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HYPERTENSION AND DIET: REDUCING RISK THROUGH LOW SATURATED FAT AND HIGH FIBER NUTRITION PROGRAMS

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HYPERTENSION AND DIET

REDUCING RISK THROUGH LOW SATURATED FAT AND

HIGH FIBER NUTRITION PROGRAMS

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ABSTRACT

This MQP analyzed data obtained from the Cancer Dietary Objectives (Can Do) Study conducted in the division of Preventative and Behavioral Medicine at the University of Massachusetts Medical School (Worcester, MA). The Can Do Study investigated the effects of dietary and lifestyle challenges on the risks of developing hypertension and related syndromes, cardiovascular disease (CVD), and certain types of cancer. This MQP focused on identifying correlations between blood pressure and hypertension risk, as related to weight loss, inches lost off waist and hips, and BMI in dieting subjects. The data indicated that dietary and lifestyle changes are correlated with a reduction in blood pressure and risk for hypertension.

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BACKGROUND

Hypertension

Description

Hypertension is defined as abnormally high pressure on the blood vessels, typically indicated by a systolic blood pressure of 140mm Hg or higher, and a diastolic blood pressure of 90mm Hg or higher (Medline Plus, 2008). A systolic measure of 120mm Hg or less, and a diastolic measure of 80mm Hg or less is considered normal blood pressure (Oparil and Lundberg, 2007). Thickening of the vessel walls and a loss of arterial elasticity are symptomatic of hypertension.

Secondary hypertension describes the presence of hypertensive symptoms from a primary disease, such as renal disease, aldosternonism, and thyroid disorders. Essential hypertension, also known as idiopathic or primary hypertension, describes the more common hypertension that occurs for unknown reasons. Individuals with essential hypertension often have high dietary sodium intake, are overweight or obese, and lead sedentary lifestyles (Medline Plus, 2008).

A person at risk for developing hypertension may be described as "pre-hypertensive" (Oparil and Lundberg, 2007), defined by a systolic pressure of 120-130mm Hg, and a diastolic pressure of 80-89mm. Numbers for normal, pre-hypertensive, and hypertensive blood pressure are standardized by the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure (Chobanian et al., 2003). Classification standards for normal, pre-hypertensive, and Stage 1 and 2 hypertension are summarized in Table I, with suggested courses of treatment.

BP Classification	SBP* mmHg	DBP* mmHg	Lifestyle Modification	Initial drug therapy	
				Without Compelling Indication	With Compelling Indications (See Table 8)
Normal	<120	and <80	Encourage		
Prehypertension	120–139	or 80–89	Yes	No antihypertensive drug indicated.	Drug(s) for compelling indications.‡
Stage 1 Hypertension	140–159	or 90–99	Yes	Thiazide-type diuretics for most. May consider ACEI, ARB, BB, CCB, or combination.	Drug(s) for the compelling indications.‡ Other antihypertensive drugs (diuretics, ACEI, ARB, BB, CCB) as needed.
Stage 2 Hypertension	≥160	or ≥100	Yes	Two-drug combination for most† (usually thiazide-type diuretic and ACEI or ARB or BB or CCB).	

DBP, diastolic blood pressure; SBP, systolic blood pressure.
Drug abbreviations: ACEI, angiotensin converting enzyme inhibitor; ARB, angiotensin receptor blocker; BB, beta-blocker; CCB, calcium channel blocker.

* Treatment determined by highest BP category.
† Initial combined therapy should be used cautiously in those at risk for orthostatic hypotension.
‡ Treat patients with chronic kidney disease or diabetes to BP goal of <130/80 mmHg.

Table 1: Classification and Management of Blood Pressure for Adults (Chobanian et al., 2003)

Risk Factors

There are many possible causes of hypertension. As stated earlier, some cases of hypertension result from pre-existing health problems. The kidneys, for example, play a large role in regulating blood pressure throughout the body, thus conditions such as renal disease or other kidney problems can lead to elevated blood pressure and hypertension (Whitney et al.,1998). Chronic kidney disease (CKD), primary aldosteronism, chronic steroid therapy, sleep apnea, thyroid disease, and drug use are also known to cause hypertension in some individuals (Chobanian et al., 2003). In women, use of oral contraceptives may increase blood pressure and the risk for hypertension increases with the duration of drug use. Menopausal hormone therapy use, however, has not been shown to raise blood pressure or risk for developing hypertension (Chobanian et al., 2003).

In essential hypertension, there is often identifiable cause for elevated blood pressure. There are, however, risk factors associated with the development of essential hypertension which include age, obesity, family history, and ethnicity. As people age, blood vessels naturally begin to loose elasticity, increasing blood pressure. Obesity is defined as a body mass index of 30 km/m2 or greater (Chobanian et. al., 2003). Obese individuals have more body mass and thus require more capillaries to reach extra body tissue. This can add miles to the circulatory system, requiring more force and higher blood pressure to allow blood to be pumped through additional vessels.

A family history of hypertension can increase the risk 2-5 times. Various studies have also shown that ethnicity plays a role, and that African Americans are twice as likely to develop hypertension than Caucasians. Hypertension in African Americans has also been shown to develop earlier in life, and become more severe than in Caucasians. Of all risk factors for essential hypertension, weight and obesity (and contributory dietary factors) are the only ones that can be controlled (Whitney et al.,1998).

Some dietary factors are also associated with the development of hypertension, including alcohol consumption and alcoholism, and high sodium intake. Moderate alcohol consumption is defined as 2-6 drinks per week for men, and 1-3 drinks per week for women (Chobanian et al., 2003).

Prevalence

According to the JNC 7 report (Chobanian et al., 2003), hypertension is the most common primary care diagnosis in the United States, with 35 million diagnoses every year. Obesity is a contributing factor to the large number if annual diagnoses - 122 million Americans are overweight or obese (JNC p21). Reducing systolic blood pressure has proved to be more difficult than diastolic blood pressure, and the JNC-7 has a set a goal control at 50%, achieved by the year 2010 (Healthy People 2010 Initiative), though current control rates fall far short of this goal. In addition, it is estimated that 30 percent of the U.S. population still has undiagnosed hypertension (Chobanian et al., 2003).

African and Hispanic populations are more susceptible to developing hypertension. Blood pressure control rates are lowest in individuals of Mexican American and Native American descent. This may be in part to traditional cultural diets that are by nature higher in saturated fat and sodium, and also in part to lack of education or diagnosis of hypertension, and socioeconomic factors (Chobanian et al., 2003). African Americans also show lower response to common drug therapies (Chobanian et al., 2003).

Approximately two-thirds of the population over the age of 65 develop hypertension. Minority populations show the poorest blood pressure control rates (Chobanian et al., 2003).

Associated Diseases

Several diseases are associated with hypertension. Some lead to hypertension while others occur because of poor blood pressure control. Women have also been shown to be at higher risk for hypertension and cardiovascular problems. Heart disease is currently the leading cause of death in women, accounting for one third of deaths annually in the United States (Chobanian et al., 2003) The risk for developing cardiovascular disease (CVD) doubles with

each 20/10mmHg incremental increase in blood pressure, starting at 115/75 mm Hg for an individual between the ages of 40 and 70 (Chobanian et al., 2003).

Higher blood pressure greatly increases the risk for heart attack, stroke, heart failure, heart disease, and kidney disease. Heart failure is primarily the result of high systolic hypertension (which is most difficult to control). Other conditions, such as peripheral arterial disease (PAD), cognitive impairment, and dementia are more common in people with high blood pressure and hypertension (Chobanian et al., 2003).

Identifiable causes of hypertension include, but are not limited to the following: chronic kidney disease, primary aldosteronism, renovascular disease, thyroid or parathyroid disease, and sleep apnea (Chobanian et al., 2003).

Prevention and Treatments

Many lifestyle changes and drug treatments are currently used to control hypertension. Most patients with primary hypertension are treated with thiazide type diuretics (Chobanian et al., 2003). These drugs work by blocking the reabsorption of sodium in the kidneys and inducing excretion of chloride, which results in increased excretion of water (Dorland's Medical Dictionary, 2008). Sodium reduction has been previously correlated with reductions in blood pressure, and diets geared towards treatment and prevention of hypertension include sodium reduction (McCarron et al., 1998). Diuretics have been most effective of all antihypertensive drug treatments in preventing onset of CVD and other complications of hypertension, and have been shown to enhance the effects of other multidrug therapies. Diuretics are also more affordable than many antihypertensive treatments (Chobanian et al., 2003).

Antihypertensive drug therapies have been shown to decrease the incidence of stroke by 35-40 percent, and to reduce the occurrence of heart failure by more than 50 percent (Chobanian et al., 2003). Studies estimate that such treatments can reduce additional cardiovascular risk factors in Stage 1 hypertensive patients and maintain a 12mm Hg reduction in systolic blood pressure over a 10 year period. Patients often require two or more antihypertensive medications to achieve their blood pressure goals. Most patients, especially those who are 50 years or older, will reach goals for diastolic blood pressure after goals for systolic blood pressure have been reached. Goals for patients with diabetes or renal disease typically attempt to reach a blood pressure of <130/80 mmHg (Chobanian et al., 2003).

Lifestyle changes are also essential for effective and lasting treatment of hypertension. Diets low in dietary sodium and saturated fat, and high in potassium and calcium (such as the DASH diet) have been shown to be effective in lowering blood pressure. Moderate to low alcohol consumption and increasing physical activity also show significant reductions in blood pressure in hypertensive patients. Public health initiatives, including programs geared towards reducing caloric intake, saturated fat and dietary sodium intake, have the potential to alter the current upward trends in hypertension. These programs, and ones that increase physical activity levels in schools and communities, will serve to counter epidemic levels of obesity in Americans, a large risk factor in hypertension and CVD (Chobanian et al., 2003).

While drug therapies and lifestyle changes have many potential benefits, they are only effective if regiments are properly followed. Various barriers may affect a patient's adherence, including misconceptions about drug therapy, denial of illness, negative affects of drug therapy, and lack of patient motivation or involvement in their treatment. Cultural and religious beliefs may also play a role in a patient's adherence to treatment. Previous experiences with physicians and the health care system are also factors to consider. Therapies will be most effective when

clinicians and doctors involve the patient in developing their treatment plan, and when the patient is motivated (Chobanian et al., 2003). Table 2 shows modifications and expected results outlined by the DASH diet.

Modification	Recommendation	Approximate SBP Reduction (Range)
Weight reduction	Maintain normal body weight (body mass index 18.5–24.9 kg/m^2).	5–20 mmHg/10 kg weight loss[23,24]
Adopt DASH eating plan	Consume a diet rich in fruits, vegetables, and lowfat dairy products with a reduced content of saturated and total fat.	8–14 mmHg[25,26]
Dietary sodium reduction	Reduce dietary sodium intake to no more than 100 mmol per day (2.4 g sodium or 6 g sodium chloride).	2–8 mmHg[25–27]
Physical activity	Engage in regular aerobic physical activity such as brisk walking (at least 30 min per day, most days of the week).	4–9 mmHg[28,29]
Moderation of alcohol consumption	Limit consumption to no more than 2 drinks (1 oz or 30 mL ethanol; e.g., 24 oz beer, 10 oz wine, or 3 oz 80-proof whiskey) per day in most men and to no more than 1 drink per day in women and lighter weight persons.	2–4 mmHg[30]

DASH, Dietary Approaches to Stop Hypertension.

* For overall cardiovascular risk reduction, stop smoking.

† The effects of implementing these modifications are dose and time dependent, and could be greater for some individuals.

Table 2: Lifestyle Modifications to Manage Hypertension (Chobanian et al., 2003)

Current Hypertension Research Trends

Many research initiatives are currently investigating how various aspects of diet affect hypertension. Researchers have examined diet through surveys, and have conducted studies using regimented diets to determine the effect of eating on hypertension and CVD.

Two studies asked subjects to follow specific diet plans: the Dietary Approaches to Stop Hypertension (DASH) diet and the Campbells' Center for Nutrition and Wellness (CCNW) Plan. The CCNW plan was designed to meet daily nutrition values for sodium, total and saturated fat, fiber, cholesterol, and carbohydrate intake (McCarron et al., 1998). 101 men and women were randomized to either the CCNW plan, or a diet of starches, fruits, low fat dairy products, vegetables, and lean meats, and asked to select their own foods. All subjects had mild to moderate hypertension. Study measurements included BP, lipids, nutrient intake, compliance, and quality of life. Both dietary interventions were shown to significantly lower blood pressure and reduce risk for cardiovascular disease, though greater results in risk and blood pressure reduction, compliance, and improved quality of life were observed with the CCNW plan (McCarron et al., 1998).

The DASH diet recommends increased consumption of fruits, vegetables, and low fat dairy products, while reducing the intake of fats, red meats, and sugary beverages and foods (Folsom et al., 2007). The DASH diet has been strongly recommended for lowering high blood pressure by both the National High Blood Pressure Education program and the American Heart Association. Folsom, Parker, and Harnack's study examined the benefits of the DASH diet and compliance. They found that hypertension was inversely associated with the level of compliance to the DASH diet. Death from coronary heart disease, stroke, and CVD were also inversely related to better dietary compliance (Folsam et al., 2007). While the DASH diet has many obvious benefits, very high compliance is necessary to gain significant improvements in blood

pressure and cardiovascular health. This reiterates the importance of a patient's involvement and understanding of the treatment plan they follow, and also the importance of a person's motivation to achieve their health goals (Chobanian et al., 2003). A patient that is unmotivated and that does not understand the importance of compliance will not be successful with the DASH diet.

A third study conducted several concurrent dietary experiments geared towards regulating the levels of fat, sodium, or fiber intake in free-living adults over three to six months. Less than 25% of participants were diagnosed with hypertension. The study aimed to find if dietary modifications were effective at modifying risk in a general, high risk population (Brunner et al., 1997). Dietary interventions collectively showed a moderately significant net decrease in blood pressure of -0.7mm Hg, and a significant decrease of -1.3mm Hg in systolic blood pressure over 3 to six months. Previous trials showed a decrease of 5mm Hg in diastolic blood pressure resulted in a 21% reduction in risk for coronary heart disease and a 34% reduction in risk of stroke (MacMahon et al., 1990). This study calculated a 14% reduction in risk for coronary heart disease, and an 8% reduction in risk of stroke, demonstrating that dietary advice and modification in free-living can moderately reduce cardiovascular risks (Brunner et al., 1997).

One early study examined the effects of a vegetarian diet vs. a nonvegetarian diet in black and white Seven Day Adventists (Melby et al., 1989). Melby's study used this specific group of Adventists subjects to eliminate confounding results from alcohol use, caffeine, and tobacco - all substances that the Seven Day Adventist Church encourages church members to avoid. Vegetarian diets tend to be low in total calories, sodium, and saturated fat, all factors that directly correlate with increased blood pressure. Vegetarians also tend to consume higher levels of potassium, calcium, and magnesium, nutrients that are associated with lower blood pressure.

Melby's study found that significantly more African American non-vegetarians used antihypertensive medications than both African American and Caucasian vegetarians. A vegetarian diet was also strongly correlated with lower systolic blood pressure in African American Adventists, more so than in Caucasian Adventists (lower blood pressure was still significantly correlated with a vegetarian diet). This evidence strongly suggests the difference in risk between races, and the need for varying treatments depending on ethnic background (Melby et al., 1989).

A survey conducted in 2007 revealed trends in hypertension prevalence (Ostchega et al., 2007). Like Melby's group, the survey found that race was a factor in risks for hypertension. Non-hispanic African Americans were significantly more likely than non-Hispanic Caucasians to have hypertension. Other significant factors included age, sex, socioeconomic factors, health care, and other health factors. 67% of adults over the age of 60 suffered from hypertension, and both men and women over the age of 70 were significantly less likely aware and less likely to control their hypertension than subjects age 60-69. Body mass index (BMI) over 25 was also associated with hypertension, higher awareness, and treatment (Ostchega et al., 2007). Measuring blood pressure every 6 months was significantly associated with greater awareness of hypertension and greater treatment in both men and women. Again, greater involvement of physicians and patients in a treatment plan is necessary for significant results (Chobanian et al., 2003).

Some studies have examined specifically how fiber may reduce blood pressure and risk for hypertension and CVD (Galisteo et al., 2008). Fiber has been shown to play a key role in controlling metabolic syndrome, a pre-diabetic condition typically occurring in overweight and obese individuals. Fiber consumption may reduce the risk for hypertension by promoting weight loss and control. Another study demonstrated that a diet high in fiber from fruits, vegetables, and

grains significantly decreased blood pressure and use of antihypertensive medications in subjects suffering from hypertension (Burke et al., 2001). In a double-blinded, placebo-controlled study of 110 subjects with high blood pressure or Stage 1 hypertension, increased soluble fiber intake over a 12 week period significantly decreased systolic and diastolic blood pressure in participants (He et al., 2004). Mean dietary fiber intake of total, soluble, and insoluble fiber was increased to 10.6, 5.6 and 4.9 g/day, respectively, and resulted in a mean decrease in of 3.4 and 2.2mm Hg of systolic and diastolic blood pressure, respectively (He et al., 2004).

Other research has shown that a diet low in sodium and high in potassium may reduce risk for hypertension and CVD. A recent study at the Oregon Health and Science University investigated a mechanism in the kidneys that is thought to regulate blood pressure (OSHU, 2007). A protein complex of WNK1, WNK3, and WNK4 kinases work together to regulate NCC, a protein that regulates salt levels in the body. The kinases work together to relay messages to regulate NCC. This OSHU study also examined familial hyperkalemic hypertension (FHHt), which results from a genetic mutation ion the WNK protein complex. When the WNK complex function is compromised, WNK cannot communicate with the NCC protein, and salt remains in the body, leading to increased blood pressure (OSHU, 2007).

The OSHU study also offers an explanation of how aldosterone affects sodium and potassium levels, and how potassium lowers blood pressure. Aldosterone function may be regulated by WNK kinases, switching aldosterone from a salt absorbing hormone to a salt excreting one. A genetic defect in the WNK kinases may turn the switch in the wrong direction, causing salt to be absorbed. This switch explains how a diet high in potassium may lower blood pressure, as potassium is involved in aldosterone secretion and in WNK kinase regulation. The WNK kinase complex and aldosterone together, when functioning properly, will work to excrete

potassium rather than reabsorb salt, lowering blood pressure as salt is lost from the body (OSHU, 2007).

The University of Massachusetts Can Do Study

This MQP analyzed a portion of data from a larger study, the Cancer Dietary Objectives "Can Do Study", conducted in the division of Preventative and Behavioral Medicine at the University of Massachusetts Medical School in Worcester, Massachusetts. The Can Do Study proposed dietary changes and lifestyle changes to reduce the risk of developing hypertension, CVD, and certain types of cancer, and also for reducing hypertensive syndromes. Thirty-five study subjects were recruited and enrolled in one of three dietary programs for 6 months. Dietary programs included a high fiber diet (30g of fiber per day), a low saturated fat diet (based on physical activity and required daily caloric intake), and a combination low saturated fat high fiber diet.

The Can Do Study obtained data on various factors including weight loss, inches lost off hips and waist, BMI, blood pressure, and blood lipid levels over the course of six months to determine risk in subjects following the diets. The study investigators are currently in the process of analyzing the data and will be reporting on their findings and conclusions later this Spring. Their hope is to conduct a larger scale study using modified methods tested in this pilot study. This MQP paper focused specifically on blood pressure and hypertension risk as related to weight loss, inches lost, and BMI in dieting subjects.

PROJECT PURPOSE

The purpose of this MQP was to analyze data obtained from the Cancer Dietary Objectives (Can Do) Study conducted in the division of Preventative and Behavioral Medicine at the University of Massachusetts Medical School in Worcester, Massachusetts. The Can Do Study investigated the effects of dietary changes and lifestyle changes on reducing the risk of hypertension, hypertensive syndromes, cardiovascular disease (CVD), and certain types of cancer. While the Can Do Study examined a wide variety of parameters, this MQP focused on the correlations between blood pressure and hypertension risk as related to weight loss, waist inches lost, and BMI in dieting subjects. Previous aforementioned studies have investigated the effects of fiber and low saturated fat on various health aspects. This MQP study focused specifically on how defined dietary recommendations and counseling affect risk for hypertension, and used nutritional counseling sessions and study appointments to assess and discuss improvements in subject's health.

METHODS AND MATERIALS

All study methods and materials implemented in the University of Massachusetts Can Do Study were designed by the study investigators. This MQP executed various aspects of the project, including potential subject screening, consent visits, and Baseline, 3 months, and 6 month study visits. Recruitment, 24-hour recalls, and nutrition counseling sessions were conducted by Can Do Study investigators.

Subject Screening

Subject screening was done over the phone by a research assistant. Potential study subjects either called the study phone number, or were called after expressing interest, and were asked a set of standardized questions to determine eligibility. Several exclusionary questions were asked during screening, including whether subjects smoked, were pregnant, had HbA1c levels over 7.0, and had a BMI either above 40 or below 25. If so, they were excluded. This form appears in the Appendix as "Screening Form"

Potential subjects meeting requirements for the study were asked to schedule a consent and baseline visit. Subjects not meeting requirements were thanked for their interest and informed of other future studies.

Consent Visits

Potential subjects met with a research assistant who explained the purpose and goals of the study. The research assistant also explained potential benefits and risks of the study, and the rights of enrolled subjects. Voluntary participation was emphasized throughout the meeting, and questions were encouraged of the potential study subjects. All forms were explained, including a

study consent form, and a standard HIPPA medical records release form. As an incentive for participation, potential subjects were told they would receive a $25 gift certificate to Trader Joe's at the end of the study.

After all forms had been explained, potential subjects were given time to read and ask questions about all study forms. If potential subjects had no questions and wished to participate in the study, forms were signed by both the subject and the research assistant, and subjects proceeded to the baseline visit.

No potential subjects who were scheduled for screening declined further participation. One subject had questions regarding the HIPPA medical release form. The subject's questions were deferred to the Primary Investigator for the Can Do Study, who further explained the purpose of the form and the subject's rights with regards to the form. Afterward the subject decided to participate in the study. This form appears in the Appendix as "Consent Form".

Baseline Visit

Anthropometric measures and blood samples were taken at the baseline visit. Anthropometric measures included blood pressure, pulse, height, weight, and waist and hip circumference. BMI was calculated from measured height and weight. Blood samples were tested for HDL, LDL, triglyceride, and glucose levels.

Subjects were also given a questionnaire to collect demographic information, medical history, medications and supplements taken, contact information, information about the subject's current dietary habits and dietary history, and questions regarding depression. This form appears in the Appendix as "Baseline Questionnaire".

3 Month Visit

Anthropometric measures and blood samples were taken at the 3 month visit. Anthropometric measures included blood pressure, pulse, weight, and waist and hip circumference. BMI was calculated from measured weight and baseline height. Blood samples were tested for HDL, LDL, triglyceride, and glucose levels. Subjects were also given a questionnaire to collect medical history since the baseline visit, medications and supplements taken and any changes since the baseline visit, information about the subject's adherence to and perceptions of the diet, and questions regarding depression. This form appears in the Appendix as "3 Month Questionnaire".

6 Month Visit

Anthropometric measures and blood samples were taken at the 6 month visit. Anthropometric measures included blood pressure, pulse, height, weight, and waist and hip circumference. BMI was calculated from measured weight and baseline height. Blood samples were tested for HDL, LDL, triglyceride, and glucose levels. Subjects were also given a questionnaire to collect medical history since the 3 month visit, medications and supplements taken and any changes since the 3 month visit, information about the subject's adherence to and perceptions of the diet, and questions regarding depression. This form appears in the Appendix as "6 Month Questionnaire".

RESULTS

As previously stated, the purpose of this MQP was to analyze data recently obtained from the University of Massachusetts Can Do Study, focusing on a subset of their project specifically identifying correlations between blood pressure and hypertension risk as related to weight loss, waist inches lost, and BMI in dieting subjects. The participants were divided into three subgroups: Combo Group, High Fiber Group, and Low Saturated Fat Group. The High Fiber Group was told to increase their daily fiber intake to 30g/day. The Low Saturated Fat Group restricted their consumption of saturated fats based on their daily caloric needs and level of physical activity. The Combo Group restricted their saturated fat and increased their daily fiber intake.

Participant Baseline Demographics

Table 3 summaries the Baseline demographics of study participants for the Can Do Study. The investigators intended this to be a pilot study to test the method design using a small group of participants before launching a full scale study in the future. As is evident in Table 3, there was a lack of patient diversity. If this Can Do study were conducted again on a larger level, subject recruitment would seek out a more ethnically diverse group. Only 3% of the study population were of non-Caucasian decent. Greater subject diversity is important for future studies given the effects of diet seen in different ethnic groups in earlier studies (Melby et al., 1989). In addition, from 83-92% of the participants were women, depending on the subgroup analyzed. Future studies should recruit an equal number of men as women to account for differences in gender in hypertension prevention and control.

Subjects did have a variety of educational backgrounds. Most subjects (72%) were married, and had 2-3 people living in their households. Of these people, 9 reported that family followed the diet they were on, while 10 reported that people the people they lived with did not follow the diet. Of the 10 who's family did not follow the diet, 5 reported that they were not confident they would stick with the diet beyond the study. Of the 9 that reported household members were following the diet, 8 said they were confident or very confident that they would stick with the diet beyond the end of the study. It thus appears that household support was important for people in their perception of their ability to succeed.

69% of the study population reported they work full time, and each group worked on average 44 hours per week. 67% of the participants also reported making over $60,000 per year.

	Overall	Combo group (n=12)	High-fiber group (n=12)	Low-sat fat group (n=12)	p-value*
Age in years (mean (SD))	47.58 (13.48)	41.33 (15.89)	48.42 (9.72)	53.00 (12.50)	0.100
Body mass index (kg/m^2) (mean (SD)	31.20 (4.05)	32.27 (4.70)	31.98 (3.78)	29.34 (3.19)	0.149
Gender					.793
Male	5 (14%)	2 (17%)	1 (8%)	2 (17%)	
Female	31 (86%)	10 (83%)	11 (92%)	10 (83%)	
Marital Status					.165
Married	26 (72%)	11 (92%)	7 (58%)	8 (67%)	
Other	10 (28%)	1 (8%)	5 (42%)	4 (33%)	
# people per household	2.57 (1.17)	2.7 (1.16)	2.13(.99)	2.75 (1.29)	.470
Ethnicity					.755
White	32 (91%)	10 (83%)	11 (92%)	11 (100%)	
Other	3 (9%)	2 (17%)	1 (8%)	0 (0%)	
Educational Level					.254
Bachelor's degree or higher	21 (58%)	9 (75%)	7 (58%)	5 (42%)	
Other	15 (42%)	3 (25%)	5 (42%)	7 (58%)	
Work Status					.083
Full time	25 (69%)	6 (50%)	8 (67%)	11 (92%)	
other	11 (31%)	6 (50%)	4 (33%)	1 (8%)	
Hours/week	44.35(6.83)	44.0 (5.48)	44.75 (7.77)	44.14 (7.53)	.979
Household income (n=27)**					.136
$59,000 or less	9 (33%)	1 (10%)	3 (43%)	5 (50%)	
$60,000 or more	18 (67%)	9 (9%)	4 (57%)	5 (50%)	

Table 3. Participants' Characteristics at Baseline, Cancer Dietary Objectives Study (Can Do Study), Worcester, Massachusetts, 2007-2008. N=36

*: p-value was from ANOVA or Chi-square test comparison of means or % among the three groups.

**: optional question on questionnaire

Study Results

Table 4 summarizes the results of changes in diet, anthropometric measures, and change in physical activity for the course of the study. While the analysis showed that none of the models gave statistically significant results (largely due to the low numbers of people in each group), trends were observed in the high fiber group that warrant further study. The fiber group saw a greater decrease in both systolic and diastolic blood pressure during the course of the study than the other two groups. The combo diet group also saw a large decrease in both systolic and diastolic blood pressure, however the decrease in diastolic blood pressure was not as large as the decrease observed in the fiber group. By the end of the study, the fiber group consumed on average greater than 25 grams of fiber per day, a significant increase from their baseline mean value of about 18 grams per day. The combo group consumed an average of 23 grams of fiber per day, an increase of only 1 gram per day from their baseline mean value of 22 grams per day. This difference may play a role in the differences seen in decreased blood pressure.

The type of dietary fiber consumed may also play a role in reducing blood pressure. The fiber and low sat-fat groups consumed similar amounts of cereal fiber over the course of the study. This may suggest that other types of fiber consumed in greater quantities by the fiber group are contributing more greatly than cereal fiber to blood pressure control and reduction.

The low sat-fat group on average lost the most weight over the course of the study, though the differences between groups were not statistically significant. Given the data collected from the other two groups, it appears that weight loss alone was not enough to reduce blood pressure, as the low sat-fat group saw very little change in diastolic, and an increase in systolic blood pressure.

There were no statistically significant differences between groups in physical activity at baseline, and no significant changes in activity over the course of the study. Fasting glucose

levels were significantly reduced in the fiber group (p = 0.04). Fasting glucose remained lowest in the fiber group for the duration of the study, but the most improvement in lowering fasting glucose was observed in the combination group.

Table 4. Change in Diet, Body Weight, Blood Lipids, Glucose, Blood Pressures and Physical Activity During the Can Do Study.

	Baseline			Intervention Effect						*p-value for intervention effect (p-value for time)
	Combo	high-fiber	Low-sat fat	3 month change from baseline			6 month change from baseline			
	n=9	n=12	n=10	Combo	high-fiber	Low-sat fat	Combo	high-fiber	Low-sat fat	
Dietary factors										
Total calories (kcal/day)	2137.37 (116.75)	2041.49 (101.10)	1710.28 (110.75)	- 638.91 (109.15)	- 464.05 (94.52)	-190.90 (103.54)	- 626.32 (109.15)	- 364.82 (94.52)	- 187.19 (103.54)	0.02 (<0.001)
% calories from carbohydrate	49.57 (2.46)	45.58 (2.13)	46.7780 (2.33)	6.4148 (2.43)	7.09 (2.11)	1.85 (2.31)	2.52 (2.43)	5.84 (2.10)	3.13 (2.31)	0.35 (0.0008)
% calories from fat	34.97 (1.90)	35.07 (1.65)	33.76 (1.81)	- 8.50 (2.14)	- 7.93 (1.85)	- 5.69 (2.03)	- 8.80 (2.14)	- 7.44 (1.85)	- 6.24 (2.023)	0.86 (<0.001)
% calories from saturated fat	10.96 (0.87)	11.51 (0.76)	11.85 (0.83)	- 4.21 (0.95)	-3.03 (0.83)	-3.09 (0.91)	- 3.48 (0.95)	-3.27 (0.83)	- 3.66 (0.91)	0.83 (<0.001)
Total dietary fiber (g/day)	22.60 (2.30)	17.90 (1.99)	14.47 (2.18)	2.65 (2.27)	7.91 (1.97)	1.49 (2.16)	1.11 (2.27)	6.68 (1.97)	2.94 (2.16)	0.15 (0.003)
Components of dietary quality										
Vegetables (servings/day)	2.71 (0.52)	3.28 (0.45)	2.62 (0.49)	0.28 (0.56)	0.28 (0.49)	0.17 (0.53)	0.11 (0.56)	-0.26 (0.49)	0.66 (0.53)	0.65 (0.72)
Fruits (servings/day)	2.45 (0.41)	1.61 (0.36)	1.94 (0.39)	-0.47 (0.50)	0.20 (0.43)	-0.81 (0.48)	-0.93 (0.50)	-0.46 (0.43)	-0.65 (0.48)	0.53 (0.05)
Nuts and legumes (serving/day)	1.61 (0.54)	1.10 (0.47)	0.62 (0.51)	0.06 (0.60)	0.25 (0.52)	1.03 (0.57)	-0.65 (0.60)	0.32 (0.52)	0.49 (0.57)	0.52 (0.33)
Ratio of white to red meat	2.05 (0.39)	1.93 (0.34)	2.48 (0.37)	0.07 (0.51)	0.46 (0.44)	0.09 (0.48)	0.28 (0.51)	0.04 (0.44)	0.50 (0.48)	0.76 (0.59)
Cereal fiber (g/d)	5.93 (1.13)	5.08 (0.97)	3.92 (1.07)	1.77 (1.29)	1.81 (1.55)	0.26 (1.22)	-1.25 (1.29)	2.72 (1.12)	2.56 (1.22)	0.04 (0.08)
Alcohol (servings/day)	0.27 (0.19)	0.77 (0.17)	0.17 (0.18)	- 0.04 (0.19)	-0.48 (0.17)	0.05 (0.18)	0.02 (0.19)	-0.49 (0.17)	0.16 (0.18)	0.08 (0.32)

	Baseline			Intervention Effect						*p-value for intervention effect (p-value for time)
	Combo	high-fiber	Low-sat fat	3 month change from baseline			6 month change from baseline			
	n=9	n=12	n=10	Combo	high-fiber	Low-sat fat	Combo	high-fiber	Low-sat fat	
Anthropometric measures										
Weight (lbs)	188.3 (9.0)	191.3 (7.7)	205.4 (8.5)	-6.7 (2.3)	-7.0 (2.0)	-9.1 (2.2)	-7.0 (2.3)	-9.1 (2.0)	-10.2 (2.2)	0.80 (<0.001)
Hip (inches)	47.6 (1.2)	46.2 (1.1)	47.3 (1.2)	-2.5 (0.6)	-1.5 (0.5)	-2.3 (0.6)	-2.1 (0.6)	-2.9 (0.5)	-2.1 (0.6)	0.19 (<0.001)
Waist (inches)	42.3 (1.4)	40.5 (1.2)	43.3 (1.3)	-2.1 (0.7)	-0.6 (0.6)	-2.3 (0.7)	-3.3 (0.7)	-2.0 (0.6)	-3.3 (0.7)	0.32 (<0.001)
Blood pressure										
Diastolic blood pressure (mmHg)	70 (2.6)	74 (2.3)	72 (2.5)	- 1.67 (2.7)	-4.17 (2.3)	- 1.90 (2.5)	1.67 (2.6)	- 2.08 (2.3)	- 3.50 (2.5)	0.67 (0.15)
Systolic blood pressure (mmHg)	119 (5.1)	122 (4.4)	125 (4.8)	- 6.9 (4.6)	- 5.8 (3.8)	- 0.9 (4.2)	0.8 (4.4)	- 4.4 (3.8)	1.4 (4.2)	0.52 (0.21)
Fasting glucose	106.6 (5.5)	90.4 (4.8)	92.8 (5.3)	-8.6 (4.3)	-0.7 (3.7)	6.8 (4.1)	-4.6 (4.3)	-4.0 (3.8)	9.1 (4.2)	0.04 (0.90)

Adjusted means and standard error were presented.
*: p-values were from mixed model fitting diet, anthropometric, physiological, and physical activity variables as the dependent variable; time measurement, treatment group, and interaction between time and group term as a fixed effect, and subject as a random effect. Treatment effect is defined as difference in changes in measures between time points: the interaction term between time and group. However, none of the interaction terms were significant in the models.

	Baseline			Intervention effect						*p-value for intervention effect (p-value for time)
	Combo	high-fiber	Low-sat fat	3 month change from baseline			6 month change from baseline			
	n=9	n=12	n=10	Combo	high-fiber	Low-sat fat	Combo	high-fiber	Low-sat fat	
Physical activity(met-hr/day)										
Total physical activity	27.08 (1.01)	25.44 (0.92)	28.09 (0.98)	- 0.37 (1.04)	0.85 (0.95)	- 0.19 (1.01)	- 0.25 (1.08)	1.85 (0.95)	- 1.88 (1.01)	0.10 (0.94)
Leisure time	1.45 (0.63)	0.89 (0.57)	2.51 (0.62)	0.22 (0.69)	0.50 (0.63)	0.45 (0.67)	-0.21 (0.71)	0.26 (0.63)	- 1.37 (0.67)	0.35 (0.09)
Household	4.47 (0.95)	2.99 (0.86)	4.98 (0.90)	-0.93 (1.14)	0.18 (1.03)	- 1.52 (1.10)	-1.34 (1.17)	2.26 (1.03)	0.04 (1.10)	0.19 (0.21)
Occupational	0.67 (0.74)	0.47 (0.68)	0.82 (0.72)	0.29 (0.74)	0.81 (0.67)	- 1.56 (1.04)	1.70 (0.77)	0.79 (0.67)	- 0.93 (1.04)	0.19 (0.20)

Adjusted means and standard error were presented.
*: p-values were from mixed model fitting diet, anthropometric, physiological, and physical activity variables as the dependent variable; time measurement, treatment group, and interaction between time and group term as a fixed effect, and subject as a random effect. Treatment effect is defined as difference in changes in measures between time points: the interaction term between time and group. However, none of the interaction terms were significant in the mode.

Table 5 and Table 6 summarize data on the reported quality of life at three and six months, respectively. This data was compiled from the 3 Month Questionnaire and 6 Month Questionnaire. Data collected on the Quality of Life was not statistically significant at three

months, however 25% of the study population reported improvement in their health. Half if these people were in the high fiber group. 44% reported their health had improved somewhat, and 35% of these people were in the high fiber group. This group reported the least hunger while on the diet, and also the greatest confidence in sticking to the diet. At three months, the combo and low sat-fat subjects equally disagreed that they were hungry on their diets. Half the sat-fat group and 40% of the combo diet group were very confident in sticking with the diet.

Study subjects were also polled on whether or not they found their diet too expensive. Subjects who reported the diet was too expensive also stated they were at least somewhat confident in their ability to stick to the diet. While expense may be an important factor in choosing a diet, there was no significant evidence that expense deterred the study population from any of the three diets

	Overall	**Combo group (n=10)**	**High-fiber group (n=12)**	**Low-sat fat group (n=10)**	**p-value***
Health status at Baseline *					.228
Excellent	3 (8%)	2 (17%)	1 (8%)	0 (0%)	
Very good	15 (42%)	6 (50%)	6 (50%)	3 (25%)	
Good	17 (47%)	4 (33%)	4 (33%)	9 (75%)	
Fair	1 (3%)	0 (0%)	1 (8%)	0 (0%)	
Poor	0 (0%)	0 (0%)	0 (0%)	0 (0%)	
Health Status at 3 Months					.776
Excellent	5 (16%)	2 (2%)	1 (8%)	2 (20%)	
Very good	14 (44%)	5 (50%)	6 (50%)	3 (30%)	
Good	13 (40%)	3 (30%)	5 (42%)	5 (50%)	
Fair	0 (0%)	0 (0%)	0 (0%)	0 (0%)	
Poor	0 (0%)	0 (0%)	0 (0%)	0 (0%)	
Change in Health by 3 months					.515
About the same	10 (31%)	5 (50%)	3 (25%)	2 (20%)	
Improved a lot	8 (25%)	2 (20%)	4 (33%)	2 (20%)	
Improved somewhat	14 (44%)	3 (30%)	5 (42%)	6 (60%)	
A bit worse	0 (0%)	0 (0%)	0 (0%)	0 (0%)	
A lot worse	0 (0%)	0 (0%)	0 (0%)	0 (0%)	
Difficulty with sticking to diet					.705
Very easy	4 (12%)	1 (10%)	1 (8%)	2 (20%)	

Somewhat easy	7 (22%)	2 (20%)	4 (33%)	1 (10%)	
Easy	14 (44%)	5 (50%)	4 (33%)	5 (5%)	
Somewhat difficult	5 (16%)	2 (20%)	2 (17%)	1 (10%)	
Very difficult	2 (6%)	0 (0%)	1 (8%)	1 (10%)	
Diet is too Expensive					.223
Strongly agree	0 (0%)	0 (0%)	0 (0%)	0 (0%)	
Somewhat agree	5 (16%)	1 (10%)	1 (8%)	3 (30%)	
Agree	2 (6%)	0 (0%)	0 (0%)	2 (20%)	
Somewhat disagree	4 (12%)	1 (10%)	2 (17%)	1 (10%)	
Strongly disagree	21 (66%)	8 (80%)	9 (75%)	4 (40%)	
Hungry while on diet					.290
Strongly agree	1 (3%)	1 (10%)	0 (0%)	0 (0%)	
Somewhat agree	3 (9%)	1 (10%)	0 (0%)	2 (20%)	
Agree	2 (6%)	0 (0%)	1 (8%)	1 (10%0	
Somewhat disagree	12 (38%)	6 (60%)	4 (33%)	2 (20%)	
Strongly disagree	14 (44%)	2 (20%)	7 (59%)	5 (50%)	
Confidence in sticking to diet					.389
Not at all confident	0 (0%)	0 (0%)	0 (0%)	0 (0%)	
Not very confident	2 (7%)	1 (10%)	0 (0%)	1 (10%)	
Somewhat confident	10 (33%)	5 (50%)	2 (17%)	3 (30%)	
Very confident	15 (48%)	3 (30%)	9 (75%)	3 (30%)	
Extremely confident	4 (12%)	1 (10%)	1 (8%)	2 (20%)	

Table 5: Participants' Responses at Baseline and 3 Months for the Can Do Study.
*Baseline: n=36, combo n=12; high fiber n=12; low saturated fat n=12. 3 months: n=32, combo n=10, high fiber n=12, low saturated fat n=10.

Data collected at 6 months (Table 6) was also not statistically significant. At 6 months, 42% of the study population reported their health had improved a lot since starting their diet. 53% of these people were in the high fiber group. In contrast to data collected at 3 months, approximately half the study population reported the diets were somewhat or very difficult to follow, and half these people were following the high fiber diet. Some people commented in their surveys that they felt less motivated during the last three months of the study because of the holiday season, because nutrition counseling sessions ended, or both. Holiday food, typically low in nutritional value, and high saturated fat, likely made consuming the recommended 30 grams of fiber/day difficult. The group did, however, increase their dietary fiber intake an average 6.68 grams during the last three months of the study. Also, 52% of study subjects reporting they were

confident or very confident in sticking to the diet were in the high fiber group. Perception of hunger is an important component of compliance, and half of the people reporting they were not hungry while on their diet were in the high fiber group.

	Overall (n=31)	Combo group (n=9)	High-fiber group (n=12)	Low-sat fat group (n=10)	p-value*
Health status at Baseline *					.228
Excellent	3 (8%)	2 (17%)	1 (8%)	0 (0%)	
Very good	15 (42%)	6 (50%)	6 (50%)	3 (25%)	
Good	17 (47%)	4 (33%)	4 (33%)	9 (75%)	
Fair	1 (3%)	0 (0%)	1 (8%)	0 (0%)	
Poor	0 (0%)	0 (0%)	0 (0%)	0 (0%)	
Health Status at 6 Months					.255
Excellent	5 (16%)	2 (22%)	2 (17%)	1 (10%)	
Very good	16 (52%)	3 (33%)	9 (75%)	4 (40%)	
Good	10 (32%)	4 (45%)	1 (8%)	5 (50%)	
Fair	0 (0%)	0 (0%)	0 (0%)	0 (0%)	
Poor	0 (0%)	0 (0%)	0 (0%)	0 (0%)	
Change in Health by 6 months					.253
About the same	7 (23%)	4 (45%)	2 (17%)	1 (10%)	
Improved a lot	13 (42%)	2 (22%)	7 (58%)	4 (40%)	
Improved somewhat	10 (32%)	3 (33%)	3 (25%)	4 (40%)	
A bit worse	1 (3%)	0 (0%)	0 (0%)	1 (10%)	
A lot worse	0 (0%)	0 (0%)	0 (0%)	0 (0%)	
Difficulty with sticking to diet					.824
Very easy	4 (13%)	1 (11%)	1 (8%)	2 (20%)	
Somewhat easy	5 (16%)	1 (11%)	4 (34%)	0 (0%)	
Easy	7 (23%)	3 (33.5%)	1 (8%)	3 (30%)	
Somewhat difficult	10 (32%)	1 (11%)	5 (42%)	4 (40%)	
Very difficult	5 (16%)	3 (33.5%)	1 (8%)	1 (10%)	
Diet will benefit health					.922
Strongly agree	19 (61%)	6 (67%)	7 (58%)	6 (60%)	
Somewhat agree	9 (29%)	2 (22%)	4 (34%)	3 (30%)	
Agree	2 (7%)	1 (11%)	0 (0%)	1 (10%)	
Somewhat disagree	1 (3%)	0 (0%)	1 (8%)	0 (0%)	
Strongly disagree	0 (0%)	0 (0%)	0 (0%)	0 (0%)	
Hungry while on diet					.020
Strongly agree	1 (3%)	1 (11%)	0 (0%)	0 (0%)	
Somewhat agree	4 (13%)	3 (33%)	0 (0%)	1 (10%)	
Agree	4 (13%)	0 (0%)	1 (8%)	3 (30%)	
Somewhat disagree	10 (32%)	4 (45%)	4 (34%)	4 (40%)	

Strongly disagree	12 (39%)	1 (11%)	7 (58%)	4 (40%)	
Confidence in sticking to diet					.333
Not at all confident	2 (6%)	0 (0%)	1 (8.3%)	1 (10%)	
Not very confident	4 (13%)	3 (33.3%)	1 (8.3%)	0 (0%)	
Somewhat confident	6 (20%)	3 (33.3%)	0 (0%)	3 (30%)	
Very confident	17 (55%)	3 (33.3%)	9 (75%)	5 (50%)	
Extremely confident	2 (6%)	0 (0%)	1 (8.3%)	1 (10%)	

Table 6: Participants' Responses at Baseline and 6 Months for the Can Do Study.
*Baseline: n=36, combo n=12; high fiber n=12; low saturated fat n=12. 6 months: n=31, combo n=9, high fiber =12, low saturated fat n=10.

Table 7 outlines antihypertensive medications taken by subjects during the study (see Appendix). Only subjects that took these types of medications are included in this table – subjects who took no antihypertensive medications during the course of the study are not included. One subject in the high fiber group added antihypertensive drugs at 3 months, and one subject in this group increased their medication dose at 3 months. One subject in the low saturated fat group added medication at 6 months.

KEY							
+ present							
- not present							
0 no change							
1 increased dose							
-1 decreased dose							
2 new medication							
-2 stopped medication							
GROUP	SUBJEC	MEDICATION	BASELINE	3-MONTH	6-MONTH	SUMMARY	COMMENTS
	ID	CATEGORY **		CHANGE CODE	CHANGE CODE	CHANGE CODE	
High fiber	7	ACE inhibitor*	+	0	0		
		thiazide diuretic	+	0	0		
		beta blocker	+	0	0		
		ARB*	-	0	0		
		CCB*	-	0	0		
						0	
	9	ACE inhibitor*	-	0	0		
		thiazide diuretic	+	1	0		*dose was ineffective
		beta blocker	-	0	0		
		ARB*	-	0	0		
		CCB*	-	0	0		
						1	
	40	ACE inhibitor*	+	0	0		
		thiazide diuretic	-	0	0		
		beta blocker	-	0	0		
		ARB*	-	0	0		
		CCB*	-	0	0		
						0	
	48	ACE inhibitor*	-	2	0		*change in health status
		thiazide diuretic	-	0	0		
		beta blocker	-	0	0		
		ARB*	-	0	0		
		CCB*	-	0	0		
						2	
Low saturate	14	ACE inhibitor*	-	0	0		
fat		thiazide diuretic	+	0	0		
		beta blocker	-	0	2		*change in health status
		ARB*	+	0	0		
		CCB*	-	0	0		
						2	
	50	ACE inhibitor*	-	0	0		
		thiazide diuretic	+	-2	0		*change in health status
		beta blocker	-	0	0		
		ARB*	+	0	-1		*change in health status
		CCB*	-	0	0		
						-3	
GROUP	SUBJEC	MEDICATION	BASELINE	3-MONTH	6-MONTH	SUMMARY	
	ID	CATEGORY		CHANGE CODE	CHANGE CODE	CHANGE CODE	
Low saturate	41	ACE inhibitor*	+	-2	0		*change in health status
fat		thiazide diuretic	-	0	0		
		beta blocker	-	0	0		
		ARB*	-	0	0		
		CCB*	-	0	0		
						-2	
Combination	21	ACE inhibitor*	-	0	0		
		thiazide diuretic	+	0	0		
		beta blocker	-	0	0		
		ARB*	+	0	0		
		CCB*	+	0	0		
						0	
	63	ACE inhibitor*	-	0	0		
		thiazide diuretic	-	0	0		
		beta blocker	+	0	2/-1		*changed brand of medication, resulting in
		ARB*	-	0	0		decreased dose
		CCB*	-	0	0		
						2/-1	

Table 7: Blood Pressure Medications.

Two other subjects in the low saturated fat and combination diet groups discontinued their use of antihypertensive medications during the course of the study. The subject in the low saturated fat group discontinued use of a thiazide diuretic at 3 months, and of an ARB at 6 months. The subject in the combination group discontinued use of an ACE inhibitor at 3 months.

DISCUSSION

Overall, this MQP analyzed a portion of the data generated in the University of Massachusetts Can Do Study, and found that dietary changes can effectively reduce blood pressure in people with hypertension or pre-hypertension, although the results of this preliminary study were not statistically significant. At three and six months, subjects in the high fiber group reduced both diastolic and systolic blood pressure. Subjects in this group showed an average 5.8mm Hg and 4.4mm Hg systolic decrease, and a 4.7mm Hg and 2.08mm Hg diastolic decrease at three and six months, respectively.

Data collected on the quality of life showed that subjects' satisfaction may play a key role in adherence and success rates. This data agrees with previously published findings (Brunner et al., 1997; Burke et al., 2001; He et al., 2004; Galisteo et al., 2008) that dietary recommendations and increased consumption of dietary fiber can effectively reduce systolic and diastolic blood pressure. Data collected on adherence and reported agreement with the diet programs also agrees with the findings of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (2003). Study visits and nutrition counseling sessions kept study subjects involved, and the study manuals gave them an active role in their treatment. Many subjects reported in their questionnaires (free response comments) that the study visits made a large difference in their motivation and their perceived success with the dietary programs.

This MQP did encounter some limitations during the course of the study. First, the study is a small pilot study, and thus the study population was small and unrepresentative of the general population. Many more women responded with interest in the study than men, and very few people of non-Caucasian ethnicities were recruited. Previous studies have shown that

hypertension is more prevalent in women (Chobanian et al. 2003). Various studies have also shown that ethnicity plays a role in risk for hypertension. African Americans are twice as likely to develop hypertension than Caucasians. Hypertension in African Americans has also been shown to develop earlier in life, and become more severe than in Caucasians (Chobanian et al., 2003). Future studies should make efforts to recruit relatively equal amounts of men and women for a study population, and also to recruit individuals of various ethnic backgrounds to further explore the impact of a simple dietary change on prevention and improvement of hypertensive symptoms.

The fact that the study population was small (36 at Baseline, and 32 at 6 months) also made it difficult to draw statistically significant conclusions. This MQP was finished before a larger full study was completed; however the study investigators are currently planning a full scale study using refined methodology implemented in the pilot Can Do Study.

The study also ran through Thanksgiving and the Holiday season, a time when many people in the United States consume larger quantities of food, and foods higher in fat and calories. Many people also tend to gain weight during this time of the year. Despite this fact, all study groups overcame this seasonal obstacle, maintaining or improving upon the dietary changes made since baseline.

Intensive nutrition counseling sessions ended after the first three months of the study, with only one visit scheduled between 3 and 6 months. These sessions took place approximately every other week. The end of these sessions corresponded with the beginning of the holiday season, thus it is somewhat difficult to determine accurately what effect these sessions may have had, and how well people would have done with the information they had learned from nutrition counseling had they not been challenged with a difficult time of year for weight management.

In the 3 and 6 month questionnaires, several subjects reported that they felt the nutrition counseling sessions were motivating and very helpful in keeping them focused on their nutritional and health goals. Many stated that they wished these sessions had continued, and felt they may have even improved their health more had these sessions continued. In the future, it may be interesting to see if there is a significant difference between groups that receive continued nutritional counseling versus a group that receives only the initial counseling.

Data on medications taken by the subjects was important, as medications may have artificially reduced blood pressure in some subjects, not related to their diets. Some subjects stopped medication following a dietary induced improvement in their blood pressure, but saw a slight increase when they stopped using medication, giving the appearance in the group mean that they did not do as well with the diet with regards to improving hypertension, thus future studies should require subjects to remain on the same medication throughout the diet period, in the same manner that physical activity remained constant. Medication is thus an important aspect to take into consideration when comparing the two diets, and assessing risk.

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APPENDICES

Forms:

Screening Form:
Eligibility criteria include:

1) BMI ≥25

2) >=21 years of age.

3) has primary care physician's approval to participate in all aspects of the study,

4) speaks, reads, and understands English at 6th grade level minimum

5) residing in local area for the duration of the study.

6) available for bi-monthly sessions (6 individual nutrition counseling visits)

Participants will be excluded under the following circumstances:

1) presence of a psychological disorder that will limit his/her ability to participate

2) unwilling to provide informed consent

3) presence of unstable medical disorder (e.g., uncontrolled hypertension, uncontrolled diabetes, etc), or a medical disorder associated with a life expectancy less than 2 years.

4) currently taking any medication known to affect weight or appetite

5) smokes more than 3 cigarettes a day on average

6) Has a dietary restriction that precludes changing to the healthy diet, i.e.; Crohn's disease, ulcerative colitis, renal disease, active diverculitis, etc.

7) currently following a specific diet plan (low saturated fat/meat, or high fiber)

8) does not have a telephone

9) Pregnant, or planning to become pregnant

Consent Form:

UNIVERSITY OF MASSACHUSETTS MEDICAL SCHOOL

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH

CONSENT TO PARTICIPATE IN A RESEARCH PROJECT

Title: **Finding a simple message to improve dietary quality for cancer and heart disease prevention**

Principal Investigator: Barbara Olendzki, RD MPH LDN

Co-Investigator(s): Yunsheng Ma, PhD, Sherry Pagoto, PhD, Ira Ockene, MD

Sponsor: American Cancer Society

Research Subject's Name:_____Date:_____

Invitation to Take Part and Introduction

You are invited to volunteer for a research study. You are asked to take part because you may be interested in improving your dietary quality for prevention of disease, and in making improvements to overall health through dietary change.

Purpose of Research

The present study will compare 2 single dietary change conditions that have high potential for beneficial effects on other unaddressed areas of diet, and consequently overall dietary quality. Results of the proposed study will help us to understand whether a single dietary recommendation can have as much or greater impact on overall dietary quality than a more complex, combination recommendation. The two conditions are selected because they each can help with risk factors of heart disease and cancer.

Your Rights

It is important for you to know that:

Your participation is entirely voluntary.

You may decide not to take part or decide to quit the study at any time, without any changes in the quality of the health care you receive.

You will be told about any new information or changes in the study that might affect your willingness to participate.

RANDOMIZATION

Since no one knows yet which dietary message is the most effective for overall dietary quality, each volunteer in the study will get either a low-saturated fat diet, or a high fiber diet education program. The decision as to whether you receive the low-saturated fat diet, or a high fiber diet education will be made by chance, like the flip of a coin, not by your doctor or based on your medical condition. You have 50% chances in the low-saturated fat diet, or a high fiber diet education. This way of studying diets provides more objective information and allows better comparisons to be made.

PROCEDURES

You are eligible to take part in this study based on the information from your physician, and from your telephone call with the research assistant, and because your body mass index (BMI) was ≥25. Your participation in the research will last for 12 months; require a total of 3 outpatient visits, 6 individual nutritional counseling sessions. You will also receive a total of 9 telephone calls to obtain information on your current diet and exercise. All outpatient visits and counseling sessions will be at the Prevention Institute located at the UMass Medical School Campus, 2nd floor Shaw Building, 419 Belmont St., Worcester, Mass.

At the **enrollment visit** the following will be discussed and performed:

- The research assistant or principal investigator will review and ask you to sign a written consent form.
- Height and weight measurements taken, along with blood pressure.
- Fasting blood sample (approximately 2 teaspoons) to measure your cholesterol will be collected.
- A questionnaire asking about past medical history, and current medications used will be given to you to complete.
- After this visit and within the next two weeks, you will begin to receive the first 3 telephone calls to obtain information about your current diet and exercise habits. This is provided for us by a

nutritionist who is not involved in your dietary change program. Each call is about 30 minutes.

The enrollment visit should take about 1 hour. After this enrollment visit, you will be randomized to one of the two dietary change education plans.

At the **initial nutrition session** the following will be discussed (you are welcome to bring someone with you who shares meals with you):

- Your current dietary habits will be reviewed with you by a trained nutritionist to identify a place to begin the dietary change program. If you are randomized to the low saturated fat program, you will be provided with a saturated fat goal specific to your body needs. The nutritionist will begin working with you to help you achieve these goals. If you are randomized to the high fiber group, you will begin to receive instruction as to how to achieve a higher dietary fiber intake. Supportive information will be provided at this first consult, with goals to achieve in the next two weeks before the next consult.
- This visit will take about 60 minutes.
- At the next 5 follow-up consults:

  If you are in the low-saturated fat group, you will receive instruction by a trained nutritionist about the saturated fat content of foods, and also about foods that can be used in place of foods with high saturated fat content. You will learn how to keep track of your saturated fat intake. You will also receive sample menus and recipes that you can use during the study, and tips on how to eat away from the home.

  If you are in the high fiber group, you will receive instruction by a trained nutritionist about the high fiber dietary recommendations and how to keep track of your fiber intake. You will also receive sample menus and recipes that you can use during the study and how to eat high fiber meals away from the home.

  In either group, you will receive instruction in keeping a food diary for the week before each session; these diaries will be reviewed at each session and feedback will be provided. Nutrition instruction will be tailored to your needs and lifestyle, working with you to achieve your nutrition goals.

These follow-up consults will take approximately 30 minutes.

At the **3-month visit**, the following will be discussed or performed:

- Fasting blood sample (approximately 2 teaspoons) to measure your cholesterol will be collected.
- Weight and blood pressure measurements will be taken.
- A questionnaire asking about recent medical history and current medication changes since the baseline visit will be given to you to complete.
- You will receive 3 telephone calls within 2 weeks, to obtain information on your current diet and exercise habits. Each call is about 30 minutes.

This visit will take approximately 30 minutes.

At **5 months,** your nutritionist will call you on the telephone to see how you are doing with your nutrition goals, and discuss ways to maintain your healthy eating habits, and work with you to make any changes that may be needed. This session will take 30 minutes.

At the **6-month visit**, the following will be discussed or performed:

- Fasting blood sample (approximately 2 teaspoons) to measure your cholesterol will be collected.
- Weight and blood pressure measurements will be taken.
- A questionnaire asking about recent medical history, and current medications used will be given to you to complete.
- Three telephone calls to obtain information on your current diet and exercise habits will take place over the next 2 weeks, each lasting about 30 minutes.

This visit will take approximately 30 minutes

CONFLICT OF INTEREST DISCLOSURE : NONE

RISKS

Dietary changes can sometimes lead to changes in digestion. Your nutritionist should be made aware of any difficulties you are experiencing, and will work with you to minimize any discomfort.

Also, it is fairly common for a harmless black and blue mark to appear at the site of the vein puncture during blood drawing. Occasionally, patients become dizzy as a consequence of having blood drawn and rarely someone may faint.

Your condition will be watched closely during the study. If you have any serious reactions or problems, the treatment will be changed or stopped to protect your health.

BENEFITS

Select one paragraph that is appropriate for your study.

If the study involves experimental therapy:

It is hoped that the dietary changes you make will decrease your risk of heart disease and cancer, and may beneficially impact your cholesterol, blood pressure, and weight. However we cannot promise that this will happen. However, your participation may help others in the future as a result of knowledge gained from the research.

REASONS YOU MIGHT BE WITHDRAWN FROM THE STUDY WITHOUT YOUR CONSENT
Please remove those that are not applicable for your study.

You may be taken out of the research study if:

1. The investigator decides that continuing in the study would be harmful to you.

2. You need treatment not allowed on this study.

3. You fail to keep your appointments as instructed.

4. The study is canceled by the American Cancer Society, or the University of Massachusetts Medical School Institutional Review Board.

ALTERNATIVES

Other treatments available for your condition include whatever your physician feels would be appropriate. Before you decide to take part in this research study your doctor will give you information and discuss the benefits and risks of these treatments.

COSTS

There will be no additional cost to you from being in this research study. The tests and dietary counseling sessions that are done for research purposes will be free.

COMPENSATION

You will receive $25 at the 6-month visit.

CONFIDENTIALITY

Your privacy is important to us. Your research records will be confidential to the extent possible. In all records, you will be identified by a code number and your name will be known only to the researchers. Your name will not be used in any reports or publications of this study. However, the study sponsor (Division of Diabetes, UMass Medical School) and/or their representatives, the U.S. Food and Drug Administration (FDA), and the UMMS Institutional Review Board and/or their representatives may inspect your medical records that pertain to this research study. We will not allow them to copy down any parts of your identifiable information (e.g. your name) or take any of your identifiable information from our offices.

YOUR PARTICIPATION IN THIS PROJECT IS ENTIRELY VOLUNTARY. YOU MAY WITHDRAW FROM THE STUDY AT ANY TIME.

THE QUALITY OF CARE YOU RECEIVE AT THIS HOSPITAL WILL NOT BE AFFECTED IN ANY WAY IF YOU DECIDE NOT TO PARTICIPATE OR IF YOU WITHDRAW FROM THE STUDY.

RESEARCH INJURY COMPENSATION

If you are injured or have any harmful effects as a direct result of your participation in this research, treatment will be made available to you at UMass/Memorial Health Care (UM/MHC). If you have health care insurance, the costs associated with this treatment may be billed to your insurer. You will not have to pay any charges resulting from the harmful effect or injury that are not covered by your insurance. If you do not have insurance, you will not have to pay any charges resulting from the harmful effect or injury. This arrangement applies only when you receive medical care at UMMHC. Only necessary medical treatment will be offered to you; you will not receive any additional compensation from UMMHC. The fact that UM/MHC provides this treatment is not an admission by UMMHC that it is responsible for the injury.

QUESTIONS

Before you sign this consent form, please feel free to ask any questions you may have about the study or about your rights as a research subject. If other questions occur to you later, you may ask Ms. Barbara Olendzki, the Principal Investigator, who is available at 508-856-5195, or via email at Barbara.olendzki@umassmed.edu. You may take as much time as needed to think this over. If at any time during or after the study, you would like to discuss the study or your research rights with someone who is not associated with the research study, you may contact the Administrative Coordinator for the Committee for the Protection of Human Subjects in Research at UMMS. The telephone number is (508) 856-4261.

OPTIONAL RESEARCH

By signing below, I do ☐ or do not ☐ give permission to have serum and plasma samples stored so that if future research suggests that we should run additional tests for lipids or other factors we would be able to do so. Any analysis of such factors would use unidentified samples.

_____ Date:_____

Subject's signature

CONSENT TO PARTICIPATE IN THE RESEARCH PROJECT

Title**: Finding a simple message to improve dietary quality for cancer and heart disease prevention**

P.I. Name: Barbara Olendzki, RD**,** MPH, LDN

Subject's Name:

I understand the purpose and procedures of this research project and the predictable discomfort, risks, and benefits that might result. I have been told that unforeseen events may occur. I have had an opportunity to discuss the risks and benefits of this research with the investigator and all of my questions have been answered. I agree to participate as a volunteer in this research project. I understand that I may end my participation at any time. I have been given a copy of this consent form.

Date:

Subject's signature

STATEMENT OF PERSON OBTAINING CONSENT

I, the undersigned, have fully explained the details of this clinical study as described in the consent form to the subject named above.

_____ Date: _____

Signature of person obtaining consent

Name: _____ Relationship to Subject:_____

(Print)

INVESTIGATOR'S DECLARATION

As the principal investigator or co-investigator on this study, I attest to the following:

- the nature and purpose of the study and study procedures, as well as the foreseeable risks, discomforts and benefits have been explained to the above-named subject
- this subject has been given the opportunity to ask questions and to have those questions answered by knowledgeable research staff
- this subject meets the inclusion/exclusion criteria for this study

I have considered and rejected alternative procedures for answering this research question.

_____ _____

PI Signature Date

Baseline Form:

Patient ID _____

MRN#_____

Can Do Study Baseline Questionnaire

Section 1 – Personal Information (this section to be done with the research assistant)

1. Today's date: _____
2. Name of participant: _____
3. **E-Mail**:
   _____
   a. *please let us know if it is *not* ok to contact you via email. This is our preferred method of contact.
4. Gender:
   ___ female

   ___ male
5. Height (measured) _____ ft. _____inches
6. Weight (measured) _____lbs.
7. Waist(measured)_____inches
8. Hips(measured) _____inches
9. Blood pressure (measured 10 minutes apart): 1st measure_____2nd measure_____
10. What medications do you currently take?

Medication	Dose	Frequency

11. Do you take any supplements (i.e. vitamins, herbal supplements, or food supplements)?

Supplement name Dosage Frequency

12. Date of Birth: ____ / ____ / ____

13. Address: _____

City, State: _____

Zip Code: _____

14. Telephone numbers

Phone number	**Best time to contact**	**Preferred contact √**
Home		
Cell		
Work		
Other		
Secondary contact: (Name + Number)		

:

Section 1A. Please fill this in, and let us know if you have any questions or require assistance:

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

___ Excellent

___ Very good

___ Good

___ Fair

___ Poor

16. Are you: ___ Single ___ Separated

___ Married ___ Divorced

___ Living with Partner ___ Widowed

17. How many people are currently living in your household? ____

18. The race category that best describes you is:

___ White

___ Asian

___ Hawaiian Native or Pacific Islander

___ Native American/ Alaskan

___ Black or African American

___ Other, specify _____

19. The ethnic category that best describes you is:

____Hispanic or Latino

____Not Hispanic or Latino

20. Please indicate which category best describes your highest level of education:

___ Less than 9th grade

___ 9th-12th, no diploma

___ High School graduate (includes GED)

___ Some college, no degree

___ Associate's degree

___ Bachelor's degree

___ Graduate or professional degree

21. What is your work status at the moment?

___ Employed full-time

If yes, how many hours do you typically work each week? _____

___ Employed part-time

___ Work as a volunteer

___ Homemaker (not looking for a job)

___ Disabled (unable to work)

___ Retired

___ Unemployed

___ Student

22. If employed, what is your typical shift at work?

___ day shift

___ evening shift (3-11 pm)

___ night shift (11pm-7am)

23. If employed, how would you best classify your position?

___ skill or craft

___ machine operator or/manual labor

___ scientific technical work

___ service work

___ professional, managerial, administrative

23. Which category represents your annual gross household income? (OPTIONAL) (Check only one)

___ less than $20,000

___ $20,000-$39,000

___ $40,000-$59,000

___ $60,000-$79,000

___ $80,000-$99,000

___ $100,000 or more

Section 2 – Medical History

1. Please check all that apply:

___ Cancer, if yes, what kind and when? _____

___ Major surgery, what kind and when? _____

____ Diabetes: type I or type II (circle one)

____ Heart disease, specify: _____

____ High blood pressure

____ High cholesterol

____ High triglycerides

____ Peripheral vascular disease (decreased blood flow to extremities),

specify: _____

____ Cerebrovascular disease (stroke): specify:

_____

____ Nephropathy (kidney disease) specify: _____

____ Eye problems (retina/cataracts/glaucoma) specify:

_____

Section 2 – Medical History, continued:

____ Neuropathy (problems with nerve conduction) specify:
_____

____ Infections: specify:_____

____ Arthritis: specify: _____

____ Gastrointestinal disease (specify)_____

____ Food allergies/intolerances (specify)_____

____ Irritable bowel disease

____ Depression

____ Other, specify: _____

____ None

2. Do you have any first degree relatives (parent/sibling) with diabetes?
____yes_____no

If yes, please list their relation to you Type I, or Type II diabetes?

3. *For women only:*
   a. Have you had a history of gestational diabetes (during pregnancy)?
      ___ yes

      ___ no

   b. Have you had a history of polycystic ovaries?
      ___ yes

      ___ no

4. Are you overweight?
   ___ yes; since what age? _____

   ___ no

5. Your body weight over the last year has:

___ decreased significantly (>10 lb)

___ decreased moderately (5-10lb)

___ remained about the same

___ increased moderately (5-10 lb)

___ increased significantly (>10lb)

6. How often do your visit primary care provider?

___ 0-2 times per year

___ 2-4 times per year

___ more than 4 times per year

7. Have you had any of the following performed / administered during the last year?

___ Comprehensive physical exam, - Month, year _____/_____

___ Cholesterol test – date of last test___/_____/_____

___ Nutritionist Counseling session. – month/year of last session_____/____

8. Do you smoke cigarettes now? ____yes ____no
   If yes…

   …how many cigarettes per day? _____

   …at what age did you start? _____

   If no…

   …have you ever smoked? ____yes ____no

   If you have quit…

   …at what age did you quit?_____

9. Do you drink alcoholic beverages? ____yes ____no

If yes…

…what would best describe your consumption?

___ less than one drink per week

___ 1-3 drinks per week

___ more than 3 drinks per week but less than 1 drink per day

___ 1-2 drinks per day

___ 3 drinks or more daily

Section 3 – Questions About Diet and Weight

1. How much support do you get (or would you get) for following a recommended dietary change plan?

…from people at work?

no support a lot of support

___ 1 ___ 2 ___ 3 ___ 4 ___ 5

…from your close friends?

no support a lot of support

___ 1 ___ 2 ___ 3 ___ 4 ___ 5

…from your spouse and/or family?

no support a lot of support

___ 1 ___ 2 ___ 3 ___ 4 ___ 5

2. How important do you think other peoples' support is in helping you change your diet?

Not important very important

___ 1 ___ 2 ___ 3 ___ 4 ___ 5

3. Have you tried to lose 10 pounds or more in the last year?

___ yes

___ no

4. What methods have you used in the past year to lose weight? (please check all that apply)

___ dietitian/nutritionist

___ special weight control program/clinics (like Weight Watchers, T.O.P.S., Diet Workshop, Jenny Craig, Weight Loss Clinic, etc.)

Please specify: _____

___ special diet supplements

Please specify: _____

___ own diet

please specify: _____

___ exercise

___ combination of diet and exercise

___ other, specify: _____

___ none

5. How difficult is it to stick to any weight loss plan?

Very easy very difficult

___ 1 ___ 2 ___ 3 ___ 4 ___ 5

6. In a typical week, how often do you eat the following meals in restaurants (or take out)?

	0-1 day/wk	2-3 days/wk	4-5 days/wk	6-7 days/wk
Breakfast	_____	_____	_____	_____
Lunch	_____	_____	_____	_____
Dinner	_____	_____	_____	_____
Snacks				
-morning	_____	_____	_____	_____
-afternoon	_____	_____	_____	_____
-evening	_____	_____	_____	_____
-other snacks	_____	_____	_____	_____

Section 4 – CES-D Scale

For the following 20 items, please select the choice that best describes how you have felt over the past week:	Rarely or none of the time (<1 day)	Some or a little of the time (1-2 days)	Occasionally or a moderate amount of time (3-4 days)	Most or all of the time (5-7 days)
1. I was bothered by things that usually don't bother me.	0	1	2	3
2. I did not feel like eating; my appetite was poor.	0	1	2	3
3. I felt that I could not shake off the blues even with help from my family or friends.	0	1	2	3
4. I felt that I was not as good as other people.	0	1	2	3
5. I had trouble keeping my mind on what I was doing	0	1	2	3
6. I felt depressed.	0	1	2	3

7. I felt that that everything I did was an effort.	0	1	2	3
8. I felt hopeless about the future.	0	1	2	3
9. I thought my life had been a failure.	0	1	2	3
10. I felt fearful.	0	1	2	3
11. My sleep was restless.	0	1	2	3
12. I was unhappy.	0	1	2	3
13. I talked less than usual.	0	1	2	3
14. I felt lonely.	0	1	2	3
15. People were unfriendly.	0	1	2	3
16. I did not enjoy life	0	1	2	3
17. I had crying spells.	0	1	2	3
18. I felt sad.	0	1	2	3
19. I felt that people disliked me.	0	1	2	3
20. I could not get “going”.	0	1	2	3

Thank you very much for your participation!

3 Month Questionnaire:

Patient ID _____

MRN#_____

Can Do Study 3-month Questionnaire

Section 1 – Personal Information (this section to be done with the research assistant)

1. Today's date: _____
2. Name of participant: _____

Changes to:

Address: _____

City, State: _____

Zip Code: _____

E-Mail (new address?):

_____

a. *please let us know if it is *not* ok to contact you via email. This is our preferred method of contact.

3. Weight (measured) _____lbs.
4. Waist(measured)_____inches
5. Hips(measured) _____inches
6. Blood pressure (measured 10 minutes apart): 1st measure_____2nd measure_____

7. Changes to Telephone numbers? (if yes, please list below)

Phone number	**Best time to contact**	**Preferred contact √**
Home		
Cell		
Work		

Brief Medication Questionnaire

Please list below all of the medications, supplements, vitamins, herbs, you took since BASELINE. For each medication you list, please answer each of the questions in the box below. See example. **Interviewer: Record details of dose changes (why change occurred, and date of change) on back.**

a. Medication name	b. Strength	c. Dose prescribed	d. How many times a day did you take it?	e. How many times did you miss a dose?	f. Is this a new medication since your last	g. Has your dose changed since your last
Prozac	30 mg	30 mg daily	once	one	no	Yes

59

Reasons for medication changes (mark as appropriate for each medication that is changed)

1. Med is ineffective (doesn't work well enough)
2. Dose or med changed due to measured effect change (like lab levels that the med influences)
3. Intolerance
4. Insurance company mandate
5. Cost issues
6. Change in prescriber, or health status that prompts review and changes in meds
7. A new med interacts, prompting change in old med
8. Medication level tested and found to prompt change in dose or med
9. Safety issues (toxicity risk uncovered)
10. Market availability change

Section 1A. Please fill this in, and let us know if you have any questions or require assistance:

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

___ Excellent

___ Very good

___ Good

___ Fair

___ Poor

11. In general, would you say your health has changed since you started the study?

_____About the same

_____Improved a lot

_____Improved somewhat

_____A bit worse

_____A lot worse

12. Has your work status changed? Yes_____(fill out below) No_____

___ Employed full-time

If yes, how many hours do you typically work each week? _____

___ Employed part-time

If yes, how many hours do you typically work each week?

___ Work as a volunteer

___ Homemaker (not looking for work outside home)

___ Disabled (unable to work)

___ Retired

___ Unemployed

___ Student

Section 2 – Medical History. Please fill this out if you have had any changes to your medical condition, otherwise, skip to the next question.

5. Please check all that apply:

___ Cancer, if yes, what kind and when? _____

___ Surgery, if yes, what kind and when? _____

____ Diabetes: type I or type II (circle one)

____ Heart disease, specify: _____

____ High blood pressure

____ High cholesterol

____ High triglycerides

____ Peripheral vascular disease (decreased blood flow to extremities),

specify: _____

____ Cerebrovascular disease (stroke): specify:

_____

____ Nephropathy (kidney disease) specify: _____

____ Eye problems (retina/cataracts/glaucoma) specify:

_____

____ Neuropathy (problems with nerve conduction) specify:

_____

____ Infections: specify:_____

____ Arthritis: specify: _____

____ Gastrointestinal disease (specify)_____

____ Irritable bowel disease

____ Depression

____ Other, specify: _____

2. Have you had any of the following performed / administered since your baseline visit?

___ Comprehensive physical exam, - Month, year _____/_____

___ Cholesterol test – date of last test___/_____/_____

3. Do you currently drink alcoholic beverages? ____yes ____no

If yes, what would best describe your consumption?

___ less than one drink per week

___ 1-3 drinks per week

___ more than 3 drinks per week but less than 1 drink per day

___ 1-2 drinks per day

___ 3 drinks or more daily

Section 3 – Questions About Diet and Weight

2. How much support did you get for following the Can Do Study recommended dietary change plan?

…from people at work?

no support a lot of support

___ 1 ___ 2 ___ 3 ___ 4 ___ 5

…from your close friends?

no support a lot of support

___ 1 ___ 2 ___ 3 ___ 4 ___ 5

…from your spouse and/or family?

no support a lot of support

___ 1 ___ 2 ___ 3 ___ 4 ___ 5

3. How important do you think other peoples' support is in helping you change your diet?

Not important very important

___ 1 ___ 2 ___ 3 ___ 4 ___ 5

3. How important was meeting with your nutritionist in helping you to change your diet?

Not important very important

___ 1 ___ 2 ___ 3 ___ 4 ___ 5

4. How difficult is it to stick to The Can Do Study goals on a daily basis?

Very easy very difficult

___ 1 ___ 2 ___ 3 ___ 4 ___ 5

5. How much do you like the diet you were prescribed to follow?

Very much hated the diet

___ 1 ___ 2 ___ 3 ___ 4 ___ 5

6. This diet is likely to benefit my health:

Strongly agree disagree

___ 1 ___ 2 ___ 3 ___ 4 ___ 5

7. This diet is too expensive.

Strongly agree disagree

___ 1 ___ 2 ___ 3 ___ 4 ___ 5

8. This diet is too complicated.

Strongly agree disagree

___ 1 ___ 2 ___ 3 ___ 4 ___ 5

9. I am always hungry on this diet.

Strongly agree disagree

___ 1 ___ 2 ___ 3 ___ 4 ___ 5

10. How confident are you that you will stick to the study diet?

____1. Not at all confident

____2. Not very confident

____3. Somewhat confident

____4. Very confident

____5. Extremely confident

11. Please let us know anything else you like to tell us:

12. In a typical week, how often do you eat the following meals in restaurants (or take out)?

	0-1 day/wk	2-3 days/wk	4-5 days/wk	6-7 days/wk
Breakfast	_____	_____	_____	_____
Lunch	_____	_____	_____	_____
Dinner	_____	_____	_____	_____
Snacks				
-morning	_____	_____	_____	_____
-afternoon	_____	_____	_____	_____
-evening	_____	_____	_____	_____
-other snacks	_____	_____	_____	_____

Section 4 – CES-D Scale

For the following 20 items, please select the choice that best describes how you have felt over the past week:	Rarely or none of the time (<1 day)	Some or a little of the time (1-2 days)	Occasionally or a moderate amount of time (3-4 days)	Most or all of the time (5-7 days)
1. I was bothered by things that usually don't bother me.	0	1	2	3
2. I did not feel like eating; my appetite was poor.	0	1	2	3
3. I felt that I could not shake off the blues even with help from my family or friends.	0	1	2	3
4. I felt that I was not as good as other people.	0	1	2	3
5. I had trouble keeping my mind on what I was doing	0	1	2	3
6. I felt depressed.	0	1	2	3
7. I felt that that everything I did was an effort.	0	1	2	3
8. I felt hopeless about the future.	0	1	2	3
9. I thought my life had been a failure.	0	1	2	3
10. I felt fearful.	0	1	2	3
11. My sleep was restless.	0	1	2	3
12. I was unhappy.	0	1	2	3
13. I talked less than usual.	0	1	2	3
14. I felt lonely.	0	1	2	3
15. People were unfriendly.	0	1	2	3
16. I did not enjoy life	0	1	2	3
17. I had crying spells.	0	1	2	3
18. I felt sad.	0	1	2	3

19. I felt that people disliked me.	0	1	2	3
20. I could not get “going”.	0	1	2	3

Thank you very much for your participation!

6 Month Questionnaire:

Patient ID _____

MRN#_____

Can Do Study 6-month Questionnaire

Section 1 – Personal Information (this section to be done with the research assistant)

1. Today's date: _____
2. Name of participant: _____

Changes to:

Address: _____

City, State: _____

Zip Code: _____

E-Mail (new address?):

_____

3. Weight (measured) _____lbs.
4. Waist (measured)_____inches
5. Hips (measured) _____inches
6. Blood pressure (*measured 10 minutes apart*): 1st measure_____
   2nd measure_____
7. *Changes* to Telephone numbers? (if yes, please list below)

Phone number	**Best time to contact**	**Preferred contact √**
Home		
Cell		
Work		

Brief Medication Questionnaire

Please list below all of the medications, supplements, vitamins, herbs, you took **since your 3 month study visit**. For each medication you list, please answer each of the questions in the box below. See example. **Interviewer: Record details of dose changes (why change occurred, and date of change) on back**

a. Medication name	b. Strength	c. Dose prescribed	d. How many times a day did you take it?	e. How many times did you miss a dose?	f. Is this a new medication since your last study visit?	g. Has your dose changed since your last study visit?
Prozac	30 mg	30 mg daily	once	one	no	Yes

Reasons for medication changes (mark as appropriate for each medication that is changed)

1. Med is ineffective (doesn't work well enough)
2. Dose or med changed due to measured effect change (like lab levels that the med influences)
3. Intolerance (due to side effects)
4. Insurance company mandate
5. Cost issues
6. Change in prescriber, or health status that prompts review and changes in meds
7. A new med interacts, prompting change in old med
8. Medication level tested and found to prompt change in dose or med
9. Safety issues (toxicity risk uncovered)
10. Market availability change

Section 1A. Please fill this in, and let us know if you have any questions or require assistance:

10. In general, would you say your health is now:

___ Excellent

___ Very good

___ Good

___ Fair

___ Poor

11. In general, would you say your health has changed since your 3 month study visit?

_____About the same

_____Improved a lot

_____Improved somewhat

_____A bit worse

_____A lot worse

12. Has your work status changed? Yes_____(fill out below) No_____(go to next page)

___ Employed full-time

If yes, how many hours do you typically work each week? _____

___ Employed part-time

If yes, how many hours do you typically work each week?

___ Work as a volunteer

___ Homemaker (not looking for work outside home)

___ Disabled (unable to work)

___ Retired

___ Unemployed

___ Student

Section 2 – Medical History. Please fill this out if you have had any changes in your medical condition *since your 3 month visit*, otherwise, skip to the next page.

1. Please check all that apply:

___ Cancer, if yes, what kind and when? _____

___ Surgery, if yes, what kind and when? _____

____ Diabetes: type I or type II (circle one)

____ Heart disease, specify: _____

____ High blood pressure

____ High cholesterol

____ High triglycerides

____ Peripheral vascular disease (decreased blood flow to extremities),

specify: _____

____ Cerebrovascular disease (stroke): specify:

_____

____ Nephropathy (kidney disease) specify: _____

____ Eye problems (retina/cataracts/glaucoma) specify:

_____

____ Neuropathy (problems with nerve conduction) specify:

_____

____ Infections: specify:_____

____ Arthritis: specify: _____

____ Gastrointestinal disease (specify)_____

____ Irritable bowel disease

____ Depression

____ Other, specify: _____

2. Have you had any of the following performed / administered since your 3 month visit?

___ Comprehensive physical exam, - Month, year _____/_____

___ Cholesterol test – date of last test___/_____/_____

3. Do you currently drink alcoholic beverages? ____yes ____no

If yes, what would best describe your consumption?

___ less than one drink per week

___ 1-3 drinks per week

___ more than 3 drinks per week but less than 1 drink per day

___ 1-2 drinks per day

___ 3 drinks or more daily

Section 3 – Questions About Diet and Weight

4. How much support did you get for following the Can Do Study recommended dietary change plan over the last 6 months?

…from people at work?

No support A lot of support

___ 1 ___ 2 ___ 3 ___ 4 ___ 5

…from your close friends?

No support A lot of support

___ 1 ___ 2 ___ 3 ___ 4 ___ 5

…from your spouse and/or family?

No support A lot of support

___ 1 ___ 2 ___ 3 ___ 4 ___ 5

5. How important is other peoples' support in helping you change your diet?

Not important Very important

___ 1 ___ 2 ___ 3 ___ 4 ___ 5

3. How important was meeting with your nutritionist in helping you to change your diet?

Not important Very important

___ 1 ___ 2 ___ 3 ___ 4 ___ 5

4. How difficult has it been to stick to the Can Do Study goals on a daily basis, over the last 3 months?

Very easy Very difficult

___ 1 ___ 2 ___ 3 ___ 4 ___ 5

5. How much do you like the diet you were prescribed to follow?

Very much Hated the diet

___ 1 ___ 2 ___ 3 ___ 4 ___ 5

6. This diet is benefiting my health:

Strongly agree Strongly disagree

___ 1 ___ 2 ___ 3 ___ 4 ___ 5

7. This diet fits well into my lifestyle.

Strongly agree Strongly disagree

___ 1 ___ 2 ___ 3 ___ 4 ___ 5

8. The people I live with (friends or family) are also following this diet. (Skip if you live alone)

Strongly agree Strongly disagree

___ 1 ___ 2 ___ 3 ___ 4 ___ 5

9. I am always hungry on this diet.

Strongly agree Strongly disagree

___ 1 ___ 2 ___ 3 ___ 4 ___ 5

10. How confident are you that you will stick to the Can Do study diet?

____1. Not at all confident

____2. Not very confident

____3. Somewhat confident

____4. Very confident

____5. Extremely confident

11. In a typical week, how often do you eat the following meals in restaurants (or take out)?

	0-1 day/wk	2-3 days/wk	4-5 days/wk	6-7 days/wk
Breakfast	_____	_____	_____	_____
Lunch	_____	_____	_____	_____
Dinner	_____	_____	_____	_____
Snacks				
-morning	_____	_____	_____	_____
-afternoon	_____	_____	_____	_____
-evening	_____	_____	_____	_____
-other snacks	_____	_____	_____	_____

12. Please let us know anything else about your diet or the study that has made, or would have made a difference to you:

Section 4 – CES-D Scale

For the following 20 items, please select the choice that best describes how you have felt over the past week:	Rarely or none of the time (<1 day)	Some or a little of the time (1-2 days)	Occasionally or a moderate amount of time (3-4 days)	Most or all of the time (5-7 days)
1. I was bothered by things that usually don't bother me.	0	1	2	3
2. I did not feel like eating; my appetite was poor.	0	1	2	3
3. I felt that I could not shake off the blues even with help from my family or friends.	0	1	2	3

4. I felt that I was not as good as other people.	0	1	2	3
5. I had trouble keeping my mind on what I was doing	0	1	2	3
6. I felt depressed.	0	1	2	3
7. I felt that that everything I did was an effort.	0	1	2	3
8. I felt hopeless about the future.	0	1	2	3
9. I thought my life had been a failure.	0	1	2	3
10. I felt fearful.	0	1	2	3
11. My sleep was restless.	0	1	2	3
12. I was unhappy.	0	1	2	3
13. I talked less than usual.	0	1	2	3
14. I felt lonely.	0	1	2	3
15. People were unfriendly.	0	1	2	3
16. I did not enjoy life	0	1	2	3
17. I had crying spells.	0	1	2	3
18. I felt sad.	0	1	2	3
19. I felt that people disliked me.	0	1	2	3
20. I could not get “going”.	0	1	2	3

Thank you very much for your participation in the Can Do Study!