recommended by the National Heart, Lung, and Blood Institute, the American Heart Association, the 2005 Dietary Guidelines for Americans, and by the United States' guidelines for treatment of high blood pressure. *JNC7* reported an average systolic BP reduction of 8-14 mmHg is possible with the application of this eating plan.

Dietary Sodium Reduction: Recent research shows that reducing sodium not only has direct lowering effects on high blood pressure but also impacts long-term CVD risk, reducing total CVD death and risk by 26% according to a randomized trial of men and women with prehypertension (Trials of Hypertension: TOPH) (Cook, 2005). Sodium intakes average 2,750 mg for women and 4,100 mg for men and far exceed the *JNC-7* recommended maximum of 2,400 mg. Discretionary salt use accounts for a mere 5-10% of sodium intake (Mattes, 1997); therefore, more concerted efforts in dietary choices are required for BP reduction purposes. Processed foods, high in sodium, are typical of Western diets and leave little room in the typical American diet for fruits and vegetables (e.g. less than 25% consume 5 or more servings per day) (NIH, 2004). Dietary sodium reduction can attribute to an average 2-8 mmHg reduction in systolic BP.

Aerobic Physical Activity: Despite the benefits of regular physical activity (PA), a majority of the U.S. population is either sedentary or insufficiently physically active. Current Surgeon General recommendations encourage Americans to either accumulate at least 30 minutes of moderate-intensity PA (3-6 METs) on preferably every day of the week or 20 minutes of vigorous-intensity PA (>6 METs) on at least three days a week (USDHHS, 2000). Yet, according to early 2004 estimates, only 30% of Americans meet current guidelines for PA (USDHHS, 2004). Consequently, this sedentary lifestyle is linked to the drastic increase in the prevalence of overweight and obesity and to the increased risk of CVD, cancer, and all-cause mortality (USDHHS, 2002; Slentz, Houmard, & Kraus, 2007). A recent report confirmed a modest amount (at least 30 minutes) of moderate, daily PA (consistent with Surgeon General & American College of Sports Medicine Guidelines) is effective for preventing the progression of disease, i.e., inactivity-related metabolic deterioration, associated with physical inactivity, particularly in those overweight and obese (Slentz et al., 2007).

Moderate intensity physical activity has been shown to significantly reduce BP, i.e. 4.8/3.1 to 4.0/2.3 mmHg, in prehypertensive and normotensive individuals across a number of trials (Halbert, Silagy, Finucane, Withers, Hamdorf, & Andrews, 1997; Whelton, Chin, Xin, & He, 2002); reductions have also been found independent of significant weight loss (Whelton et al., 2002). Cornelissen and Fagard's (2005) recent meta-analysis included prehypertensive patients (average BMI= 26.3), finding a significant 1.7/1.7 mmHg reduction associated with PA averaging 65% intensity (maximum oxygen uptake), ~ 45 minutes duration, ~ 3 sessions/week for ~ 16 weeks. JNC7 estimates 4-9 mmHg reduction in systolic BP could be obtained by adding regular, moderate physical activity on most days of the week.

Prehypertension: Challenges in Treatment. The progression of hypertension can ideally be prevented or the condition's onset delayed through these nonpharmacological treatments. However, there is a general lack of a standard of care for how providers can diagnose and treat individuals with prehypertension (Pacini et al., 2008). Unlike hypertension, because *prehypertension* is not a disease-stage category, a pharmacological intervention is not the first line of defense. Dietary intervention, for example, receives little attention from primary care providers who simply cannot afford the necessary time investment given the structure of the reimbursement system (Mitka, 2007). In addition, low adherence to DASH is plausible given the *health care system's inadequate ability to merge lifestyle management into clinical practice* (Mitka, 2007, p.165). In general, providers rarely propose additional counseling in lifestyle modification to this population, especially those with hypertension, given they can be treated pharmacologically (Hajjar, Kotchen, & Kotchen, 2006). Prehypertension and hypertension, at the nonpharmacological level, seem to be conditions that the primary care and medical system cannot adequately treat.

JNC7 reported primary prevention *measures should be introduced to minimize disease risk in populations* (NIH, 2004). Though it has not been the case thus far, this should serve as the impetus for investigations to evaluate systems that would aid in bridging the gap between these progressive syndromes and our health care delivery system's inability to effectively treat these syndromes with lifestyle modification programs. However, in doing so, researchers must aim at the outset to devise effective programs and, primarily, delivery systems that are not heavily dependent on medical personnel. Such systems would have more prospect of adoption considering primary care personnel lack adequate training in behavioral medicine and management of health behavior interventions and lack time, equipment, and a reimbursement

structure to support such efforts. Employing such strategies as home blood pressure monitoring is well matched with current systems and is recommended for overcoming many of these limitations, e.g. BP measurement, cost, and efficiency, inherent in traditional office settings (Pickering et al., 2008).

Prehypertension: Lifestyle Modification & Previous Trials

Lifestyle Modification. Systolic BP is the more potent risk factor for CVD; it increases with age, and continues to rise in sharp contrast to diastolic BP, especially in those over the age of 50 (NIH, 2004). More primitive societies do not evidence such increases suggesting this course is highly attributable to environmental factors (Izzo, 2007). Additional research confirms no *applicable portion* of hypertension is attributable to known genetic abnormalities. Lifestyle modification is, therefore, highly appropriate and the primary recommended treatment for prehypertension (NIH, 2004).

Previous Trials: DASH: Dietary Approaches to Stop Hypertension (DASH Collaborative Research Group, 1999; DASH Investigators, 1995). These salient studies were conducted by the National Heart, Lung, and Blood Institute and found a particular diet pattern, or eating plan, to effectively reduce blood pressures in study participants. DASH was an 8-week multicenter randomized controlled-feeding study comparing three dietary patterns (control diet, fruits & vegetables diet, combination diet) in adults (N=456) whose mean SBP/DBP was <160/80-95 mmHg. The combination diet was considered the *ideal* dietary pattern, informed by epidemiologic data to be consistent with BP lowering. This diet was characterized by low-fat dairy, lean meat, natural vegetables and fruits, whole grains, and nuts. It was, therefore, low in total and saturated fats and high in fiber, potassium, magnesium, and calcium (DASH Collaborative Research Group, 1999; DASH Investigators, 1995). Similar to other nonpharmacologic studies (e.g., Morris, Sacks,

& Rosner, 1993 and Swain, Rouse, Curley, & Sacks, 1990), DASH reported BP reduction to be greater in those with hypertension (DASH Collaborative Research Group, 1997). Significant SBP and DBP reductions were detected in both intervention diet groups: 2.8 and 1.1 mmHg for the fruits and vegetable diet and 5.5 and 3.0 mmHg for the combination diet. The unique aspect of the DASH studies comes is that they focused on dietary patterns and lower BP among populations, as opposed to focusing simply on individual nutrients. Investigators further concluded that DASH is optimal for attenuating the effects of age-related increases in systolic BP (Svetky et al., 2005).

Previous Trials: PREMIER TRIAL (PREMIER Collaborative Research Group 2006; The Writing Group of the PREMIER Collaborative Research Group, 2003; Obarzanek et al., 2007). PREMIER evaluated the effects of multiple lifestyle behavior changes on blood pressure control in adults (N=810) with prehypertension and stage 1 hypertension, having mean SBP/DBP of 134.9/84.8 mmHg. The 18-month, multi-site trial compared an advice only condition with two treatment conditions, each implementing weight loss, dietary sodium reduction, increased physical activity, and reduced alcohol consumption, with one condition augmenting the DASH Eating Plan (the combination diet). The advice only group received information on national lifestyle modification recommendations (i.e., National High Blood Pressure Education Program); this included advice to follow the DASH diet. Participants in the behavioral intervention groups (the *Established* and *Established plus DASH*) received identical contact and behavior change strategies. Behavioral intervention components consisted of 14 group sessions and 4 individual sessions, incorporated aspects of behavioral self-monitoring (i.e. food diaries, monitoring of caloric sodium intake, minutes of PA), and personalized feedback (using self-monitoring data), plus motivational enhancement through social support. Group and individual treatment sessions were faded after seven months.

Significant changes were achieved for specific dietary outcomes, especially in the *Established plus DASH* condition, i.e., fruit and vegetable intake and total and saturated fat (compared to both *Established* and advice groups). Sodium, measured by excretion of urinary sodium, and weight in kg (approximately 4% reduction from baseline to 18 months) was also significantly reduced in both behavioral interventions compared to the advice only condition. Participant outcomes for sodium reduction, however, were modest, and were likely achieved based on relatively high baseline levels of sodium, 172 mmol/d (PREMIER Collaborative Research Group, 2006). *Small increases* in PA were reported, with no significant statistical differences found between the two treatment conditions and the advice only condition. At 6 months, decreases in mean SBP from baseline were observed for participants in the advice only, -6.6(9.2), in the *Established*, -10.5(10.1), and in the *Established plus DASH*, -11.1(9.9). At 18 months, SBP decreases from baseline were observed but statistically significant differences between groups were not detected, -7.4(10.8) mmHg, -8.6(11.6) mmHg, and -9.5(10.8) mmHg, respectively.

The PREMIER trial uniquely attempted to demonstrate that multiple lifestyle behavior modifications can be achieved simultaneously in lowering BP for the prevention of and treatment of hypertension. The investigators' efforts can be used to inform future nonpharmalogical interventions. For instance, it is notable that better results were observed at 6-months for both behavioral intervention conditions. Statistically significant differences were found for most outcomes between the *Established* and *Established plus DASH* vs. the advice only conditions at 6 months. A 4 % weight reduction as a result of following the DASH eating plan seems to be the strongest finding of the trial.

At the individual level, further consideration must be given to variability in treatment dose-response. Increasing participant/patient involvement in his or her self-care is often a strategy for successful lifestyle interventions, i.e. glucose control and weight management. For this reason, home blood pressure monitoring (HBPM) may serve not only as a diagnostic tool but also as a means for improving BP control by providing immediate feedback to individuals (Pickering et al, 2008). Mounting evidence supports HBPM as an intervention for better BP control compared to usual care (Cappuccio, Kerry, Gorbes, & Donald, 2004) and indicates HBPM as useful in predicting target organ damage and CVD events (Pickering et al., 2008). Recent studies indicate increased compliance and efficacy of treatment (i.e. lower BP) in hypertensive patients self-monitoring BP at home (Wetzel et al., 2007; Yamasue, Tochikubo, Kono, & Meada, 2006).

Self-monitoring, as well as goal-setting, are Social Cognitive Theory (SCT)-based self-regulatory behaviors or skills conceived to be essential for changing health behaviors (Bandura, 2004). Self-regulatory behaviors, i.e. planning and tracking, have been shown to directly influence health behaviors, such as fruit and vegetable intake (Anderson, Winett, & Wojcik, 2007) and physical activity participation (Anderson, Wojcik, Winett & Williams, 2006). Though SCT has been used as the rationale for lifestyle modification interventions in people with hypertension and prehypertension, some studies measured only select psychosocial variables (i.e. self-efficacy and outcome expectation: Vander Weg et al., 2008), while others did not incorporate HBPM (eg., Svetkey et al., 2005). A recent study assessed a home based system for hypertension management for the purpose of modulating drug therapy based on patient's reporting of home BP. Though self-regulatory strategies of SCT, e.g. self-monitoring, goal-setting, and corrective self-regulation, served as the substratum, these variables were not

measured. Authors concluded HBPM is a reliable tool for BP measurement, relative to office BP measurement (Rudd et al., 2004). Research suggests there are opportunities to further explore how SCT-based behaviors may operate in people with prehypertension engaging in HBPM and other health or lifestyle modifications.

Current Project Rationale

Healthy People 2010 identified two goals relating to blood pressure in their 12th focus area of heart disease and stroke: to reduce the number of adults with high BP and to increase the number of adults with high BP whose BP is under control. Reaching these goals will not only require implementing national guidelines for diet and PA, but also effective dissemination of systematic nonpharmacologic BP interventions aimed at treating early stages of this progressive syndrome, prehypertension. In theory, treating prehypertension is essentially changing the fundamental management of CVD. While larger trials such as DASH and PREMIER support the use of intensive interventions, there is still *need for improved behavioral interventions, including those appropriate for delivery in the clinical setting, that enable individuals with or at risk for hypertension to adopt long-term healthier lifestyles* (PREMIER Collaborative Research Group, 2006, page 493). In addition, while the clinical effects and health benefits of habitual eating of low-energy dense diets patterns and regular PA are well-documented, the psychological mechanisms by which people initiate and adhere to such lifestyle changes are less clear, as evidenced by the attenuation of favorable trends in PREMIER from 6-18 months.

The primary goal of this project was to develop, implement, and evaluate a lifestyle modification intervention that did not require extensive contact and would increase certain health behaviors known to improve blood pressure. The early efficacy study aimed to systematize the standard of care, specifically promote and support consistent participation in a healthy diet and

physical activity in prehypertensive adults over a 10-week period. The intervention was based on an integrated approach to disease prevention and health promotion. Incorporating clinical practices and psychological approaches to behavior change, this intervention primarily implemented the DASH Eating Plan, a walking program, and applied social cognitive theory to health behavior change, specifically self-regulation for self-monitoring and management of BP, diet, exercise, and weight.

Specific objectives for this intervention were as follows:

- To increase fruit and vegetable consumption through the adoption and maintenance of the Dietary Approaches to Stop Hypertension (DASH) Eating Plan.
- To decrease sodium intake through dietary sodium reduction and through the adoption and maintenance of the Dietary Approaches to Stop Hypertension (DASH) Eating Plan.
- To increase adoption and maintenance of regular moderate physical activity, i.e. walking, among middle-aged, prehypertensive people; to meet Surgeon General's recommendations for weekly physical activity through adherence to walking program (i.e., acquiring *at least* 30 minutes of moderate-intensity physical activity on most days of the week).
- To evaluate cognitive and behavioral self-regulatory processes involved in self-monitoring diet, physical activity, and twice, daily blood pressure readings.

METHODS

Participants & Design

Individuals targeted for this study were overweight to obese, adults with prehypertension, ages 45 to 65. As shown in the Consort Diagram (Figure 3), 155 individuals were successfully recruited through local advertising in various forms of print media (i.e. Roanoke Times 'Current' Section, See Appendix), posted fliers, and listserv ads. These individuals were assessed for initial

eligibility using a standardized screening phone Eligibility Questionnaire (See Appendix). Ninety-seven were identified as eligible and were assessed at baseline. Twenty-seven individuals met full eligibility criteria for the study and were randomized to one of two treatment groups, the *DASH 2 Wellness Only* (D2W Only) or the *DASH 2 Wellness Plus* (D2W Plus) group. Twenty-three individuals completed a baseline, 5-week, and 11-week assessment of the 10-week intervention, for a study attrition rate of 15%.

Participants

Study participants met *JNC7* criteria for prehypertension, having a SBP between 120-139 mmHG or a DBP of 80-89 mmHG (NIH, 2004), except for 3 individuals who averaged approximately 1 mmHG below threshold for meeting criteria; these participants evidenced at least one prehypertensive reading of four over the course of two baseline laboratory assessments. Participants were overweight to obese, BMI of ≥ 25 and ≤ 40 [Body Mass Index: weight (kg)/height(m)²], did not have any major chronic diseases; were not taking medications known to influence blood pressure, body weight, or food intake; were non-smokers; were not depressed, and did not have an eating disorder. In addition, any participant reporting current medications, e.g., statins, HRT, osteoporosis prevention drugs and had been on a stable dose for at least 6 months were instructed to continue to do so throughout the duration of the study in order to minimize potential medical confounds unless otherwise instructed by their physician. Level of PA participation was used as an assessment tool to determine eligibility for the study to ensure participants were not exceeding Surgeon General's recommendations for PA (USDHHS, 2000).

The sample (N=27) consisted of a total of 23 participants providing demographic, blood pressure, nutrition, step-count, and psychosocial data at baseline and follow-up. Two individuals discontinued prior to the 5-week assessment, one of which contacted the project director and

explained participation in the study required too much effort given other life circumstances; the other did not respond to emails sent by the project director and initially entered into the project with the caveat she may not be able to finish due to care of an elderly parent. Two additional participants discontinued after the 5-week assessment, one of which contacted the project director and had suffered a serious bicycling injury; the other did not respond to emails sent by the project director. The sample of 23 participants had a mean age of 54.3, an average weight of 87.80 kg (193.56 lbs.), average BMI of 31.48, were 69.5% female, 95% Caucasian, 5% Mexican-American, and 60.8% reported a household annual income above \$60,000. In terms of physical activity, 12 participants reported no regular PA, 8 reported engaging in moderate PA but did not meet American College of Sports Medicine (ACSM) guidelines of at least 30 minutes/day for 5 days/week; 3 reported vigorous activity and met ACSM guidelines, *mean exercise time*= 45 minutes (standard deviation= 15) (ACSM: Haskell et al., 2007). At baseline, participants averaged 6500(2827) steps per day and were considered “low active” (Tudor-Lock & Bassett, Jr., 2004). Participants’ baseline average daily steps varied across conditions in terms of level of activity; specifically, nine were considered sedentary (<5000), 5 were considered low active and typical of daily activity (5000-7500), 6 were considered somewhat active (7500-9999), and 3 were considered active (9999-11999). At baseline, average blood pressure for the sample was 127/75 mmHg, average daily fruit and vegetable intake was 4.6, and average sodium intake was 3364.53 mg. (*Demographics*, Table 3).

Design

The study employed a randomized design, in which the 27 participants were randomized at the individual level using a random number generator, *DASH 2 Wellness Only* (N=12) and

DASH 2 Wellness Plus (N=15). Incentives were offered in the form of dietary nutritional counseling, a weight scale, and a pedometer for those eligible for the study and a \$200 prize drawing for those completing all 3 assessments; all individuals eligible at baseline also received a pedometer for participation. All procedures and measures were approved by the Institutional Review Board of Virginia Tech prior to recruitment and data collection (See Appendix).

Procedures

Enrollment & Eligibility

Enrollment for the DASH 2 Wellness study took place from February to May 2008 and targeted “healthy, middle-aged adults” in local advertising efforts for “an online blood pressure reduction study”. Individuals interested in participating in the study either emailed the project director or called the research laboratory (Center for Research in Health Behavior-CRHB, Department of Psychology, Virginia Tech) and received a brief description of the study from the project director or from one of four research assistants. If still interested, the researcher obtained verbal consent to continue with a brief health history to determine the individual’s eligibility for the study. Once eligibility was confirmed, the participant was scheduled for a baseline assessment appointment time to come to the research laboratory. Each participant was then sent an email with his/her appointment time, directions to the lab, contact information for the staff, and instructions to abstain from eating, exercise, and caffeine prior to the appointment. All laboratory assessments took place between the hours of 6 am and 12 pm. This is consistent with *JNC7* recommendations and ensures consistency in the BP measure, reducing introduction of confounds in BP readings.

Session 1 Baseline Assessment. Participants arrived at the research lab, were greeted, given a description of the study, completed an informed consent document (ICD, See Appendix)

and provided a copy, and completed a Health History Questionnaire (See Appendix). Baseline blood pressure, height, and weight measurements were taken. Participants whose BP measures were within the prehypertensive range, and whose BMI was ≥ 25 and ≤ 40 also completed the Health Beliefs Survey, the Risk Perception for Developing Hypertension, and Beck's Depression Inventory. Participants were also instructed on completing a 4-Day Food Intake Record and a 7-Day Step Log, provided with an Accusplit 120XL Pedometer, and scheduled for a second baseline assessment. A second and, in some cases, a third assessment was needed to complete baseline assessments and to establish stable baseline BP; this was done by taking multiple BP readings on multiple days. (See *Measures* for detailed BP procedure and Questionnaire/Log explanation.)

Session 2 Baseline Assessment. Upon arrival to the lab, BP measure readings were taken, the 4-day Food Intake and 7-Day Step Log were collected. Participants whose BP continued to fall within the prehypertensive range met with a Registered Dietician (RD) and were then randomized to one of the two treatment groups. The RD had over 80 hours of training specializing in healthy eating for hypertensives and specifically, the DASH Eating Plan; the RD spent approximately 60 minutes educating and instructing the participants on how to follow DASH. Education and instructions were standardized for all participants; however, the RD individualized DASH according to a brief dietary assessment of eating habits during the counseling session and provided each participant with a DASH Eating Plan Guide (USDHHS, 2006). Counseling focused on realistic goal setting for integrating DASH into current dietary habits. Participants were then randomized to one of two treatment groups for the DASH 2 Wellness Program, *D2W Only*, who received a standard form of care/treatment or *D2W Plus*, who received the 10-week intervention. The RD was blind to randomization. Those in the *D2W*

Only were given a digital weight scale and were instructed:

Here is your pedometer and scale. We hope that you will use these to be more active and to better manage your weight. Try to follow the DASH eating plan, which you went over with Registered Dietician and try to get in 30 minutes of physical activity a day. These things will help you lose weight, which will lower your blood pressure and your cardiovascular disease risk. We will schedule you to come in for a check-up visit 5 weeks from now and again at 10 weeks when the study ends. Thank you again for your participation in our research study!

Those in the *D2W Plus* were given a Omron Automatic Blood Pressure Monitor (Model HEM-712C: See Appendix) and a Tanita Digital Weight Scale, were instructed by the project director on use of the BP monitor, and were provided instructions on completing weekly tracking forms online, the *Wellness Tracker* and *Dash Diary*. They were instructed:

Each week you will have electronic visits with your project director, Ashley. She will support you in your lifestyle changes and she will provide you information on the DASH (Dietary Approaches to Stop Hypertension) Eating Plan and in an exercise walking program. For the next 10 weeks, she will provide guidance and feedback in planning, goal-setting, and tracking of various lifestyle behaviors including daily vegetable, fruit, and sodium intake, and daily weight, exercise, and self-monitored blood pressure readings; she will also provide assistance trouble-shooting problems with adherence and with daily weight, food, exercise, and BP monitoring.

It was confirmed that all study participants still had his or her pedometers and either an appointment was set or an estimated date agreed on by the participant and the researcher for the 5-week mid-program assessment.

Session 5 Mid-Program Assessment & Session 10 Post Assessments. At the 5-week mid-point, participants in *D2W Only* and *D2W Plus* groups came to the CRHB study lab for height, weight, and blood pressure readings and to schedule an 11-week post assessment. Post assessment Sessions 10-A and 10-B were similar to Sessions 1 and 2 baseline assessments.

Measures & Treatment Conditions

Measures

Participants were given a description of the study as well as an outline of their expected involvement. All participants were given identical questionnaires that consisted of the following:

(1) Health History Questionnaire (Human Integrative Physiology Laboratory in the Department of Human Nutrition, Foods and Exercise, Virginia Tech), (2) Health Beliefs Survey (Modified) (Anderson et al., 2007), (3) Risk Perceptions Survey for Developing Prehypertension (Modified from Risk Perceptions Survey for Developing Diabetes (RPS-DD: Michigan Diabetes Research and Training Center (MDRTC), 2007), and (4) Beck's Depression Inventory (Beck, Steer, Ball, & Rainieri, 1996). Each week, *D2W Plus* participants were to complete (1) Physical Activity Enjoyment Scale (PACES; Kendzierski & DeCarlo, 1991), (See Appendix).

Height, Weight, & Body Mass. At assessments, participants were weighed using a high-capacity weight digital weight scale, the Detecto® High-Capacity Digital Weight Scale (Model 6855). Height was measured in inches without shoes using a balance scale. Measurements were obtained with subjects wearing light indoor clothing and without shoes. BMI was calculated as weight (kg)/height (m)². Laboratory height and weight were used in final analyses.

Sodium & Macronutrients. To determine habitual dietary intake, 4-Day Food Intake Records (See Appendix) were obtained at baseline and post assessments from all participants. Participants were instructed by the project staff in methods to accurately record their food and beverage intake. Measuring spoons, cups, and food models were used to determine portion sizes. (Project staff were trained and guided by the D2W Program Registered Dietician). All food records were reviewed for accuracy and completeness prior to analysis. Analyses were conducted using the NDS-R 2006 Nutritional Analysis software program (University of Minnesota, Minneapolis, MN). Information derived from food records provided measures of energy and macronutrient intake, as well as micronutrients related to BP (i.e. sodium, potassium, magnesium, and calcium), and specific DASH Eating Plan indicators of DASH Dairy, Fruit and Vegetable, and Saturated Fat Intake. Information used for fruit categories included: juice, fruit,

avocado, fried fruits, and fruit-based savory snacks, and for vegetable categories: vegetable juice, dark, green vegetables, deep yellow vegetables, tomatoes, white potato, fried potato, other starch vegetables, other vegetables, and fried vegetables; these data were used in final analyses.

Physical Activity. PA measurements of daily steps taken at baseline and post-intervention assessments were used in final analyses. Step counts were measured using a pedometer, Accusplit 120XL. The pedometer was chosen based on previous research supporting the device as reliable, providing accurate step counts (Bassett, Jr., Ainsworth, Leggett, Mathien, Main, & Hunter et al., 1996). Baseline step counts were measured using the 7-Day Step Log: each participant was provided a demonstration and directions for pedometer use and asked to record all daily steps for the period of 7 days and the average was taken to represent an average daily step count.

Resting Casual Blood Pressure (BP). Laboratory BP measurements were taken by trained research staff and according to *JNC7* standardized guidelines at both baseline assessments, at a 5-week mid-program assessment, at both post assessments using a professional non-invasive blood pressure (NIBP) monitor. The automated GE Dinamap® Pro Care (Model 120: See Appendix) is a vital signs monitor ensuring reliable performance and provided researchers with a non-invasive determination of systolic and diastolic blood pressure readings. To minimize variability in testing conditions from baseline to mid-program and post assessments, all assessments took place between the hours of 6 am and 12 pm; study participants were instructed to abstain from eating, exercise and caffeine prior to their assessments. For accurate in-office measurement, all resting casual BP measurements were taken in a quiet environment after a seated 5-minute rest period, with participants' feet supported and arm supported at heart level. For individuals with an arm circumference >35cm, a regular-sized adult

cuff was used, and for those with arm circumference >45cm, a large adult cuff was used. Baseline and post BP were determined using the mean of two consecutive BP readings within 6 mmHg (at least 3 BP readings were taken for each assessment), which were taken on two separate days, obtained over approximately a one-week period. BP readings at 5-weeks were determined according to similar standards, except with a minimum of 4 readings and during a single testing session.

Both BP monitors, the lab GE Dinamap Pro Care and the at-home Omron Automatic Blood Pressure Monitor, first underwent a validation study in which BP test readings were randomized between project director and multiple laboratory researchers prior to the intervention study.

Health History. The Health History Questionnaire (Human Integrative Physiology Laboratory in the Department of Human Nutrition, Foods and Exercise, Virginia Tech) requested general demographic information from the participants (i.e. age, sex, ethnicity, marital status). Participants reported medical history and current health problems, family health history, as well as tobacco and alcohol history, cardiorespiratory/metabolic history, musculoskeletal history, nutritional habits, obstetric/ gynecological history, physical activity, and sleep history.

Social Cognitive Measures

Health Beliefs Survey. The Health Beliefs Survey has been used in previous Center for Research in Health Behavior projects and has been shown to have good reliability (Anderson et al., 2007; Anderson et al., 2006). The survey included social cognitive measures to assess participants' self-efficacy, outcome expectancy, social support, and self-regulation related to healthy eating and physical activity. Factor structure of each measure was determined in previous

studies through principal axis factoring, in which items loading less than .4 were eliminated from final analyses.

Self-Regulation: Self-regulation for healthy eating was measured by three scales, regulating calories and fat, planning and tracking, and regulating fiber, fruits, and vegetables with previously established reliability ($\alpha = .90$, $\alpha = .91$, $\alpha = .85$, respectively; Anderson et al., 2007). Items inquired *How often* a certain behavior was performed during the previous two months and was measured from 1-5 (*Never to Repeatedly*), e.g., *How often (did you) work toward the goal to eat more vegetables*. Items were averaged to yield a total healthy foods self-regulation score (12 items, $\alpha = .90$). Subscales scores included Self-regulating Calories and Fat ($\alpha = .70$), Planning and Tracking ($\alpha = .72$), and Self-regulating Fiber, Fruits, and Vegetables ($\alpha = .89$).

Self-regulation for physical activity was measured by one scale, which assessed exercise planning, monitoring, and goal-setting shown to have good reliability ($\alpha = .83$: Anderson et al., 2006). Items were measured similarly, from 1-5 (*Never to Repeatedly*), e.g., *How often (did you) keep track of how many steps you were taking each day?* Items were averaged to yield a total PA self-regulation score (5 items, $\alpha = .91$).

Self-efficacy: Self-efficacy for healthy eating was measured by three scales, self-regulatory efficacy for decreasing fat, for increasing fiber, fruit, and vegetables, and for reducing sugar (previously established reliability, $\alpha = .89$, $\alpha = .90$, $\alpha = .76$: Anderson et al., 2007). Items inquired *How certain* a person is he/she can perform a behavior and was measured from 1-10 (*Certain I cannot to Certain I can*), e.g., *How certain are you that you can, every day, keep track of whole grain foods?* and *How certain are you that you can set a goal and make plans to eat vegetables for a snack?*. Items were averaged to yield a total healthy foods self-efficacy score

(15 items, $\alpha = .87$). Subscale scores included Self-Efficacy for Increasing Fruits and Vegetables ($\alpha = .82$), Self-Efficacy for Decreasing Fat ($\alpha = .66$), and Self-Efficacy for Reducing Sugar ($\alpha = .74$).

Self-efficacy for physical activity was measured similarly and assessed participants' ability to create time for health-related behaviors and for continuing exercise despite various barriers (previously established reliability, $\alpha = .89$, $\alpha = .91$: Anderson et al., 2006). Items inquired, for example, *How certain are you that you can, all or most of the time, take small breaks during the day to take a walk or do other exercise?* Items were averaged to yield a total PA self-efficacy score (18 items, $\alpha = .88$). Subscales included Self Efficacy for Increasing PA ($\alpha = .78$) and Self Efficacy for Overcoming Barriers ($\alpha = .87$).

Social Support: Social support items were to intended to assess the amount of perceived social support for healthy eating and were measured by 4 scales, support for fat (family and friends) and support for fiber, fruit, and vegetables (family and friends) (previous reliability established for family, $\alpha = .89$, $\alpha = .89$: Anderson et al., 2007). Items were measured from 1-5 (*Strongly Disagree* to *Strongly Agree*) and inquired about perceptions of friends or family members thoughts and behaviors related to eating healthy, e.g., *(to what extent do you agree) that family members or friends try to eat low-fat dairy foods*. Items were averaged to yield a total social support for healthy foods score (12 items, $\alpha = .80$).

Social support for physical activity was measured similarly and assessed amount of perceived support for exercise-related thoughts and behaviors (previously established reliability for family support, $\alpha = .71$: Anderson et al., 2006). Items inquired, for e.g., *(to what extent do you agree) that family members or friends make time to walk or do other exercise*. Items were averaged to yield a total social support for PA score (6 items, $\alpha = .77$).

Outcome expectancy: Items assessing both positive and negative expectations related to outcomes for engaging in healthy eating (previously established reliability, $\alpha = .90$, $\alpha = .82$; Anderson et al., 2007). Items were measured on 1-5 (*Strongly Disagree* to *Strongly Agree*). Items specifically inquired about expectations of what would happen when eating healthier foods, e.g., *If I eat healthier foods every day, I expect I will have more energy*. Items were averaged to yield a positive outcome expectancy score (10 items, $\alpha = .87$). Items were averaged to yield a negative outcome expectancy score (12 items, $\alpha = .92$).

Outcome expectancy items for physical activity have previously been established as reliable (positive: $\alpha = .93$, negative: $\alpha = .81$; Anderson et al., 2006). Items were measured according to 1) *Do you agree?*, based on 1-5 scale (*Strongly Disagree* to *Strongly Agree*), and 2) *Will it matter?*, based on 1-5 scale (*Strongly Disagree* to *Strongly Agree*). Items inquired specifically about expectations of what would happen *if a person were to walk or do other exercise most days of the week* and then, how much would it matter for these things to happen, e.g., *If I slowly and steadily build up to walking or doing other exercise most days of the week, I expect I will ... sleep better* or *I expect I will have to change my normal routine*. Items were averaged to yield a positive outcome expectancy score (8 items, $\alpha = .59$, Standardized Items = .70). Items were averaged to yield a negative outcome expectancy score (8 items, $\alpha = .79$).

Modifications were made to approximately 30 of 217 questions to measure DASH Eating Plan goals, e.g. eating increased fruits and vegetables and less sodium, and 8 questions were added to measure BP goals, e.g., monitoring/tracking blood pressure at home (8 items, $\alpha = .78$).

Intervention & Standard of Care of Conditions

Following randomization, participants in both the standard of care treatment group, *D2W Only*, and the intervention group, *D2W Plus*, began the *DASH 2 Wellness Program*. The standard

of care treatment condition received no additional contact throughout the 10-week program with the exception of the 5-week, mid-program assessment. Weekly *DASH 2 Wellness Sessions* were completed by those participants in the *D2W Plus* condition for the duration of the 10-week program. Contact information for the research director and research lab was made available to all participants should they have experienced or have needed to report any adverse events during the program.

The *DASH 2 Wellness Plus* treatment condition received a multi-component lifestyle modification program, which involved three main intervention components: nutrition, physical activity, and support for lifestyle modifications. The *D2W* intervention was internet-based and electronically delivered. Each week, participants had electronic “sessions” with the project director. *Sessions* were primarily derived from pre-drafted scripts based on social cognitive theory and previous similar research studies (e.g. CRHB Walking Pilot & Guide to Health) to provide instruction, guidance, and feedback to participants. Weekly *Sessions* took the form of an electronic newsletter, previously piloted to a similar cohort of individuals in a walking program, the CRHB Walking Pilot. *Sessions* came in two distinct newsletters, 1) individualized feedback from project director on participant’s Wellness Tracker and Dash Diary, and 2) topics of support and education for successful health behavior change; specifically topics included planning, tracking, goal-setting, negative thoughts, stress management, enjoyment, social support. In general, newsletters were designed to 1) support and encourage participants in lifestyle changes, to provide information and guidance on the DASH Eating Plan, in an exercise walking program, and in self-monitored home BP readings, 2) provide direction and feedback in planning, goal-setting, and tracking of various lifestyle behaviors including daily vegetable, fruit, and sodium intake, and daily weight, physical activity, and self-monitored blood pressure readings, and 3)

provide assistance trouble-shooting problems with adherence and with daily weight, food, exercise, and BP monitoring. (See Example Sessions, Appendix).

Primary Intervention Components. Considering intraindividual variability exists with a measurement such as blood pressure (Izzo, 2007), and given the strength of other key indicators that have BP lowering effects, i.e. healthful diet and regular physical activity, these key measures were also considered as primary outcomes in this study. Participants in *D2W Plus* were to specifically track weekly health behaviors as part of their program.

Nutrition: In addition to following the DASH Eating Plan Guide (NIH Publication No. 06-4082) the *D2W Plus* participants were asked to adhere to, track, and report on specific aspects of the eating plan. The **DASH Diary** (See Appendix) was a log provided for tracking weekly intake of vegetables, fruits, sodium caution, and sodium restriction foods. The **DASH Diary** provided researchers with estimates of daily fruit and vegetable and sodium intake and served as the primary source for providing feedback to the participant regarding his/her adherence to certain DASH Eating Plan goals. Protocol and scripted feedback was consistent with the DASH Eating Plan; feedback encouraged a goal of 9-10 fruits and vegetables per day, combined, and a goal of less than or equal to 2,300 milligrams of sodium per day [the highest level considered acceptable by the National High Blood Pressure Education Program or recommended by the 2005 US Dietary Guidelines for Americans]; feedback provided guidance and support in the form of lists of high-sodium foods to be avoided, potential alternatives to supplement diet, menus, recipes, and other tips.

Physical Activity: The physical activity (PA) component was delivered, tracked, and reported in a similar format. The PA goal was to increase steps, as measured by the Accusplit 120XL pedometer, in incremental goals of steps/day, i.e. 500 steps/day increase, over a baseline

mean and subsequent week's daily step mean. Specifically, increases were successive goals of the number of steps/day over a participant's baseline step count, obtained from the baseline 7-Day Step Log, and were aimed at gradually reaching a goal of 3000 steps over baseline through increased daily activity and increased PA through walking on 5 days per week (USDHHS, 2000). Participants were also encouraged not to go below the baseline mean on non-walk days. Participants used the **Wellness Tracker** (See Appendix) as a weekly log of daily steps, weekly walks, PA-related enjoyment, and PA-related perceived exertion. The Wellness Tracker monitored daily/weekly step count information and served as the primary source for providing feedback to the participant regarding his/her adherence to the walking program goals. Prescriptions and scripted feedback were consistent with DASH PA recommendations and with ACSM and AHA (American Heart Association) guidelines for moderate physical activity; feedback was adapted from CRHB's walking pilot studies previously conducted by the project director and the CRHB Guide To Health Project; feedback provided guidance and support in the form of daily steps goals, weekly walking goals, strategies to overcome barriers to PA participation, and other tips, such as ways to make daily PA more feasible, consistent, and enjoyable.

For nutrition and PA outcomes, it was hypothesized that both conditions would increase fruit and vegetable consumption in servings/day, decreasing sodium consumption in mg/day (measured by the 4-Day Food Record), and would increase levels of physical activity in step counts/day (measured by the 7-Day Step Log). It was also hypothesized that the *D2W Plus* condition would obtain statistically significant greater differences on these measures than the *D2W Only* condition.

Participants in *D2W Plus* were also instructed to on how to monitor their weight and BP daily and to also track these weekly health behaviors as part of their program.

Weight: Participants were asked to monitor and report their weight in pounds using the digital scale given to them by the research staff at the second baseline assessment session. For consistency in weighing behaviors across study participants, each person was instructed to weigh themselves in the morning, at the same time each day, wearing little to no clothing, and prior to eating. This weight was recorded on the Wellness Tracker and served as the primary source for providing feedback to the participant regarding his/her adherence to the daily weighing. Feedback primarily encouraged *D2W Plus* participants to continue tracking their weight daily, to at least maintain their current weight, to consider the impact of their changing health behaviors on their weight changes, and general supportive strategies that also impact weight, e.g., drinking more water, to support increased PA and fruit and vegetable intake.

Blood Pressure: *D2W Plus* participants were asked to monitor and report their BP using a digital home blood pressure monitor. A monitor was given to participants by the research staff at the second assessment session. How the monitor worked was first demonstrated and each participant practiced taking his or her own BP in the research lab. For consistency in monitoring behaviors and accuracy in BP readings, a standard set of instructions were printed and given to the participants with the Omron Automatic Blood Pressure Monitor (Model HEM-712C: See Appendix); BP monitors also came with the manufacturer's instructions. Standardized conditions for home BP monitoring were also explained and required participants to record two BP readings in the morning and in the evening. BP readings were to begin after a 5-minute seated rest, were to occur approximately 3-5 minutes apart, with feet on the floor, and arm supported at heart level. Morning BP readings were to be taken while in a fasting state (i.e., in the morning before

breakfast, with caffeine and exercise avoided prior to measurement). These instructions are consistent with the *JNC7* recommended procedures, *Accurate Blood Pressure Measurement* criteria (NIH, 2004). For evening measures, participants were instructed to follow recommended procedures, to be mindful of the impact of physical exertion, alcohol, and caffeine on BP, and were encouraged to adhere to at least a 5-minute seated rest prior to measurements. BP readings were also to be recorded on the Wellness Tracker and served as the primary source for providing feedback to the participant regarding his/her adherence to the daily monitoring. It was anticipated that the combination of *D2W* Program lifestyle modification efforts would have additive effects in contributing to a reduction in blood pressure. Therefore, feedback primarily encouraged *D2W Plus* participants to continue monitoring their BP daily and to consider the impact of their changing health behaviors on their BP changes.

It was hypothesized for the outcomes of weight and BP, primarily systolic, that both groups would show improved outcomes but with *D2W Plus* demonstrating greater improvements over *D2W Only*. Additional outcomes included social cognitive and affective measures, which were assessed at pre- and post-assessments. It was also expected that health beliefs including, self-regulation, social support, self-efficacy, social support, would improve for those in the *D2W Plus* condition compared to those in the *D2W Only* condition.

Figure 1. The DASH 2 Wellness Program protocol was comprised of the following intervention components:

DASH 2 WELLNESS ONLY (Standard of Care-Treatment: Condition 1)	DASH 2 WELLNESS PLUS (Intervention-Treatment: Condition 2)
BASELINE: Blood Pressure, Weight, Height 4-Day Food Record Physical Activity Record Eating Disorders & Beck's Depression Inventories Social Cognitive Measures Personal Home Digital Weight Scale Personal Pedometer	BASELINE: Blood Pressure, Weight, Height 4-Day Food Record Physical Activity Record Eating Disorders & Beck's Depression Inventories Social Cognitive Measures Personal Home Digital Blood Pressure Monitor Personal Home Digital Weight Scale & Pedometer
INTERVENTION: <ul style="list-style-type: none"> <u>DASH Eating Plan Guide</u> <ul style="list-style-type: none"> o Recommended low-sodium diet o DASH Eating Plan counseling from RD <ul style="list-style-type: none"> <u>Walking & Weight Program</u> <ul style="list-style-type: none"> o Provided digital weigh scale o Provided Pedometer 	INTERVENTION: <ul style="list-style-type: none"> <u>DASH Eating Plan Guide</u> <ul style="list-style-type: none"> o Recommended low-sodium diet o DASH Eating Plan counseling from RD <u>DASH DIARY Self-Monitoring</u> <ul style="list-style-type: none"> o Instructed to self-monitor F&V, high-Na foods <u>Walking & Weight Program</u> <ul style="list-style-type: none"> o Instructed to track weight daily using scale o Instructed to increase steps & PA through walking and using pedometer <u>Wellness Support for Lifestyle Modification</u> <ul style="list-style-type: none"> o Weekly feedback & goal-setting provided; continued support thru problem-solving
MIDPOINT: Blood Pressure, Weight, Height Assessments	MIDPOINT: Blood Pressure, Weight, Height Assessments
POST: Blood Pressure, Weight, Height 4-Day Food Record Physical Activity Record Social Cognitive Measures	POST: Blood Pressure, Weight, Height 4-Day Food Record Physical Activity Record Social Cognitive Measures

Medical Oversight and Procedures for Adverse Events

Jose Rivero, M.D., served as the medical director and primary consultant if any health concerns to arise throughout the course of the study. All of the study procedures were in accordance with JNC7 standards for BP measurement and used consistently in the CRHB laboratory; equipment was tested and validated prior to usage. Recognizing side effects are possible in any research study, despite high standards of care, and could occur through no fault of the participant(s) or the study staff, the project staff believed it was necessary to take all possible safeguards to minimize any known and potential risks to the participant(s)' well-being.

Overall, it was believed that risks of participation were minimal and primarily included a slight possibility for bruising from the blood pressure cuff that was used during assessments and during home self-monitoring of BP. However, if more serious complications were to occur, i.e. elevated blood pressure readings, all participants in both the *D2W Only* and *D2W Plus* conditions were provided not only with the contact information for the Center for Research in Health Behavior study lab, but also the contact information for the project director. In the case of an adverse event, participants were asked to take the specific steps (See Appendix).

Throughout the 10-week intervention the project director also monitored participants' logs of twice daily BP readings reported on the weekly *Wellness Trackers*. If a participant had recorded but not reported an elevated BP reading, once it was observed from the participant's log, the project director then could initiate contact with the participant; confirmed no adverse events followed; ensured that subsequent BP readings returned to a safe level; obtained additional information regarding the situation surrounding the elevated BP reading; continued with previous steps of contacting the participant's private MD, or the Medical Director if the participant did not have a private MD, for further advice on a potential course of action, should one need to be taken. Instances regarding blood pressure in which specific action and medical attention may have been required are also detailed in the Appendix. They were used to guide researchers during assessments, and were included with the take-home BP monitor informing the *D2W Plus* participants to contact the project director immediately in any of the instances. Documentation procedures were, therefore, in effect for actions that could be taken by the researchers and actions that could be taken by the participants. Also, if a participant did not have a private MD, he/she could have been referred to Dr. Rivero's office for a follow-up. No adverse events were reported or detected throughout the course of the assessments or the intervention.

RESULTS

Sample Size Calculations

As an initial goal, the total number of recruited participants was 200. Estimating 50% eligibility and a conservative 25% attrition across the course of the study, would yield an estimated total of approximately 75 participants, roughly 30 participants per condition *D2W Only* (standard of care treatment group) and *D2W Plus* (intervention treatment group). However, with lower rates of eligibility and lower rates of attrition, a total sample of 27 was obtained. Minimal detectable differences for outcomes were initially estimated using a sample size of N=30 per group but were recalculated conservatively to reflect actual recruitment N=12 per group (See Below Figure 2). The alpha error was set at 0.05 and the beta error at .20 to adjust for the potential outcome variance due to baseline covariates and for the usual population variances (based on previous research from the PREMIER Trial, the Center for Research in Health Behavior, and Davy et al., 2002), respectively. Within subject correlations are not included in the table, as all outcomes, except for sodium and percent kcal from fat, are change variables.

Figure 2. Minimal Detectable Differences: Predicted & Actual SDs and Differences

Outcome	Predicted SDs	Minimum Detectable Difference^a	Actual SDs	Actual Detected Difference
Weight change (kg)*	3.20	3.79 kilograms	3.52	3.31 kg
F&V Servings / day change*	2.8	3.31 servings/day	2.05	1.09 f&v
% fat kcal*	7.9	9.35 percent	2.49	.41 %
Steps/day change**	2592.36	3069.15 steps/day	2073.59	2263.75 steps
Sodium/day***	1200.66731	1421.49 mg/day	1020.27	224.13 mg
Systolic BP change*	9.2	10.89 mmHg	8.53	10.52 mmHg
Diastolic BP change*	6	7.46 mmHg	7.76	3.69 mmHg

*Premier Trial: The Premier Collaborative Research Group, 2006; **Guide To Health; ***Davy, Melby, Beske, Ho, Davrath, & Davy, 2002; ^a With 12 participants per group and 2 measurement points

Sample size calculations were determined based on the ability to detect clinically significant differences between groups based on previous research. With a N=12, this study was powered to detect significant changes in weight, fruits and vegetables, and percent kilocalories

from fat at least equivalent to those found in the PREMIER Trial. In addition, this study was powered to detect a significant change in steps counts per day and sodium reduction per day similar to those reported by Guide to Health and by Davy et al. (2002), respectively. Results show smaller actual standard deviations were detected for changes in steps per day and changes in SBP, allowing smaller differences to be detectable between groups.

Data Analysis

Preliminary Analyses

An independent samples t-test was performed to compare baseline lifestyle behaviors and health beliefs scores for *D2W Only* and *D2W Plus* conditions. There were no significant differences in baseline health behaviors ($\alpha < .05$). Conditions differed on one health beliefs score, self-regulation for healthy eating, $t(21) = 2.604$, $p = .017$, $\eta^2 = .245$, [*D2W Plus* ($M = 2.43$, $SD =$), *D2W Only*, ($M = 3.13$, $SD =$)]. The magnitude of this difference was large ($\eta^2 = .245$); however, randomization was used for group assignment. Data analyses were run using Statistical Package for the Social Sciences (SPSS, Version 16, 2008).

Primary Analyses

In exploration of differences between treatment conditions and to reduce potential alpha inflation, 3 between groups multivariate analyses of variance (MANOVAs) were performed. Each analysis used the independent variable, treatment condition (*DASH 2 Wellness Plus* versus *DASH 2 Wellness Only*) and used 1) lifestyle change variables, 2) nutrition (healthy food) health beliefs variables, and 3) physical activity health belief variables, as dependent variables to determine whether statistically significant differences existed between these conditions.

Lifestyle Behaviors. A one-way MANOVA was performed to investigate differences in healthy and preventive lifestyle behaviors (Table 2). Four dependent variables were used: change

in total daily fruit and vegetable intake, change in total daily step count, change in systolic BP, and change in weight (kg). Three participants data were identified and eliminated from analyses due to invalid assessment of step count or nutrition data; these included two *D2W Plus* participants whose post intervention 4-day food record indicated significantly higher numbers of daily fruits and vegetables relative to other study participants and one *D2W Only* participant whose post intervention step log indicated significantly lower average daily steps relative to other study participants. Further preliminary assumption testing was conducted to check for normality, linearity, homogeneity of variance-covariance matrices, and multicollinearity, with no serious violations noted. There was a significant difference between the treatment conditions on the combined dependent variables: $F(4,15) = 3.46$, $p = .034$; Wilks' $\lambda = .52$; canonical correlation = .69. Follow-up univariate analyses revealed treatment condition effects for three of the four measures, weight change ($p = .032$, $\eta^2 = .26$), daily step change ($p = .011$, $\eta^2 = .35$), and systolic BP change ($p = .003$, $\eta^2 = .44$).

An inspection of the mean scores indicated that the intervention group, *DASH 2 Wellness Plus*, evidenced a larger increase in average daily steps ($M = 2900.14$, $SD = 1903.83$) than the standard of care treatment condition, *DASH 2 Wellness Only*, ($M = 636.39$, $SD = 1653.26$) and a larger decrease in systolic BP (mmHg) ($M = 15.14$, $SD = 4.33$) than the standard of care treatment condition, *D2W Only*, ($M = 4.61$, $SD = 8.28$). *D2W Plus*, also evidenced a larger decrease in weight (kg) ($M = 4.78$, $SD = 3.81$) than the standard of care treatment condition, *DASH 2 Wellness Only*, ($M = 1.47$, $SD = 2.57$).

Health Beliefs. Two one-way between groups MANOVAs were calculated, examining the effects of treatment condition on a set of 1) nutrition health beliefs and 2) physical activity health beliefs.

Nutrition Health Beliefs. The first MANOVA performed to investigate differences in nutrition health beliefs included five dependent variables, changes in Healthy Food Strategies, Healthy Food Social Support, Healthy Food Self-Efficacy, Negative Outcome Expectancy, and Positive Outcome Expectancy (Table 3). Once again, preliminary assumption testing was conducted to check for normality, linearity, homogeneity of variance-covariance matrices, and multicollinearity, with no serious violations noted. No significant difference between the treatment conditions on the combined dependent variables were found, $F(5,14) = 1.92, p = .155$; Wilks' $\lambda = .59$; canonical correlation = .64. When the results for the dependent variables were considered separately, the only difference to reach statistical significance, change in self-regulation of nutrition, or healthy food strategies ($p = .007, \eta^2 = .40$).

An inspection of the mean scores indicated that the intervention group, *DASH 2 Wellness Plus*, evidenced a larger increase in self-regulation/strategies change ($M = 1.29, SD = 0.71$) than the standard of care treatment condition, *DASH 2 Wellness Only*, ($M = 0.34, SD = 0.69$).

Physical Activity Health Beliefs. The second MANOVA was calculated, examining the effects of treatment condition on a set of physical activity health beliefs and included five dependent variables: changes in PA Self-Regulation, PA Social Support, PA Self-Efficacy, PA Negative Outcome Expectancy, and PA Positive Outcome Expectancy (Table 4). Once again, preliminary assumption testing was conducted to check for normality, linearity, homogeneity of variance-covariance matrices, and multicollinearity, with no serious violations noted. A significant effect was found for treatment condition, $F(5,14) = 3.32, p = .035$; Wilks' $\lambda = .46$; canonical correlation = .77, on the combined PA measures. When the results for the dependent variables were considered separately, one PA health beliefs measure was statistically significant, self-regulation for PA ($p = .001, \eta^2 = .55$).

An inspection of the mean scores indicated that the intervention group, *DASH 2 Wellness Plus*, evidenced a larger increase in change of PA self-regulation change ($M= 1.78$, $SD= 0.75$) than the standard of care treatment condition, *DASH 2 Wellness Only*, ($M= 0.55$, $SD= 0.57$).

Lifestyle Behaviors and Health Beliefs Outcomes Correlations

Correlations between measured variables (Table 5) highlight additional significant relationships. A decrease in weight was significantly correlated with a decrease in systolic BP, ($r=.49$, $p=.028$), and with an increase in F&V, ($r=.50$, $p=.026$). An increase in steps/day was significantly correlated with decreased systolic BP, ($r=.66$, $p=.001$). Increased PA self-regulation was significantly correlated with increased healthy foods self-regulation, ($r=-.54$, $p=.013$), and with decreased PA negative outcome expectancy, ($r=-.55$, $p=.011$). Increased PA positive outcome expectancy was significantly correlated with increased PA self-regulation, ($r=-.58$, $p=.007$).

Discussion

The primary purpose of this current project was to develop, implement, and evaluate a lifestyle modification intervention as a nonpharmacologic approach to lower BP in middle-aged adults with prehypertension. A principal objective was to assess if an approach could accomplish changing key health behaviors and lowering BP comparable to the standard of care without extensive personal contact. The project emphasized self-regulation and used an electronic therapeutic course as an avenue for supporting continued health behavior change in the prevention of hypertension and CVD risk. Primary and secondary outcomes comparing group's behavior change and change in health beliefs from baseline to post intervention were tested via 3 MANOVAs. Analyses demonstrated a significant difference between conditions on lifestyle

behaviors, systolic blood pressure, and physical activity health beliefs but not for nutrition health beliefs.

Lifestyle Behavior Outcomes

For lifestyle behaviors, as hypothesized, the *D2W Plus* treatment condition evidenced a larger increase in average daily steps, a larger decrease in weight (kg), and a larger decrease in systolic BP change (mmHg) than the standard of care treatment condition, *D2W Only*. *D2W Plus* condition evidenced a 2900 average increase in daily steps compared to a 636 daily step increase in the *D2W Only* condition. Overall, *D2W Plus* participants were close to reaching their program goal of 3000 steps over baseline; according to verbal reports and weekly Wellness Tracker data, many accomplished this goal primarily by gradually increasing their PA through planned walks but also by engaging in lifestyle activities, such as taking the stairs and parking further away from retail or work locations. In addition, *D2W Plus* showed a mean 4.55 kg (10 lbs) weight loss versus the *D2W Only* mean loss of 1.36 kg (3 lbs.). Traditionally, it has been quite difficult to have people maintain a PA regimen, especially for longer than 6 months. Even PA trials have only been modestly effective (Marcus et al., 2006; Sallis et al., 2006). Therefore, it is likely even more difficult for medical providers to help people increase PA because medical personnel are in less frequent contact with patients and because increasing patients' PA is not traditionally a primary goal in treatment. However, increasing PA should remain a priority as a recent meta-analysis of BP and aerobic exercise (Whelton et al., 2002) found significant changes in BP even with minimal weight loss.

Lifestyle behaviors to reduce bodyweight are perhaps the most difficult to change and sustain. However, research suggests the benefits of weight loss on blood pressure, specifically in prevention of hypertension, are long-lasting, as demonstrated by TOHP's weight loss group that

evidenced a 77% reduction in odds for hypertension at 7 year follow-up (Trials of Hypertension Prevention, TOHP: He, Whelton, Appel, Charleston, & Klag, 2000). Moreover, the health and quality of life benefits of weight loss extend well beyond hypertension prevention. *D2W Plus* weight loss may be best explained by the increased PA and decreased average daily kilocalories (*D2W Plus*: $M=-341.44$, $SD=1053.49$ & *D2W Only*: $M=-235.36$, $SD=399.18$). Therefore, *D2W Plus* expended about 1050 kcals/week with their 3000 steps/day increase, and participants reported consuming about 2380 fewer kcals/week for a combined 3430 kcal/week deficit (3500 kcal/week deficit is needed for a 1 lb loss /week). These data support the fidelity of the program in that *D2W Plus* participants lost 10 lbs in 10 weeks.

All *D2W Plus* participants moved from the prehypertensive category to a normal, even optimal BP category except for one participant whose post BP was 121/74; whereas, 5 of 11 *D2W Only* participants evidenced reductions to fall into the normal BP range and the remaining 6 participants' BPs remained in the prehypertensive category. In sum, results are consistent with a recent meta-analysis comprising 25 RCTs ($N=4874$) demonstrating $-4.4/-3.6$ mmHg and approximately a 5 kg reduction via increased PA, restricted diet, or both increased PA or restricted diet (Neter, Stam, Kok, Grobbee, & Geleijnse, 2003).

While conditions did not significantly differ on daily sodium reduction or fruit and vegetable increase, *D2W Plus* evidenced a larger decrease in average sodium (mg) intake, ($M= 932.22$, $SD= 1019.22$) than *D2W Only*, ($M= 423.64$, $SD= 749.15$) and a larger increase in average daily fruit and vegetable intake, ($M= 2.10$, $SD= 1.73$) than *D2W Only*, ($M= 1.02$, $SD= 2.24$). There may be some reasons why these differences were not significant. Prior to randomization, *all* participants received DASH counseling and were provided with educational materials which detailed specific goals, i.e. ideal sodium intake, and even provided an avenue for

reaching these goals, e.g. strategies for increasing fruits and vegetables and healthy alternatives for increasing low-fat dairy and lean protein. *D2W Plus* additionally received weekly newsletter support and feedback to augment the initial DASH counseling. While *D2W Plus* were close to reaching program goals averaging 7.2 fruits and vegetables per day (including outliers, ~9 F&V/day) and to meeting daily sodium goal of 2400mg with 2792 mg/day, *D2W Only* increased to 5.4 F&V/day and decreased sodium to average 2568 mg/day. Therefore, it would seem *D2W Plus*'s key changes in BP largely occurred through increased PA and decreased weight, likely a combination of PA and calorie reduction via improved food choices, i.e. more F&V. Engaging in healthy eating and sodium reduction may require more specific or structured guidance, similar to that provided for engaging in PA and weight loss efforts.

Health Belief Outcomes

Conditions were also significantly different based on change in health beliefs for physical activity, as *D2W Plus* evidenced a larger increase in change of PA self-regulation change than *D2W Only*; *D2W Plus* went from *seldom/occasionally* to *often/repeatedly* using strategies versus *D2W Only* which went from *occasionally* to *occasionally/often* using strategies. Self-regulation strategies included PA planning, tracking, monitoring, and goal-setting. Changes in PA Social Support, PA Self-Efficacy, PA Negative Outcome Expectancy, and PA Positive Outcome Expectancy did not significantly contribute to overall group differences.

Specifically, changes in PA self-regulation (SR) were significantly correlated to changes in other PA health beliefs and suggests negative PA outcome expectancy (OE) may decrease as actual SR strategies are employed, and that lower SR is associated with having lower positive PA OE. Daily sodium intake seemed to be particularly linked to PA health beliefs, and suggest sodium reduction occurred with increased PA self-efficacy and higher PA positive OE.

It was expected conditions would be significantly different based on nutrition health beliefs. While overall results of group differences were not significant, an inspection of the mean scores indicated *D2W Plus* evidenced a larger increase in change of self-regulation/healthy food strategies than *D2W Only*; *D2W Plus* went from *seldom/occasionally* to *often* using strategies versus *D2W Only* which went from *occasionally* to *occasionally/often* using strategies. Strategies included regulating calories and fat, planning and tracking, and regulating fiber, fruits, and vegetables. Changes in Healthy Food Social Support, Healthy Food Self-Efficacy, Negative Outcome Expectancy, and Positive Outcome Expectancy did not significantly contribute to overall group differences. However, it is notable that significant differences between groups on nutrition health beliefs may be partially captured by the strength of relationship with PA self-regulation.

Strengths and Limitations

These clinical interpretations must be considered within the limitations of the design. Controlling for demographic and other characteristics potentially impacting BP in analyses was limited given the small number of observations. The strength of the intervention compensated for the small sample size in terms of power, as some effects of the intervention remained statistically detectable. In addition, the comparison for *D2W Plus* was a standard of care program, not an untreated control group, which further demonstrates the efficacy of the *D2W* intervention. However, an additional concern pertaining to a small N study is that with such sample sizes and intensive contact, experimenter and participant effects are plausible. In efforts to control for such bias, participants were not initially randomized to condition until after baseline assessments were completed; the nutritionist was blind to assigned condition, assessors were blind to assigned condition at 5-week assessment, and some assessors were blind at post. *D2W Plus* participant's

weekly feedback was based on general scripts and only individualized to reflect a participant's weekly reported averages in order to increase the likelihood that the content of the contact was the source of change, and not other aspects of personal contact. Limitations with external validity may exist as individuals self-selected for study participation.

Conclusion

A primary aim of this project was to systematize the standard of care for the behavioral treatment of prehypertension in adults and to provide further support for the additive effects of combining two (or more) lifestyle modifications in lowering BP (Writing Group of the PREMIER Collaborative Research Group, 2003; NIH, 2004). Strengths of the study include the standardization of measurement, random assignment after assessment, the one-on-one DASH education, the equipment and tools provided to participants, and the comparison group as a good quality usual care approach.

The framework of the current study recognizes multiple components contribute and maintain the condition of prehypertension; therefore, it emphasizes a multicomponent approach to management and prevention of progression to stage 1 hypertension. Broadly, such an approach can improve our understanding of the cognitive and behavioral processes that accompany adoption and adherence to lifestyle change, which are essential to alleviating the burden of many chronic diseases. More specifically, this study demonstrates how a tailored electronic intervention may be successful in guiding individuals through improvement of multiple lifestyle and health behaviors while remaining time and cost-efficient. A next step would include a larger N, would have a longer timeline for treatment and then fading treatment, and include a long-term follow-up to appropriately examine maintenance. A venue suitable for such a trial would be a major medical center or primary care clinic. Adding a control condition

and considering separate intervention components may also be beneficial, e.g. comparing those involved with HBPM vs. those without or altering specific nutritional outcomes.

Technology-based interventions may be preferable for people who do not think they need treatment and, therefore, do not receive treatment, or for people who do not prefer more typical medical treatment. Electronic or technology-based interventions may also be preferable because these interventions can be immediately directive, individualized and aid in proactive self-care likely better than a completely self-help behavior change approach. Interventions with an electronic therapeutic course may require more *active* participation from an individual than typical participation in medical or completely self-help approaches. A primary benefit includes the ability to guide individuals through health behavior change in such a way that is research-supported and shown to be an effective means to change, such as Social Cognitive Theory, especially improved self-regulation skills (Bandura, 2004). An additional benefit for the interventionist is that the data on treatment progression is immediate, and for the participant, an emphasis can be placed on skill generation, maintenance, and generalization.

Generally, there is limited use of similar computerized participant management systems; however, recent research suggests programs can be clinically effective for reducing BP (Bavikati, Sperling, Salmon, Faircloth, Gordon, & Franklin et al., 2008) and just as effective at cardiovascular risk reduction compared to a physician- and nurse- supervised program and a contemporary phase 2 cardiac rehab program (Gordon, English, Contractor, Salmon, Leighton, & Franklin et al., 2002). In the former, however, there was no control group and regression toward the mean may partially explain results. Nevertheless, with no long-term follow-up and no BP-related diet (i.e., DASH or low-sodium), results remained clinically relevant, i.e., people

(n=2082) with prehypertension decreased SBP 7(12) mmHg and DBP 6(3) mmHg, and the intervention required little oversight and included no direct medical involvement.

Future clinical research should have a two-fold focus: 1) making dissemination more feasible through the systemization of programs that could be used in diverse settings, and 2) prescribing recommended BP lifestyle modifications and emphasizing incremental changes, self-monitoring of not only diet, PA, but also of BP and weight. To reduce systolic BP in the population by an estimated 5 mmHg would translate to a 14% reduction in mortality caused by stroke, 9% caused by coronary heart disease, and 7% in all-cause mortality (Whelton et al., 2002; Stamler, 1991). Therefore, reducing risk in the prehypertensive population warrants continued efforts. In addition, focusing on lifestyle modifications will benefit individuals in managing other risk factors and controlling coexisting problems which contribute to overall cardiovascular risk and compounds the risk from hypertension (i.e. obesity & type II diabetes, high cholesterol and increased high-density lipoprotein, and others) (NIH, 2004). There is need to further evaluate a systematized standard of care for the treatment of prehypertension, to develop and test the efficacy of interventions not requiring extensive face-to-face individual or group contact, which is evidenced based, and builds on prior work, especially with recommended BP lifestyle modifications, including BP self-monitoring. Concentrating efforts not only towards adoption and initiation but also towards the provision of innovative risk-reduction strategies for long-term maintenance of a healthy lifestyle once initial changes have been accomplished is paramount.

References

- Anderson, E.S., Wojcik, J.R., Winnett, R.A., & Williams, D.A. (2006). Social Cognitive Determinants of Physical Activity: The Influence of Social Support, Self-Efficacy, Outcome Expectations, and Self-Regulation. *Health Psychology, 24* (4), 510-520.
- Anderson, E.S., Winnett, R.A., & Wojcik, J.R. (2007). Self-Regulation, Self-Efficacy, Outcome Expectations, and Social Support: Social Cognitive Theory and Nutrition Behavior (2007). *Annals of Behavioral Medicine, 34* (3), 304-311.
- Agency for Healthcare Research and Quality (2004). *Prehypertension is a Considerable Health Risk, Particularly for People Age 45 and Over*. Agency for Healthcare Research and Quality, Rockville, MD. Retrieved on May 30, 2007 from <http://www.ahrq.gov/news/press/pr2004/prehyppr.htm>
- Bandura, A. (2004). Health promotion by social cognitive means. *Health Education and Behavior, 31*, 143-164.
- Bassett, D.R., Jr, Ainsworth, B.E., Leggett, S.R., Mathien, C.A., Main, J.A., Hunter, D.C., & Duncan, G.E. (1996). Accuracy of five electronic pedometers for measuring distance walked. *Medicine & Science in Sports Exercise, 28*, 1071-1077.
- Beck, A.T., Steer, R.A., Ball, R., & Raneiri, W. (1996). Comparison of Beck Depression Inventories –IA and –II in psychiatric outpatients. *Journal of personality assessment, 67* (3), 588-597.
- Burt, V.L., Whelton, P., Roccella, E.J., Brown, C., Cutler, J.A., Higgins, M., Horan, M.J., & Labarthe, D. (1995). Prevalence of hypertension in the US adult population. Results from the Third National Health and Nutrition Examination Survey, 1988-1991. *Hypertension, 25*(3), 305–313.
- Cappuccio, F.P., Kerry, S.M., Forbes, L., & Donald, A. (2004). Blood pressure control by home monitoring: meta-analysis of randomised trials. *British Medical Journal, 329*:499.
- Centers for Disease Control (CDC) (2007). U.S. Obesity Trends form 1985-2006. Retrieved on August 30, 2007 from <http://www.cdc.gov/nccdphp/dnpa/obesity/>
- Cook, N. (2005). NHLBI Research Highlights at American Heart Association’s Scientific Sessions: Findings on Women and Heart Disease, Metabolic Syndrome in African Americans, Impact of Sodium Reduction on Risk of Cardiovascular Disease or Death. Retrieved on May 30, 2007 from <http://www.nhlbi.nih.gov/new/press/05-11-15b.htm>
- Cornelissen, V.A. Fagrad, R.H. (2005). Effects of endurance training on blood pressure, blood pressure-regulating mechanisms, and cardiovascular risk factors. *Hypertension, 46*, 667-675.

- DASH Collaborative Research Group (1997). A clinical trial of the effects of dietary patterns on blood pressure. *New England Journal of Medicine*, 336, 1117-1124.
- DASH Collaborative Research Group (1999). Dietary Approaches to Stop Hypertension: Rationale, Design, and Methods. *Journal of American Dietetic Association*, 99, S12-S18.
- DASH Investigators (1995). Rationale and Design of the Dietary Approaches to Stop Hypertension Trial (DASH): A Multicenter Controlled-Feeding Study of Dietary Patterns to Lower Blood Pressure. *Annals of Epidemiology*, 5(2), 108-118.
- Davy, B.M., Melby, C., Beske, S.D., Ho, C.R., Davrath, L.R., Davy, K.P. (2002). Oat Consumption Does Not Affect Resting Casual and Ambulatory 24-H Arterial Blood Pressure in Men with High-Normal Blood Pressure to Stage 1 Hypertension. *Journal of Nutrition*, 132, 394-398.
- Giles, T.D., Berk, B.C., Black, H.R., Cohn, J.N., Kostis, J.B., Izzo, J.L., & Weber, M.A., (2005). *Journal of Clinical Hypertension*, 7, 505-512.
- Hajjar, I., Kotchen, J.M., & Kotchen, T.A. (2006). Hypertension: Trends in Prevalence, Incidence, and Control. *Annual Review of Public Health*, 27, 465-490.
- Haskell, W.L., Lee, I. Pate, R.R., Powell, K.E., Blair, S.N., Franklin, B.A., Macera, C.A., Heath, G.W., Thompson, P.D., Bauman, A. (August 1, 2007). Physical Activity and Public Health: Updated Recommendation for Adults from the American College of Sports Medicine and the American Heart Association. Retrieved in February 2009 from www.acsm.org.
- Halbert, J.A., Silagy, C.A., Finucane, P., Withers, R.T., Hamdorf, P.A., & Andrews, G.R. (1997). The effectiveness of exercise training in lowering blood pressure: a meta-analysis of randomized controlled trial of 4 weeks or longer. *Journal of Human Hypertension*, 11, 641-649.
- He, J., Whelton, P.K., Appel, L.J., Charleston, J., & Klag, M.J. (2000). Long-term effects of weight loss and dietary sodium reduction on incidence of hypertension. *Hypertension*, 35, 544-549.
- Izzo, J.L. (2007). Prehypertension: Demographics, Pathophysiology, and Treatment. *Current Hypertension Reports*, 9, 264-268.
- Kshirsagar, A.V., Carpenter, M., Bang, H., Wyatt, S.B., Colindres, R.E. (2006). Blood pressure usually considered normal is associated with an elevated risk of cardiovascular disease. *American Journal of Medicine*, 119, 133-141.
- Lawes, C.M.M., Vander Hoorn, S. & Rodgers, A. (2008). Global burden of blood-pressure-related disease. *The Lancet*, 371, 1513-18.

- Lawes, C.M.M., Vander Hoorn, Law, M.R., Elliot, P., MacMahon, S., & Rodgers, A. (2006). Blood pressure and the global burden of disease 2000. Part II: Estimates of attributable burden. *Journal of Hypertension*, 24, 423-430.
- Mahan, L.K., & Escott-Stump, S. (2004). *Krause's Food, Nutrition, & Diet Therapy (11th Edition)*. Philadelphia, PN: Saunders.
- Marcus, B.H., Williams, D.M., Dubbert, P.M., Sallis, J.F., King, A.C., Yancey, A.K. et al., (2006). Physical Activity Intervention Studies: What we know and what we need to know. *Circulation*, 114, 2739-2752.
- Mattes, R.D. (1997). The taste for salt in humans. *American Journal of Clinical Nutrition*, 65, 692S-697S.
- Mayo Foundation for Medical Education & Research (2006). High Blood Pressure: Prehypertension. Retrieved on May 30, 2007 from <http://www.mayoclinic.com/health/prehypertension>
- Michigan Diabetes Research and Training Center (MDRTC) (2007). Risk Perceptions Survey for Developing Diabetes (RPS-DD). Retrieved on August 30, 2007 from <http://www.med.umich.edu/mdrtc/survey/index.html>
- Mitka, M. (2007). DASH Dietary Plan Could Benefit Many, But Few Hypertensive Patients Follow It, *Journal of American Medical Association*, 298(2), 16-165.
- Morris, M.C., Sacks, F., & Rosner, B. (1993). Does fish oil lower blood pressure? *Circulation*, 88, 523-533.
- National Institutes of Health (NIH) (2004). The Seventh Report of the Joint National Committee on Prevention, Evaluation, and Treatment of High Blood Pressure (NIH Publication No. 04-5230). Bethesda, MD: National Heart, Lung, and Blood Institute (NHLBI) Information Center.
- Neter, J.E., Stam, B.E., Kok, F.J., Grobbee, D.E., & Geleijnse, J.M. (2003). Influence of Weight Reduction on Blood Pressure: A meta-analysis of Randomized Controlled Trials. *Hypertension*, 42,878-884.
- Obarzanek, E., Vollmer, W.M., Lin, P., Cooper, L.S., Young, D.R., Ard, J.D., Stevens, V.J., Simons-Morton, D.G., Svetkey, L.P., Harsha, D.W., Elmer, P.J., & Appel, L.J. (2007). Effects of Individual Components of Multiple Behavior Changes: The PREMIER Trial. *American Journal of Health Behavior*, 31 (5), 545-560.
- Pacini, R., Patel, D.R., Bavikati, V., & Sperling, L.S. (2008). Prehypertension: Detection Evaluation, and Management. *Current Treatment Opinions in Cardiovascular Medicine*, 10, 273-282.

- Pickering, T.G., Miller, N.H., Ogedegbe, G., Krakoff, L.R., Artnian, N.T., & Goff, D. (2008). Reimbursement for Home Blood Pressure Monitoring: A Joint Scientific Statement From the American Heart Association, American Society of Hypertension, and Preventive Cardiovascular Nurses Association. *Journal of Cardiovascular Nursing*, 23(4), 299-323.
- PREMIER Collaborative Research Group (2006). Effects of Comprehensive Modification on Diet, Weight, Physical fitness, and blood Pressure, Control: 18-month Results of A Randomized Trial. *Annals of Internal Medicine*, 144(7), 485-495.
- Quereshi, A.I., Suri, M.F., Kirmani, J.F., Divani, A.A. (2005). Prevalence and trends of prehypertension and hypertension in United States: National Health and Nutritional Examination Surveys 1976-2000. *Medical Science Monitor*, 11, CR403-409.
- Rosendorff, C., Black, H.R., Cannon, C.P., Gersh, B.J., Gore, J., Izzo, J.L., Kaplan, N. M., O'Connor, C.M., O'Gara, P.T., Oparil, S. (2007). Treatment of Hypertension in the Prevention and Management of Ischemic Heart Disease: A Scientific Statement From the American Heart Association Council for High Blood Pressure Research and the Councils on Clinical Cardiology and Epidemiology and Prevention. *Circulation*, 115, 2761-2788.
- Rudd, P., Miller, N.H., Kaufman, J., Kraemer, H.C., Bandura, A., Greenwald, G., & Debusk, R.F. (2004). Nurse Management for Hypertension. *American Journal of Hypertension*, 17, 921-927.
- Sallis, J.F., Cervero, R.B., Ascher, W., Henderson, K.A., Kraft, M.K., & Kerr, J. (2006). An Ecological Approach to Creating Active Living Communities. *Annual Review of Public Health*, 27, 297-322.
- Slentz, C.A., Houmard, J.H., & Kraus, W.E. (2007). Modest Exercise Prevents the Progressive Disease Associated with Physical Inactivity. *Exercise and Sport Sciences Reviews*, 35(1), 18-23.
- Stamler, R. (1991). Implications of the INTERSALT study. *Hypertension*, 17, 116-20.
- Svetky, L.P., Erlinger, T.P., Vollmer, W.M., Feldstein, A., Cooper, L.S., & Appel, L.J., Ard, J.D., Elmer, P.J, Harsha, D., & Stevens, V.J. (2005). Effect of Lifestyle modifications on blood pressure by race, sex, hypertension status and age. *Journal of Human Hypertension*, 19, 21-31.
- Swain, J.F., Rouse, I.L., Curley, C.B., & Sacks, F.M. (1990). Comparison of the effects of oat bran and low-fiber wheat on serum lipoprotein levels and blood pressure, *New England Journal of Medicine*, 322, 147-152.
- Tudor-Locke, C. & Bassett, Jr., D.A. (2004). How many steps per day are enough? Preliminary pedometer indices for public health. *Sports Medicine*, 34(1), 1-8.

- United States Department of Health and Human Services (USDHHS) (2006). National Heart Lung and Blood Institute: Diseases and Conditions Index. Retrieved on May 30, 2007 from http://www.nhlbi.nih.gov/health/dci/Diseases/Hbp/HBP_WhatIs.html.
- United States Department of Health and Human Services (2000). Healthy People 2010: Understanding and Improving Health. Washington DC: U.S. Government Printing Office.
- United States Department of Health and Human Services (1999). The 1996 Surgeon General's Report on Physical Activity and Health. Atlanta: National Center for Chronic Disease Prevention and Health Promotion. Retrieved on August 1, 2005, from <http://www.cdc.gov/nccdphp/sgr/order.htm>.
- Vander Weg, M.W., Klesges, R.C., Ebbert, J.O., Lichty, E.J., DeBon, M., North, F., Schroeder, D.R., & Dubbert, P.M. (2008). Trial design: Blood pressure control and weight gain prevention in prehypertensive and hypertensive smokers: the treatment and prevention study. *Contemporary Clinical Trials*, 29, 281-292.
- Wetzel, G.E.C., Nelemans, P.J., Schouten, J, S.A.G., Dirksen, C.D., van der Weijden, T., Stoffers, H.E.J.H., Jankegt, R., de Leeuw, P.W., & Prins, M.H. (2007). Electronic Monitoring of Adherence as a Tool to Improve Blood Pressure Control: A Randomized Controlled Trial. *American Journal of Hypertension*, 20, 119-125.
- Whelton, P.K., Chin, A., Xin, X., & He, J. (2002a). Effect of aerobic exercise on blood pressure: a meta-analysis of randomized controlled trials. *Annals of Internal Medicine*, 136, 493-503.
- Whelton, P.K., He, J., Appel L.J., Cutler, J.A., Havas, S. Kotchen, T.A., T. A., Roccella, E. J., Stout, R., Vallbona, C., Winston, M. C., and Karimbakas, J. (2002b). Primary prevention of hypertension: clinical and public health advisory from The National High Blood Pressure Education Program, *Journal of American Medical Association*, 288, 1882-1888.
- World Health Report (2002). Reducing risks, promoting healthy life. Geneva, Switzerland: World Health Organization. Retrieved on May 30, 2007 from <http://www.who.int/whr/2002/>
- Writing Group of the PREMIER Collaborative Research Group (2003). Effects of Comprehensive Lifestyle Modification on Blood Pressure Control: Main Results of the PREMIER Trial. *Journal of American Medical Association*, 289(16), 2083-2093.
- Yamasue, K., Tochikubo, O., Kono, E., Meada, H. (2006). Self-monitoring of home-blood pressure with estimation of daily salt intake using a new electrical device. *Journal of Human Hypertension*, 20. Retrieved on June 4, 2007 from <http://www.nature.com/jhh/index.html>

Figure 3. Consort Diagram.

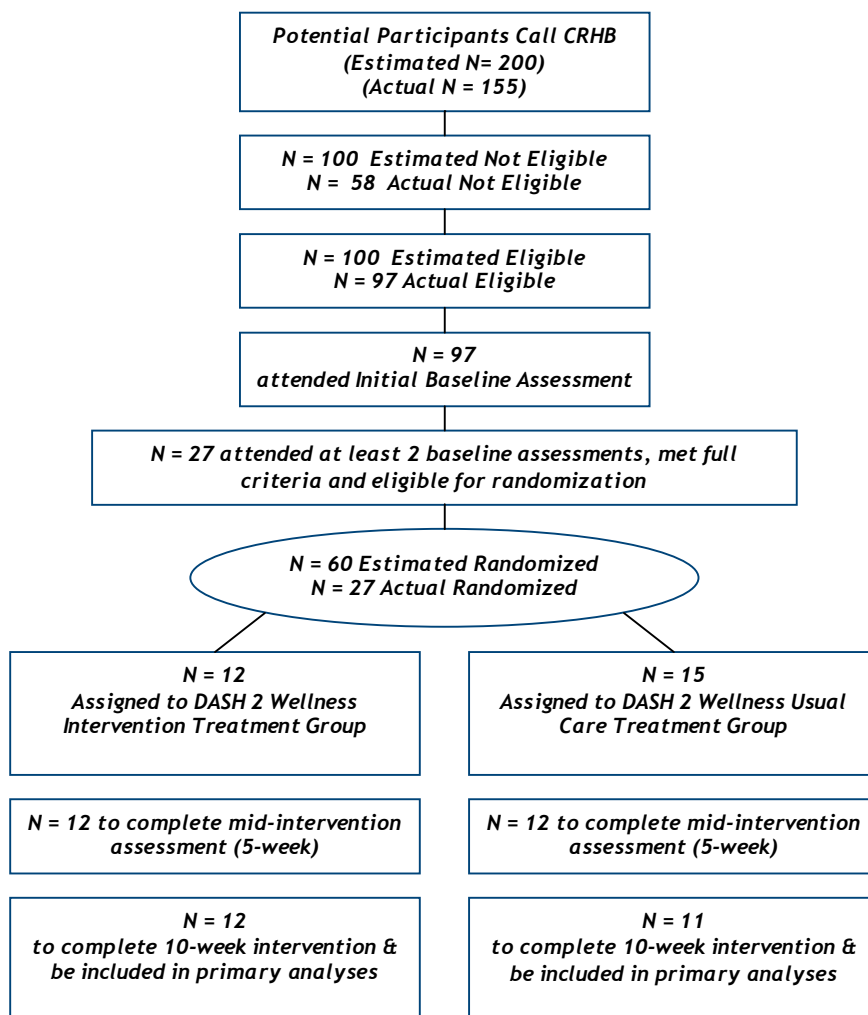


Table 3. Demographics

Demographic Characteristic	Participant Data (N= 23)
Age	54.3 years
Gender	
Female	16
Male	7
Weight	87.80 kg (193.56 lbs)
BMI	31.48
Marital Status	
Married	19
Single	2
Divorced	2
Ethnicity	
Caucasian	22
Mexican American	1
Education	
High School	2
Some College	9
4 Year College	2
Masters Degree	2
Post Masters	8
Income	
20,001-30,000	1
30,001-40,000	3
40,001-50,000	0
50,001-60,000	4
60,001-70,000	0
70,001-80,000	2
80,001-90,000	6
Greater than 90K	6
N/A	1
Daily Steps	6507
Average SBP/DBP	127/75
Average Daily F&V	4.6
Average Daily Sodium	3364.53

Table 4. Changes in Clinical Outcome Measures in Dash 2 Wellness

Outcome Measures	Dash 2 Wellness Only			Dash 2 Wellness Plus		
	Baseline	Post	Change	Baseline	Post	Change
Weight (lbs.)	183.02 (32.58)	179.80 (33.72)	3.23 (5.66)*	200.57 (40.27)	190.02 (37.35)	10.54 (8.39)*
Steps/day	6661.02 (2425.87)	7297.40 (2426.74)	636.39** (1653.26)	6419.58 (3640.02)	9319.72 (3737.14)	2900.14** (1903.83)
Systolic BP(mmHg)	125.28 (7.4)	120.66(8.95)*	4.61 (8.28)**	127.27 (4.4)	112.42 (4.8)*	15.14(4.33)**
F & V/day	4.43 (1.82)	5.45 (2.08)	1.02 (2.24)	5.10 (2.29)	7.21 (2.99)	2.10 (1.73)

Values expressed as *Means (SD)*.
* indicates significant difference between conditions at $p < .05$
** indicates significant difference between conditions at $p < .01$

Table 5. Changes in Nutrition Health Beliefs in Dash 2 Wellness

Outcome Measures	Dash 2 Wellness Only			Dash 2 Wellness Plus		
	Baseline	Post	Change	Baseline	Post	Change
1. Healthy Food Strategy	3.32 (0.73)*	3.57 (0.46)	0.34 (0.69)**	2.56 (0.41)*	3.85 (0.56)	1.29 (0.71)**
2. Healthy Food Social Support	2.95 (0.51)	3.02 (0.78)	0.06 (0.60)	3.04 (0.52)	3.09 (0.58)	0.04 (0.45)
3. Healthy Food Self-Efficacy	8.69 (0.99)	8.66 (0.64)	-0.03 (0.74)	7.97 (1.01)	8.02 (1.18)	0.05 (1.02)
4. Healthy Food Negative OE	2.64 (0.63)	2.41 (0.49)	0.23 (0.57)	3.01 (0.58)	2.80 (0.51)	0.21 (0.53)
5. Healthy Food Positive OE	4.51 (0.39)	4.40 (0.41)	-0.11 (0.54)	4.33 (.45)	4.26 (0.53)	-0.08 (0.40)

Values expressed as *Means (SD)*.
* indicates significant differences between conditions at $p < .05$
** indicates significant differences between conditions at $p < .01$

Table 6. Changes in Physical Activity Health Beliefs in Dash 2 Wellness

Outcome Measures	Dash 2 Wellness Only			Dash 2 Wellness Plus		
	Baseline	Post	Change	Baseline	Post	Change
1. PA Self-Regulation	3.21 (1.18)	3.76 (0.88)	0.55 (0.57)***	2.46 (1.04)	4.24 (0.68)	1.78 (0.75)***
2. PA Social Support	3.41 (0.54)	3.44 (0.78)	0.30 (0.68)	3.50 (0.56)	3.41 (0.63)	-0.93 (0.58)
3. PA Self-Efficacy	8.01 (1.44)	7.66 (1.23)	-0.35 (0.86)	7.85 (0.90)	7.50 (1.23)	-0.35 (1.16)
4. PA Negative OE	2.85 (0.61)	2.80 (0.60)	0.06 (0.76)	3.35 (0.62)	3.04 (0.48)	0.31 (0.62)
5. PA Positive OE	4.51 (0.35)	4.45 (0.35)	-0.05 (0.30)	4.50 (0.30)	4.19 (0.42)	-0.32 (0.44)

Values expressed as *Means (SD)*.
 *** indicates significant differences between conditions at $p < .001$

Table 7. Lifestyle Behaviors and Health Beliefs Outcomes Correlations

	age	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	
age	1.000																		
1. BMIChng	-.094	1.000																	
2. WeightChg	-.065	.995**	1.000																
3. StepChg	.382	.248	.277	1.000															
4. SysChng	.137	.500*	.490*	.663**	1.000														
5. Na_change	-.176	.336	.316	.254	.240	1.000													
6. FVChange	.059	.489*	.495*	.319	.348	.229	1.000												
7. kcalchng	.520*	-.205	-.160	.118	.011	-.713**	-.090	1.000											
8. HFSCChng	-.237	.650**	.631**	.158	.442	.394	.354	-.532*	1.000										
9. HFSSc	.207	.085	.045	-.008	.189	.288	.222	-.349	.198	1.000									
10. HFEChng	-.232	-.064	-.101	-.079	-.181	.580**	.116	-.550*	.301	.213	1.000								
11. POEChng	.223	.045	.043	.345	.114	.010	-.181	.224	-.049	-.188	-.001	1.000							
12. NOEChng	-.150	.407	.384	-.112	.028	.402	.114	-.257	.355	.336	.490*	-.107	1.000						
13. SRpaChng	.138	.276	.304	.268	.317	.337	.190	-.177	.543*	-.085	.190	-.065	.126	1.000					
14. PAssChng	-.167	.154	.138	.073	.145	.152	.077	-.391	.346	.433	.179	-.326	.270	.114	1.000				
15. SepaChng	.129	-.014	-.038	.174	-.097	.530*	-.050	-.188	.040	.144	.637**	.321	.442	-.034	-.087	1.000			
16. POEpaC	.101	-.413	-.437	-.212	-.277	-.464*	-.352	.162	-.346	-.009	-.022	.044	-.113	-.581**	-.137	.076	1.000		
17. NOEpaC	-.462*	.590**	.563**	.099	.368	.571**	.235	-.394	.554*	-.076	.448*	.072	.578**	.148	.168	.366	-.169	1.000	

Table 8. Baseline and Post Demographic and Outcomes Means and Standard Deviations Among Participants in Dash 2 Wellness Only and Dash 2 Wellness Plus

	<i>D2W Only (N=11)</i>				<i>D2W Plus (N=9)</i>			
	<i>Baseline</i>		<i>Post</i>		<i>Baseline</i>		<i>Post</i>	
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>
Age	52.91	5.21			56.00	5.17		
Body Weight (lbs)	183.02	32.58	179.79	33.71	200.57	40.27	190.02	37.35
Body Mass Index	29.99	3.66	29.38	3.85	33.20	4.14	31.51	4.30
Average Daily Steps	6661.01	2425.87	7297.40	2426.73	6419.58	3640.02	9319.72	3737.14
Fruit & Vegetables per day	4.43	1.83	5.45	2.08	5.10	2.29	7.21	2.99
Sodium Intake per day	2991.73	775.92	2568.09	984.06	3724.44	871.40	2792.22	1109.36
Kilocalories per day	1869.18	297.24	1633.82	373.86	2111.11	448.53	1769.67	921.00
Systolic BP	125.27	7.45	120.66	8.95	127.27	4.4	112.42	4.8
Diastolic BP	75.48	6.33	73.20	7.99	74.83	6.34	69.94	7.52
Healthy Foods SR Total	3.32	.73	3.57	.46	2.56	.41	3.85	.56
SR Calories & Fat	3.43	.63	3.82	.68	2.72	.69	3.83	.57
SR Planning	2.42	1.16	2.82		1.81	.56	3.43	
SR Fiber, F & V (FFV)	3.85	.82	4.09	.58	3.15	.65	4.30	.75
HF Social Support Total	2.95	.61	3.02	.78	3.04	.52	3.85	.56
Family Support- Fat	3.03	.86	2.93	.90	3.00	1.10	3.36	.99
Friend Support- Fat	3.18	.55	3.23	1.00	3.47	.34	3.33	.73
Family Support- FFV	2.55	.97	2.77	1.00	2.44	.88	2.61	1.17
Friend Support- FFV	3.05	.69	3.14	.98	3.28	.51	3.06	.58
HF Self-efficacy Total	8.69	.99	8.66	.64	7.97	1.01	8.02	1.18
SE for Decreased Fat	8.67	1.14	8.56	.97	8.03	1.19	7.85	1.83
SE for Decreased Sugar	8.56	1.04	8.49	.81	8.02	.94	7.98	.92
SE for Increased FFV	8.83	1.09	8.94	.85	7.87	1.22	8.24	1.18
HF Positive Outcome Exp	4.51	.39	4.40	.41	4.33	.46	4.26	.53
HF Negative OE	2.64	.63	2.41	.49	3.01	.58	2.80	.51
PA Self-Regulation Total	3.21	1.18	3.76	.88	2.46	1.04	4.24	.68
PA Social Support Total	3.41	.54	3.44	.78	3.50	.56	3.41	.63
PA Family Support	3.42	.92	3.52	1.01	3.16	1.03	3.78	.88
PA Friend Support	3.39	.73	3.36	.82	3.78	.88	3.59	.81
PA Self-Efficacy Total	8.01	1.44	7.66	1.23	7.85	.90	7.50	1.23
PA Self-Efficacy	8.22	1.39	7.54	1.46	8.15		7.95	1.52
SE to Overcome Barriers	7.80	1.68	7.31	1.55	7.54	1.23	7.15	2.21
PA Positive Outcome Exp	4.51	.35	4.45	.35	4.50	.30	4.19	.42
PA Negative OE	2.85	.61	2.80	.60	3.35	.62	3.04	.48

Appendix A

Medical Oversight for Adverse Events

In the case of an adverse event, participants were asked to take the following steps:

Call or have some responsible party call the research lab/project director; this will call be received or the person will leave a message, and once the person is reached will answer a series of questions regarding the adverse event and details surrounding the event; this information will be adequately documented; first, the study investigators will be contacted by the project director, who will at that point make an official decision as to whether the adverse event experienced by the participant warrants no action at all, simple instruction to forgo future occurrences, further medical attention, discontinuance from the intervention, or otherwise. If necessary, the participant's private MD or the medical director may be contacted.

Instances regarding blood pressure in which specific action and medical attention may have been required are detailed in below. They were used to guide researchers during assessments, and were included with the take-home BP monitor informing the *D2W Plus* participants to contact the project director immediately in any of the instances.

*If a participant had three or more readings on separate days over 140/90 (SBP or DBP), he/she should notify the study coordinator and also their private M.D., who will determine if additional medical intervention (i.e. medication) is warranted. In order for the participant to continue, it will be necessary to for the participant to obtain a note from the private MD stating he/she is allowed to continue with the program.

*If a participant has any readings over 170/100 (SBP/DBP), he/she should notify the project director immediately who will then schedule a time (within 24 hours) to officially recheck the values in the research lab to verify. The participant will also be encouraged see their private MD for follow-up. The project director will also ask for medical consent to contact the participant's private MD, in this case, to better inform them of the situation.

*If a participant reports a reading of $\geq 200/100$ (SBP/DBP), he/she is considered to be experiencing a "hypertensive emergency" (i.e., at risk for a stroke) and should go to the emergency room, or call their private MD immediately. Again, the participant will also be encouraged see their private MD for follow-up. The project director will also ask for medical consent to contact the participant's private MD, in this case, to better inform them of the situation.

In above scenarios, documentation of actions taken on behalf of the researchers and known actions taken on behalf of the participant would have been adequately noted. Also, if a participant did not have a private MD, he/she could have been referred to Dr. Rivero's office for a follow-up.

Appendix B

IRB Approval



Office of Research Compliance
 Institutional Review Board
 1880 Pratt Drive (0497)
 Blacksburg, Virginia 24061
 540/231-4991 Fax: 540/231-0959
 E-mail: moored@vt.edu
www.irb.vt.edu
 FWA00000572(expires 1/20/2010)
 IRB # is IRB00000667

DATE: August 2, 2007
 MEMORANDUM

TO: Richard A. Winett
 Ashley Dorough
 Brenda M. Davy

Approval date: 8/2/2007
 Continuing Review Due Date: 7/18/2008
 Expiration Date: 8/1/2008

FROM: David M. Moore

SUBJECT: **IRB Expedited Approval:** "DASH 2 Wellness: Effects of a Multi-Component Lifestyle Modification Program on Blood Pressure in Prehypertensive Middle-Aged Adults A Randomized Controlled Trial", IRB # 07-378

This memo is regarding the above-mentioned protocol. The proposed research is eligible for expedited review according to the specifications authorized by 45 CFR 46.110 and 21 CFR 56.110.

As Chair of the Virginia Tech Institutional Review Board, I have granted approval to the study for a period of 12 months, effective August 2, 2007.

As an investigator of human subjects, your responsibilities include the following:

1. Report promptly proposed changes in previously approved human subject research activities to the IRB, including changes to your study forms, procedures and investigators, regardless of how minor. The proposed changes must not be initiated without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subjects.
2. Report promptly to the IRB any injuries or other unanticipated or adverse events involving risks or harms to human research subjects or others.
3. Report promptly to the IRB of the study's closing (i.e., data collecting and data analysis complete at Virginia Tech). If the study is to continue past the expiration date (listed above), investigators must submit a request for continuing review prior to the continuing review due date (listed above). It is the researcher's responsibility to obtain re-approval from the IRB before the study's expiration date.
4. If re-approval is not obtained (unless the study has been reported to the IRB as closed) prior to the expiration date, all activities involving human subjects and data analysis must cease immediately, except where necessary to eliminate apparent immediate hazards to the subjects.

Important: If you are conducting **federally funded non-exempt research**, this approval letter must state that the IRB has compared the OSP grant application and IRB application and found the documents to be consistent. Otherwise, this approval letter is invalid for OSP to release funds.

Appendix C

Newspaper Advertisement

VIRGINIA POLYTECHNIC INSTITUTE
& STATE UNIVERSITY

PARTICIPANTS NEEDED:

Virginia Tech Research Study

We are conducting a weight loss and blood pressure reduction study in healthy middle-aged adults. Participants must be in good health, overweight, and between the ages 45-65. Participation will involve 5 visits to the Virginia Tech campus over a 3-month period of time. Participation will also involve weekly online sessions (i.e., emails, reporting & feedback) with the project director and will therefore require participants have access to the internet. For more information, please call Ashley Dorrough, MS at the Center for Research in Health Behavior with the Department of Psychology at Virginia Tech, 231-8747 or email Ashley at adorough@vt.edu. Please leave your name and daytime phone number.

Appendix D

Telephone Eligibility Screening Form: Prehypertension Study

Name _____ Date _____ Interviewer _____
 Address _____ Phone (H) _____ Availability: _____
 _____ (W) _____

Age _____
 *must be 45-65 yrs

Height _____ (in) x 2.54 = _____ (cm) / 100 = _____ (m) **BMI** _____ kg/m²
 Weight _____ (lbs) / 2.2 = _____ (kg) *must be ≥ 25 & ≤ 40

Are you currently weight stable (within about 5 pounds of current weight for past year?) _____
 Are you a smoker? N ___ Y ___ *must be weight stable and nonsmoker to participate

Current Medications (including over the counter):

Do you have a history of diabetes, heart, lung, or kidney disease, thyroid problems or cancer?

N ___ Y (explain) _____

Do you have a history of eating disorders or depression? N ___ Y (explain) _____

Do you have any food allergies or restrictions? _____

Past Medical History:

Do you drink alcohol? N ___ Y ___ if yes, how many drinks/week? _____

Do you use hormone replacement therapy? N ___ if Y, how long _____

This is a blood pressure and weight loss reduction study that would involve 5 visits to the Virginia Tech campus over 12 weeks. You will be randomly assigned to either one of two treatment groups: one will follow the DASH Eating Plan (a specific low-sodium diet, rich in fruits and vegetables) and will also follow a physical activity walking program. This group would receive weekly feedback on nutrition, exercise, and at-home blood pressure monitoring from the project director; or you may be assigned to the a standard of care treatment group, which will receive printed literature on the DASH Eating Plan. If you are assigned to this group, you will go through some of the testing but not receive the same weekly nutrition, exercise, and blood pressure monitoring feedback from the project director. However, if you are in the standard of care treatment group, you must continue with your usual physical activity level throughout the study. You will be asked to complete 2 initial, 1 mid-point, and 2 follow-up assessments at the research laboratory at Virginia Tech. The assessments would include tests of height, weight, and blood pressure. The assessments would include a health history form and various questionnaires to assess your motivation towards multiple health behaviors. You will be asked to record daily food intake, physical activity, blood pressure, and weight. All of the testing will be provided free of charge and you will receive your results at the end of the study.

Are you interested in participating? N ___ Y, schedule initial visit _____

*if yes: vehicle make _____ Model _____ License plate # _____

May we contact you for future studies? N ___ Y _____

Appendix E

Information Sheet & Consent Document Center for Research in Health Behavior Department of Psychology Virginia Tech University

TITLE: DASH 2 Wellness: Effects of A Multi-Component Lifestyle Modification Program on Blood Pressure in Prehypertensive Middle-Aged Adults
A Randomized Controlled Trial

INVESTIGATORS: Ashley E. Dorough, M.S.; Richard A. Winett, Ph.D.;
Brenda M. Davy, PhD, RD; Eileen S. Anderson, Ed.D.;
George Clum, Ph.D.; Emily Martin, B.A.

MEDICAL DIRECTOR: Jose Rivero, M.D.

Purpose

You are being asked to participate in an experimental research study. Before you agree to be a volunteer in our study, we want you to understand what your participation will involve. Please read this form thoroughly prior to your first visit and let us know if you have any questions about its contents. The following information describes the study and your role as a participant.

People over the age of 55 have a 90% increase in risk for developing high blood pressure. *Hypertension* is a medical condition characterized by chronically high blood pressure. Controlling high blood pressure and preventing the progression of hypertension can reduce a person's risk for heart disease, heart attack, stroke, and kidney disease. Making lifestyle changes such as eating a healthy diet, engaging in regular physical activity, and weight reduction can lower blood pressure. It is therefore important to study health behaviors in middle-aged and older adults and how these can delay or even prevent progression to hypertension and other chronic diseases.

Sixty people will participate in this study. To participate, you must be between the ages of 45 and 65, be prehypertensive (systolic blood pressure of 120-139 mmhg or diastolic blood pressure of 80-89 mmhg), and also overweight. If you smoke, if you have been told by a doctor that you have a major chronic disease, for example, diabetes, cancer, chronic lung disease, kidney disease or thyroid disease, or if you are taking drugs that could affect your blood pressure, weight or appetite, you may not participate in this study. If the questionnaires that you fill out for us suggest that you have an eating disorder or that you may be depressed, you will not be able to participate in the study. Finally, if you have food allergies you may not be able to participate.

Procedures

If you are interested in participating in this study, you will be required to visit the Center for Research Health Behavior for initial screening tests. You would be randomly assigned (like flipping a coin) to one of two groups.

One of these groups (*DASH 2 Wellness Plus* Group) will be prescribed a walking program, the DASH Eating Plan (a low-energy-dense, low-sodium diet), and at-home blood pressure monitoring to help with blood pressure and weight loss for a period of 10 weeks. This group will receive tailored planning, goal setting, and feedback on diet and physical activity through weekly electronic reporting and feedback interactions with the project director. The other group will

receive a standard form of care; individuals assigned to this group will undergo all study procedures, will also be asked to follow the DASH Eating Plan, and will be asked to not change their existing exercise habits.

There will be approximately 5 visits (2 initial, 1 mid-point, 2 follow-up sessions) to the Center for Research in Health Behavior. This is a research lab of Virginia Tech's Department of Psychology located in Collegiate Plaza at 460 Turner Street in Blacksburg, VA.

All of these visits will take place over a 3-month period. The actual number and order of visits may vary depending upon on your schedule and the availability of the study staff. All study procedures described in this document are done at no cost to participants.

Each week you will have electronic visits with your project director. She will support you in your lifestyle changes, provide you information on the DASH (Dietary Approaches to Stop Hypertension) eating plan and in an exercise walking program, provide assistance/guidance and feedback in planning, goal-setting, and tracking of various lifestyle behaviors including daily vegetable, fruit, and sodium intake, and daily weight, exercise, and self-monitored blood pressure readings, provide assistance trouble-shooting problems with adherence and with daily weight, food, exercise, and blood pressure monitoring.

On-Site Visits

Session 1 (2 hours): First we will explain the study to you, and have you read this information sheet. If you choose to participate, the following screening tests will be done:

Health History – You will be asked to complete a medical history questionnaire. This procedure is used to screen for pre-existing disease or other reasons you should not participate in this study. Your height and weight will also be measured at this time. Your body weight will be measured on a standard balance scale and will include the weight of light indoor clothing or hospital gown without your shoes.

Blood Pressure -You will be asked to sit quietly for 15 minutes. We will then measure your resting blood pressure using a stethoscope and standard blood pressure cuff and a professional blood pressure monitor.

Eating Habits and Depression Questionnaires – You will complete two questionnaires that will be used to assess your eating habits and feelings of depression. If your scores on these questionnaires suggest that you may be depressed or have an eating disorder, you will be provided with contact information for the VT Psychological Services Center at 231-6914. You would be responsible for any costs related to follow-up care, if you decide to seek it.

4-Day Food Record- You will be given instructions for how to record your food and beverage intake for four consecutive days. This may take you about 10-15 minutes total time each day. You will turn this in at the next visit.

Physical Activity Record & Food Diary- You will be asked to track/record your steps and food intake throughout the program. This will be what you report to the project director and what you will receive direct and personal feedback on; this information will be most important to help you in reaching your goals!

Social Cognitive Measures- You will complete various measures that assess your beliefs, responses, motivations regarding health behaviors and your experiences with integrating these into your everyday life.

Subjects will be given a weight scale and a pedometer and those in the *DASH 2 Wellness Plus* Group will also receive a take-home blood pressure monitor.

Session 2 (30 minutes):

4- Day Food Record - You will turn in your food record at this visit.

Physical Activity Record- You will turn in your physical activity record at this visit.

We will measure your weight and your blood pressure when you arrive for this visit. This visit will be scheduled in the morning, typically beginning between 8a and 10:30a.

Session 3 (20 minutes):

We will measure your blood pressure and your weight when you arrive for this visit.

Session 4 (1 hours):

This visit will be similar to Session 1. It will not include the Health History Form.

Session 5 (30 minutes):

This visit will be exactly like Session 2.

On-Line Visits**Weekly Sessions 1-10 (time will vary):**

We will individualize your feedback on nutrition, physical activity, blood pressure, and weight monitoring.

DASH Eating Plan- You will be given information on the DASH Eating Plan and instructed to follow a low-sodium diet, rich in fruits and vegetables which should help lower your blood pressure and help you lose weight. We will provide you a list of healthy ‘alternatives’, sample recipes/menus, a list of caution ‘high-sodium’ foods, and other tips to use during this part of the study. You will be asked to follow this eating plan for 10 weeks.

Walking Program- You will be asked to increase your daily step counts, as measured by a pedometer, through a weekly walking program. You will be instructed in how to safely increase your steps and your perceived exertion throughout the program. We will also consider ways in which you can increase your enjoyment and help you overcome barriers to making physical activity a part of your daily life.

The total time commitment for this study will range from approximately 15-20 hours.

SUMMARY OF SUBJECT RESPONSIBILITIES

The subject should:

- Provide an accurate history of any health problems or medications you use before the study begins.
- Inform the experimenters of any discomfort or unusual feelings before, during or after any of the on-site sessions.
- Inform the experimenters of any discomfort, unusual feelings, or of any high at-home blood pressure readings during the 10 weeks.
- Be on time and attend all of the scheduled on-site sessions.
- Maintain weekly on-line contact with and reporting to project director.
- Follow all participant instructions for each on-site and on-line session.

- Record the food you eat and physical activity you do as instructed by the study investigators.

RISKS OF PARTICIPATION

Weight Gain: Weight gain is common following weight loss programs. It is possible that you will gain some or all of the weight you lost during the study. We can make no promises or commitments on the long term success of maintaining your weight loss. This is a possibility that you should consider before you agree to participate.

It is not possible to identify all potential risks in an experiential study; however the study doctors and study staff will take all possible safeguards to minimize any known and potential risks to your well-being. We believe the overall risks of participation are minimal.

All of the procedures are well established and used routinely in the study investigators laboratory. Side effects are possible in any research study despite high standards of care, and could occur through no fault of your own or the study staff.

BENEFITS OF PARTICIPATION

Your participation will provide you with:

- Information on your blood pressure and body mass index
- Information on the DASH Eating Plan, supervised by a registered dietitian
- Information on a physical activity walking program, supervised by a
- A Digital Weight Scale
- A Pedometer
- An at-home Blood Pressure Monitor
- Virginia Tech Water Bottle or Coffee Mug

CONFIDENTIALITY

The data from this study will be kept strictly confidential. No data will be released to anyone but those working on the project without your written permission. Data will be identified by subject numbers, without anything to identify you by name.

FREEDOM TO WITHDRAW

You are free to withdraw from the study at any time for any reason. Simply inform the experimenters of your intention to cease participation. Circumstances may arise causing the researcher to determine that you should not continue as a subject in the study. For example, lack of compliance to instructions, failure to attend on-site or on-line sessions and illness could be reasons for the researchers to stop your participation in the study.

INJURY DURING PARTICIPATION IN THIS STUDY

Neither the researchers nor the university have money set aside to pay for medical treatment that would be necessary if injured as a result of your participation in this study. Any expenses that

you incur including emergencies and long-term expenses would be your own responsibility. You should consider this limitation before you consider participating in this study.

APPROVAL OF RESEARCH

This research has been authorized, as required, by the Institutional Review Board for Research Involving Human Subjects at Virginia Tech, and by the Department of Psychology. You will receive a copy of this form to take with you.

SUBJECT PERMISSION

I have read the informed consent and fully understand the procedures and conditions of the project. I have had all my questions answered, and I hereby give my voluntary consent to be a participant in this research study. I agree to abide by the rules of the project. I understand that I may withdraw from the study at any time.

If you have questions, you may contact:

Principal Investigator: Richard Winett, Assistant Professor, Center for Research in Health Behavior, Department of Psychology. (540) 231-8747

Co-Investigator: Ashley Dorough, Graduate Researcher, Center for Research in Health Behavior, Department of Psychology (540) 231-8747

Co-Investigator: Brenda Davy, Assistant Professor, Department of Human Nutrition, Foods, and Exercise. (540) 231-6784

Chairman, Institutional Review Board for Research Involving Human Subjects: David Moore, (540) 231-4991

Name of Subject (please print) _____

Signature of Subject _____

Date _____

Appendix F

Virginia Tech
Center for Research in Health Behavior
Department of Psychology

HEALTH HISTORY QUESTIONNAIRE

STUDY _____

DATE _____

SUBJECT ID # _____

PLEASE PRINT

1. GENERAL Demographic Information: Age: _____

Sex: _____

Marital Status: _____

Race and/or Ethnic Origin:

- American Indian or Alaskan Native Asian or Pacific Islander Black, not of Hispanic Origin
- Hispanic White, not of Hispanic Origin Other

How many adults, age 18 or older live in your home? _____**How many children, under age 18 live in your home?** _____**Please list the ages of the children living in your home:**

Child #1 Age _____

Child #2 Age _____

Child #3 Age _____

Child #4 Age _____

Child #5 Age _____

Child #6 Age _____

How many years of school have you completed? (Circle One)

1 2 3 4 5 6 7 8 9 10 11 12 Some College 4 year college Masters Degree Post
 Masters

What is your specific occupation? If you work at a plant or a factory, or if you are in the military, please list the job you do there. If you are retired, disabled or unemployed, please list your most recent job:

What is the annual income of your household (include all *adults* working)?

- | | | |
|--------------------------|------------------------|--------------------------|
| a) \$10,000 or less/year | e) \$40,001 - \$50,000 | i) \$80,001 - \$90,000 |
| b) \$10,001 - \$20,000 | f) \$50,001 - \$60,000 | j) Greater than \$90,000 |
| c) \$20,001 - \$30,000 | g) \$60,001 - \$70,000 | |
| d) \$30,001 - \$40,000 | h) \$70,001 - \$80,000 | |

2. GENERAL MEDICAL HISTORY

Do you have any current medical conditions? YES NO
If Yes, please explain:

Are you allergic to any medications? YES NO
If Yes, please explain:

Have you had any major illnesses in the past? YES NO
If Yes, please explain:

Have you ever been hospitalized or had surgery? YES NO
If Yes, please explain: (include date and type of surgery, if possible)

Are you currently taking any medications or supplements, including aspirin, hormone replacement therapy, or other over-the-counter products?

YES NO

If Yes, please explain:

<u>Medication/Supplement</u>	<u>Reason</u>	<u>Times taken per Day</u>	<u>Taken for how long?</u>
------------------------------	---------------	----------------------------	----------------------------

Have you ever had an EKG? YES NO
If Yes, please explain:

Have you been diagnosed with diabetes? YES NO
If Yes, please explain:

Age at diagnosis_____

3. FAMILY HISTORY

	Age (if alive)	Age of Death	Cause of Death
Father	_____	_____	_____
Mother	_____	_____	_____
Brothers/Sisters	_____	_____	_____
	_____	_____	_____
	_____	_____	_____

Do you have a family history of any of the following: (Blood relatives only, please give age at diagnosis if possible)

	YES	NO		Relation	Age at Diagnosis
a. High blood pressure		<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
b. Heart Attack		<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
c. Coronary bypass surgery	<input type="checkbox"/>	<input type="checkbox"/>		_____	_____
d. Stroke	<input type="checkbox"/>	<input type="checkbox"/>		_____	_____
e. Diabetes	<input type="checkbox"/>	<input type="checkbox"/>		_____	_____
f. Obesity	<input type="checkbox"/>	<input type="checkbox"/>		_____	_____

4. TOBACCO/ALCOHOL HISTORY (check one)

None	<input type="checkbox"/>	
Quit	<input type="checkbox"/>	(when) _____
Cigarette	<input type="checkbox"/>	
Cigar	<input type="checkbox"/>	
Pipe	<input type="checkbox"/>	
Chew Tobacco	<input type="checkbox"/>	
Snuff	<input type="checkbox"/>	

CURRENT TOBACCO USE

(if applicable)

per day

Cigarette	_____
Cigar	_____
Pipe	_____
Chew Tobacco	_____
Snuff	_____

Total years of tobacco use _____

Do you consume alcohol? Drinks per day _____ Drinks per week _____

5. CARDIORESPIRATORY/METABOLIC HISTORY

	YES	NO
Are you presently diagnosed with heart disease?	<input type="checkbox"/>	<input type="checkbox"/>

	YES	NO
Do you have any history of heart disease?	<input type="checkbox"/>	<input type="checkbox"/>
Do you have a heart murmur?	<input type="checkbox"/>	<input type="checkbox"/>
Occasional chest pain or pressure?	<input type="checkbox"/>	<input type="checkbox"/>
Chest pain or pressure on exertion?	<input type="checkbox"/>	<input type="checkbox"/>
Episodes of fainting?	<input type="checkbox"/>	<input type="checkbox"/>
Daily coughing?	<input type="checkbox"/>	<input type="checkbox"/>
High blood pressure?	<input type="checkbox"/>	<input type="checkbox"/>
Shortness of breath?		
At rest?	<input type="checkbox"/>	<input type="checkbox"/>
lying down?	<input type="checkbox"/>	<input type="checkbox"/>
After 2 flights of stairs?	<input type="checkbox"/>	<input type="checkbox"/>
Do you have asthma?	<input type="checkbox"/>	<input type="checkbox"/>
Do you have a history of bleeding disorders?	<input type="checkbox"/>	<input type="checkbox"/>
Do you have a history of problems with blood clotting?	<input type="checkbox"/>	<input type="checkbox"/>
Do you have high total cholesterol?	<input type="checkbox"/>	<input type="checkbox"/>
Do you have low good (HDL) cholesterol?	<input type="checkbox"/>	<input type="checkbox"/>
Do you have thyroid problems?	<input type="checkbox"/>	<input type="checkbox"/>

If you checked YES to any of the above, you will be asked to clarify your response by an investigator so we can be sure to safely determine your ability to participate.

6. MUSCULOSKELETAL HISTORY

	YES	NO
Any current muscle injury or illness?	<input type="checkbox"/>	<input type="checkbox"/>
Any muscle injuries in the past?	<input type="checkbox"/>	<input type="checkbox"/>
Do you experience muscle pain at rest?	<input type="checkbox"/>	<input type="checkbox"/>
Do you experience muscle pain on exertion?	<input type="checkbox"/>	<input type="checkbox"/>
Any current bone or joint (including spinal) injuries?	<input type="checkbox"/>	<input type="checkbox"/>

- Any previous bone or joint (including spinal) injuries?
- Do you ever experience painful joints?
- Do you ever experience swollen joints?
- Do you ever experience edema (fluid build up)?
- Do you have pain in your legs when you walk?

If you checked YES to any of the above, you will be asked to clarify your response by an investigator so we can be sure to safely determine your ability to participate.

7. NUTRITIONAL HABITS

Have you ever dieted? YES NO

If YES, have you dieted within the past 12 months or are you currently on a diet?

YES NO

If YES, please describe the diet:

a). Name (if applicable): _____

b). Prescribed by a Physician/nutritionist? YES NO

c). Have you lost weight? YES NO

d). Duration of diet _____

What was your weight 24 months ago? _____ 12 months ago? _____ 6 months ago? _____

Have you dieted other than in the past 12 months? YES NO

If YES, please answer the following:

a). How many times have you dieted?

b). How old were you?

c). Weight loss (amount)?

You may be asked to complete a more detailed diet survey if you are volunteering for a research study.

8. PHYSICAL ACTIVITY SURVEY

Compared to a year ago, how much regular physical activity do you get? (Check one)

- Much less
- Somewhat less
- About the same
- Somewhat more
- Much more

Exercise is a physical activity that is planned or structured. It involves repetitive bodily movement done to improve or maintain one or more of the components of physical fitness – cardiorespiratory endurance (aerobic fitness), muscular strength, muscular endurance, flexibility, and body composition.

How many weeks, out of the past 12 weeks, have you exercised at least 3 days per week? (Please give your best estimate).

- 1 2 3 4 5 6 7 8 9 10 11 12

If YES, what type of exercise do you regularly participate in? (check those that apply)

	Days per week	Minutes per session	Intensity
		(1=easy, 10=very hard)	
Walking	<input type="checkbox"/>	_____	_____
Running	<input type="checkbox"/>	_____	_____
Cycling	<input type="checkbox"/>	_____	_____
Swimming	<input type="checkbox"/>	_____	_____
Aerobics	<input type="checkbox"/>	_____	_____
Weight Training	<input type="checkbox"/>	_____	_____
Martial Arts	<input type="checkbox"/>	_____	_____
Other (describe)		_____	_____

You may be asked to complete a more detailed diet survey if you are volunteering for a research study.

9. OBSTETRIC/GYNECOLOGICAL HISTORY

Do you have a normal menstrual cycle (1 menses each ~1 month)? **YES** **NO**

If no, please indicate frequency _____

Do you take any kind of contraceptive (oral, injectable, implant)?
If yes, please indicate type and name _____

How many full term pregnancies have you had? _____

How long ago was your more recent pregnancy? _____

Have long since you have last breast fed? _____

10. SLEEP HISTORY

Please answer yes/no or circle appropriate answer.

Do you snore? **YES** **NO**

Don't Know

Snoring loudness

- Loud as breathing
- Loud as talking
- Louder than talking
- Very loud. Can be heard in nearby rooms.

Snoring frequency

- Almost every day
- 3-4 times per week
- 1-2 times per week
- 1-2 times per month
- Never or almost never

Does your snoring bother other people? **YES** **NO**

Has anyone told you that you quit breathing during your sleep?

How often have your breathing pauses been noticed?

- Almost every day
- 3-4 times per week
- 1-2 times per week
- 1-2 times per month
- Never or almost never

Are you tired after sleeping?

- Almost every day
- 3-4 times per week
- 1-2 times per week
- 1-2 times per month
- Never or almost never

Are you tired during waketime?

- Almost every day
- 3-4 times per week
- 1-2 times per week
- 1-2 times per month
- Never or almost never

Have you ever fallen asleep while driving?

- Almost every day
- 3-4 times per week
- 1-2 times per week
- 1-2 times per month
- Never or almost never

Appendix G

Pedometer Instructions

Using your Step Counter Pedometer

How to open your Pedometer

With your pedometer in your hand the same way it would be on your waistband, hold the top of the clip with one hand and with your other hand take your thumb and push the clasp on the cover away from you.

Resetting your Pedometer

Press the yellow "RESET" button

Things to Remember

Your pedometer is an electronic digital device and care must be taken to:

- Not get your pedometer wet.
- Not drop or throw your pedometer.
- Not force your pedometer clip onto something that is too thick.
- Always use your safety strap to protect your pedometer (see page 1).

Using the Safety Strap

Loop the thin end of the safety strap onto the clip on the pedometer. Then loop the thick end of the safety strap onto a belt loop or safety pin. Attach safety pin to inside of clothing.

How to Wear your Pedometer

Correct positioning of your pedometer is essential to obtaining accurate step counts. Everyone has a unique body shape and people differ in their walking style. For these reasons it is highly recommended that you **experiment to find the ideal placement** of your pedometer.

The most common placement is on your belt or waistband. In order for the counting mechanism to function correctly the pedometer must be clipped on such that it is not tilted (forward or backward). The face of the pedometer should be level such that the writing on the label is horizontal. See pictures below:

Incorrect (tilted forward) Correct Incorrect (tilted forward)
Correct

Testing the position of the Pedometer

In order to know if your pedometer is in a good location perform this test.

1. Reset pedometer by pressing the yellow reset button.
2. Find a long open place and take 20 steps with the pedometer closed.
3. Check the number of steps the pedometer counted. It should be between 19 and 21 steps.
4. If the count was not right, try to move the pedometer forward (toward your belly button) or back (toward your hip) on your waist.
5. Repeat this until you get the best count of your steps.
6. Once found, place your pedometer in this spot each day.

How the Pedometer Measures Steps

Hold the case vertically and shake it up and down with its display facing towards you. By doing this, the pendulum inside starts to click gently indicating that it is functioning properly.

The pedometer is intended to use on reasonably flat ground. Incorrect measurements may result if you:

- walk with irregular steps or drag your feet.
- walk up or down very steep slopes
- subject the pedometer to vertical or vibrating motions
- suddenly stand up or sit down
- jump or participate in sports

Battery Replacement

When the display goes dim it may be time to replace the battery. The Yamax pedometer uses an LR44 battery. This is a standard battery that can be found in many retail stores. To replace the battery:

- There is a slit in the bottom of the unit. Place a coin in the slit. When you turn the coin the unit will pop open.
- Gently remove the cover off the unit being careful not to break the clips that hold the cover in place.
- Take note of the battery placement before you remove it (+ side faces the user) as the replacement battery must be inserted in the same manner as the original.
- Align and clip the cover on top of the unit by firmly pressing down on the ends of the cover. This will make sure an even distribution of weight is applied to the cover and will ensure that no damage will be done to the plastic clips on the unit.
- Perform pedometer self test.

Pedometer Self-Test

To insure the unit is working properly it is recommended to initiate a self-test:

- Press and hold down the reset button for several seconds (about 5).
- When the unit goes blank you can release the button(s) and the following data will be displayed “8; 8;8;8;8” then “0”.

Appendix H

Instructions for Keeping Your Food Intake Record

When to keep record: Dates of your FIR: _____ to _____.

Your food intake record (FIR) should be kept for four consecutive days. This should include three weekdays and one weekend day, for example, either Wednesday through Saturday or Sunday through Wednesday.

What to Record: Please write down everything that you eat and drink each day. Include water, coffee, tea, diet sodas, and chewing gum. Include any additions to foods, such as sugar and creamer used in your coffee, mustard and mayonnaise spread onto your sandwich, etc. Remember to include all meals and snacks. Provide brand names of products whenever possible. It is also very helpful if you are able to provide **food labels** for items eaten. For beverages, indicate whether or not ice was included in the drink.

Record portion sizes for all items. The **Food Diagrams** (models), which have been provided, should help you to accurately estimate your portion sizes. Refer to the example on the back of this page for how to record food portions using the diagrams. If you have access to an accurate scale, the item may be weighed (record whether the item was weighed raw or cooked). Measuring cups and spoons may also be used.

Record how items were prepared. For example, was the item baked or fried? If fried, what type of fat was used (e.g. corn oil, lard, crisco shortening, etc)? Was the poultry skin removed prior to cooking or was it left on? Was the item chopped or sliced? If you are able to provide a **recipe** for an item that was made at home or at a friend's house, please include this with your FIR.

How to complete your Food Intake Record Form:

Please record only one item per line. Record foods on your record as soon as they are eaten, otherwise it is easy to forget! Carry the record and the diagrams with you while you are keeping your FIR. For an example, see the back of this page. Please call the study dietitian at 491-3373 if you have questions.

What about food eaten at a restaurant or a friend's house? Describe the food in as much detail as you can. Include portion sizes (please use the diagrams). Often you can get information from your server or from the menu. Indicate whether you ate the whole portion that was served to you, or the fraction that you did eat. Include the name of the restaurant on your record.

Your efforts to carefully and accurately record the foods you eat will help us get better results. Your diligence is greatly appreciated!

Appendix J

DASH 2 WELLNESS TRACKER

Use this log to keep track of your daily blood pressure, step-counts, and weight.		MON	TUES	WED	THU	FRI	SAT	SUN
End of Day Step Count <i>(Reset your step counter every day).</i>		# steps	# steps	# steps	# steps	# steps	# steps	# steps
Time	<i>How many minutes was the walk?</i>	# mins	# mins	# mins	# mins	# mins	# mins	# mins
Exertion	<i>How much exertion did the walk take?</i> <i>Use the scale below</i>	(6-20)	(6-20)	(6-20)	(6-20)	(6-20)	(6-20)	(6-20)
Enjoyment	<i>How much did you enjoy the walk?</i> <i>Use the scale below.</i>	(0-10)	(0-10)	(0-10)	(0-10)	(0-10)	(0-10)	(0-10)
Blood Pressure (am)	<i>What were your 2 blood pressure readings this morning?</i>	1	1	1	1	1	1	1
		2	2	2	2	2	2	2
Blood Pressure (pm)	<i>What were your 2 blood pressure readings this evening?</i>	1	1	1	1	1	1	1
		2	2	2	2	2	2	2
Weight	<i>How much did you weigh this morning?</i>	lbs	lbs	lbs	lbs	lbs	lbs	lbs

Exertion														
6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
No exertion (Watch TV)	Extremely light		Very light		Light (Can sing/walk)	Moderate (Can talk/walk)	Somewhat hard		Hard (Can't talk/walk)		Very hard		Extremely hard	Max Exertion

Enjoyment										
0	1	2	3	4	5	6	7	8	9	10
Very Unpleasant (I hated it)		Unpleasant		Somewhat Unpleasant		Somewhat Pleasant		Pleasant		Very Pleasant (I loved it)

DASH DIARY

DASH Good Health Foods



GOAL: Eat & Track 9-10 servings of F & V
(*Eat low-fat dairy, lean protein & whole grains)

	Fruits & Vegetables		
Day 1	<input type="checkbox"/>	<input type="checkbox"/>	<p>Vegetables 1 serving = 1 Cup lettuce/salad greens 1/2 C raw or cooked vegetables</p> <p>Fruits 1 serving = 1 C grapes, berries or melon 1/2 C fruit 1/4 C dried fruit 6 oz fruit juice medium piece of fruit</p> <p>Use this link for nutrition facts: http://www.nutritiondata.com/</p>
Day 2	<input type="checkbox"/>	<input type="checkbox"/>	
Day 3	<input type="checkbox"/>	<input type="checkbox"/>	
Day 4	<input type="checkbox"/>	<input type="checkbox"/>	
Day 5	<input type="checkbox"/>	<input type="checkbox"/>	
Day 6	<input type="checkbox"/>	<input type="checkbox"/>	
Day 7	<input type="checkbox"/>	<input type="checkbox"/>	

DASH High-Sodium Caution Foods

* Example of caution food serving size:
each of these servings contains 400 mg Na

GOAL: Limit to < 2 servings of high-sodium caution foods per day.

Day 1	<input type="checkbox"/>	Drinks		High Sodium Chips, Crackers, &
Day 2	<input type="checkbox"/>	18 fluid oz Low Sodium Tomato Juice		20 potato chips or small pretzels
Day 3	<input type="checkbox"/>	28 fluid oz Gatorade or similar Sports Drinks		1/4 12 inch thin pizza crust
Day 4	<input type="checkbox"/>	High Sodium Dairy		High Sodium Meats
Day 5	<input type="checkbox"/>	2 ounces hard cheese		1 slice lunch meat
Day 6	<input type="checkbox"/>	3/4 cup cottage cheese		1 1/2 oz canned or packaged tuna, salmon, or crab
Day 7	<input type="checkbox"/>	1/2 C (1 scoop) ice cream		1 small hot dog
		1 ice cream bar		3 slices bacon
		8 oz whole milk		
		1 slices cheese		
				High Sodium Extras
				1/4 tsp salt
				1 tsp soy sauce
				2 tbsp catsup, mustard, BBQ, chili sauce
				4 tbsp tarter sauce
				2 tbsp salad dressing
				4 medium olives
				4 tbsp sweet pickle relish

DASH High-Sodium Foods To Avoid

GOAL: Intake of these foods should be avoided, unless considered as servings in caution foods category above.

1. Smoked, processed, cured meats & fish (e.g. cold-cuts, ham, bacon, corned beef, sausage, tongue, salt pork, pickled herring, anchovies, sardines), meat extracts, meat sauces
2. Salted snacks (tortilla chips, & salted nuts, crackers, pretzels, chips, popcorn)
3. Prepackaged frozen foods (casseroles, noodles & rice dishes, burritos, potato dishes, oriental foods, spaghetti & pasta dishes, pot pies, sauces (e.g., gravies), and vegetables soaked in brine (salt & water)
4. Canned soups, vegetable juices-including tomato juice (unless prepared without salt)
5. Prepared dressings, condiments, sauces (salad dressings, catsup, BBQ, soy, etc.)
6. Processed cheese/spreads

Appendix K

Physical Activity Enjoyment Scale (PACES)
(Kendzierski and DeCarlo, 1991)

Please rate how you feel *at the moment* about the physical activity you have been doing over the past 3 months.

I enjoy it	*1	2	3	4	5	6	7	I hate it
I feel bored	1	2	3	4	5	6	7	I feel interested
I dislike it	1	2	3	4	5	6	7	I like it
I find it pleasurable	*1	2	3	4	5	6	7	I find it unpleasurable
I am very absorbed in this activity	*1	2	3	4	5	6	7	I am not at all absorbed in this activity
Its no fun at all	1	2	3	4	5	6	7	Its a lot of fun
I find it energizing	*1	2	3	4	5	6	7	I find it tiring
It makes me feel depressed	1	2	3	4	5	6	7	It makes me feel happy
It's very pleasant	*1	2	3	4	5	6	7	It's very unpleasant
I feel good physically while doing it	*1	2	3	4	5	6	7	I feel bad physically when doing it
It's very invigorating	*1	2	3	4	5	6	7	It's not at all invigorating
I am very frustrated by it	1	2	3	4	5	6	7	I am not at all frustrated by it
It's very gratifying	*1	2	3	4	5	6	7	It's not at all gratifying
It's very exhilarating	*1	2	3	4	5	6	7	It's not at all exhilarating
It's not at all stimulating	1	2	3	4	5	6	7	It's very stimulating
It gives me a strong sense of accomplishment	*1	2	3	4	5	6	7	It does not give me any sense of accomplishment
It's very refreshing	*1	2	3	4	5	6	7	It's not at all refreshing
I felt as though I would rather be doing something else	1	2	3	4	5	6	7	I felt as though there was nothing else I would rather be doing

* Item is reversed score (ie: 1=7, 6=2, 7=1)

Appendix L

**Health Beliefs Survey
(Anderson et al., 2006)**

Food Beliefs: Healthier Food Strategies

Please, tell us what you have done in the past **2 months** to eat healthier foods.

Use this scale to tell us how often in the past **2 months** you did the following:

1 **2** **3** **4** **5**
Never **Seldom** **Occasionally** **Often** **Repeatedly**

In the past 2 months how often did you—	How Often (1-5)				
1. Remind yourself that fat-free does not mean calorie-free.	1	2	3	4	5
2. Remind yourself to read food labels and compare nutrition facts.	1	2	3	4	5
3. Tell yourself that fruits and vegetables are low in calories.	1	2	3	4	5
4. Remind yourself that fruits and vegetables will help you feel full and satisfied.	1	2	3	4	5
5. Tell yourself that fruits and vegetables are good substitutes for high-calorie and high-fat foods.	1	2	3	4	5
6. Remind yourself that fruits and vegetables are “heart-healthy”.	1	2	3	4	5
7. Tell yourself that eating less sodium could lower your blood pressure.	1	2	3	4	5
8. Work toward the goal to eat more whole grain foods.	1	2	3	4	5
9. Work toward the goal to eat more vegetables.	1	2	3	4	5
10. Work toward the goal to eat more fruit.	1	2	3	4	5
11. Work toward the goal to pay closer attention to serving sizes.	1	2	3	4	5
12. Work toward the goal to eat less saturated fat.	1	2	3	4	5
13. Work toward the goal to eat smaller portions.	1	2	3	4	5
14. Work toward the goal to eat less sodium.	1	2	3	4	5
15. Work toward the goal to avoid ice cream, cheese, and other high-fat dairy foods.	1	2	3	4	5

Use this scale to tell us how often in the past 2 months you did the following:

1 **2** **3** **4** **5**
Never **Seldom** **Occasionally** **Often** **Repeatedly**

In the past 2 months how often did you—	How Often (1-5)
16. Work toward the goal to avoid sweets, regular sodas and other sugar sweetened beverages.	1 2 3 4 5
17. Work toward the goal to include more lean protein in your diet.	1 2 3 4 5
18. Work toward the goal to avoid alcohol intake.	1 2 3 4 5
19. Plan to eat fewer sweet snacks, desserts, and added sugars.	1 2 3 4 5
20. Plan to drink fewer sodas and other sugared beverages.	1 2 3 4 5
21. Keep track of sweets and added sugars you have each day.	1 2 3 4 5
22. Plan to eat 8 or more servings of fruit and vegetables each day.	1 2 3 4 5
23. Work toward the goal to eat fruits and vegetables for snacks.	1 2 3 4 5
24. Keep track of how many servings of fruits and vegetables you eat each day.	1 2 3 4 5
25. Plan to eat only a certain number of calories a day.	1 2 3 4 5
26. Keep track of the number of calories in the foods you eat.	1 2 3 4 5
27. Plan to eat fewer high-sodium foods.	1 2 3 4 5
28. Work toward the goal to avoid high-sodium foods.	1 2 3 4 5
29. Keep track of how many high-sodium foods you have each day.	1 2 3 4 5
30. Plan to eat 6-8 servings of whole-grain foods each day.	1 2 3 4 5
31. Keep track of whole-grain foods you eat each day.	1 2 3 4 5
32. Plan to eat 2-3 servings of low-fat dairy each day.	1 2 3 4 5
33. Keep track of the low-fat dairy you eat each day.	1 2 3 4 5
34. Plan to eat around 5 1 ounce servings of lean protein each day.	1 2 3 4 5
35. Keep track of the lean protein you eat each day.	1 2 3 4 5

Food Beliefs: Healthier Social Support

What do the members of your family do and think about eating healthy foods? We just want your opinion even if you are not sure.

Use this scale to tell us if you agree with the following statements:

1 Strongly Disagree	2 Disagree	3 Neither Agree or Disagree	4 Agree	5 Strongly Agree
Members of my family...				Agree or Disagree (1-5)
36. keep track of the number of calories they eat each day				1 2 3 4 5
37. try to eat whole-grains every day.				1 2 3 4 5
38. avoid regular sodas, sweets and added sugars or sugared drinks.				1 2 3 4 5
39. try to eat 8 or more servings of fruits and vegetables every day.				1 2 3 4 5
40. avoid high-fat and high-sodium snacks.				1 2 3 4 5
41. try to eat low-fat dairy foods.				1 2 3 4 5
42. choose lean protein like chicken or fish over high-fat meats.				1 2 3 4 5
43. avoid cooking with a lot of fat.				1 2 3 4 5
44. try to eat lower-fat foods at fast-food and other restaurants.				1 2 3 4 5
45. avoid adding table salt to their meals.				1 2 3 4 5
46. read nutritional labels to compare nutritional content.				1 2 3 4 5

Food Beliefs: Healthier Social Support

What do your closest friends do and think about eating healthy foods? We just want your opinion even if you are not sure.

Use this scale to tell us if you agree with the following statements:

1 Strongly Disagree	2 Disagree	3 Neither Agree or Disagree	4 Agree	5 Strongly Agree	
					Agree or Disagree (1-5)
My closest friends ...					
47. keep track of the number of calories they eat each day					1 2 3 4 5
48. try to eat whole-grains every day.					1 2 3 4 5
49. avoid regular sweets and added sugars or sugared drinks.					1 2 3 4 5
50. try to eat 8 or more servings of fruits and vegetables every day.					1 2 3 4 5
51. avoid high-fat and high-sodium snacks.					1 2 3 4 5
52. try to eat low-fat dairy foods.					1 2 3 4 5
53. choose lean meats over high-fat meats.					1 2 3 4 5
54. avoid cooking with a lot of fat.					1 2 3 4 5
55. try to eat lower-fat foods at fast-food and other restaurants.					1 2 3 4 5
56. avoid adding table salt to their meals.					1 2 3 4 5
57. read nutritional labels to compare nutritional content.					1 2 3 4 5

Food Beliefs: Healthier Foods Efficacy

These questions ask how CERTAIN you are that you can do different things to eat healthier foods.

You will be asked to decide how certain or how sure you are that you can do these things on most days and in lots of different situations.

Think about times when it will be easy to do these things and when it will be harder.

When deciding how sure you are you can do these things, we want you to think about doing them:

ALL or MOST of the time, not just once or twice.

For a long time...until next year...or even longer!

In a lot of different situations – like when you are...

- deciding what to eat when at home, alone, watching TV or doing chores...
- eating with your family...
- eating out with friends or at a party ...
- at a fast-food restaurant...
- buying food at the grocery store

Food Beliefs: Healthier Foods Efficacy

Use any number from 1 to 10 on the following scale to tell how certain you are that you can – all or most of the time:

1 Certain I CAN NOT	-----	10 Certain I CAN
<u>Keeping Track</u>		
How certain are you that you can, every day, <i>keep track</i> of each of the following foods you eat:...		How certain? (1-10)
58. fruits		1 2 3 4 5 6 7 8 9 10
59. vegetables		1 2 3 4 5 6 7 8 9 10
60. high-sodium foods		1 2 3 4 5 6 7 8 9 10
61. low-fat dairy foods		1 2 3 4 5 6 7 8 9 10
62. sweets and added sugars		1 2 3 4 5 6 7 8 9 10
63. whole grain foods		1 2 3 4 5 6 7 8 9 10
64. regular sodas or other sweet beverages		1 2 3 4 5 6 7 8 9 10
65. lean meats, fish, and poultry		1 2 3 4 5 6 7 8 9 10
<u>Goals and Plans</u>		
How certain are you that you can set as a goal and make plans to...		
FRUITS AND VEGETABLES GOALS AND PLANS		
66. have a piece of fruit with breakfast or as a mid-morning snack?		1 2 3 4 5 6 7 8 9 10
67. add an extra vegetable or two to your dinner?		1 2 3 4 5 6 7 8 9 10
68. eat fruit with fat-free, low-fat, or frozen yogurt for dessert instead of full-sugar or full-fat ice cream?		1 2 3 4 5 6 7 8 9 10
69. bring fruit and/or vegetables to work/school for a snack?		1 2 3 4 5 6 7 8 9 10
70. eat vegetables for a snack (e.g. carrot, tomato, celery)?		1 2 3 4 5 6 7 8 9 10
71. eat fruit for a snack (e.g. apple, bananas, grape, orange, peach, strawberries)?		1 2 3 4 5 6 7 8 9 10
72. have fruit or fruit cup instead of chips or French fries when dining out?		1 2 3 4 5 6 7 8 9 10

73. have a side salad instead of chips or French fries when dining out?	1 2 3 4 5 6 7 8 9 10
LOW-FAT DAIRY GOALS AND PLANS	How certain? (1-10)
74. drink 1%, ½%, or fat-free (skim) milk?	1 2 3 4 5 6 7 8 9 10
75. switch to low-fat or fat-free ice cream, ice cream bars, or frozen yogurt?	1 2 3 4 5 6 7 8 9 10
76. have 2 to 3 servings of low-fat dairy everyday?	1 2 3 4 5 6 7 8 9 10
77. eat low-fat cheese?	1 2 3 4 5 6 7 8 9 10
WHOLE GRAIN FOODS GOALS AND PLANS	
78. eat whole-grain bread?	1 2 3 4 5 6 7 8 9 10
79. eat whole grain cereal ?	1 2 3 4 5 6 7 8 9 10
80. eat brown rice instead of white?	1 2 3 4 5 6 7 8 9 10
81. eat 6 or more servings of whole-grain foods every day?	1 2 3 4 5 6 7 8 9 10
82. eat whole grain pasta?	1 2 3 4 5 6 7 8 9 10

SWEETS & ADDED SUGARS GOALS AND PLANS	
83. avoid eating sweets for snacks?	1 2 3 4 5 6 7 8 9 10
84. drink water or flavored water instead of regular soda or sugared beverages?	1 2 3 4 5 6 7 8 9 10
85. avoid eating sweets for dessert?	1 2 3 4 5 6 7 8 9 10
86. eat fruit for dessert instead of sweets?	1 2 3 4 5 6 7 8 9 10
87. eat half a dessert in a restaurant and take the rest home?	1 2 3 4 5 6 7 8 9 10
88. cut back on the size of sodas and sugared beverages?	1 2 3 4 5 6 7 8 9 10
SALTY SNACKS GOALS AND PLANS	
89. avoid eating high fat chips and crackers as snacks?	1 2 3 4 5 6 7 8 9 10
90. avoid eating high-sodium snacks?	1 2 3 4 5 6 7 8 9 10
91. switch to low-sodium or sodium-free snacks?	1 2 3 4 5 6 7 8 9 10
92. eat monounsaturated (healthier) fats as snacks, like unsalted almonds or walnuts?	1 2 3 4 5 6 7 8 9 10
93. read labels to compare nutrition content?	1 2 3 4 5 6 7 8 9 10

MEAL PREPARATION GOALS AND PLANS	How certain? (1-10)
94. use low-fat spreads on bread (e.g. low-fat mayo)?	1 2 3 4 5 6 7 8 9 10
95. use low-fat toppings for potatoes and other vegetables?	1 2 3 4 5 6 7 8 9 10
96. use low-fat or fat-free salad dressing?	1 2 3 4 5 6 7 8 9 10
97. avoid frying food	1 2 3 4 5 6 7 8 9 10
98. avoid using fat when cooking	1 2 3 4 5 6 7 8 9 10
99. switch to olive oil or vegetable oil instead of butter or lard	1 2 3 4 5 6 7 8 9 10
100. avoid salting foods	1 2 3 4 5 6 7 8 9 10
101. avoid eating fried foods when dining out	1 2 3 4 5 6 7 8 9 10
LEAN MEATS GOALS AND PLANS	
102. eat lean meats like poultry and/ or fish, instead of beef .	1 2 3 4 5 6 7 8 9 10
103. prepare poultry without skin, trimming away visible fats?	1 2 3 4 5 6 7 8 9 10
104. broil, roast or poach poultry and fish when cooking?	1 2 3 4 5 6 7 8 9 10

Food Beliefs: Healthier Food Outcomes

Now, tell us what you expect will happen when you eat healthier foods.
Use this scale to tell us if you agree the following will happen:

1	2	3	4	5
<i>Strongly Disagree</i>	<i>Disagree</i>	<i>Neither Agree or Disagree</i>	<i>Agree</i>	<i>Strongly Agree</i>

If I eat healthier foods every day, I expect—	Do you agree? (1-5)
105. I will lower my blood pressure.	1 2 3 4 5
106. I will have more energy.	1 2 3 4 5
107. I will lose weight.	1 2 3 4 5
108. I will feel healthier and happier.	1 2 3 4 5
109. I will live longer.	1 2 3 4 5
110. I will feel better in my clothes.	1 2 3 4 5
111. I will be hungrier.	1 2 3 4 5
112. I will be unhappy and irritable.	1 2 3 4 5
113. My health will improve.	1 2 3 4 5
114. I will miss eating the foods I love.	1 2 3 4 5
115. I will have healthier skin, hair, or teeth.	1 2 3 4 5
116. I will be less likely to get cancer or heart disease.	1 2 3 4 5
117. Shopping for healthy foods will be a lot of trouble.	1 2 3 4 5
118. I will be bored with what I have to eat.	1 2 3 4 5
119. I will have to change a lot of my favorite foods.	1 2 3 4 5
120. I won't be able to eat the same foods as the rest of my family.	1 2 3 4 5
121. I will have to spend too much time keeping track of what I eat.	1 2 3 4 5
122. The food I eat will not taste good.	1 2 3 4 5
123. It will take too long to prepare meals and snacks.	1 2 3 4 5
124. I will have to plan my meals too far in advance.	1 2 3 4 5
125. I will be more attractive.	1 2 3 4 5
126. I will be doing what I know I should.	1 2 3 4 5
127. I won't be able to stick with it – I'll just go back to my old habits.	1 2 3 4 5

Physical Activity Beliefs: Strategies

Please, tell us what strategies you have used in the past 2 months to successfully walk or do other exercise.

Use this scale to tell us how often in the past month you did the following:

1 **2** **3** **4** **5**
Never **Seldom** **Occasionally** **Often** **Repeatedly**

In the past month how often did you:	How Often (1-5)?
128. Set aside time each day to walk or do other exercise?	1 2 3 4 5
129. Make a plan to walk or do other exercise?	1 2 3 4 5
130. Keep or make a new plan based on how well you were doing with your walking or other exercise?	1 2 3 4 5
131. Set a goal for the number of days you walked or exercised each week?	1 2 3 4 5
132. Keep track of how many steps you take each day?	1 2 3 4 5
133. Keep track of the number of days you walked or exercised each week?	1 2 3 4 5
134. Keep track of how long your walks or exercise sessions were?	1 2 3 4 5
135. Plan to walk or exercise 5 days a week?	1 2 3 4 5
136. Plan to make your walking or exercise sessions a little longer?	1 2 3 4 5
137. Set goals for how long your walking or exercise sessions will be?	1 2 3 4 5
138. Plan your walking or other exercise sessions so they are enjoyable?	1 2 3 4 5
139. Get together with someone else to walk or do other exercise?	1 2 3 4 5
140. Keep track of how much you enjoy your walking or other exercise?	1 2 3 4 5
141. Keep track of how fast you walked or how hard you did other exercise?	1 2 3 4 5

Physical Activity Beliefs: Social Support

What do the members of your family do and think about walking or other exercise? We just want your opinion even if you are not sure.

Use this scale to tell us if you agree with the following statements:

1 Strongly Disagree	2 Disagree	3 <i>Neither Agree or Disagree</i>	4 Agree	5 Strongly Agree	
					Agree or Disagree (1-5)
<i>The members of my family ...</i>					
142. make time to walk or do other exercise.					1 2 3 4 5
143. set goals to walk or exercise.					1 2 3 4 5
144. plan to walk or do other exercise.					1 2 3 4 5
145. exercise or walk most days of the week.					1 2 3 4 5
146. make their walks or other exercise as enjoyable as possible.					1 2 3 4 5
147. keep track of their walking or other exercise.					1 2 3 4 5
148. keep or make new plans based on how well they are doing with their walking or other exercise.					1 2 3 4 5
149. set goals to walk or exercise longer.					1 2 3 4 5
150. gave me encouragement to stick with my exercise program.					1 2 3 4 5
151. offered to exercise with me.					1 2 3 4 5

Physical Activity Beliefs: Social Support

**What do your closest friends do and think about walking or other exercise?
We just want your opinion even if you are not sure.**

Use this scale to tell us if you agree with the following statements:

1 Strongly Disagree	2 Disagree	3 <i>Neither Agree or Disagree</i>	4 Agree	5 Strongly Agree
				Agree or Disagree (1-5)
<i>My closest friends ...</i>				
152. make time to walk or do other exercise.				1 2 3 4 5
153. set goals to walk or exercise.				1 2 3 4 5
154. plan to walk or do other exercise.				1 2 3 4 5
155. exercise or walk most days of the week.				1 2 3 4 5
156. make their walks or other exercise as enjoyable as possible.				1 2 3 4 5
157. keep track of their walking or other exercise.				1 2 3 4 5
158. keep or make new plans based on how well they are doing with their walking or other exercise.				1 2 3 4 5
159. set goals to walk or exercise longer.				1 2 3 4 5
160. gave me encouragement to stick with my exercise program.				1 2 3 4 5
161. offered to exercise with me.				1 2 3 4 5

Physical Activity Beliefs: Self-Efficacy

These questions ask how CERTAIN you are that you can do different things to make sure you:

take a walk or do other exercise most days of the week under lots of different conditions.

Think about times when it will be easy to walk and when it will be harder.

When deciding how sure you are, we want you to think about walking or doing other exercise most days of the week, not just once or twice, but

for a long time...until next year ...or even longer!

In a lot of different situations ...

- when the weather is bad ...
- when you are feeling stressed or depressed ...
- when you can't find someone to walk with you ...
- when you are busy.

Physical Activity Beliefs: Self-Efficacy

Use any number from 1 to 10 on the following scale to tell how certain you are that you can – all or most of the time:

1 ----- ----- ----- 10
Certain I CAN **Certain I CAN**
NOT

How certain are you that you can ...	How certain? (1-10)
161. ...get up early during the week to walk or do other exercise?	1 2 3 4 5 6 7 8 9 10
162. ...get together with someone else to walk or do other exercise?	1 2 3 4 5 6 7 8 9 10
163. ...walk most days of the week?	1 2 3 4 5 6 7 8 9 10
164. ...keep track of when and how long you walk or do other exercise?	1 2 3 4 5 6 7 8 9 10
165. ...go to social events or fun activities only after reaching your waking goal?	1 2 3 4 5 6 7 8 9 10
166. ...take small breaks during the day to take a walk or do other exercise?	1 2 3 4 5 6 7 8 9 10
167. ...begin walking again if you miss a day or two?	1 2 3 4 5 6 7 8 9 10
168. ...increase the enjoyment of your walks or other exercise?	1 2 3 4 5 6 7 8 9 10
169. ...make a plan to walk or do other exercise?	1 2 3 4 5 6 7 8 9 10
170. ...plan your walks or other exercise so you will enjoy them?	1 2 3 4 5 6 7 8 9 10
171. ...each week, increase how long you walk or do other exercise?	1 2 3 4 5 6 7 8 9 10
172. ...find a place to walk during bad weather?	1 2 3 4 5 6 7 8 9 10
173. ...change your normal routine to get in a walk or do other exercise?	1 2 3 4 5 6 7 8 9 10
174. ...stay up later to make time for taking a walk or do other exercise?	1 2 3 4 5 6 7 8 9 10
175. ...monitor your blood pressure at home twice in the morning?	1 2 3 4 5 6 7 8 9 10
176. ...monitor your blood pressure at home twice in the evening?	1 2 3 4 5 6 7 8 9 10
177. ...track your home blood pressure monitoring (e.g. write it down)?	1 2 3 4 5 6 7 8 9 10

Physical Activity Beliefs: Self-Efficacy

Use any number from 1 to 10 on the following scale to tell how certain you are that you can – all or most of the time:

1
Certain I
CAN NOT

10
Certain I CAN

How certain are you that you can walk or do other exercise when ...	How certain? (1-10)
178. you are feeling stressed?	1 2 3 4 5 6 7 8 9 10
179. you are tired?	1 2 3 4 5 6 7 8 9 10
180. your family wants more time?	1 2 3 4 5 6 7 8 9 10
181. your muscles might be a little sore?	1 2 3 4 5 6 7 8 9 10
182. you get busy at work?	1 2 3 4 5 6 7 8 9 10
183. you have social activities?	1 2 3 4 5 6 7 8 9 10
184. you have chores or errands to do?	1 2 3 4 5 6 7 8 9 10
185. you need a babysitter to do so?	1 2 3 4 5 6 7 8 9 10
186. you are feeling depressed?	1 2 3 4 5 6 7 8 9 10

Physical Activity Beliefs: Outcomes

These questions ask about what you expect will happen *if you were take a walk or do other exercise most days of the week*. They also ask about how much it would matter to you for these things to happen.

Use this scale to tell us if you agree the following will happen:

1	2	3	4	5
Strongly Disagree				Strongly Agree

Use this scale to tell us how much it will matter:

1	2	3	4	5
It will not matter at all				It will matter very much

	Do you agree? (1-5)	Will it matter? (1-5)
187. ...lower my blood pressure	1 2 3 4 5	1 2 3 4 5
188. ...decrease my chance of becoming ill or disabled.	1 2 3 4 5	1 2 3 4 5
189. ...have to give up some of my normal activities.	1 2 3 4 5	1 2 3 4 5
190. ...have to take more time than usual to plan my day.	1 2 3 4 5	1 2 3 4 5
191. ...have one more thing to worry about getting done.	1 2 3 4 5	1 2 3 4 5
192. ...not have enough time for other things I want to do.	1 2 3 4 5	1 2 3 4 5
193. ...have to change my normal routine.	1 2 3 4 5	1 2 3 4 5
194. ...sleep better.	1 2 3 4 5	1 2 3 4 5
195. ...have less time to spend with my family.	1 2 3 4 5	1 2 3 4 5
196. ...have less time to spend with my friends.	1 2 3 4 5	1 2 3 4 5

Use this scale to tell us if you agree the following will happen:

1
2
3
4
5
Strongly

Strongly
Disagree

Agree

Use this scale to tell us how much it will matter:

1
2
3
4
5
It will not matter

It will matter
at all

very much

If I slowly and steadily build up to walking or doing other exercise most days of the week, I expect I will ...	Do you agree? (1-5)	Will it matter? (1-5)
197. ...lower my blood pressure	1 2 3 4 5	1 2 3 4 5
198. ...decrease my chance of becoming ill or disabled.	1 2 3 4 5	1 2 3 4 5
199. ...have to give up some of my normal activities.	1 2 3 4 5	1 2 3 4 5
200. ...have to take more time than usual to plan my day.	1 2 3 4 5	1 2 3 4 5
201. ...have one more thing to worry about getting done.	1 2 3 4 5	1 2 3 4 5
202. ...not have enough time for other things I want to do.	1 2 3 4 5	1 2 3 4 5
203. ...have to change my normal routine.	1 2 3 4 5	1 2 3 4 5
204. ...sleep better.	1 2 3 4 5	1 2 3 4 5
205. ...have less time to spend with my family.	1 2 3 4 5	1 2 3 4 5
206. ...have less time to spend with my friends.	1 2 3 4 5	1 2 3 4 5
207. ...make me feel depressed.	1 2 3 4 5	1 2 3 4 5
208. ...be happier.	1 2 3 4 5	1 2 3 4 5
209. ...feel good physically.	1 2 3 4 5	1 2 3 4 5
210. ...feel very invigorated	1 2 3 4 5	1 2 3 4 5
211. ...be frustrated.	1 2 3 4 5	1 2 3 4 5

212. ...be gratified.	1 2 3 4 5	1 2 3 4 5
213. ...feel exhilarated.	1 2 3 4 5	1 2 3 4 5
214. ...feel a strong sense of accomplishment.	1 2 3 4 5	1 2 3 4 5
215. ...not want to do anything else.	1 2 3 4 5	1 2 3 4 5
216. ...be very absorbed by it.	1 2 3 4 5	1 2 3 4 5
217. ...feel refreshed.	1 2 3 4 5	1 2 3 4 5