3-25-2022

Personalized Meal Plans as An Intervention to Enhance Dash Diet Adherence in Hypertensive Adults

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PERSONALIZED MEAL PLANS AS AN INTERVENTION TO ENHANCE DASH DIET ADHERENCE IN HYPERTENSIVE ADULTS

A Thesis Presented to The Faculty of the School of Medicine Yale University

In Candidacy for the degree of Master of Medical Science

December 2022

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Abstract

The Dietary Approach to Stop Hypertension (DASH) diet is more effective as a standalone treatment at lowering blood pressure than any pharmaceutical intervention alone, but adherence is poor and current interventions to improve adherence only show marginal improvements. Personalized meal plans are effective at improving diet adherence in other chronic conditions and may serve as an effective intervention for DASH diet adherence. In a randomized controlled trial, we will determine whether nutritional counseling plus personalized meal planning (intervention) improves DASH adherence more than nutritional counseling alone (control). We will randomize n=178 adults with primary hypertension to either the intervention or control condition and compare DASH adherence scores after 3- and 12-months. Adherence scores will be compared using Student's t-tests and a 1.56-point change will be considered clinically significant. Improving DASH diet adherence has the potential to improve medical management of hypertension and lessen its massive social and economic burden.

Chapter 1: Introduction

1.1 Background

Over 50% of all US adults aged 18 years and older are diagnosed with hypertension (HTN), and modifiable risk factors for HTN, such as obesity, continue to rise [1,2]. HTN also poses an immense economic burden, with some estimating HTN to cost the US healthcare system over $131 billion annually due to medication costs and its associated comorbidities[3]. The increasing prevalence of HTN and related risk factors highlight the need for better preventative care and implementation of these measures. The current standard of care for patients suffering from HTN include pharmaceutical and nonpharmacological interventions [4]. Nonpharmacological interventions include smoking cessation, decreased alcohol intake, exercise, weight loss, and a heart-healthy diet such as the Dietary Approach to Stop Hypertension (DASH) or Mediterranean diet [5]. While both the DASH and Mediterranean diet are deemed "heart healthy", the DASH diet has more evidence to support its effectiveness [4,6]. Dietary intervention is considered the most effective intervention for blood pressure management, which includes limiting alcohol intake and following a heart healthy diet or notably the DASH diet [7,8]. Collectively, non-pharmaceutical interventions are considered the first line interventions for HTN, making implementation and adherence to these interventions crucial for proper HTN management [9].

1.2 Advantages of the DASH Diet

The DASH diet was developed in the early 1990s when the National Institute of Health started funding several research projects to determine whether specific dietary interventions were useful in treating HTN. They discovered that specific dietary interventions could reduce systolic blood pressure (SBP) by up to 11 mm Hg in hypertensive and normotensive individuals in just 8 weeks, prompting DASH to become the first line treatment for HTN along with other lifestyle

modifications [10]. The original DASH diet recommended eating vegetables, fruits, and whole grains, but limiting foods high in saturated fats or added sugar. The original DASH trial did not evaluate the effects of sodium reduction, as sodium intake was maintained at 3 g/d for both treatment and control diets [10]. However, reduced salt intake is now an important component of the DASH diet. A dose response metanalysis by Filippini *et al.* included 85 eligible trials with sodium intake ranging from 0.4 to 7.6 g/d; upon follow up from 1 to 36 months, the authors found a linear relationship between sodium intake and systolic and diastolic blood pressure (DBP) [11]. This meta-analysis revealed a 5.4 mm Hg reduction in SBP for every 2.3 g/d decrease in sodium intake, which was similar to Huang *et al,* who found a 5.8 mm Hg decrease in SBP for every 2.3 g/d decrease in sodium intake [11,12]. These findings strongly support that reduced sodium intake is an important dietary intervention in patients with hypertension.

The most persuasive clinical trial that demonstrated a link between the effects of salt intake and blood pressure was the DASH-Sodium trial. A rigorously controlled dose-dependent trial among patients aged 22 years and older and from various ethnic groups investigated the effects of three different salt intakes (1.5 g, 2.5 g, and 3.3 g per day) among two distinct diets: DASH and typical American diets [13]. To ensure adherence, participants were given all of their meals and had to eat dinner or lunch onsite during weekdays. Additionally, researchers monitored 24-hour urinary excretion of sodium, potassium, phosphorus, and urea nitrogen to objectively monitor intake. Like previous trials, it showed that the DASH diet decreased SPB by a significantly greater amount (-2.2 to -5.9 mmHg) than the typical American diet (control) at each level of salt intake [10,13]. This result reinforces that there is an additional mechanism by which DASH diet can reduce blood pressure other than reduced sodium intake. In demonstrating that reduced sodium intake significantly lowered SBP in each of the major subgroups studied,

the trial highlighted how restricting sodium intake to less than 1.5 g can reduce blood pressure compared to a more traditionally recommended sodium limit of 2.3 g [13]. The American Heart Association/American College of Cardiology (AHA/ACC) now recommends reducing sodium intake as part of the DASH diet [14].

Foods that are recommended in the DASH diet are also high in potassium, which has been associated with reductions in blood pressure [14]. A metanalysis of 33 randomized controlled trials (RCTs) has documented a significant inverse relationship between potassium intake and blood pressure. More specifically, overall pooled estimates of the effect size of potassium supplementation in adults correlated with SBP and DBP reductions of 4.4 mm Hg and 2.5 mm Hg, respectively [15]. The preferred source of potassium is through diet rather than pills, and the 2,100-kcal version of the DASH diet provides approximately 4.7 g/d of potassium [10]. This is the potassium intake level that the AHA recommends based on the levels used in clinical trials [15].

Dietary approaches to prevent and treat HTN include moderation of alcohol intake, sodium restriction, and an overall healthy eating pattern – which are all lifestyle guidelines within the DASH diet. There are numerous studies that evaluate the effect of reducing alcohol intake on blood pressure. Overall pooled estimates of the effect of alcohol reduction on SBP and DBP were -3.31 mmHg and -2.04 mmHg, respectively [16]. These changes to SBP and DBP suggest that there is a clear benefit of alcohol reduction, and it should be advised to patients as a part of dietary counseling. The DASH diet also includes foods rich in potassium, which have effects of lowering blood pressure independent of other lifestyle changes. Providers should routinely encourage lifestyle intervention and take all available measures to ensure successful implementation of these interventions in motivated patients. Current recommendations for

interested patients with HTN are referrals to dieticians for diet education and frequent follow up [14].

1.3 Statement of the Problem

Lifestyle interventions, such as implementation of the DASH diet, are more effective, accessible, and offer a more favorable side effect profile than pharmaceutical intervention alone. Despite these advantages, a systematic review of nine RCTs concluded that DASH adherence was poor [17]. Most measures of DASH compliance were calculated using either DASH adherence scores or urinary excretion of various electrolytes, such as potassium, phosphorus, and sodium. Included in the systematic review was one RCT which involved 57 adolescent participants who had HTN or were pre-disposed to HTN. The study found that only 21% participants properly followed the DASH diet after counseling with a registered dietician. This is in stark contrast to blood pressure medication adherence (83.8%), where one study used pharmacy claim data from the 2015 Maine Health Data Organization's All-Payer Claims Database to calculate medication adherence using the proportion-of-days-covered method [18,19]. A cross-sectional study of 49 primary care providers from the Denver Colorado metropolitan area surveyed the most commonly held beliefs by physicians for poor DASH diet adherence among their patients [20]. According to these physicians, the most common barriers to increasing adherence were lack of patient motivation, inability to implement the DASH diet (e.g. time constraints, lack of available dieticians, personal lack of belief in DASH effectiveness) , and a lack of educational resources [20]. A different cross-sectional study of 200 outpatients from Iran with essential HTN were surveyed to assess barriers to following a heart healthy diet, such as the DASH eating plan [21] From the perspective of these patients, the most important barriers were environmental barriers (e.g. lack of transportation), social gatherings, ability to comply with diet recommendations, emotional

factors, and cost [21]. It behooves the research and healthcare community to develop and implement new solutions to overcome these barriers. Outside of verbal counseling and informational websites on the DASH diet, there exists no method that providers use to facilitate successful DASH diet implementation.

It is clear that current interventions for improving DASH adherence are ineffective, and new methods are needed to improve DASH diet implementation. Personalized meal planning is a strategy that can help mitigate many of the documented barriers to adherence. Newer meal planning technology makes meal planning seamless, by automatically calculating nutritional needs and providing recipes that accommodate to patients' dietary restrictions. These technologies usually have high quality recipes that help improve palatability, with some that allow for creating a healthy meal plan in minutes. These advantages may not have been available during the assessment of meal planning in older studies. There has been emerging evidence that personalized meal planning is effective at improving diet adherence and outcomes in other chronic conditions (*e.g.*, diabetes mellitus) with similar risk factors to HTN [22]. Current technology advancements and evidence supporting the effectiveness of meal planning in other chronic conditions suggests that meal planning may be an effective tool to improve DASH diet adherence and HTN management. At the time of this writing, there are no RCTs that evaluate the effectiveness of personalized meal planning in improving DASH diet adherence and HTN management.

1.4 Goals and Objectives

The aim of this study is to evaluate if personalized meal planning with verbal counseling can significantly improve DASH diet adherence at 12 months in American adults suffering from stage 1 or higher primary HTN. The DASH diet meal plan has other health benefits aside from

lowering blood pressure, such as weight loss and lowering cholesterol levels. As such, the proposed study will evaluate if personalized meal planning with verbal counseling significantly decreases the following secondary outcomes: SBP, low-density lipoproteins (LDL), total cholesterol, 10-year atherosclerotic cardiovascular disease (ASCVD) risk, waist circumference, and body mass index (BMI).

1.5 Hypothesis

Adults with stage one or higher primary HTN – who start on a personalized meal plan and receive verbal counseling from dieticians (intervention group)– will have significantly higher mean DASH diet adherence scores after 12 months, relative to patients who receive verbal counseling alone (control group). Individuals in the intervention group are hypothesized to have significantly improved (lower) secondary outcomes after 12 months compared to those in the control group. Secondary outcomes include SBP, LDL, total cholesterol, 10-year ASCVD risk, waist circumference, and BMI. In the absence of baseline between group differences, an unpaired Student's t-test will be performed to assess for differences in mean DASH adherence scores, as well as all mean secondary outcomes from baseline to 3 months, 3 months to 12 months, and from baseline to 12 months. Alternatively, generalized linear models, which can include baseline covariates, will be used. In addition, the impact of DASH score change on secondary outcomes will be evaluated using a residualized change model (change controlling for baseline DASH score) within the intervention group only.

1.6 Definitions

Primary Hypertension: Hypertension is defined by the AHA and ACC as a SBP in the office or clinic ≥130 mm Hg and/or DBP ≥80 mm Hg following repeated examination. Primary hypertension is idiopathic hypertension, where its presence cannot be explained by any other disease processes.

10-year ASCVD Risk: The ASCVD risk calculator was developed by the AHA/ACC in 2013 and allows users to determine the 10-year risk of having cardiovascular event such as myocardial infarction and stroke. It is meant for only adult patients aged 40-75 years of age without known ASCVD and with an LDL <190 mg/dL.

DASH: A dietary pattern that requires no special foods and instead provides daily nutritional goals. This plan recommends eating vegetables, fruits, and whole grains, but limiting foods high in saturated fats, sodium, or added sugars [23]. It also emphasizes foods rich in micronutrients such as potassium, calcium, magnesium, fiber, and protein.

Mediterranean Diet: This eating pattern is based on the traditional cuisine of countries bordering the Mediterranean Sea [24]. While there is no single definition of the Mediterranean diet, it is typically composed of meals high in vegetables, fruits, whole grains, beans, seeds, and olive oil.

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Chapter 2: Literature Review

2.1 Introduction

A literature search in PubMed, Scopus, Cochrane library, and OVID databases (including OVID Medline, EMBASE, and AMED) was conducted to evaluate meal planning as a method for enhancing adherence to dietary advice and diet adherence amongst HTN patients. The 2017 AHA/ACC Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults guidelines were used for referencing current HTN recommendations [1]. Studies that utilized meal planning and/or nutritional counseling were reviewed individually to decide the optimal method for operationalization of interventions and outcomes (see subsections 2.6-2.8). Studies included in these searches were RCTs, clinical trials, observational studies, reviews, meta-analyses, and systematic reviews. Key terms used either individually or in combination included: hypertension, heart disease, blood pressure, diet, adherence, compliance, accordance, meal, plan, menu, nutrition, weight, exercise, activity, alcohol, salt, disparity, racial, race, potassium, sodium, DASH diet, heart healthy, epidemiology, interventions, management, pathophysiology, and treatment. References listed in retrieved articles were further hand searched.

2.2 Barriers to Diet Adherence

Adherence rates to dietary advice are poor for chronic conditions such as diabetes mellitus, celiac disease, and HTN [2-4]. 320 adult patients (mean age = 53.8 ± 9.1 years) with type 2 diabetes in a prospective cohort study were surveyed using a questionnaire about barriers to compliance with a nutritional plan at baseline, and then again after receiving barrier-specific nutritional counseling at 3 months, 1 year, and 2 years [5]. At baseline, the most common barriers to diet adherence were lack of information on an adequate diet (24.7%), social circumstances

(19.7%), and lack of motivation (14.4%) [5]. After verbal counseling with a dietician to address and mitigate these barriers, a 37% reduction in the number of adult patients have successfully overcome these barriers by the 2-year follow up [5]. Those with persistent barriers were shown to have higher hemoglobin A1c and triglyceride levels compared to individuals with no reported barriers [5]. This result highlights some common barriers can be overcome through verbal counseling.

A low-income background and lack of equity associated with historically underrepresented ethnic groups are very complex factors that contribute differentially to the patients' identity and health. These patients are disproportionately affected by HTN, making it particularly important to understand and address barriers among this population [6]. A recent survey of 99 low-income minority patients with type 2 diabetes and their providers (n=50) aimed to characterize perceived barriers to diet adherence [7]. The results of the study showed divergent perceptions of barriers to diet adherence between patients and adults [7]. Some of the providers' explanations for poor diet adherence included a lack of motivation, high consumption of fast food, poor family support, and a lack of cooking skills. In contrast, the most common barriers to adherence for patients who identified as being highly motivated were: difficulty giving up unhealthy food (75%), cost of healthy food (54%), and a lack of available education (80%) [7]. Responses and feedback from providers in this study shared a common theme of patient inadequacy. However, patients displayed motivation. This discrepancy highlights the fact that individuals' low socioeconomic status inhibits the necessary resources for DASH diet implementation to treat type 2 diabetes. In fact, this divergence in perception between patients and providers is likely non-constructive and may serve as a barrier itself.

A systematic review on facilitators and barriers of gluten-free diet adherence analyzed 40 studies across four continents per the PRISMA guidelines [2]. The facilitators and barriers were categorized into individual, interpersonal, organizational, community, and system wide factors. Individual barriers were the most consistently reported barrier type among all the studies analyzed and included four main factors: education/income, health status, knowledge, and intention/motivation [2]. Individuals with a lower level of education, income, and knowledge, were unaware of the negative health aspects of non-adherence and did not have the skills needed to follow a gluten-free diet. The Mediterranean Diet, which is a diet that has similar benefits to the DASH diet, has been shown to have several short-term and long-term barriers to adherence [8]. An analysis of participants' baseline characteristics in the PREDIMED trial's intervention groups were performed to test for an association between specific baseline characteristics and adherence to the Mediterranean diet at one-and four year-follow up [8]. Participants in the study were men and women living in Spain aged 55-80 at high risk for ASCVD and were randomized to the Mediterranean diet supplemented with complementary extra-virgin olive oil or tree nuts. The analysis found that individuals experiencing greater baseline cardiovascular risk factors–*e.g.,* larger waist circumference, lower physical activity levels–adhered poorly to the diet both short-term and long-term. The authors of the study noted that these factors can be used to characterize a patient's baseline health status, which may further indicate how much a person values their health. Therefore, if patients have multiple high-risk characteristics, then these factors can help providers identify those who may need more intensive facilitation of lifestyle interventions.

2.3 Existing Methods for Improving Diet Adherence in Patients with Chronic Diseases

2.3.1 Multiple Interventions Improve Mediterranean Diet Adherence

Combination of intervention methodologies is more effective for increasing diet adherence than any singular intervention alone. In 2014, a systematic review was conducted on 15 RCTs to analyze interventions that may improve healthy eating or Mediterranean diet adherence in adults [9]. These studies mainly focused on nutritional counseling. The review found that nutritional counseling is effective at improving dietary habits; methodologies that combine multiple interventions (e.g., telephone counseling, group sessions, educational materials) were more effective than individual counseling alone.

Since this review, a 2020 sub analysis of a more recent RCT (CARDIOPREV) also found that multiple interventions were effective at improving Mediterranean diet adherence [10,11]. The CARDIOPREV study is a RCT from 2016 that aimed to compare the effects of a Mediterranean diet and a low-fat diet on new cardiovascular events, which included 1,002 patients aged 20 to 75 years who suffered from coronary heart disease [10]. To ensure adherence to the randomized diet, a team of registered dieticians conducted the same intervention in both groups. The participants would partake in individual counseling sessions every 6 months, bimonthly telephone interviews, and group sessions every 3 to 4 months with a registered dietician. These sessions were educational and provided the participants with motivation and materials to maintain diet compliance. A 137-item food frequency questionnaire (FFQ) was utilized to monitor diet quality at baseline and then every 12 months. Diet adherence was assessed at all visits (individual, group, and telephone) using Mediterranean diet adherence scores, where a score ≥ 10 is high adherence, a score of 6–9 is medium adherence, and a score ≤ 5 is low adherence. A separate analysis of the CARDIOPREV study aimed to evaluate the effectiveness of these interventions at

improving Mediterranean diet adherence [11]. They found from baseline to 5 years, there were significant increases in Mediterranean diet adherence scores (8.9 to 11.4) and in percentage of patients considered highly adherent (41 to 89%). These studies support that comprehensive dietary intervention (e.g., educational materials, multiple counseling sessions, self-monitoring) results in improved Mediterranean diet adherence. The Mediterranean diet has similar indications and benefits to the DASH, making these study results relevant to DASH diet implementation. More specifically, these studies support that a multifactorial intervention may be more effective at improving DASH diet adherence than a less comprehensive intervention.

2.3.2 Type 2 Diabetes Studies Reveal Mobile Applications are Effective in Improving Diet Adherence

Type 2 diabetes and HTN are both risk factors for one another and share many of the same risk factors, such as obesity and dyslipidemia [12,13]. Therefore, methods that have been shown to improve diet adherence in type 2 diabetes may also have implications in HTN management. A 2021 systematic review by Enricho *et al*, analyzed six RCTs that assessed the effectiveness of diabetes self-management education and support (DSMES) apps on treatment adherence in patients with type 2 diabetes [14]. This review has shed light on the utility of mobile health applications in improving chronic disease management [14]. DSMES apps have been used to improve patient compliance in all aspects of type 2 diabetes care, including medical prescriptions, exercise, and diet plans. The authors found that DSMES apps had a significantly small to moderate effect on all aspects type 2 diabetes treatment adherence [14]. One study in the review was an RCT on 204 subjects aged 25-70 years old with type 2 diabetes evaluating the effectiveness of a multifactor intervention in increasing adherence to the Mediterranean diet [15]. The intervention was composed of an educational food workshop, five walks, and receipt of a

DSMES app for three months. After three months, the intervention group had significant improvements in diet adherence and diet quality compared to the control group [15] ($p < 0.05$). These studies support that the current smartphone applications and educational interventions are effective at improving patient compliance with type 2 diabetes treatment regimens.

2.3.3 Mobile Applications and Lifestyle Counseling Improve Diet and Exercise Levels

Two RCTs that evaluated the effectiveness of mobile applications and websites in conjunction with some form of coaching, showed significantly improved physical activity and diet adherence ($P < 0.05$). Spring *et al.,* studied 212 Chicago adults with a poor baseline diet and low activity [16]. The interventions were personalized remote coaching in conjunction with an accelerometer and smartphone app for behavior monitoring. The smartphone app outlined specific dietary goals and provided feedback on their choices. Coaches provided remote feedback on physical activity based on accelerometer data, and perfect diet and exercise adherence was awarded $5 per week. The interventions produced significant, sustained improvements compared to control, and brought all diet and activity behaviors to guideline levels. Another RCT of 210 community-dwelling inactive women, who were given personalized workout plans in conjunction with a mobile phone app, showed clinically significant improvements in physical activity compared to the control group [17]. While not related solely to diet adherence, these studies showed that personalized health plans with specific goals could result in clinically significant outcomes.

2.3.4 Studies That Utilized DASH Adherence Scores as an Outcome Measure

Though there is relatively limited data on specific interventions that improve DASH adherence, there are several RCTs that have used DASH adherence as a primary or secondary or outcome measure (Table 1). Three notable RCTs that had effective interventions will be

discussed further and include: (1) transtheoretical model-based behavioral intervention (TBI), (2) group and individual TBI sessions, and (3) DASH meal delivery services [18-20].

A multiethnic RCT by Rodriguez *et al.* [18] on 533 individuals with uncontrolled HTN evaluated the effect of TBI compared to a non-tailored intervention or usual care on DASH adherence. The TBI emphasized the individual's ability to regulate behavior by setting goals, shared decision making, and tailoring the conversation to the individual's stage of change (precontemplation, contemplation, action, or maintenance). The TBI intervention utilized months telephone counseling for 6 months and resulted in a significant DASH score increase of 1.28 points (range 8-40) but no significant change in individual food groups. Additionally, the intervention resulted in significant advancements in the participant's stage of change ($p < 0.05$). [18]. This is one of the few RCTs in Table 1 that were specifically designed to improve DASH adherence, making it relevant to shaping the RCT proposed in this paper. Similar to other studies listed, this study found that nutritional counseling is beneficial in promoting diet adherence. However, an important limitation is that a similar study by Racine *et al* [21] found that personalized medical nutrition therapy resulted in no significant changes in DASH adherence (Table 1). These conflicting results, compounded by the modest effect that TBI had, highlight the need for a more impactful intervention.

The second study that utilized personalized counseling was the PREMIER study, a multiethnic RCT of 810 adults (mean age 50 +/- 8.9 years) whose aim was to evaluate the effect of lifestyle intervention on blood pressure [22]. This study was designed to evaluate the effects of the DASH diet, weight loss, increased physical activity, and limited alcohol intake simultaneously on blood pressure. To implement dietary intervention, the researchers utilized personalized nutritional and behavioral counseling, tailored to their stage of change (similar to

TBI intervention in Rodriguez *et al* [18]). See Table 1 for a more detailed outline of treatment and control groups. A sub analysis of the results of the PREMIER study showed significant improvements in DASH food intakes among those receiving intensive group and individual counseling on the DASH diet compared to the control group [19]. Additionally, the intervention groups had significant reductions in SBP and DBP compared to control. The RCT by Rodriguez *et al* [18] and this sub analysis of the PREMIER trial highlight the possible effectiveness of verbal counseling and motivational interviewing on DASH adherence. While this does help inform the intervention in our proposed study, the PREMER trial has some notable limitations. Similar to the results of Rodriguez *et al,* the results were modest and the percentage of participants that met the DASH intake goal for saturated fat, cholesterol, and sodium at 6 months were 10.6%, 7.2%, and 0%, respectively [19]. Additionally, the control group did not receive personalized DASH diet intake goals like the intervention group, and instead, were just educated about the DASH diet. The PREMIER trial was not focused solely on DASH adherence, therefore there were multiple aspects of the intervention that were absent in the control group, making it difficult to establish cause and effect.

In addition to counseling techniques (e.g., TBI, group, and individual counseling), meal delivery services have also been shown to be effective at improving DASH adherence. Troyer *et al.,* conducted a 12-month long RCT of 298 mostly low-income (56.7% were >165% of poverty level) individuals (82.9% female) with hyperlipidemia or HTN in which individuals were assigned to one of four groups: (1) literature on management of their disease, (2) therapeutic meals, (3) medical nutrition therapy, or (4) medical nutrition therapy coupled with therapeutic meals [20]. Medical nutrition therapy is a diagnosis-specific nutrition therapy delivered by a registered dietician over the span of three sessions. Therapeutic meals were seven dietician

deigned meals that were developed using the American Dietetic Association medical nutrition therapy protocols for caloric and nutrient content requirements outlined in the DASH diet [23]. The meals were delivered cost-free directly to the patient's home. The goal of the study analysis focused on individuals who received meals and those who did not receive therapeutic meals. 24-hour food recall questionnaires were completed by participants at baseline, 6, and 12 months to evaluate for change in DASH adherence. An overall and intermediate DASH score was calculated using the Mellen index [3]. After 6 months, participants who received the meals were 20% more likely (P=0.001) to reach intermediate DASH accordance. After 12 months, individuals receiving the meals were 18% more likely to meet saturated fat accordance (P = 0.007). While the results were significant, an important limitation includes the applicability of these results. Premade meal delivery services can be costly, making these services inaccessible to low-income populations who are disproportionately affected by HTN [24]. A strength of this study was the inclusion of the intention to treat analysis cases, making these results of therapeutic meals particularly robust. While the results were significant, the authors' noted tailoring meals to the individual's taste would likely increase diet adherence further. This is an advantage of personalized meal planning using modern tools, which allows patients to customize their plans with meals they enjoy.

2.3.5 Limitations of Current Interventions to Improve DASH Adherence

While these studies are informative for designing the intervention and control group in our proposed RCT, they have several important limitations. Notably most RCTs listed in Table 1 were not originally designed with the intention to test DASH adherence. Therefore, these studies did not have the adequate controls needed to fully evaluate the effectiveness of the intervention on DASH adherence. Secondly, the interventions used in studies that were designed to test

DASH adherence either had conflicting results (personalized nutrition counseling) or are not generalizable to much of the population (meal delivery services). In most of these interventions, DASH adherence was still suboptimal and far lower from the adherence levels in the original DASH trials [25]. There is some evidence supporting that to achieve satisfactory results from implementing the DASH diet, adherence needs to be similar to that of the original DASH trial [26]. Therefore, additional measures need to be made to further improve DASH adherence.

Our proposed study will utilize regular nutritional counseling as one component to improve DASH adherence. The literature reviewed in this paper supports that verbal nutritional counseling is the most consistent method to improve adherence in non-DASH diets. While there is a lack of RCTs designed to test interventions for improving DASH adherence, personalized nutritional counseling (at varying levels of intensity) was the most consistent method to improve adherence. In fact, the only study to achieve near perfect DASH adherence (98.7%) was the original DASH trial. To ensure adherence in the original DASH study, a team of nutrition professionals carefully curated a meal plan that met the patient's nutritional goals and premade meals which were delivered directly to the patient. Additionally, these professionals provided financial incentives for proper adherence. Troyer *et al.* replicated some of the beneficial effects using meal delivery services – not personalized meal planning – on DASH compliance. However, this service only resulted in a 11.3 % DASH accordance after 6 months [20]. This pales in comparison to the original DASH trial, where up to 98.7% of participants met the food and nutrient intake goals. Perhaps the premade meal plan accounts for the significant differences seen in DASH adherence between the original DASH trial and the study by Troyer *et al*. Additionally, most individuals in the original DASH trial were minorities (>60%), unlike Troyer *et al* (60% white), suggesting that meal planning may be beneficial for those disproportionately affected by

HTN [20,25]. As such, meal planning shares the strengths of other effective methods for diet facilitation, such as the ability to personalize the intervention to the patient's needs. These studies suggests that meal planning is a promising intervention (discussed more in Section 2.5) that is practical and in combination with nutritional counseling, may help patients see the benefit of the DASH diet to its greatest extent.

Table 2. RCTs whose primary or secondary outcome was DASH diet adherence.

Author	**Duration (months)**	**Intervention**	**Control**	**Adherence Outcome Measures**	**Results**
Troyer *et al.* [20]	12	Verbal counseling and meal delivery services	Verbal counseling	Mellen index (range 0-9)	Significant increase in compliance at 6 (P = 0.001) and 12 months (P = 0.007)
Rodriguez *et al.* [18]	6	Monthly telephone TBI sessions for six months tailored to their stage of change	A non-tailored intervention or usual care	Harvard DASH score (range 8-40)	TBI had a 1.28-point increase in DASH score ($p \leq .01$)
Lin *et al.* [19]	18	Intervention 1: Same as the control plus 18 intensive group and individual counseling sessions with addition of counseling on the DASH diet intake goals Intervention 2: Same as the control plus 18 intensive group and individual counseling sessions without DASH specific counseling	Brief 30-minute educational sessions on the non-pharmacological approaches to lowering blood pressure (weight, sodium intake, DASH diet, and physical activity)	Nutrient intakes based on the DASH diet and dietary reference intakes	Proportion of participants who met DASH nutrient intake levels and dietary reference intakes were significantly increased in the intervention groups (P<0.01)

Steinberg *et al.,* [27]	12	The TRACK intervention was intensive and included five components: tailored behavioral goals, self-monitoring of these goals, daily self-weighing, skills training materials (both print and video), and multiple weight loss counseling sessions with a registered dietician and/or a primary care physician	Usual primary care	FFQ were used at baseline and 12 months to calculate a DASH adherence score using a method similar to the Mellen index (range 0-9) [3,27]	DASH score improvement of 1.28 in intervention and 0.20 in control ($P < 0.001$)
Steinberg *et al* [28]	3	App-based diet tracking with DASH diet specific feedback via text The texts also incorporated automated recommendations on how to improve DASH adherence	App-based diet tracking	Weekly automated self-administrated recall tools were used to calculate a DASH adherence score using the Mellen index (range 0-9)	Both treatment and controls improved DASH adherence score (mean change of 0.8) but there was no significant difference There were no significant blood pressure changes between treatment and control groups
Booth *et al.* [29]	3	DASH diet with counseling that included lifestyle advice, feedback, and goal setting	Low fat diet with the same behavioral intervention as	% of individuals meeting the target fruit, vegetable,	The intervention group had a significant increase in

			the intervention group	and dairy intake	vegetable intake between weeks 2 and 8
Epstein *et al.* [30]	4	Intervention 1: DASH with weekly counseling sessions focused on discussing goals Intervention 2: As above but with additional calorie restriction, behavior modification, and aerobic exercise sessions	The usual diet control group was asked to continue their daily routine for diet and exercise	DASH adherence score (range 1-10)	Both intervention 1 and 2 resulted in significant increases post treatment consumptions of DASH foods and adherence scores compared to the control group
Couch *et al.* [31]	3	A clinic and phone/mail based behavioral intervention that emphasized the DASH diet	Single session with a dietician to assess habits and set diet goals (routine care)	Analysis of individual food components in the DASH diet	Post-treatment, there were greater increases in fruit servings in the intervention group. Also, at 3 months follow up, there were greater levels of low-fat dairy servings ($P<0.001$) in the intervention group
Racine *et al.* [21]	12	Medical nutrition therapy, characterized by nutritional assessments, goal setting, and self-management training	The information group received brochures and educational factsheets regarding	Mellen index (range 0-9)	There were no changes in DASH score at 6- and 12-months post intervention

			disease management		

2.4 Personalized Meal Plans as a Method to Improve DASH Diet Adherence

Although there are few studies that analyze interventions for improving dietary adherence in HTN individuals, a 2013 Cochrane review investigated approaches to enhance adherence to dietary advice in other related diseases [32]. The purpose of this review was to provide guidance on the best interventions to improve patient adherence to dietary advice, but many of the studies were deemed low quality and had inconsistent methods. Consequently, the review concluded that no single method was consistently effective and highlighted the need for more research and advancements in this field. One type of intervention evaluated in this review was the use of nutritional tools, such as ingredient substitutions, portion size examples, and meal plans as a method to improve diet adherence. Since the publication of this review, there have been advancements in technology that better utilize nutritional tools, such as smartphone applications [33].

While most of the nutritional tools were ineffective at improving adherence, the 2013 Cochrane review did note an RCT that highlighted the effectiveness of meal planning in improving dietary adherence among patients suffering from chronic kidney disease [34]. The patients enrolled in this study were male and female adults who were clinically stable, had no history of cognitive impairment, and were on peritoneal dialysis. The study took place at the Peking University First Hospital in Beijing, China. The patients were randomly assigned to one of two groups: group one, where patients received nutritional counseling; and group two, where patients received nutritional counseling and individualized menu suggestions based on their food preferences. The main outcome was meeting a protein goal of 0.8 to 1.2 g/kg/d. Compliance was

22.9% in group one and 57.1% in group two ($p < 0.05$), suggesting menu planning may improve diet adherence in chronic kidney disease patients [34]. There have also been many advancements in meal planning tools since 2013, perhaps making the current appraisal of personalized meal plans outdated.

Meal planning has also been shown to be effective in the management of type 2 diabetes, another chronic disease where lifestyle intervention is the cornerstone of management. A pilot study at the University of Alberta, evaluated the effectiveness of a personalized menu plan in managing type 2 diabetes [35]. Study participants were predominately white (80%), adult men and women who spoke English, and had no dietary restrictions. The study used hemoglobin A1c levels as a measure of disease management. hemoglobin A1c is a blood test that measures average blood sugar levels over the past 3 months and is commonly used to detect prediabetes and diabetes (normal values are <5.7%). hemoglobin A1c after the meal planning intervention decreased by 1.0% over a 12-week period, and there were significant reductions ($p<0.05$) in weight, BMI, waist circumference and fat mass. Perceived dietary adherence score also increased significantly ($p<0.05$). Since 2014, the same group has launched a larger trial at the University of Alberta, using the same intervention in patients with type 2 diabetes and found similar results that were maintained for the entire duration of the study (12 weeks) [36]. The participants in this study were predominately white (~88%), adult men and women, who mostly (~78%) had an annual income of greater than $60,000. The results of these studies are particularly important for HTN management because both type 2 diabetes and obesity are modifiable risk factors for HTN [37]. These results further suggest that personalized meal plans may be an effective method for managing HTN.

A 2021 retrospective cohort study of 1,740 predominately female (84%) adults with obesity who used FoodSmart, a digital personalized meal planner with virtual registered dietician support, showed that their meal planning service resulted in 5% body weight loss in 33% of participants over a three year period [38]. Additionally, a recent 2021 retrospective analysis was performed on 643 adults (64% female) enrolled in the FoodSmart platform with at least two self-reported hemoglobin A1c entries [39]. About 81% of these individuals were overweight or obese, 47% had HTN, and 57% had high cholesterol. Ethnicity and income data were not collected. Among participants with diabetes at baseline (43.5%), there was a mean reduction of hemoglobin A1c by 0.35%, 0.45%, and 0.7% with a follow up time of 6, 12, and 24 months, respectively. This new technology has been approved by several insurance plans including Medicare. Since the Cochrane review in 2013, newer evidence is supporting the claim that personalized meal plans improve dietary adherence from those suffering from chronic conditions such as chronic kidney disease, type 2 diabetes, and obesity [36]. Companies such as FoodSmart are aware of the effectiveness of meal planning and are trying to make practical tools, *e.g.*, telenutrition, for patients and providers to improve diet adherence.

Though there is evidence that improving adherence to a heart healthy diet improves HTN management, studies that evaluate interventions to improve diet adherence in HTN are scarce [40]. One recent study in Toronto, Canada, evaluated the effectiveness of expert-driven and user-driven lifestyle interventions in patients suffering from HTN. Patients in this study were mostly white (72.7%) male and female adults with 66% of participants having a household annual income of greater than $60,000**.** The user driven groups were given weekly electronic reminders of the prescribed lifestyle interventions with educational materials. Participants in the expert-driven group received the same hypertension management recommendations for lifestyle change

as the user-driven group however, the weekly emails consisted of predetermined exercise and dietary goals that were specific and prescriptive. The expert-driven intervention was more specific than the user-driven group and required less effort to develop exercise and meal plans. The control group was unique from the intervention groups because it was limited to educational materials and no electronic reminders. The results showed that the expert-driven group was significantly more effective than the control group at the 4- month follow-up in reducing systolic blood pressure, pulse pressure, total cholesterol, and 10-year ASCVD risk. This study highlights that individuals may be more likely to follow dietary advice appropriately when the advice is specific and prescriptive. Personalized meal plans are specific, prescriptive, and have also been successful in managing other chronic diseases like chronic kidney disease and type 2 diabetes.

2.6 Measures to Quantify DASH Diet Adherence

There are four DASH diet scoring methods that are used in the majority of cohort studies: the traditional DASH diet scoring, the modified DASH score, the Mellen index, and the ideal diet index. The traditional DASH diet scores were originally described by Fung *et al* [41], where individuals are given a score based on the intake of 8 food and nutrient components that are emphasized in the DASH diet: fruits and vegetables, nuts and legumes, low-fat dairy products, whole grains, low intake of sodium, sweetened beverages, and red and processed meats. The original DASH diet emphasized limiting saturated fats which is reflected in this score by limiting red and processed meats. Participants are then classified into quintiles according to their intake ranking for each of the eight food components, which is based on a validated FFQ. For example, if participants ate less than 0.7 servings/day for a food component, then they would be in the first quintile (1 point). However, if they consumed more than 4.1 servings per day, then they would be in the fifth quintile (5 points). Any intake level between those two values were quintiles 2-4.

Each individual component score is then added up to provide a DASH score which ranges from 8 to 40, with 8 being the lowest level of adherence and 40 being the highest level. Limitations of the score in this study include that the food components are measured in servings per day over a twelve-month period, which can be difficult to conceptualize and keep track of for study participants.

The modified DASH score was described by Yu *et al*,.[42] and reflects seven main components of the DASH diet: fruits; vegetables; dairy; meat, poultry, fish, and eggs; nuts, seeds, and legumes, fats and oils, and sodium. The maximum point for each component is 10 and the possible score ranges between 0 to 70 points. A validated FFQ that was used originally in the Nurses' Health Study was used to quantify food frequency over 12 month period [43]. These scores are then to be converted into servings used in the DASH diet: 80 g/serving for vegetables and fruit, 245 for dairy, 28 for meat, poultry, and fish, 50 for eggs, 43 for nuts, 28 for seeds, 113 for legumes, and 15 for fats and oils. Serving frequency for each food component are converted into points and the scores for each component provide a total score to reflect overall diet adherence. This scoring system was made because the study population consumed very low levels of whole grains and sweetened beverages. Therefore, the researchers did not include it in data collection, making this measure slightly less comprehensive than the traditional DASH score.

The ideal diet index, which was adapted from DASH following AHA definition of ideal cardiovascular health, includes eight dietary components: fruits and vegetables, fish, whole grains, sodium, added sugar, nuts/seeds and legumes, processed meat, and energy percentage from saturated fat [44]. Individuals were given a score of 1 for meeting the component cutoff and 0 if they did not. See M. Cuenca-García *et al*., supplemental Table 2 for more details regarding the point thresholds for each component [44]. Total scored ranged from 0 (worst adherence) to 8 (best

adherence). This scoring system does not account for component scores that were close to threshold, and therefore, is less descriptive of the adherence overall.

The Mellen index was described by Mellen *et al.*,[3] and it uses 9 nutrient targets (total fat, saturated fat, protein, fiber, cholesterol, calcium, magnesium, and potassium), which represent the goals originally purposed by the DASH diet with the addition of sodium. Sodium was included because it is now recommended as a component of the DASH diet, due to the results of the DASH-Sodium trial [45]. The DASH score is then generated by sum of all nutrient targets with a maximum score of nine. Individuals meeting at least half of the DASH targets (DASH score ≥ 4.5) were considered adherent. This score is commonly used in the literature and is calculated by meeting nutrient targets rather than food servings. It also incorporates sodium intakes, reflecting the newer AHA/ACC recommendations after the DASH-Sodium trials [45].

The Mellen index is the most commonly used scoring system by RCTs evaluating DASH adherence [46] (Table 1). Heterogeneity amongst DASH adherence scoring systems makes it difficult for comparing interventions across different studies and therefore, has been noted as a limitation in the current literature [47]. Therefore, we will utilize the Mellen index in our own study to address this limitation and better compare our results to other RCTs.

2.7 Secondary Outcomes

The primary outcome to be measured in the purposed study is adherence to the DASH diet. However, there are many secondary outcomes in which to aid our assessment of the effectiveness of nutritional counseling in conjunction to implementation of the DASH diet. Since DASH diet provides many health benefits, secondary outcomes for quantifying effectiveness include measuring changes in blood pressure, LDL, total cholesterol levels, risk for CVD, waist circumference, and BMI [48-51]. The DASH diet has previously been shown to positively impact

glycemic control and reduce the risk for developing type 2 diabetes [52]. Hence, results from quantifying the above-mentioned secondary outcomes would be pertinent to our proposed study because implementing the DASH diet among participants should significantly lower these secondary outcomes in both treatment and control groups.

A systematic review and dose-response meta-analysis of prospective cohort studies by Soltani *et al.,* [53] found that even modest increases in adherence are associated with a lower risk of all-cause and cause-specific mortality. The inclusion criteria were met by 17 studies where they converted all measures of adherence to the conventional DASH scoring method. The linear dose-response analysis showed that a five-point increase in DASH adherence score was associated with a 5%, 4%, 3%, and 3% lower risk for all-cause mortality, CVD, stroke, and cancer mortality, respectively. Additionally, the non-linear dose-response analysis found that the DASH-mortality association becomes more significant once the adherence score exceeds 20 points, which correlates with a medium to high level of adherence. This study is significant because if our intervention (personalized meal planning) does improve DASH diet adherence scores, then we should see a corresponding change in SBP, LDL, total cholesterol levels, 10-year risk for ASCVD, waist circumference and BMI.

2.8 Meal Plan Development

All meal plan development in this proposed study will be done using the FoodSmart meal planning software. This program has demonstrated to support its effectiveness in producing clinically significant weight loss and hemoglobin Alc reduction [38,39]. Additionally, it is more affordable than traditional medication management for type 2 diabetes and is approved by Medicare and Medicaid health plans [38,39]. The meal planning software will be used by the registered dietician to construct a meal plan that accommodates to the patient's taste preferences

without veering from nutrient and food serving targets (Section 3.5A). Meal plan development is complex, and requires understanding an individual's physical activity level, anthropometric data, and subsequent weight goals. See Appendix A and Table 2 for an explanation of the components needed to calculate total energy expenditure (TEE). There have been numerous predictive equations used to estimate resting energy expenditure (REE), which have varying accuracy depending on the population of interest, with the original being the Harris-Benedict equation [54,55]. The most commonly used predictive equations used in clinical practice are the Harris-Benedict, Mifflin-St Jeor, Owen, and World Health Organization/Food and Agriculture Organization/United Nations University (WHO/FAO/UNU). See Table 3 in Appendix A for the equations and notable features of each equation.

A systematic review by Frankenfield *et al*, analyzed 10, 25, 13, and 0 validation studies for the Mifflin-St Jeor, Harris-Benedict, Owen, and WHO/FAO/UNU equations, respectively [56]. At the time of this review, there were no WHO/FAO/UNU validation studies that looked at individual prediction accuracy. All studies looked at group prediction accuracy, therefore, they couldn't compare the accuracy of this equation to the other equations evaluated in the review. The other equations were evaluated on their ability to prediction for caloric needs for individuals, not groups. The review concluded that the Mifflin-St Jeor was most accurate for estimating resting metabolic rate in both obese and non-obese individuals, and also had the narrowest error range. It defined accuracy as predicting resting metabolic rate within 10% of actual resting metabolic rate when measures with indirect calorimetry. Given that obesity is prevalent among individuals with HTN [57], this is the equation utilized in the proposed RCT. An estimated physical activity level (PAL) will be used as a multiplier of the REE to estimate the participants TEE. See Table 4 and associated text in Appendix A for a more detailed discussion of these calculations.

2.9 Conclusion

The abovementioned studies listed in Table 1 suggest that personalized meal plans could be effective in improving DASH diet adherence among patients suffering from HTN. Personalized meal plans could overcome several well recognized barriers to diet adherence, particularly accessibility, palatability, and nutritional literacy. Novel tools such as FoodSmart make meal plans that require little to no effort on behalf of the patient and are personalized to the patient's taste, without veering from diet parameters. The current evidence suggests that personalized meal plans may be an effective intervention for the management of HTN.

The aim of the proposed study is to evaluate the effectiveness of personalized meal plans at improving DASH diet adherence and subsequently, HTN management. We will conduct a randomized controlled trial in which the control group would receive verbal advice describing the DASH diet and an information pamphlet from the dietician. The intervention group would receive the same education as the control but include a printed and electronic DASH diet meal plan, personalized to the patients' preferences by the same dietician. The study population would be adults suffering from primary stage one or higher primary HTN as defined by the AHA/ACC [1]. Primary outcomes would include changes in DASH scores using FFQ and computational analysis.

Effective implementation of treatment regimens, including diet, exercise, and pharmacologic interventions, are important for clinical practice. Determining the best lifestyle implementation strategies will help guide us as clinicians and ensure that we are helping our patients reach their health and wellness goals. This study could also serve as a guide to registered dieticians, shaping their future practice as they manage nutrition needs in patients. The current

standard of care for outpatient diet implementation in hypertensive patients include verbal advice along with portion visualizations, diet label education, and a list of low sodium foods [58]. Personalized meal plans have historically been time consuming and under-utilized. However, new technology is simplifying the meal planning process for both providers and patients. Aside from changes in implementation, improving HTN management would alleviate some of the economic burden that HTN and its related diseases cause. Lifestyle interventions have been known to be an effective and affordable treatment for patients. Our implementation strategy would help patients see the impact of dieting to its greatest extent possible.

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Chapter 3: Study Methods

3.1 Study Design - Overview

This study will be a randomized, clinical trial with two parallel groups. Subjects will participate for a period of 12 months. The study subjects will be patients who are seeking care from their primary care providers at Yale New Haven Hospital (YNHH) primary care facilities and who have been diagnosed with stage one or higher primary HTN as defined by the AHA/ACC [1]. Patients seeking care between 06/01/2022-12/01/2022 at their primary care providers will be screened for study eligibility (Table 5). Eligible patients who give informed consent, will be referred to a registered dietician within the YNHH health care system and will undergo stratified randomization with allocation to either the intervention or control group. The primary outcome will be adherence to a DASH eating pattern, measured using the mean DASH score (Table 6 in Appendix B) at 3- and 12-months post-randomization. Secondary outcome measures will also be measured at 3- and 12-months post-randomization.

Table 5. Inclusion and exclusion criteria for trial enrollment.

	Inclusion	**Exclusion**
Age	Age ≥ 18	
Health Requirements	Have a SBP ≥ 130 mm Hg and/or DBP ≥80 mm Hg Have been on the same HTN medications for the past six months Low suspicion of secondary causes of HTN per provider judgement	Diagnosis of any other CVD SBP ≥ 180 mm Hg and/or DBP ≥ 120 mm Hg
Other	Have had a diagnosis of HTN for ≥ 6 months Have autonomy over diet and food purchasing decisions	Low predicted likelihood of changing dietary habits in the absence of intervention according to the Prochaska stages of change model

		Inability to access YNHH and primary care facilities

3.2 Study Population and Sampling

Study participants will be patients who satisfy all the inclusion criteria (Table 5) from YNHH primary care facilities and that are seeking care from their primary care provider between 06/01/2022-12/01/2022. Three primary care clinics are located in New Haven, CT and East Haven, CT. Based on CDC and American Academy of Family Physicians data, it is estimated that these clinics will come into contact with at least 2,250 patients with HTN during this time [2,3]. Employed registered dieticians within the outpatient Nutrition Services department at YNHH will be contacted for willingness to participate in the study. Enrolled patients will be referred to Nutrition Services at YNHH for dietary counseling and/or personalized meal planning. Recruitment will occur on a rolling basis over the six-month recruitment period and the randomization will be performed prior to the first nutrition services appointment by a research assistant.

3.3 Subject Protection and Confidentiality

Prior to the recruitment period, this study will be proposed to the Human Investigation Committee of the Yale School of Medicine to gain approval from the Institutional Review Board (IRB). The proposal will include evidence of successfully completed Yale Human Subject Protection and Health Insurance Portability and Accountability Act (HIPAA) privacy training for each researcher involved. No member of the research team will have any financial nor non-financial relationship with the proposed research that may pose a conflict of interest. The proposal will also include the following: completed protocol, consent forms, debriefings, recruitment materials, assessments (FFQs), and measures (DASH score and all secondary

outcomes). The informed consent document (Appendix C) will contain the following components: a description of the clinical investigations; confidentiality; compensation; medical treatments in event of injury; contact information of the research team; alternative treatments available; and statement noting that participation is voluntary. Consent forms will be made available in English, Spanish and Portuguese, representing local community composition. The information in the consent form will be presented verbally by the research assistant with assistance as well as in writing. My Accessible Real-Time Trusted Interpreter, a HIPPA-approved, two-way video and audio translator will be utilized during the consenting process if the participant is non-English speaking. The individual's questions will be answered as needed, after verbal presentation by the research assistant.

Data confidentiality, in accordance with the IRB and HIPAA, will be maintained by deidentifying all Protected Personally Identifiable Information using research identification codes. Access to the master code list and all research information will be limited only to relevant research team members. All files will be passcode encrypted and HIPAA authorization forms will be stored securely separate from research data. Confidentiality will be maintained throughout all stages of research and this process will be explained during the consenting process as mentioned above.

3.4 Recruitment

Research assistants will identify eligible participants by searching the electronic health record for all scheduled clinic patients during the 12-month recruitment phase at the YNHH primary care sites. All providers will be notified about their eligible patients and will introduce the study to the patient if they intend on referring them to a registered dietician for dietary intervention. The provider will give the patient a card with the research assistant's contact

information and instruct them to contact the research assistant at least 24 hours prior to their appointment if they are interested**.** Patients will be able to contact the research assistant and schedule a time to meet prior to the appointment with the registered dietician, who will explain all details of the study (rationale, time commitment, etc.) and proceed with the consenting process (Section 3.3). If the participant agrees, then baseline DASH adherence will be calculated by the research assistant during a visit prior to randomization. Additionally, data for baseline characteristics (Table 9) will be collected and TEE will be calculated by the research assistant during the same visit. Subsequently, the participant's registered dietician will be called and instructed to provide either the intervention or control, based on a random number generator.

3.5 Study Variables and Measures

3.5.1 Interventions and Control

The intervention has two components: education about the DASH diet and a personalized meal plan developed by the registered dietician. The beginning of the appointment will include an educational conversation about the DASH diet from the RD using resources and handouts provided by the National institute of Health website. The research team will curate these handouts to create a standardized package of materials to be used by the registered dieticians. The registered dieticians at YNHH have been professionally trained in dietary counseling and meal plan development. The conversation will cover topics including defining the DASH diet and describing how the participant will follow the diet, including associated health benefits. The RD will then allow the patient to ask any questions regarding the new intervention and have the participant summarize their conversation to ensure mutual understanding. This would conclude the verbal counseling portion of the intervention, to be followed by meal plan development. To check the fidelity of the intervention and control, random audio recordings of the conversations

between participants and registered dieticians will be collected and analyzed by the research assistants. Any concerns of fidelity will be addressed directly with the registered dietician by the research assistant and noted, so that they may be accounted for in analyses as necessary.

The first step of meal planning would include collecting the subject's dietary restrictions and cuisine preferences to find meals that the participant will find as enjoyable. Using the FoodSmart meal planning software, the RD will collaborate with patients to find five breakfasts, lunches, dinners, and snacks (20 total) that look palatable without veering from diet parameters. Anthropometric measures of the patient will be obtained to calculate the patients' REE using the Mifflin-St Jeor equation (Table 3). TEE will be estimated by multiplying the patient's REE by a PAL that the patient identifies with (Table 4). If the patient has overweight or obesity, the RD will subtract 500-1,000 calories per day, which would correlate to 1-2 pounds of weight loss per week [4]. The rate of weekly weight loss will be a clinical decision made by the RD and the goal would be to eventually achieve a healthy BMI. However, it is acknowledged that a healthy BMI would not be attainable for all participants in the timeframe of this study. The meal plan would be adjusted back to maintenance calorie intake if a heathy BMI is attained per CDC BMI calculators [5]. The daily nutrient target and food serving intake will mimic that of the original DASH trial with the exception of sodium intake, where a limit of 1,500 mg will be imposed (Table 7). RD will then build a weekly meal plan that meets these nutrient intake goals as close as possible whilst incorporating the patient's meal preferences. Possible meal replacements will be incorporated into the plan and also be tailored to the subjects' preferences in a similar fashion, without veering from diet parameters. A weekly grocery list of all ingredients and cooking instructions for each recipe will be generated and accompany the printed meal plan. The registered dietician will provide educational counseling on meal plan development to the

participants throughout the personalization process. This will conclude the meal planning intervention. The patient will schedule follow up visits every three months until the conclusion of the study to provide verbal counseling and address any concerns that the patient may have.

The control group will receive the same verbal counseling, energy calculation, weight loss goal, and follow up frequency as the intervention group; however, these participants will not receive a personalized meal plan. To ensure approximately equal time is spent with the participants in each group (controlling for dietician contact time), the registered dieticians in the control group will counsel on the process of creating a meal plan tailored to their energy requirements and preferences. However, the participants in the control group will not receive a personalized meal plan.

Table 7. Daily nutrient and food serving targets of the DASH trial with modification of sodium intake.

Nutrients	**Nutrient Target**
Fat (% of total calories)	37
Saturated	16
Polyunsaturated	13
Monounsaturated	8
Carbohydrates (% of total calories)	48
Protein (% of total calories)	15
Cholesterol (mg/day)	300
Fiber (g/day)	31
Potassium (mg/day)	4,700
Magnesium (mg/day)	500
Calcium (mg/day)	450
Sodium (mg/day)	1,500
Food groups (no. of servings/day)	
Fruits and juices	5.2
Vegetables	3.3
Grains	6.9
Low-fat Dairy	0
Regular-fat dairy	0.3
Nuts, seeds, and legumes	0.6
Beef, pork, and ham	1.8
Poultry	0.4
Fish	0.3
Fat, oils, and salad dressing	5.3

Snacks and sweets	1.4

3.5.2 Diet Adherence

DASH diet adherence at baseline will be assessed pre-randomization using a validated FFQ used originally in the Nurses' Health Study [6] (See Appendix D) to document their average daily intake for the 12 months prior to enrollment in the study. A modified FFQ (3 month versus 12-month recall) will be delivered at 3 months after enrollment to assess short term changes in DASH scores. A final FFQ will be delivered at 12 months after enrollment to assess for long term changes in eating patterns. Research assistants will collect all FFQ data and calculate DASH scores. FFQs will first be screened by research assistants for proper completion. Forms that were not properly filled out would be subsequently returned to the participant with instructions that highlight sections that need to be revised or completed. The FFQs that were rectified and screened will be sent to the research team's RD for interpretation and calculation of their DASH score, which quantifies adherence at baseline and 12-months follow-up. All FFQ would be analyzed by a second trained RD to verify the initial interpretation. When discrepancies occur, a third-party RD would be brought in to interpret the results, and their interpretation would be the deciding opinion. Once the FFQ review is finalized by the RD, average daily nutrient intakes will be estimated using Nutritionist Pro™ software by multiplying the frequency of consumption by the nutrient content of a standard portion size. This is a process that has been described previously in both DASH and non-DASH diets [7,8]. The DASH adherence scores will be calculated using the scoring system originally described by Mellen *et al* [9] (Table 6 in Appendix B). Diet adherence assessment will be done for both the treatment and control groups. Analysis of all FFQs and DASH adherence scores will be calculated by a research assistant.

3.5.3 Secondary Outcome Measures

Baseline SBP will be measured in the clinic using a validated blood pressure device following a similar protocol to the one described in the 2017 AHA/ACC Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults guidelines (Table 8 in Appendix E) [1]. A fasting lipid panel (triglycerides, total cholesterol, HDL, LDL, and non-HDL levels) will be assessed by serum analysis. The CDC adult BMI calculator will be used to calculate the BMI for adults aged 20 years and older. Otherwise, the CDC BMI calculator for children and teens will be utilized for participants younger than 20 years old. The ASCVD calculator developed by the ACC will be utilized in all eligible patients to estimate the patient's 10-year ASCVD risk score [10]. Waist circumference will be measured in centimeters. As previously described, all secondary outcome measures and baseline DASH adherence scores will be taken prior to randomization and at the 3 and 12-month timepoint by the research assistant for research purposes only. Change in all measures between these assessments will be calculated by the research assistants. The patient's participation in the study is complete once these final measurements are obtained.

3.5.4 Baseline Characteristics

In addition to baseline adherence scores and secondary outcome measures, baseline sociodemographic characteristics and food security scores will be collected. Food insecurity will be assessed using the validated Food Insecurity Experience Scale (FIES). Baseline characteristics will be analyzed for any statistically significant differences and to ensure successful randomization. See Table 9 for all baseline characteristics.

Table 9. Baseline patient characteristics and statistical analysis plan.

	Total	**Intervention**	**Control**	**P-value**
Age (years) [1]	(Mean +/- SD)	(Mean +/- SD)	(Mean +/- SD)	Student's t-test

Men	(N/%)	(N/%)	(N/%)	Chi square
College Education or Higher	(N/%)	(N/%)	(N/%)	Chi square
Smoker	(N/%)	(N/%)	(N/%)	Chi square
Heavy alcohol use	(N/%)	(N/%)	(N/%)	Chi square
Black	(N/%)	(N/%)	(N/%)	Chi square
White	(N/%)	(N/%)	(N/%)	Chi square
Hispanic	(N/%)	(N/%)	(N/%)	Chi square
Asian	(N/%)	(N/%)	(N/%)	Chi square
Other	(N/%)	(N/%)	(N/%)	Chi square
Answer "Yes" to ≥1 FIES question	(N/%)	(N/%)	(N/%)	Chi square
Employed	(N/%)	(N/%)	(N/%)	Chi square
Mean Household Income [2]				
≥ 165% of Poverty Level	(N/%)	(N/%)	(N/%)	Chi square
≤ 165% of Poverty Level	(N/%)	(N/%)	(N/%)	Chi square
LDL[1]	(Mean +/- SD)	(Mean +/- SD)	(Mean +/- SD)	Student's t-test
SBP[1]	(Mean +/- SD)	(Mean +/- SD)	(Mean +/- SD)	Student's t-test
Total Cholesterol[1]	(Mean +/- SD)	(Mean +/- SD)	(Mean +/- SD)	Student's t-test
BMI[1]	(Mean +/- SD)	(Mean +/- SD)	(Mean +/- SD)	Student's t-test
DASH Score[1]	(Mean +/- SD)	(Mean +/- SD)	(Mean +/- SD)	Student's t-test
10 – year risk for ASCVD[1]	(Mean +/- SD)	(Mean +/- SD)	(Mean +/- SD)	Student's t-test
Patients eligible for 10 – year ASCVD risk calculation	(N/%)	(N/%)	(N/%)	Chi square
Waist Circumference (cm) [1]	(Mean +/- SD)	(Mean +/- SD)	(Mean +/- SD)	Student's t-test

1. A Mann-Whitney U test will be used for comparison of if the variable is not normally distributed.

2. Poverty level is defined by the U.S. Census Bureau and based on information collected in the 2021 and earlier Current Population Survey Annual Social and Economic Supplements [11].

3.6 Methodological Considerations

One of the roles of the research assistant will be dedicated to ensuring successful randomization, starting with assigning each eligible participant to either intervention or control group in a 1:1 ratio by using a random number sequence generator. As needed, our analysis will control for baseline differences in race, age, food security, employment status, smoking status, heavy alcohol use, and education level, which are seven possible confounders that may influence DASH adherence and secondary outcomes. Income and education level are considered social determinants of health by the CDC [12]. There is substantial literature to support that African Americans are disproportionately affected by HTN [13]. Additionally, age is the most important non-modifiable risk factor for HTN, while cigarette use, and heavy alcohol use are important modifiable risk factors [14]. Heavy alcohol use is defined by the National Institute on Alcohol Abuse and Alcoholism as consuming more than 4 drinks on any day or more than 14 drinks per week for men; and consuming more than 3 drinks on any day or more than 7 drinks per week for women [15]. All confounders with exception of age, are dichotomous variables and classifications will be based on what is documented in the patient's electronic health record. The research assistant conducting randomization will communicate with the onsite research assistant about the patient's allocation status privately. Due to the nature of the study, blinding of the intervention to the study group is not possible as they either receive a meal plan or not. Another research assistant will perform statistical analysis and will never work with patients directly to reduce bias during analysis.

3.7 Sample Size Calculation

This study's design entails two-sided hypothesis testing, a confidence interval of 95%, and power of 80%. We hypothesize that DASH adherence score will increase by 0 in the control

group and 2 in the intervention group 12 months. We estimated a SD of 1.5 points for both intervention and control group, resulting in an effect size of 0.46. This is considered a medium effect size by Cohen's d [16]. With an alpha of 0.05, a sample size of 148 will allow us to detect a mean difference of 0.7 units in DASH adherence scores between intervention and control groups. Based on a similar trial protocol, we assumed a conservative attrition rate of 20% in our study resulting in a final analytical sample size of 178 participants (Appendix F) [17]. The estimated effect size was calculated based on two RCTs that used interventions, controls, and outcome measures similar to the ones proposed in this paper. The estimates for the control group are based on an RCT that examined the effect of medical nutrition therapy, or nutritional counseling relevant to the patient's diagnosis, on DASH adherence, and dietary knowledge [18]. After 12 months, the patients in the medical nutritional therapy group had a mean change in DASH adherence score of -0.18 ($P > 0.05$) [18]. While there are no studies that investigate the impacts of meal planning on DASH diet adherence, one pilot RCT used personalized nutritional counseling with regular feedback via a smartphone application [19] (Table 1). Feedback outlined specific food recommendations similar to the personalized meal plans in our intervention. This pilot RCT revealed an increase in DASH adherence score by 0.9 points after 3 months of meal planning. The same authors used this data to estimate a change in DASH score by 2 points at 6 months in the ongoing Nourish trial; an RCT that will evaluate the effectiveness of a smartphone application and counseling on DASH adherence [17]. Similar to the Nourish protocol, power calculations in this paper were based on the expected DASH score differences between groups. We used these data to make conservative effect size estimates for our proposed RCT, given that both of these prior studies used the Mellen index (range 0-9) to measure DASH adherence [9]. Not only does personalized meal planning outline exactly what the patient needs to eat, it is less

intensive (does not require food logging, self-monitoring, etc), and therefore, we anticipate greater adherence to the DASH diet compared to the interventions in these prior studies.

3.8 Statistical Analysis

First, all outcome and covariate data will be examined for missing and out of range values as well as for statistical normality. Decisions will be made based on these descriptions about the need for imputation to address missing data, transformation of key variables, and/or the use of non-parametric vs. parametric tests. Next, all baseline data will be assessed for significant between group differences (Table 9). If there any differences in baseline characteristics, any comparisons of between group means will be adjusted for those differences. Assuming statistical normality, all primary and secondary outcomes are continuous variables and will be displayed as mean +/- SD. Mean DASH scores will be obtained for both intervention groups and control groups via FFQ at baseline, 3, and 12 months. In the absence of baseline between group differences, an unpaired Student's t-test will be performed to assess for differences in mean DASH adherence scores, as well as all mean secondary outcomes from baseline to 3 months, 3 months to 12 months, and from baseline to 12 months (models examining secondary outcomes will also control for medication adherence). Alternatively, generalized linear models, which can include baseline covariates, will be used.

An intention to treat analysis will be used to detect any statistically significant differences defined as $P < 0.05$. Small increases (5 points) in traditional DASH adherence scores (range 8-40) have been found to result in significant decreases in specific cause and all-cause mortality [20]. This correlates to approximately a 1.56-point increase in the Mellen index, which will be used to evaluate the clinical significance of our intervention. Therefore, we will also examine the

proportion of each group that reports a clinically significant increase in DSH adherence, comparing the groups using a Chi Squared test.

In addition to the analysis of secondary outcomes discussed above, the impact of DASH score change on secondary outcomes will be evaluated using a residualized change model (change in DASH scores, taking into account baseline scores) within the intervention group only. Testing for the association between residualized changed DASH adherence scores and secondary outcomes will be performed using generalized linear models from baseline to 3 months, 3 months to 12 months, and from baseline to 12 months.

3.9 Timeline and Resources

Recruitment for this study would occur between 06/01/2022 and 12/01/2022. Assignment of participants into the intervention and control groups will occur on a rolling basis (Section 3.2). A FFQ for assessment of the 12 months of prior feeding habits would be given at baseline and then at 12 months, marking the conclusion of the study for that individual. All participant data will be collected by 01/01/2024, marking the beginning of the data analysis period. See Table 10 for personnel required and their role on the research team. Essential locations are listed in Table 11 along with a description of how they will be utilized.

Table 10. Description of the research team and their respective roles.

Title	Task	Number needed for task	Description of Task
Registered Dietician	Nutrition Counseling	5	DASH diet counseling and development of individualized meal plans
Research Assistant	Data collection and analysis, recruitment, consenting, and randomization	5	Most of the logistical research tasks will be performed by research assistants affiliated with Yale University

Primary Investigator	Oversee all research operations	1	Oversee study operations, interpretation of data, and publication of results
Primary care providers	Recruitment of eligible patients from Yale affiliated primary care centers	10	Refer eligible patients to our RDs and introduce the clinical study

Table 11. Essential study locations and description of space utilization.

Facility Type	Name of Facility	Duration of Use	Facility Purpose
Hospital	YNHH – Nutrition Services	2 years	Appointments with RD for meal plan development and/or DASH diet counseling
University	Yale University Classrooms	2 years	Workspace for research assistants and primary investigators
YNHH Primary Care Centers	Northeast Medical Group Internal Medicine	2 years	These are the New Haven area primary care centers where recruitment of patients will occur. There are two in New Haven, CT and one in East Haven, CT.

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Chapter 4: Conclusion

4.1 Advantages and Disadvantages:

This study would be the first RCT to evaluate the effectiveness of personalized meal planning on DASH diet adherence in patients suffering from HTN. There are few studies that evaluate the effect of personalized meal planning using modern technology on diet adherence, and none that evaluates its effect on the DASH diet. RCTs promote internal validity and have the benefit of minimizing bias and demonstrate causality given successful randomization and a high-quality control group. This study will also employ an intention-to-treat analysis, which preserves randomization while reducing selection bias. Additionally, our meal planning intervention is more personalized to patient preferences compared to other studies that investigate the effectiveness of meal planning. This higher level of customization requires no extra effort on behalf of the patient and will highlight the benefit of meal planning to its greatest extent.

This study also has unique secondary outcome measures compared to many other RCTs investigating DASH diet adherence. Most other RCTs' trialing methods to improve DASH adherence do not include blood pressure, LDL, total cholesterol, 10-year ASCVD risk, waist circumference, nor BMI as secondary outcome measures (Table 1). Studies have found that the DASH diet improves many aspects of health, such as body mass, lipid levels, and other chronic disease risk factors [1-4]. If personalized meal planning improves DASH adherence, perhaps it may improve other relevant risk factors for CVD. The secondary outcome measures used in this study will help shed light on the answer.

Lastly, it has been noted in another systematic reviews, that the lack of consistent measures for diet adherence makes it difficult for comparing the effectiveness of different interventions [5]. Our study will utilize the Mellen index, a type of DASH score that is commonly

utilized in other RCTs that evaluate DASH adherence (Table 1). Using the Mellen index will facilitate the comparison of our intervention to interventions used in previous studies.

It is important to note that this study has some limitations, including its generalizability and methodology. The benefit of conducting this study in association with a large academic center such as YNHH, is the feasible recruitment process of study subjects. However, restricting our study to one healthcare system is limiting because we are only sampling the New Haven area; therefore, the results may not be generalizable to populations from unique geographical areas. Additionally, the entire trial must be completed in 24 months. This limits our ability to perform an 18- or 24-month assessment that could assess whether changes were maintained in the absence of an active intervention and attest to the long-term effects of personalized meal planning. Secondly, as noted in Section 2.8, predictive equations and estimates for PAL are not the gold standard for calculating nutrient requirements and will have some margin of error. This is compounded by the fact that PALs are subjective and will also add an additional level of error during TEE estimation. However, predictive equations and activity level estimates are practical in a clinical setting, unlike calorimetry or doubly labeled water techniques.

4.2 Clinical and Public Health Significance:

HTN poses an immense burden on our society, affecting over 50% of adults and is the one of the most highly implicated risk factors for CVD [6,7]. Despite its immense impact, we have effective interventions such as the DASH diet [8]. The DASH diet is the one of the most effective interventions for HTN, but its adherence is strikingly low [9-12]. There lacks an intervention method that markedly improves DASH diet adherence (Table 1). Additionally, there is some evidence that supports adherence needs to match that of the original DASH trial for acquiring complete antihypertensive effects of the DASH diet [13]. This highlights the importance of

effective interventions to improve DASH adherence. The literature review in Chapter 2 supports that personalized behavioral interventions are effective at improving DASH adherence. Coupled to personalized behavioral intervention, personalized meal plans are effective in managing other chronic conditions similar to HTN (Section 2.5). This RCT may shed light on the effectiveness of meal planning in improving DASH adherence and other risk factors for CVD. Future HTN management may include referral to registered dietician colleges for personalized meal planning to ensure proper DASH implementation.

As mentioned in Section 2.7 and 3.8, a five-point increase in the traditional DASH score (range 8-40) is associated with significant lowering of all-cause and specific-cause mortality rates. This relationship becomes even stronger once DASH scores exceed 20 [4]. If personalized meal plans improve DASH adherence scores, this intervention methodology has significant implications for improving patient outcomes at low cost. Other studies have considered a minimal clinically important difference in BMI, LDL, and total cholesterol to be 5% [14-16], whereas a reduction of 5 mm Hg in SBP and 2.5 mm Hg in DBP is considered clinically important blood pressure reductions [17]. We will use these measures to aid our interpretation of the clinical relevance of our results. Personalized meal planning for the DASH diet may also have benefits beyond HTN, and a reduction in other clinically significant measures such as BMI, could have implications in other conditions like type 2 diabetes. In summary, this RCT will have implications for diet implementation and chronic disease management, with a particular focus on HTN.

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Appendices

Appendix A: Energy Calculations

TEE is the sum of the REE, thermal effect of food (TEF) and activity energy expenditure (AEE). AEE is a sum of an individual's non-exercise activity thermogenesis (NEAT) and exercise energy expenditure (ExEE). See Table 2 for brief description of TEE components, determinants of components, and measurement approaches.

Calorimetry is the process of measuring heat production during the combustion of carbohydrates, protein, fat, and alcohol [1]. This measurement can be used to estimate the energy expenditure of a specific activity. Alternatively, one can closely estimate energy expenditure by oxygen consumption and/or carbon dioxide production, which is called indirect calorimetry [2]. Most measurements of human energy expenditure today are done by indirect calorimetry [3]. Indirect calorimetry can be performed by metabolic chambers which assess energy expenditure over an extended period of time (24 hours up to a couple of days). The gold standard measurement for TEE, however, is the doubly labeled water technique. [3] This technique uses isotope ratio mass spectrometry on 1-2 weeks of urine samples to estimate the rate of CO2 production, which can be converted to average TEE [3]. Despite being considered the gold standard technique for estimating TEE, it is unable to provide any information on the TEE components, including the AEE, TEF, and REE (Table 2). Both calorimetry and the doubly labeled water techniques are not practical to employ in our study and therefore, predictive equations remain the most clinically relevant method for calculating TEE [3,4].

Table 3. Components of TEE and various measurement approaches.

TEE = REE + TEF + AEE AEE = ExEE +NEAT			
Component	**Description**	**Determinant**	**Measurement Approach [3]**

REE	Similar to basal metabolic rate but measured under less strict conditions and defined as energy expended at rest by a fasted individual in a thermo-neutral environment	Largest component of TEE and is affected by various factors including age, gender, body size, body composition, fitness level, hormonal status, and genetic/environmental influences [5-9]	Indirect calorimetry
TEF	The increase in metabolic rate after ingestion of a meal and is controversial in regard to its role in weight regulation	Meal size and meal composition [10]. Larger meal sizes, high carbohydrate, and high protein content increase the TEF	Indirect calorimetry
AEE	This represents all energy expended above the resting level and TEF. It is a direct measure of the energy from physical activity and has exercise and non-exercise components	It is influenced by the specific task being performed as well as the same factors that affect REE [11]	Indirect calorimetry, heart rate monitoring, accelerometry, global positioning system, pedometry, questionnaires, observation

Table 4. Equations for estimating resting metabolic rate (RMR).

Name	**Equation**		**Notes**
	Men	Women	
Mifflin-St Jeor equation [12]	Estimated RMR for man = (10 × your weight in kg) + (6.25 × your height in cm) – (5 × your age in years) + 5	Estimated RMR for woman = (10 × your weight in kg) + (6.25 × your height in cm) – (5 × your age in years) – 161	It was derived from a sample of 498 males (n = 251) and females with BMI's ranging from normal weight to severely obese. The racial composition was not specified, and older adults (75 to 84 years) were not well represented
The Harris-Benedict equation [13]	Estimated RMR for man = 66.4730 + 13.7516 x weight in	Estimated RMR for woman =655.0955 +	Data was based mostly on normal-weight Caucasian

	kg + 5.0033 x height in cm – 6.7550 x age in years.	9.5634 x weight in kg + 1.8496 x height in cm – 4.6756 x age in years.	men and women ages 16-63 and 15-74, respectively. Oldest and most extensively studied with accurate predictions occurring in 45%-80% of individuals [14]
Oven Equation [15,16]	RMR = 879 + 10.2 x body weight (kg)	Nonathletes RMR = 795 + 7.18 kg Athletes RMR = 50.4 + 21.1 kg	The range of RMR per kilogram body weight was wide for nonathletic but narrow for athletic women
FAO/WHO/UNU equation [17]	Representative equation: for men aged 30–60 y: RMR = 14.7 × body weight (kg) + 496	Representative equation for women aged 30–60 y: RMR = body weight (kg) + 829	Data were derived from European military recruits with an age range of 19-82 years with 45% of Italian descent [18-21]

Given an individual's REE, a PAL can be used as a multiplier to estimate the TEE mathematically [3]. The PALs represent the average excess activity output over a 24 period and is the TEE/RMR ratio [3]. Average PAL values for a population of interest can be used to predict the energy requirement for an individual based on their perceived activity. The most accurate way to measure PAL is to estimate TEE using the doubly labeled water technique and direct calorimetry for the REE [2]. However, more practical ways to calculate TEE have been used by estimating PAL with metabolic equivalents (METs). METs are numerical values that represent multiples of RMR to estimate the metabolic demand for a specific activity [22]. The average of these METs over a 24 period can be used to estimate PAL. The PALs utilized in our study come from Brooks *et al*, [23] (Table 4) which utilized doubly labeled water measurements of TEE from studies published in the MEDLINE database.

Table 5. PAL categories and walking correlates*.

PAL category	PAL value	Walking equivalence (miles/d) for a 70 kg individual walking at 3-4 miles/h
Sedentary	1.25	0
Low active	1.5	2.2
Active	1.75	7.3
Very Active	2.2	16.7

*This table was derived from Table 1 by Brooks *et al* [23]

Appendix B: Calculating DASH Score Using Mellen Index

Table 6. Method for calculating DASH adherence using a score derived from Mellen *et al* [24]. One point for meeting DASH diet target and 0.5 point for meeting intermediate target. If the participant does not meet the intermediate target, then they get a score of zero for that nutrient component.

Nutrient	DASH Diet Target	Intermediate target
Total fat	27% of total calories	32% of total calories
Saturated Fat	6% of total calories	11% of total calories
Protein	18% of total calories	16.5% of total calories
Cholesterol	71.4 mg/1,000 kcal	107.1 mg/1,000 kcal
Fiber	14.8 g/1,000 kcal	9.5 g/1,000 kcal
Magnesium	238 mg/1,000 kcal	158 mg/1,000 kcal
Calcium	590 mg/1,000 kcal	402 mg/1,000 kcal
Potassium	2,238 mg/1,000 kcal	1,534 mg/1,000 kcal
Sodium	1,500 mg	2,300 mg

Appendix C: Consent Form

COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH STUDY

YALE PHYSICIAN ASSOCIATE PROGRAM

Study Title: PERSONALIZED MEAL PLANS AS AN INTERVENTION TO ENHANCE DASH DIET ADHERENCE IN HYPERTENSIVE ADULTS

Principal Investigator (the person who is responsible for this research):
Christopher Shimwell; Yale Physician Associate Program, 100 Church Street South, Suite A250 New Haven, CT 06519
Phone Number: (**860) 712-1866**

Research Study Summary:

- We are asking you to join a research study.
- The purpose of this research study is study to examine the effectiveness of personalized meal planning in improving diet adherence.
- Participation in this study will involve meeting with a registered dietician to build a meal plan that is tailored to your preferences and will help you follow the Dietary Approaches to Stopping Hypertension (DASH) diet. You will also have several educational counseling sessions on dieting with a registered dietician and meet monthly to monitor progress and provide counseling. Your involvement will require one hour per month for a total of 12 months. We will assess your eligibility for the study today, then if you are eligible and choose to participate, we will ask you to complete three research assessments over the course of 12 months.
- Research assessments will include questionnaires, physical measurements and blood work.
- There are some risks from participating in this study; however, the risks of participating in this study are considered to be small. There are no physical risks associated with participating in this study. However, some of the questions in the questionnaires may make you feel uncomfortable and there is a possible risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. If there are questions in our questionnaires that you feel uncomfortable asking, you have every right to refuse to answer.
- The study may have benefits for you. There are a number of potential benefits to participating in this study. If the intervention is successful, those who are randomized to the intervention group may experience direct health benefits. Beyond the benefits to individual participants, we hope that this research study may tell us how best to facilitate diet implementation amongst those suffering with chronic disease.

- Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You can also change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.
- If you are interested in learning more about the study, please continue reading, or have someone read to you, the rest of this document. Take as much time as you need before you make your decision. Ask the study staff questions about anything you do not understand. Once you understand the study, we will ask you if you wish to participate; if so, you will have to sign this form.

Why is this study being offered to me?
We are asking you to join a research study because you are an adult who has been diagnosed with stage 1 hypertension and are seeking care at one of our participating facilities.

Who is paying for the study?
This study is supported by the Yale Physician Associate Program.

What is the study about?
The goal of the study is to understand if personalized meal plan improves DASH diet adherence and other markers of your health (weight status, cholesterol, blood pressure, waist circumference and likelihood of cardiovascular disease) .

What are you asking me to do and how long will it take?
If you agree to take part in this study, this is what will happen:

If you decide to participate, you will begin the study today and will remain enrolled and in contact with us for 12 months. During that time, you will complete three research assessments and three blood draws. These research assessments will take place at the beginning of the study and at 3 and 12 months after enrollment. You will also have monthly check in visits with the registered dietician or sooner if deemed necessary by the dietician. These visits will be an opportunity for you to ask questions and discuss and diet implementation challenges. These visits will be approximately 15-60 minutes. All visits with the registered dieticians will be recorded and reviewed by the research team.

If you decide to participate in the study, we will ask you to complete a few activities today:

1. We will ask you to complete three questionnaires to determine your eligibility, food security level, and evaluate your diet
2. We will measure your weight, height, weight status (based on how healthy your weight is for your height), blood pressure, waist circumference, and obtain blood work

These activities will take approximately 60 minutes to complete. If you remain eligible for the study after completing these activities, you will be enrolled in the study.

Upon enrollment, you will be asked to participate in the first (baseline) assessment. This assessment can take place today or can be scheduled for another convenient time. During this

assessment you will be asked to complete a series of questionnaires. These questionnaires will ask questions about your health, diet, access to food, household income, history of alcohol or tobacco use, employment status, ethnicity, and sex assigned at birth. We will also obtain blood work to evaluate your cholesterol levels and hemoglobin A1c (used to calculate risk of cardiovascular disease). Other measurements will be obtained including your height, weight, age, and blood pressure.

After you complete the first (baseline) research assessment, you will be randomly assigned to one of two study groups. This assignment will determine the activities that you will complete over the next 12 months. Individuals will receive either 12 months of DASH diet education and personalized meal planning services (the study intervention) or six months of DASH diet education alone. This is called a 'control' group and we will compare outcomes between those receiving the intervention and the control group to see if the intervention has a positive impact diet adherence and overall health to those who receive it. Random assignment means that you will be put into a group by chance - it is like flipping a coin, you will not be able to choose the group.

Three months after the initial research assessment you will be asked to complete a second research assessment. We will ask you several of the same questionnaires about your health, diet, and obtain blood work to measure your cholesterol levels and hemoglobin A1c (used to calculate risk of cardiovascular disease). We will also measure your height, weight, weight status (based on how healthy your weight is for your height), blood pressure, and waist circumference. Finally, we will ask some questions about any costs you might have accrued while taking part in the study. These activities will again take around 60 minutes to complete.

Nine months later (12 months after your initial enrollment) we will repeat the same assessment for a third and final time. This final assessment will also take around 60 minutes to complete.

Medical Record Review

Once your participation in the study is complete, we will access any medical records that are kept about your hypertension care at both your primary care provider's office and Yale New Haven Hospital. We will collect information about your primary care visits, any emergency care, hospitalizations and inpatient stays, use of preventative services (dental, foot clinic, mental health services), and any medications prescribed.

Return of information to participants

At each research assessment we will provide feedback on your height, weight, weight status (based on how healthy your weight is for your height), hemoglobin A1c, risk of cardiovascular disease, diet adherence, and blood pressure. At the time of your last research assessment, or after it is completed, you may request a copy of all of the information collected about you, including the information abstracted from your medical records. Investigators will provide that information to you.

At the conclusion of this research study, when assessments have been completed on all research participants, we will collate the outcomes of the study and return information about the key study

findings to participants. This will occur in the form of a brief study report with information about where to access more detailed study reporting.

What are the risks and discomforts of participating?
There are some risks associated with participating in this study; however, the risks of participating in this study are considered to be small. During the physical assessments you may experience a small amount of discomfort from the venipuncture, and/or pressure from the arm cuff used to measure blood pressure. Some of the questions in the questionnaires or the interviews may make you feel uncomfortable and there is a possible risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. If there are questions in our questionnaires or interviews that you feel uncomfortable answering, you have every right to refuse to answer.

You will continue with your usual hypertension care during the study. The intervention we are testing is a behavioral intervention and there are no experimental procedures or drugs involved.

How will I know about new risks or important information about the study?
We will tell you if we learn any new information that could change your mind about taking part in this study. This information will be communicated to you either by phone or with an in-person visit.

How can the study possibly benefit me?
Participating in this research study may have benefits to you. If the intervention approach we are testing is successful, it may help you to manage your hypertension. Regardless of which group you are assigned to, we will give you feedback during each research assessment about your health, including your weight status, cholesterol levels and blood pressure. If at any research assessment you are determined to have worsening control of your hypertension, we will provide referrals to appropriate health care providers. Beyond the benefits to individual participants, we hope that this research study may tell us how best to deliver hypertension care and improve outcomes for those suffering from hypertension.

How can the study possibly benefit other people?
The study might help other people and science by helping us understand more about how to better implement dietary interventions.

Are there any costs to participation?
You will not have to pay to take part in this study. Study assessments will take place at the registered dietician's offices. Costs you may incur will include providing transportation to the appointments (which will take place every month; 12 sessions total).

Will I be paid for participation?
You will be paid for taking part in this study. You will receive $20 after completing each study assessment (baseline, 3 months post-randomization, and 12-months post-randomization). You may be responsible for paying state, federal, or other taxes for the payments you receive for being in this study. Taxes are not withheld from your payments.

How will you keep my data safe and private?

We will keep information we collect about you confidential. We will share it with others if you agree to it or when we have to do it because U.S. or State law requires it. For example, we will tell somebody if we learn that you are hurting a child or an older person.

Study Assessments

All of your responses to study questionnaires, along with your clinical measures (i.e., cholesterol levels, blood pressure values, waist circumference, weight, and height), and information extracted from your medical records will be held in confidence. Only the researchers involved in this study and those responsible for research oversight (such as representatives of the Yale University Human Research Protection Program and the Yale University Human Subjects Committee) will have access to any information that could identify you.

You will be assigned a unique study ID number. Any time you complete a study questionnaire, we collect a physical measurement, and this ID number will be the only thing used to identify you. The code linking your ID number with your name will be stored separately from any information about you, in a locked file cabinet. When we publish any results from this study, we will do so in a way that does not identify you unless we get your specific permission to do so.

We may share your data from this study with other researchers so that they can check the accuracy of our conclusions but will only do so if we are confident that your confidentiality is protected. We may also share your data with other researchers for use in future research studies. You, or your legally authorized representative, will not be asked to provide additional informed consent if that were to occur. We will do our best to protect your identity. We will only share de-identified data with others. They will not be able to link the ID number assigned to your data to you. We follow strict security safeguards to avoid other people knowing your identity.

Except as permitted by law, your health information will not be released in an identifiable form outside of the Yale University research team. Note, however, that your records may be reviewed by those responsible for the proper conduct of research such as the Yale University Human Research Protection Program, Yale University Human Subjects Committee or representatives of the U.S. Department of Health and Human Services or the National Institutes of Health. Information may be re-disclosed if the recipients are not required by law to protect the privacy of the information. At the conclusions of this study, any identifying information related to your research participation will be destroyed, rendering the data anonymous.

What Information Will You Collect About Me in this Study?

The information we are asking to use and share is called "Protected Health Information." It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission. If you want, we can give you more information about the Privacy Rule. Also, if you have any questions about the Privacy Rule and your rights, you can speak to the Yale Privacy Officer at 203-432-5919.

The specific information about you and your health that we will collect, use, and share includes:

- Research study records
- Any medical and laboratory records from Yale New Haven Hospital and your primary care provider's electronic health record that are relevant to your hypertension care/management and are created during the 12 months in which you are enrolled in this research study.
- Responses to questions asked in interviews and/or group discussions

How will you use and share my information?

We will use your information to conduct the study described in this consent form.
We may share your information with:

- The U.S. Department of Health and Human Services (DHHS) agencies
- Representatives from Yale University, the Yale Human Research Protection Program and the Institutional Review Board (the committee that reviews, approves, and monitors research on human participants), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.
- The study sponsor or manufacturer of study drug/device
- Health care providers who provide services to you in connection with this study (for example if we needed to refer you for care).
- The Principal Investigator of the study
- Co-Investigators and other investigators
- Study Coordinator and Members of the Research Team
- Data and Safety Monitoring Boards and others authorized to monitor the conduct of the Study

We will do our best to make sure your information stays private. But, if we share information with people who do not have to follow the Privacy Rule, your information will no longer be protected by the Privacy Rule. Let us know if you have questions about this. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

Why must I sign this document?

By signing this form, you will allow researchers to use and disclose your information described above for this research study. This is to ensure that the information related to this research is available to all parties who may need it for research purposes. You always have the right to review and copy your health information in your medical record. However, because this study is testing an intervention, if you sign this permission form, you will not be allowed to look at or copy your study related information until after the research is completed.

What if I change my mind?

The authorization to use and disclose your health information collected during your participation in this study will never expire. However, you may withdraw or take away your permission at any time. You may withdraw your permission by telling the study staff or by writing to ***Christopher Shimwell; Yale Physician Associate Program,* 100 Church Street South**, Suite A250 New Haven, CT 06519

If you withdraw your permission, you will not be able to stay in this study but the care you get from your doctor outside this study will not change. No new health information identifying you will be gathered after the date you withdraw. Information that has already been collected may still be used and given to others until the end of the research study to insure the integrity of the study and/or study oversight.

What if I want to refuse or end participation before the study is over?
Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits. Not participating or withdrawing later will not harm your relationship with your own doctors or with this institution.

To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want to take part.

What will happen with my data if I stop participating?
Information that has already been collected may still be used and given to others until the end of the research study to ensure the integrity of the study and/or study oversight.

Who should I contact if I have questions?
Please feel free to ask about anything you don't understand.

If you have questions later or if you have a research-related problem, you can call the Principal Investigator, Christopher Shimwell, at **(860) 712-1866**

If you have questions about your rights as a research participant, or you have complaints about this research, you call the Yale Institutional Review Boards at (203) 785-4688 or email hrpp@yale.edu.

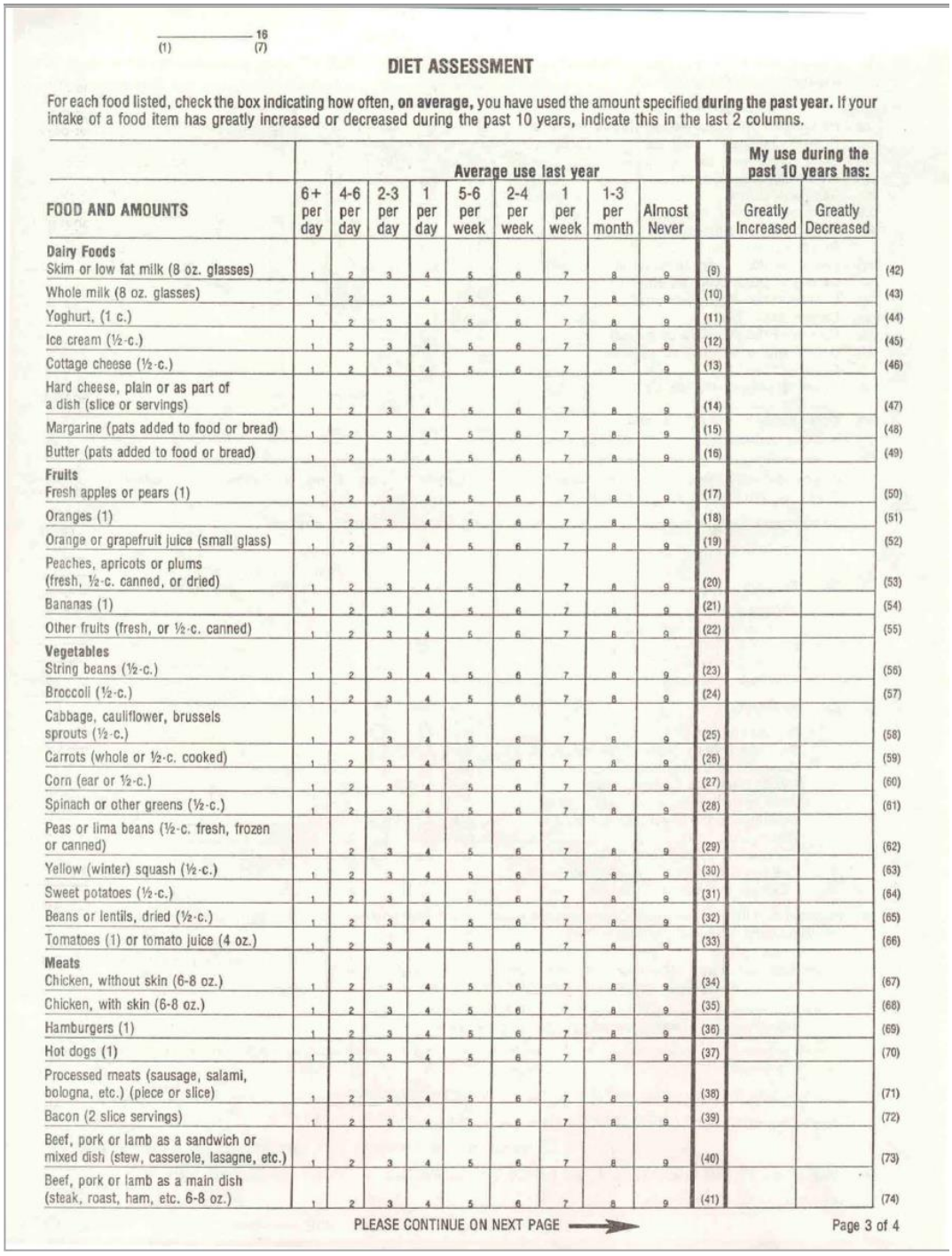
A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Authorization and Permission
Your signature below indicates that you have read this consent document and that you agree to be in this study.

We will give you a copy of this form.

Participant Printed Name	Participant Signature	Date
Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date

Appendix D: Food Frequency Questionnaire From Nurses' Health Study



(1) _____ 16 (7)

DIET ASSESSMENT

For each food listed, check the box indicating how often, **on average,** you have used the amount specified **during the past year.** If your intake of a food item has greatly increased or decreased during the past 10 years, indicate this in the last 2 columns.

FOOD AND AMOUNTS	Average use last year: 6+ per day	4-6 per day	2-3 per day	1 per day	5-6 per week	2-4 per week	1 per week	1-3 per month	Almost Never		My use during the past 10 years has: Greatly Increased	Greatly Decreased	
Dairy Foods													
Skim or low fat milk (8 oz. glasses)	1	2	3	4	5	6	7	8	9	(9)			(42)
Whole milk (8 oz. glasses)	1	2	3	4	5	6	7	8	9	(10)			(43)
Yoghurt, (1 c.)	1	2	3	4	5	6	7	8	9	(11)			(44)
Ice cream (½-c.)	1	2	3	4	5	6	7	8	9	(12)			(45)
Cottage cheese (½-c.)	1	2	3	4	5	6	7	8	9	(13)			(46)
Hard cheese, plain or as part of a dish (slice or servings)	1	2	3	4	5	6	7	8	9	(14)			(47)
Margarine (pats added to food or bread)	1	2	3	4	5	6	7	8	9	(15)			(48)
Butter (pats added to food or bread)	1	2	3	4	5	6	7	8	9	(16)			(49)
Fruits													
Fresh apples or pears (1)	1	2	3	4	5	6	7	8	9	(17)			(50)
Oranges (1)	1	2	3	4	5	6	7	8	9	(18)			(51)
Orange or grapefruit juice (small glass)	1	2	3	4	5	6	7	8	9	(19)			(52)
Peaches, apricots or plums (fresh, ½-c. canned, or dried)	1	2	3	4	5	6	7	8	9	(20)			(53)
Bananas (1)	1	2	3	4	5	6	7	8	9	(21)			(54)
Other fruits (fresh, or ½-c. canned)	1	2	3	4	5	6	7	8	9	(22)			(55)
Vegetables													
String beans (½-c.)	1	2	3	4	5	6	7	8	9	(23)			(56)
Broccoli (½-c.)	1	2	3	4	5	6	7	8	9	(24)			(57)
Cabbage, cauliflower, brussels sprouts (½-c.)	1	2	3	4	5	6	7	8	9	(25)			(58)
Carrots (whole or ½-c. cooked)	1	2	3	4	5	6	7	8	9	(26)			(59)
Corn (ear or ½-c.)	1	2	3	4	5	6	7	8	9	(27)			(60)
Spinach or other greens (½-c.)	1	2	3	4	5	6	7	8	9	(28)			(61)
Peas or lima beans (½-c. fresh, frozen or canned)	1	2	3	4	5	6	7	8	9	(29)			(62)
Yellow (winter) squash (½-c.)	1	2	3	4	5	6	7	8	9	(30)			(63)
Sweet potatoes (½-c.)	1	2	3	4	5	6	7	8	9	(31)			(64)
Beans or lentils, dried (½-c.)	1	2	3	4	5	6	7	8	9	(32)			(65)
Tomatoes (1) or tomato juice (4 oz.)	1	2	3	4	5	6	7	8	9	(33)			(66)
Meats													
Chicken, without skin (6-8 oz.)	1	2	3	4	5	6	7	8	9	(34)			(67)
Chicken, with skin (6-8 oz.)	1	2	3	4	5	6	7	8	9	(35)			(68)
Hamburgers (1)	1	2	3	4	5	6	7	8	9	(36)			(69)
Hot dogs (1)	1	2	3	4	5	6	7	8	9	(37)			(70)
Processed meats (sausage, salami, bologna, etc.) (piece or slice)	1	2	3	4	5	6	7	8	9	(38)			(71)
Bacon (2 slice servings)	1	2	3	4	5	6	7	8	9	(39)			(72)
Beef, pork or lamb as a sandwich or mixed dish (stew, casserole, lasagne, etc.)	1	2	3	4	5	6	7	8	9	(40)			(73)
Beef, pork or lamb as a main dish (steak, roast, ham, etc. 6-8 oz.)	1	2	3	4	5	6	7	8	9	(41)			(74)

PLEASE CONTINUE ON NEXT PAGE →

FOOD AND AMOUNTS	Average use last year										My use during the past 10 years has:	
	6+ per day	4-6 per day	2-3 per day	1 per day	5-6 per week	2-4 per week	1 per week	1-3 per month	Almost Never		Greatly Increased	Greatly Decreased
Fish (6-8 oz.)	1	2	3	4	5	6	7	8	9	(9)		
Eggs (1)	1	2	3	4	5	6	7	8	9	(10)		
Sweets, Baked Goods, Cereals Chocolate (1 oz.)	1	2	3	4	5	6	7	8	9	(11)		
Candy without chocolate (1 oz.)	1	2	3	4	5	6	7	8	9	(12)		
Pie, home made (slice)	1	2	3	4	5	6	7	8	9	(13)		
Pie, ready made (slice)	1	2	3	4	5	6	7	8	9	(14)		
Cake, (slice)	1	2	3	4	5	6	7	8	9	(15)		
Cookies (1)	1	2	3	4	5	6	7	8	9	(16)		
Cold breakfast cereal (½-c.)	1	2	3	4	5	6	7	8	9	(17)		
White bread (slice)	1	2	3	4	5	6	7	8	9	(18)		
Dark or whole grain bread (slice)	1	2	3	4	5	6	7	8	9	(19)		
Miscellaneous Peanut butter (tbsps)	1	2	3	4	5	6	7	8	9	(20)		
Potato or corn chips (small bag or 1 oz.)	1	2	3	4	5	6	7	8	9	(21)		
French fried potatoes (4 oz.)	1	2	3	4	5	6	7	8	9	(22)		
Nuts (1 oz.)	1	2	3	4	5	6	7	8	9	(23)		
Potatoes, mashed (½-c.) or baked (1)	1	2	3	4	5	6	7	8	9	(24)		
Rice or pasta (½-c.)	1	2	3	4	5	6	7	8	9	(25)		
Coffee, not decaffinated (cups)	1	2	3	4	5	6	7	8	9	(26)		
Tea (cups)	1	2	3	4	5	6	7	8	9	(27)		
Beer (bottles or cans)	1	2	3	4	5	6	7	8	9	(28)		
Wine (glasses)	1	2	3	4	5	6	7	8	9	(29)		
Liquor - whiskey, gin, etc. (drinks)	1	2	3	4	5	6	7	8	9	(30)		
Coca Cola, Pepsi, other cola (glasses)	1	2	3	4	5	6	7	8	9	(31)		
Low calorie carbonated drink (glasses)	1	2	3	4	5	6	7	8	9	(32)		
Other carbonated beverage (root beer, ginger ale, 7-Up, etc.) (glasses)	1	2	3	4	5	6	7	8	9	(33)		
Fruit-flavored punch or non-carbonated beverage (glasses)	1	2	3	4	5	6	7	8	9	(34)		
Home-fried food, any type (servings)	1	2	3	4	5	6	7	8	9	(35)		
Artificial sweetner (packet, tablets, etc.)	1	2	3	4	5	6	7	8	9	(36)		

How often do you eat liver (3-4 oz. servings)? (9) ☐ 1 per week ☐ 2-3 per month ☐ 1 per month or less ☐ never

What do you do with the visible fat on your meat? (10) ☐ eat most of it ☐ eat some of it ☐ eat as little as possible

What kind of fat do you usually use for baking? (11) ☐ lard or butter ☐ vegetable oil ☐ vegetable shortening ☐ margarine

What kind of fat do you usually use for frying? (12) ☐ lard or butter ☐ vegetable oil ☐ vegetable shortening ☐ margarine

What kind of cold breakfast cereal do you most often use? (specify exact brand) (13) _____

Do you use a microwave oven? (15) ☐ Yes ☐ No **If yes,** for how many years? (16) _____

Are you currently on a special diet? (18) ☐ Yes ☐ No **If yes,** (19) for _____ years: type of diet (21) _____

How many teaspoons of sugar do you add to your food **daily**? (include for coffee, tea, cereal etc.) (23) _____ tsp.

In what form do you usually use your margarine? (25) ☐ Stick form ☐ Tub form

What percentage of the time do you eat your meat cooked well done? (26) _____ %

What was your weight at age 18? (29) _____ pounds

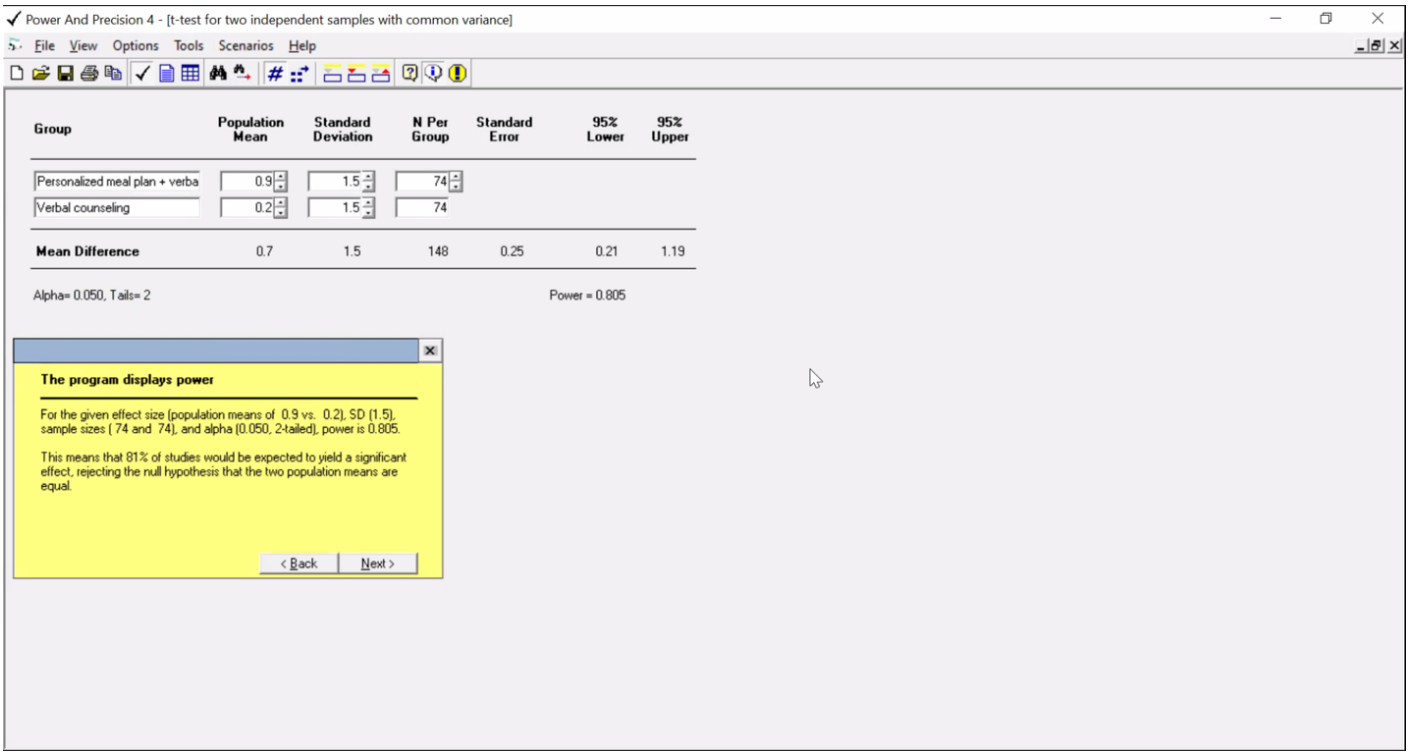
THANK YOU. Please return completed questionnaire in the pre-paid envelope to: NURSES HEALTH STUDY, Frank E. Speizer, M.D., Harvard Medical School, 180 Longwood Avenue, Boston, Massachusetts 02115

Appendix E: Technique for Blood Pressure Measurement

Table 8. Stepwise process for proper blood pressure measurement. This is derived from Table 8 in the 2017 AHA/ACC Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults [25].

Step Number	Instructions
1. Prepare the patient.	1. Patient should be relaxed in a quiet environment sitting in a chair for >5 min and ensure that they have emptied their bladder. 2. Patient should avoid caffeine, exercise, and smoking for at least 30 minutes before measurement. 3. Remove all clothing covering the location of cuff placement.
2. Proper technique for blood pressure measurements	1. Use the study's validated electronic blood pressure device. 2. Support the patient's arm and position the middle of the cuff (using the correct size) on the patient's upper arm at the midpoint of the sternum. 3. Ensure that the bladder encircles 80% of the arm.
3. Properly measuring and documenting blood pressure	1. At the first visit, record BP in both arms and use the average of these two readings. Use the arm that gives the higher reading for readings at future visits. 2. The next day the patient will return, repeat processes 1 to 3.1. 3. The average of the first two visits will constitute baseline blood pressure (3 measurements total). 4. Repeat steps 1 to 3.1 for all subsequent blood pressure measurements (12 measurements total)

Appendix F: Sample Size Calculation


Power And Precision 4 - [t-test for two independent samples with common variance]
File View Options Tools Scenarios Help
Group
Population Mean
Standard Deviation
N Per Group
Standard Error
95% Lower
95% Upper
Personalized meal plan + verba
0.9
1.5
74
Verbal counseling
0.2
1.5
74
Mean Difference
0.7
1.5
148
0.25
0.21
1.19
Alpha= 0.050, Tails= 2
Power = 0.805
The program displays power
For the given effect size (population means of 0.9 vs. 0.2), SD (1.5), sample sizes (74 and 74), and alpha (0.050, 2-tailed), power is 0.805.
This means that 81% of studies would be expected to yield a significant effect, rejecting the null hypothesis that the two population means are equal.
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