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Thinking beyond health to motivate dietary change: piloting a vegan healthy eating program for obesity management

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Thinking Beyond Health to Motivate Dietary Change:
Piloting a Vegan Healthy Eating Program for Obesity Management.

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ABSTRACT

THINKING BEYOND HEALTH TO MOTIVATE DIETARY CHANGE FOR OBESITY MANAGEMENT

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This pilot study assessed the feasibility, acceptability and efficacy of a novel approach to facilitating dietary change and weight loss in obese adults by presenting vegan environmental, health and farm animal treatment information in a 6 week, group-based, educational nutrition program (called a "vegan healthy eating program"). Twenty-nine (29) medically stable, obese adults were recruited from 3 ambulatory care clinics at UCSF and enrolled using partial randomization into one of two serially occurring intervention groups (Group 1 n=14, followed by Group 2 n=15). A delayed intervention control group (n=9) was used, consisting of participants enrolled in Group 2 who were available for collection of baseline measures prior to the start of Group 1's intervention. All intervention participants provided data immediately following their vegan healthy eating program (2 months post baseline) and again at 3 and 9 months post baseline. 10% of initial contacts (29 patients) met inclusion and exclusion criteria and were enrolled; 25 participants were retained at 3 months, 20 at 9 months. Mean intervention session satisfaction as measured by anonymous surveys using a 1-7 Likert scale (1=extremely unsatisfied, 7=extremely satisfied) was 6.2 (SD=1.1). Statistically significant reductions in calories from animal products, percent fat, cholesterol and increases in the recommended food score, fruits and vegetable servings were observed within the intervention group only, at all timepoints. Mean weight change was +2.8 lbs (3.0, n=8, p=0.035) in control participants after 4.3 weeks, and -3.4 lbs (5.0, n=25, p=0.002), -5.9 lbs (7.7, n=25, p=0.001), and -8.8 lbs (14.2, n=20, p=0.012) after 7.3, 15.6 and 41.7 weeks in intervention participants, respectively. In conclusion, this vegan healthy eating program demonstrated good feasibility, high satisfaction, and facilitated a shift towards a plant-based diet and modest, progressive short-term weight loss among intervention participants.

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This thesis was made possible by the invaluable assistance, support and generosity of numerous people. The following individuals made noteworthy contributions to this work.

Co-investigators

The study outlined in this thesis could not have been completed without the invaluable contributions of the co-investigators: Robert Baron, Ruth Marlin, Christine Chi, Kuo-Chiang Lian, and Dean Ornish. In particular, Christine and Kuo each put tremendous energy and effort into innumerable aspects of this study.

Mentors

Without the selfless mentorship provided by the following four physicians, my interest in research might not have developed and this project certainly would not have come to fruition.

Ruth Marlin provided tireless mentorship and invaluable support throughout every phase of this project. Her enthusiasm, unshakeable faith, and dedication to mentoring enabled me to overcome the barriers inherent to clinical research. Robert Baron generously acted as the attending physician for this study and provided thoughtful and patient guidance at critical points in the study's design and execution. Dean Ornish's research paved the way for the research line initiated by this study (and, of course, countless other research paths). He was a constant source of inspiration, support and guidance. David Katz has been a pivotal mentor of mine since the beginning of medical school. His wisdom and compassion inspired my interest in the study of dietary behavior change. His experience, clinical and research skills and knowledge in nutrition, obesity, behavior change, and clinical research design were invaluable throughout this project.

Consultants

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Research Participants

Without the generous involvement of research participants no clinical research could take place. I am especially grateful to our participants for their willingness to participate in an unusual pilot trial, and for their eagerness to contribute to science for both the betterment of others and also for my development as a both a clinician and researcher. I learned a tremendous amount from their struggle, their wisdom and their compassion.

Finally, none of this would have come to fruition without the loving support and guidance from my parents, brother and dear friends and family.

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A note from the author:

The thesis proposed in the following pages is a description and examination of a clinical trial designed and carried out by the author at the University of California, San Francisco from July 2002 through to December 2003. Thus references to this thesis will often be listed as “this study”.

BACKGROUND & SIGNIFICANCE

The global obesity[i] epidemic: *prevalence*

The epidemic of obesity is no longer restricted to affluent western nations. Indeed, data from every region of the world clearly indicates that we are in the midst of a global obesity epidemic.[1] The World Health Organization has estimated that over one billion adults worldwide are overweight, of which at least 300 million are obese.[2] Current prevalence statistics are alarming and appear to be worsening in virtually[ii] every nation.[1]

In the US, age-adjusted obesity prevalence among adults increased from 14.5% in 1971-74 to 22.9% in 1988-94 to 30.5% in 1999-2000. This trend stems from an increase in body mass index (BMI) in all age-gender-race groups.[3] Similar trends are evident in other industrialized countries, where prevalence estimates currently range between 14 and 20%.[4] For example, in the majority of European countries, obesity prevalence has increased by 10-40% in the past 10 years.[1]

A rapid increase in obesity is also evident in developing nations, although data from these countries is more limited. In urban China, for example, childhood obesity prevalence increased from 1.5% in 1989 to 12.6% in 1997. Similarly, the prevalence of overweight increased from 14.6 to 28.9% during the same period. The rate of increase of BMI among Chinese children has been calculated as 0.2 kg/m^2 per year in urban areas and 0.1 kg/m^2 per year in rural areas.[5]

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[i] Obesity, among adults, is defined by the Body Mass Index (BMI) – a ratio of weight to height squared (in metric units) – with a BMI of 25.0 kg/m^2 or greater defining overweight and 30.0 kg/m^2 defining obesity. *Please see footnote iii related to this definition.*

[ii] The possible exception is among women in some Scandinavian countries, whose obesity prevalence may be stabilizing.**[1]**

Contrary to the perception that obesity is a disease of affluence, obesity is now strongly associated with poverty around the globe.[6] And for the first time in history, several developing nations have a similarly high prevalence of both underweight or under-nourished people and overweight or obese people.[1]

The global obesity epidemic: *etiology*

Although genetics play an important role in the etiology of weight gain and obesity, diet and activity patterns are more significant contributors to the current obesity epidemic.[7, 8] Support for this conclusion stems from the dramatic, consistent and steady rise in obesity prevalence in the last two to three decades, during which significant changes in the global gene pool are highly unlikely. Furthermore, these population-based changes have correlated with measurable and putative environmental changes. In the US, for example, the rise in obesity has coincided with a steady increase in portion sizes,[9] total food consumption,[10] and total caloric intake.[11] Increases in sedentary behavior have also had a dramatic impact,[12] especially in UK where obesity prevalence has doubled in the last 10 years.[13] However, in the US, prevalence of individuals with no leisure-time physical activity (a measure of sedentary behavior) appears to have peaked in 1996 and has since declined while obesity has increased.[14] This suggests that no leisure-time physical activity trends do not fully capture energy expenditure trends and/or that decreases in sedentary behavior in recent years have not been able to compensate for increasing caloric intake.

Thus, a relatively simplistic model of energy expenditure (i.e. weight gain is a function of an increase in energy intake and/or a decrease in energy expenditure) suffices to explain much of modern day obesity. However, the factors leading to this energy expenditure imbalance on both individual and population levels are complex, numerous and often contentious. The so-called 'environmental' contributors include a host of factors almost too long to list. Among them are political and economic forces (federally supported agricultural subsidies, corporate marketing practices, increasing access to high calorie foods, national school lunch programs, decreasing resources for school physical education programs, etc.), cultural forces (decreases in breast feeding, the high status associated with overweight in several developing nations, etc.), technological forces (increased car ownership, continuing introduction of energy-saving devices and technologies into work, school and home environments, etc.), popular nutritional beliefs and weight management practices (yo-yo dieting, national food pyramids, widespread misconceptions about nutrition, popular diet books, etc.), etc., etc. Weighing the relative impact of each of these environmental factors is important when considering public health initiatives to prevent and treat obesity, but is beyond the scope of this thesis.

As previously discussed, the laws of thermodynamics dictate that weight gain is the direct result of specific behaviors that lead to changes in dietary intake and/or activity. The genetic and epi-genetic determinants of these behaviors and of weight gain are considerably complex and have vast implications for the future of obesity treatment and prevention.[15] Despite the complexities, the discovery of numerous genes and gene-products that favor weight gain is consistent with and can be predicted by our current understanding of evolution and physiology. As first suggested in 1962 by James Neel in his "thrifty gene hypothesis",[16] it is likely that our ancestors evolved during lengthy periods of food scarcity, and thus an enhanced (and genetically based) ability to conserve energy and accumulate fat stores would have conferred a significant survival advantage during times of famine. Those ancestors possessing 'thriftier' genes would be more likely to survive than those lacking 'thrifty genes' and would create offspring who would also possess and pass on these 'thrifty genes', and so on. This teleological perspective suggests that, variations aside, a genetic predisposition to weight gain in times of food abundance is now widespread among most if not all humans. Thus genetic traits that once conferred a significant advantage are now disadvantageous in the modern environment.

Evidence for genetically controlled weight gain also comes from the observation that despite infinite variations in intake and expenditure that occur over any period of time, the human body is able to maintain a remarkably stable weight over a great length of time, under certain conditions.[17] This and other evidence suggest there is strong genetically based control of weight and/or the behaviors that regulate weight. Collectively these observations suggest that population-wide weight gain in inevitable as calorically-dense food becomes increasingly available and that genetic factors may mediate this process.[18] Indeed, this view is consistent with global obesity trends which demonstrate rising obesity prevalence in concert with the global spread of a "Western" or a food-abundant environment. However, the corollary of this argument is that excessive weight gain only occurs in an environment that facilitates access to excessive caloric intake. And since the environment is under some degree of conscious human control, population-wide weight gain does not have to be an inevitability of modernization.

Ultimately, genetic and environmental explanations for the current obesity epidemic must converge into a single model. In this vain, research examining the interaction between genetic expression and environmental forces is furthering our understanding of obesity and will likely lead to enhanced prevention and treatment strategies. The field of peri-natal programming, for instance, has contributed strong evidence that factors such as maternal glycemic control,[19] breast feeding,[20] and parental rearing strategies[21, 22] have a significant influence on appetite, dietary and activity patterns, and weight gain in childhood. This is important because childhood obesity is a strong predictor for adulthood obesity[23] and because it suggests novel approaches for obesity prevention.

In summary, the high prevalence of obesity can be attributed mostly to environmental forces that have led to both increasing caloric intake and decreasing caloric expenditure. The obesity epidemic is a result of a worsening population-wide energy imbalance acting on a highly prevalent genetic predisposition to weight gain. Our evolving understanding of the etiology of the current obesity epidemic suggests many potential interventions for both the treatment and prevention of obesity and its consequences.

Obesity: *mortality, morbidity, and costs*

Adulthood obesity and overweight are associated with significant decreases in life expectancy.[24, 25] Data from Framingham, for example, suggests an average of 7 years of life lost to a 40 year-old non-smoker with obesity.[25] In fact, the rational for using the BMI to define obesity stems in part from the observation that at a BMI of 30 kg/m^2 risk of mortality increases by approximately 30% and continues to increase as BMI increases.[26] At a BMI of 40 kg/m^2 or more, for example, risk of premature mortality increases by 100% or more.[26] It is important to point out, however, that the definition of obesity as a BMI ≥ 30 is generous, as the major morbidities associated with obesity are linearly related to increasing BMI starting at a BMI of 19 or 20 kg/m^2.[27] Thus, optimal life-expectancy[iii] in non-smoking adults is estimated to be most likely at a BMI of approximated 20 kg/m^2.[6]

[iii] For this and other reasons some authors have suggested that a global definition of frank obesity of a BMI of 25 kg/m^2 or greater may be more appropriate, with the upper limit of normal BMI being 22.9 kg/m^2.[6]

A conservative estimate suggests that mortality attributable to overweight in 2000 increased by 76.6% from 1991 and for the first time accounted for almost as many deaths as tobacco (385,000 vs. 435,000).[28] Since a slight decline in smoking prevalence has been observed in this period and tobacco related deaths did not change significantly[iv], linear extrapolation would predict that overweight has or soon will overtake tobacco as the number one cause of death in the US. For this reason, and the enormous contribution to morbidity (discussed below), some authors have deemed obesity to be the number one public health problem in the US.[25, 29]

Morbidity (and death) from obesity stems primarily from its strong association with type 2 diabetes, cardiovascular disease, and certain cancers.[30] Approximately 57% of type 2 diabetes,[31] 17% of cardiovascular disease[31] and 14-20% of all cancers[32] are attributable to obesity. Obesity also contributes significantly to gallbladder disease, polycystic ovarian syndrome, gestational diabetes, menses disorders and other gynecological conditions, osteoarthritis, obstructive sleep apnea, amongst other medical conditions.[29, 33] As expected, health related quality of life is decreased in obesity.[34] Obesity is also associated with significant social stigma and poor self esteem.[35] Furthermore, obese individuals suffer from discrimination,[36] and economic disadvantage.[37]

The economic impact of obesity is considerable. Annual healthcare costs attributable to obesity are estimated to be $75 Billion[38] to $100 Billion[39] in 2003 dollars. At present, a conservative estimate suggests that obesity accounts for 5.3% of total medical expenditures.[38] The total cost

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[iv] The 1991 estimate by McGinnis and Foege of 400,000 deaths attributable did not include deaths to second-hand smoke or maternal smoking. The estimate for the year 2000 by Mokdad et al did include these causes of death. They estimated 435,000 deaths attributable to tobacco with 35,000 of these caused by second-hand smoke and 1,000 by maternal smoking.[28] Thus, it is reasonable to conclude that tobacco related deaths did not change significantly between 1991 and 2000, or may even have declined slightly.

to society is understandably difficult to calculate but can be assumed to be significantly greater than the cost of healthcare expenses alone.

In summary, obesity confers a significantly increased risk for morbidity and premature mortality and has important psychosocial ramifications. The economic costs attributable to obesity are considerable. Given that obesity prevalence continues to rise, obesity can be considered the number one public health problem in this country at least.

Obesity: *clinical treatment & maintenance of weight loss*

Overweight and obese individuals can gain significant benefits from modest weight loss.[40] The medical benefits of modest weight loss are well established and include clinically significant improvements in blood pressure,[41] glycemic control,[42] cholesterol and other cardiovascular risk factors.[40, 43, 44] These benefits are likely a direct effect of weight loss and are independent (to a degree) of the means of weight loss.

Advances in the clinical treatment of obesity have led to a variety of strategies including dietary, behavioral, activity-focused, pharmacological and surgical approaches that have been successful at inducing modest (5-10% of body weight) *short-term* weight loss.[45] Neither the scientific nor popular literature point to a single best approach to short-term weight loss. Rather, almost any approach (assuming it favorably alters the ratio of calories in to calories out) can induce short-term weight loss. Distinguishing between various approaches can be difficult, especially for the lay population, and must take into account safety, sustainability, additional benefits, as well as both short and long-term cost-efficacy. This is particularly important in light of the currently held view that obesity is a chronic disease warranting chronic (long-term or lifelong) treatment.

In contrast to short-term weight loss, *long-term* maintenance of weight loss in an environment that promotes weight gain represents a considerable challenge.[7] The data on success of *long-term* (defined here broadly as 1 to 5 years), modest weight loss in structured university-based programs presents a mixed picture. The proportion of a sample maintaining successful long-term weight loss ranges from zero or near-zero[46-48] to a more hopeful outlook of 13-53%.[49-52] While the latter may be more consistent with weight loss maintenance in non-academic settings (i.e. in the general public),[53] this still suggests that the majority of overweight and obese individuals do not achieve these broad but modest definitions of successful long-term weight loss, in academic weight management settings. Recently, however, Wing and Hill proposed a definition of *long-term* weight loss maintenance as intentionally losing 10% of initial body weight and keeping it off for at least 1 year.[52] This definition was proposed largely because of the established medical benefits of losing 5-10% of body weight, but also in part because of the challenge inherent to long-term weight loss maintenance. The authors felt that with this definition approximately 21% of overweight/obese individuals could achieve successful long-term weight loss.[52]

The relative lack of success observed in obesity trials can not be blamed on lack of interest or effort on the part of patients. In fact, the majority of obese Americans appear to be concerned about being overweight as evidenced by observations from the CDC's Behavioral Risk Factor Surveillance System which found that 65.7% of obese adults claimed to be actively trying to lose or maintain their weight.[54]

Despite the pessimism that pervades clinical obesity treatment, it is clear that some individuals are able to successfully maintain modest, long-term weight loss. The National Weight Control Registry was set up to study these successful weight loss maintainers. Three common factors have been identified as being common among these individuals: 1) eating a diet low in fat and high in carbohydrates, 2) frequent self-monitoring and 3) regular exercise.[52]

With respect to clinical interventions aimed at the above mentioned behaviors, more intensive and/or longer interventions generally produce more substantial results in both the short and long-term, as would be expected.[45, 55, 56] Similarly, multi-disciplinary interventions are more likely to produce more significant results than single component interventions. Still there is no consensus that any one program or combination of interventions is more effective or cost-effective.[57] For this reason, along with the alarming trends in obesity prevalence there is a clear need for novel strategies for assisting in long-term weight loss maintenance.[52, 57]

Of particular challenge and interest is the development and testing of novel strategies to assist individuals in maintaining healthy dietary behavior change conducive of healthy weight loss or weight maintenance.[58] While it can be predicted that dietary interventions have greatest efficacy when combined with other lifestyle modifications, there remains utility in testing stand-alone dietary interventions for obesity management (as is done in this thesis). **It must be stressed, however, that the end goal of this line of research is not a stand-alone intervention but an intervention that could be integrated into a comprehensive, multi-disciplinary obesity treatment strategy.** The added benefit of examining dietary change in an obese population is the potential to apply the principles learned to other aspects of chronic disease prevention or treatment.

Diet and Disease: ***in relation to obesity and other chronic diseases***

This study is designed to pilot a novel behavioral approach that could facilitate the maintenance of weight loss in obese individuals by helping to initiate long-term dietary change. A key premise of this study is that shifting to a plant-based diet will confer a breadth of health benefits independent of benefits gained from facilitating improved weight management. The following section provides a brief rational for this premise.

Although much remains unknown, the connection between diet and disease is strong and well-established. The combination of poor diet and physical inactivity accounted for at least 400,000 or 16.6% of all US deaths in 2000 (up from 300,000 or 14% in 1990).[28] Extrapolating the trends from this data (obtained from the Centers for Disease Control and Prevention) suggests that poor diet and inactivity is or soon will be the number one cause of preventable death in the US. At present, diet represents a modifiable risk factor for the top 3 causes of death (heart disease, malignant neoplasm, cerebrovascular disease) which collectively account for approximately 1.4 million of the 2.4 million deaths each year.[28]

While even a cursory overview of the impact of diet on disease is beyond the scope of this thesis, it is possible to highlight some relevant themes that evolve from the literature which support the use of the proposed study intervention:

- **A distinction between foods of plant vs. animal origin, with foods derived from plants conferring protection against several chronic diseases and those from animals conferring added risk for several chronic diseases.**[59]
    - There are several notable exceptions including fish oil, a source of omega-3 fatty acids, which has been shown to reduce death from cardiac events;[60, 61] hydrogenated

vegetable oils, a source of trans-fats, and highly saturated vegetable oils (e.g. palm oil), both of which are thought to promote cardiovascular disease[62, 63] and type 2 diabetes.[64] Similarly, it is also important to emphasize that plant-based diets by virtue of minimizing animal products alone are not necessarily health-promoting. For example, french-fries, soda, candy, refined pasta, and white rice are all plant-derived foods that are more likely to promote than prevent chronic disease.[65]

  - However, several explanations have been proposed for the benefits attributed to many plant-based dietary patterns, including high intake of various classes of plant-based foods (e.g. fruits and vegetables, as discussed below), lower intake of total fat, saturated fat, animal protein, heterocyclic amines and cholesterol and higher intake of fiber, grains, legumes, magnesium, folate, boron and other trace minerals, vitamin C and E and other antioxidants, carotenoids and other phytochemicals.[66-68]

- **Perhaps the most well established health benefits are those derived from the consumption of whole fruits and vegetables**. Fruit and vegetable intake has been consistently associated with reduced risk for coronary artery disease,[69-72] type 2 diabetes,[73-75] stroke,[76, 77] hypertension,[78] cancer,[79, 80] metabolic syndrome,[81] and obesity.[82]
- **The benefits of whole grains and detriments of refined grains have been demonstrated** especially with regards to cardiovascular disease,[83, 84]and type 2 diabetes.[85-87] Whole grains, as well as other low-glycemic index foods also show promise in promoting weight loss.[88-90]
- **Nuts, olives and olive oil are thought to confer protection** against cardiovascular disease,[91-93] and type 2 diabetes.[94] However, given that nuts, seeds, olives and other oil rich foods tend to be rich in calories because of their high fat content there is still uncertainty over their role in diets designed for obese individuals.

- **Red meat has been consistently associated with increased risk** of heart disease,[95, 96] and type 2 diabetes.[97, 98] Red meat, especially well done meat and processed meat, contributes to colorectal cancer,[99-101] breast cancer,[102, 103] lung cancer[104, 105], pancreatic, renal and prostate cancers.[68] Several mechanisms have been proposed for this association, including the formation of heterocyclic amines in well-done meat[68], the high content of heme iron which contributes to N-nitrosation,[106, 107]and the saturated animal fat content of meat.[102]
  - Given their relative similarities in biochemical composition, it is not clear why red meat has a much stronger association with the above diseases than the so-called white meats (chicken, pork, etc.). Several explanations exist, including differences in fatty acid composition, heme content and other atherogenic or carcinogenic compounds. Or perhaps more likely, this paradoxical association may be explained by the well-observed co-segregation of white-meat consumption with a dietary pattern that contains a high proportion of protective substances of plant-origin and lower proportion of disease promoting substances of animal or plant-origin.[108-111] Importantly, this protective or "prudent" dietary pattern is also associated with lower rates of obesity.[82, 112]
- **The rearing of animals for food is increasingly being recognized as a major threat to public health, mostly because of food safety issues pertaining to foodborne illnesses and antibiotic resistance.**
  - Foodborne diseases cause approximately 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths in the United States each year.[113] The USDA's Economic Research Service estimated the annual U.S. economic costs (including both medical costs and indirect costs such as lost productivity) incurred for the major

bacterial pathogens: *Escherichia coli O157:H7* and other pathogenic *E. Coli*, *Campylobacter*, *Listeria monocytogenes*, and *Salmonella* to be at least $6.9 billion in 2000 dollars.[114] In addition to acute illness these bacteria are associated with several chronic or sub-acute illnesses such as reactive arthritis, Guillain-barré syndrome, and hemolytic uremia syndrome[115]

- Importantly, the vast majority of foodborne illness stem from animal-agricultural practices and the consumption of animal-products. For example, cases of *Salmonella*, *Listeria*, and *Toxoplasma* are either traced to the consumption of animal products or the use of animal manure, and account for more than 75% of deaths caused by known pathogens.[113]
- Historically, the majority (if not all) of the major infectious epidemics arose from close contact with animals domesticated for food production or from close contact with wild animals.[116] Modern day diseases that stem from our dependency on massive, centralized, confinement-rearing animal agriculture include SARS,[117] the Asian Bird Flu ,[118, 119] and Bovine-Spongiform Encephalopathy.[120]
- Of even greater public health concern is antibiotic resistance which stems from inappropriate use or overuse of antibiotics. Approximately 50% of antibiotics are used in non-human animals mostly for sub-therapeutic uses such as growth promotion of livestock.[121] The combination of over-crowded conditions for farm animals, the overuse and improper use of antibiotics in animal agriculture, the use of antibiotics used to treat human disease in agriculture, the fact that many pathogenic bacteria can infect both humans and other animals, and contact between humans and farm animals or animal-products, makes the generation of multi-drug resistant pathogenic bacteria

inevitable. An example of such a phenomenon is the rapid emergence of *Salmonella DT104* resistant to Ampicillin, Chloramphenicol, Streptomycin, Sulfonamides, and Tetracycline. Prevalence of multi-drug resistant DT104 increased from less than one percent in 1979 to 34% in 1996 and has been linked to the heavy use of these antibiotics in the rearing of cattle and other livestock.[122, 123] Antibiotic resistant strains of *Salmonella* are now commonly isolated in retail ground meats, with some strains resistant to 12 antibiotics.[123]

Several other themes important to this thesis remain controversial. For example, there is great debate over the ideal proportion of fat intake in an obese population.[124] Similarly, it is unclear whether animal protein is an independent risk factor for chronic disease and thus there is not consensus as to the need to independently reduce or eliminate it from the diet. Certainly, the evolving role for animal protein as a causative agent in osteoporosis, renal disease and hypertension deserves careful consideration.[125] **Nonetheless, there is agreement among most nutrition experts that shifting to a plant-based diet would confer both clinical and public health benefits[v]. The optimal degree of "shift" and the means to accomplish this challenging goal are important and under-explored areas of research.**

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[v] For example, the U.S. Department of Health and Human Services' established the Healthy People 2010 nutritional goals in order to "Promote health and reduce chronic disease associated with diet and weight". These goals aim to: increase fruit, vegetable, and grain consumption; increase worksites that offer nutrition or weight management classes and physician counseling on diet and nutrition; and to reduce fat and saturated fat consumption and weight/BMI. While some progress has been made in recent years, there remains considerable disparity between current national dietary patterns and these goals. Moreover, for some goals, such as reducing BMI, recent data demonstrates trends away from targets.[50] Thus, shifting the population towards a plant-based dietary pattern represents an important but substantial challenge.

Shifting patients to plant-based diet: *a novel approach*

This study aims to pilot a novel approach to shifting obese patients to a plant-based diet. The study intervention is based on behavioral motivators that enable vegetarian[vi] and vegan individuals to initiate and maintain strict dietary change. Vegetarians (and vegans) represent an ideal population from whom to draw novel dietary and weight management strategies for reasons pertaining to both the dietary pattern itself and the psychology that often accompanies it:

- Compared to non-vegetarians, vegetarians have lower Body Mass Indexes (BMIs), lower rates of obesity and eat more complex carbohydrates and fiber but less animal fat and alcohol.[126-128]
- A vegetarian dietary pattern, particularly a low-to-moderate fat, whole-food, vegetarian diet, has been associated with reduced risk of several chronic diseases, including hypertension, hyperlipidemia and coronary artery disease (CAD),[95, 129-132] stroke,[133] type 2 diabetes,[98, 130] and several cancers.[80, 134]
- Randomized controlled trials have employed these dietary patterns (usually in concert with other lifestyle modifications) to demonstrate reversal of heart disease,[135-138] prevention and treatment of type 2 Diabetes,[56, 139-144] reductions in hypertension,[145] hyperlipidemia,[136, 137, 146, 147] and weight.[136, 137, 142]
- Observational data suggests that self-selected vegetarian diets tend to be particularly long-lived.[148, 149] This is important as an efficacious but unsustainable diet would not be an appropriate model for long-term dietary change interventions.

[vi] Similar to the term "plant-based diets", the terms vegetarian (a diet devoid of animal flesh but that may contain eggs or dairy) and vegan (a vegetarian diet devoid of all animal products) describe plant-based diets of considerable variability. **Note that in this thesis the term vegetarian is often used instead of 'vegetarian and vegan'.**

- Contrary to popular perception, satisfaction with vegetarian diets in a clinical setting is as high if not higher than non-vegetarian diets.[150] This may be true in a non-clinical setting as well, for example one study of young adults suggested that for some a vegetarian dietary pattern may be easier to adhere to than other weight-loss diets.[151] Of course, this may reflect satisfaction with the dietary pattern for reasons pertaining to personal preferences (e.g. taste) and/or effect (e.g. weight loss, perception of health) and/or the strength of motivators that lead to adopting a vegetarian diet. Regardless, it clear that long-term adherence to a vegetarian dietary pattern in both free-living and structured settings is possible; however, for patients enrolled in clinical lifestyle modification programs structured support is likely needed for maximal adherence.[152]

Motivation for dietary adherence in vegetarians: *a wide range of potential motivators*

The literature demonstrates that a wide range of motivators influence the choice and maintenance of a vegetarian diet and that many, if not most, 'strict vegetarians' are motivated by more than one factor.[153-156] These motivators are not limited to a concern for health or body-image but also include ethical and environmental concerns surrounding intensive-confinement animal agriculture, other socioeconomic and political issues, taste and spiritual or religious beliefs. **Given the highly personal nature of these motivators, it is not known whether the motivational factors that influence self-initiated, vegetarian dietary patterns (other than concern for health) can be employed in a clinical setting to facilitate long-lived, plant-based dietary patterns and their benefits in non-vegetarians.** The rational for employing these other motivators stems from the observation that ethical & environmental concerns (referred to here collectively as ecological concerns) play a significant role in strict adherence to a vegetarian/vegan dietary pattern for many, if not most, vegetarians.[157-159] The strength of the various motivators has not been studied but seems to vary from one nation or population to another. For example, concern for health is often cited as the prime motivator to maintain a vegetarian diet in the US,[159] but in certain populations, namely British and Australian vegetarians[155, 156, 160, 161] and in teens,[162-164] ecological concern is likely the prime motivator. **Nonetheless, the observation that health and ecological nutrition goals are remarkably confluent[151, 155, 156] suggests the potential utility of merging these motivators to induce salutary dietary change and, in turn, weight loss or maintenance of weight loss in non-vegetarians – a hypothesis that is largely unexplored.**

Dietary Adherence: *a biological, theoretical and historical perspective*

Joanna Dwyer, Ph. D. observed that throughout history the basis for restricting food intake in an environment of abundant food is primarily philosophical.[165] Whether the philosophy is based on morals, values, spirituality, religion, superstition, or beliefs about health and disease differs by population and time period. Still, a common element of all groups that are successful at long-term dietary adherence is the possession of a philosophy or culture that leads to dietary restriction despite the presence of abundant food. This is certainly true for self-selected vegetarians in Western civilizations.

To suggest that philosophy and culture (beliefs, attitudes, etc.) impacts dietary behavior is not to say that biological mechanisms do not contribute to varying abilities to adhere to a relatively restrictive dietary pattern. For example, the difficulty some people experience in avoiding high fat or sugar-rich foods may be related to an opiod-like effect of fat and sugar molecules on the brain, which induces neurobiological changes that eventually lead to behaviors designed to acquire more fat or sugar.[166] In a related yet polar example, it is felt that once Anorexia Nervosa begins physiologic disturbances may result that serve to perpetuate the illness.[167] Thus it is likely that philosophical, cultural and biological mechanisms contribute to the behavior of food restriction.

On the other hand, there are strong biological and teleological explanations for over-eating in the presence of food abundance. As mentioned above, it is thought that we evolved through significant periods of food scarcity. This situation selected for genetically-based (and perhaps culturally-based) mechanisms that led to increased food intake in the presence of abundance and an efficient ability to store food-energy as adipose tissue. An example of such a phenomenon is sensory specific satiety[vii], which accounts for why we eat more at buffets or multi-course meals and why no matter how much is eaten there is always room for dessert![168] Although this is an overly simplistic overview of the biological basis of eating behavior, it is fair to state that there is sufficient evidence that a species-wide predilection for over-eating and fat storage exists that can explain in part the cause of the current obesity epidemic: **This predilection in concert with increasing abundance of readily accessible high-calorie foods (caused by several factors) and decreasing energy expenditure (due to technological advances, for example) is a certain recipe for population-wide weight gain.**

Thus, from a dietary perspective there are 3 major strategies that can be employed to decrease food consumption in the presence of growing food abundance: 1) Decrease the food abundance

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[vii] Sensory Specific Satiety, more specifically, is a phenomenon regulated by the hypothalamus which encourages maximal food intake. It appears as though the hypothalamus has different receptor thresholds for satiety for specific flavors or attributes of food. If a meal contains both salty and bitter items for example, enhanced satiety occurs when the receptor thresholds are met for both salty and bitter. (Thus salty *and* bitter items must be eaten in sufficient quantity to reach satiety)The threshold for sweet is the highest of all thresholds, explaining why there is always room for a sweet dessert after dinner and why virtually every culture has dessert at the end of a meal.

(through government regulation, taxation, incentives, etc.); 2) Facilitate food restriction via a variety of educational and behavioral approaches; and 3) Facilitate food restriction via surgical, pharmacological or genetic means. **Given the extent of the current obesity epidemic there is sufficient rational for applying all available means of treatment and prevention. This thesis discusses an educational and behavioral approach that aims to impart both a scientific and philosophical approach to healthy, long-term food restriction (i.e. dietary adherence) for improved weight management.**

Dietary Behavior Change: *theory and application*

The theoretically-based field of dietary behavior change is still in its infancy. It is a recent outgrowth of the broader field of behavior change which was developed largely by psychologists to aid attempts at inducing smoking cessation. It is not known to what degree concepts or principles of behavior modification for smoking cessation, for example, can be applied to dietary change. However, well-established principles of behavior change likely bear some relevance for efforts aimed at dietary behavior change. This review will not serve as a comprehensive review of behavior change or dietary behavior change theory. Rather, the text that follows provides a brief overview of concepts that influenced the design and rational for the intervention being studies.

The theoretical model that most heavily influenced the design of the study intervention is the Pressure Systems Model (PSM) of Behavior Change. The PSM was developed by David Katz in an attempt to combine the most efficacious components of current behavioral change models into a single, clinically oriented model.[169] The PSM asserts that change occurs when net motivation exceeds net resistance. Using this simple model, the PSM attempts to guide clinicians to provide stage-appropriate, efficient and effective counseling. For example, if a patient's resistance to change a particular behavior is exceeding high, efforts to enhance motivation to change will likely be futile. Instead, efforts aimed at reducing resistance would be more appropriate. In theory, one can also apply this model to group interventions by using a balance of strategies aimed at raising motivation and lowering resistance to change.

From a motivational standpoint, the study intervention (called "the vegan healthy eating program") can be described as a meaning-based approach to achieving dietary change and weight loss. This terminology is borrowed from a branch of psychology developed by Victor Frankl termed logotherapy.[170] The basic premise of logotherapy is that helping a patient find meaning or purpose in a difficult situation can aid the patient's ability to deal with that situation. Within reason, it can be theorized that any struggle can be endured if it is deemed meaningful enough by the person undergoing it. This concept can be applied in one of two ways to dietary behavior change. First, because some psychologists argue that dysfunctional eating habits stem from more general psychological/psychiatric processes (e.g. lack of self-esteem, meaning, etc.), logotherapy can be used to target those dysfunctional processes and thus indirectly change eating habits.[171] Alternatively, as is the case with the study intervention, our goal was to help patients discover a meaning that can help them endure the struggle of changing eating patterns. As discussed above, our intervention was based on applying the motivations that allow vegans and vegetarians to maintain strict, long-term adherence. Another way to view these motivators is as cognitive processes that impart a meaning that outweighs the challenge of changing eating patterns; or in the terms of the PSM, a motivation that outweighs the resistance. It is important to note, however, that this study was not designed to test these theories and hypotheses. If anything, this study will help further develop hypotheses best tested by other methods.

The behavioral constructs and goals underlying the content of the study intervention were intended to be consistent with the Pressure System's Model as well as the key components of the leading theoretical models, including the Transtheoretical Model (i.e. the stages & processes of change),[172] Social Cognitive or Social Learning Theory (i.e. self-efficacy, locus of control),[173-175] the Theory of Reasoned Action (i.e. belief sets shape attitudes, intentions and behaviors)[176] and the Health Beliefs Model.[177] For instance, participants were selected based on their stage of plant-based dietary change (i.e. those in an active phase were excluded) to ensure that the informative / educational nature of the intervention was stage appropriate. One of the intervention goals was to advance participants' stage of plant-based dietary change. Thus the intervention was geared towards a pre-contemplative or contemplative stage. The breadth of the topics covered and their mode of delivery was intended to influence several beliefs and attitudes about food choices, while internalizing health, nutrition and social loci of control. An attempt was also made to address several barriers to behavioral change including poor self-efficacy, attitudinal ambivalence, and optimistic bias.[viii] However, given the novelty of this intervention, future research will be needed to determine optimal formats for delivery of this type of educational intervention, with respect to both specific patient populations and group vs. individualized settings.

[viii] Self-efficacy is defined as the belief that one can accomplish a specific task. High self-efficacy is thus task specific and has been consistently linked to improved health-related outcomes.[178] Attitudinal ambivalence refers to the fact that individuals "do not always have clear-cut attitudes, but rather can be ambivalent about foods and about healthy eating, and this factor might impact on the translation of beliefs and attitudes into behavior." Optimistic bias refers to the observation that most people tend to significantly underestimate their risk of injury or disease.[178] Low ambivalence is likely needed to allow new attitudes and beliefs to translate into dietary behaviors.[180]

Preliminary Studies

Barnard et al have completed a weight loss intervention (publication pending) comparing a low-fat vegan diet to an American Heart Association's Step 2 diet. Participants included 64 overweight and obese post-menopausal women with an average BMI of 33, recruited via newspaper ads in Washington, D.C. The intervention consisted of 14 weekly, one hour group meetings which provided detailed nutrition information and cooking instructions to participants and their spouses/family members. Energy-intake limits were not prescribed and participants were asked not to change current exercise habits. At 14 weeks, mean intervention group body weight had dropped 5.8 ± 3.2 kg, compared to 3.8 ± 2.8 kg in the control group ($P < 0.05$). Changes in intervention group body fat percentage were negatively correlated with fat intake ($r = -0.40$, $P < 0.05$) and energy intake ($r = -0.38$, $P < 0.05$). Longer term follow-up is still underway to assess the sustainability of dietary changes and weight loss in this population.

While Barnard et al's study tests the efficacy of a vegan diet (independently) to affect weight loss, it differs from ours in 3 important ways: their intervention did not include an ecological nutrition component, included only women and may have included a healthier population that is not fully representative of a university weight management clinic population (i.e. both overweight and obese individuals, likely with less co-morbidities compared with our target population).

While researchers continue to examine the health impacts of plant-based dietary patterns and the mechanisms that underlie food choices, a review of the literature and contact with experts in the fields of vegan nutrition, obesity and dietary change do not reveal ongoing intervention studies addressing the potential clinical application of ecological nutrition education.

SUMMARY OF BACKGROUND & SIGNIFICANCE:

The benefits of plant-based dietary patterns on weight and other health parameters are becoming increasingly well understood. However, little is known about how to facilitate long-lived plant-based dietary patterns in obese individuals. Furthermore, it is not known whether patients seen at university-clinics can be motivated to adopt strict plant-based diets for the purpose of weight control and health promotion. If a diverse set of motivational factors that influence self-initiated, vegetarian dietary patterns can be employed to facilitate dietary change in non-vegetarians in a clinical setting, this approach may have both important clinical and public health implications. A pilot study as outlined in this thesis would provide preliminary evidence that might warrant longer-term investigation of this approach.

Regardless of the efficacy of the intervention, this study will also help identify the feasibility of and barriers to recruiting patients to participate in a behavioral intervention that employs other motivators in addition to personal health and well-being in a manner consistent with current dietary behavior change theories.

PURPOSE

The purpose of this study was to pilot a novel approach to facilitating dietary change in obese adults, with the hope that this approach may eventually aid attempts to achieve longer-lived changes compared to currently available treatments.

Primary Aim:

To determine whether exposure to vegan environmental, health and ethical issues can influence a short-term change in dietary pattern in obese adults, when delivered in the context of personal health promotion, through a group-based, educational nutrition program (***referred to as a vegan healthy eating program***).

Secondary Aims:

1. To determine whether participation in an vegan healthy eating program can facilitate weight loss, a change in blood pressure, glycemic control or lipids, or help maintain recent weight loss in obese adults.

2. To provide pilot data for a future, more extensive RCT, including the ability to recruit and general acceptability of this approach to dietary education.

3. To begin validation of an intervention specific behavioral questionnaire, which will assess psychosocial variables, as well as diet and lifestyle behaviors.

Hypothesis:

It is hypothesized that participation in a vegan healthy eating program will facilitate a shift towards a plant-based dietary pattern and will contribute to weight loss or the maintenance of weight loss in obese adults. The weight loss achieved from this approach is hypothesized to confer the same medical and psychological benefits that are widely described in the literature and are outlined in the Background section.

Hypothesis testing:

While this study was designed to have sufficient power to detect a change in several important indicators of dietary pattern, it is likely to be underpowered to detect changes in the other measures. (*please see methods section below for further details*) The data on these measures will serve as valuable pilot data for designing future longer term, controlled trials to asses the efficacy of a vegan healthy eating program in long-term weight management and comprehensive lifestyle modification programs.

METHODS

General Study & Intervention Design

This study was initially designed as a partially randomized and controlled, prospective pilot intervention trial with a total of 3 months of follow-up. However, preliminary analyses suggested positive outcomes and participants were invited to continue in the study for an additional 6 months.

The identical intervention (described below) was given sequentially to 2 groups of participants (Group 1 N=14, Group 2 N=15). Prior to enrolling it was disclosed that one group one convene on a Monday night the other on a Wednesday night. Participants who were able to attend either group were randomized to one group or the other. Participants who were enrolled in the second group 4 or more weeks prior to its commencement were asked for two sets of baseline data (once upon enrolling, once just prior to commencing the intervention), thus providing some "controlled" data. This "control period" was designed to measure the short-term effect of enrolling in the study, without any other intervention.

Data (behavioral and food-frequency questionnaires, BMI, blood pressure, Duel-Energy X-Ray Absorptiometry (DEXA) scan, 4-day Activity Monitor, and serum samples to examine lipid levels and H_{A1c}) were collected from all participants at baseline, and following the intervention period at approximately 3 months after baseline, and again at 9 months after baseline for those who continued the study. In addition, the behavioral and food frequency questionnaires, and body measurements were repeated at the end of the control period and after the intervention was completed (approximately 2 months post baseline).

The intervention was a 6 week vegan healthy eating program modeled after Barnard et al's intervention. However, this program contained less intensive health and nutrition education and incorporated in depth discussions on the ethical and environmental impacts of personal food choices. The program consisted of 6 weekly, two and a half to three hour sessions and approximately half an hour of suggested "homework" between sessions. Each session included 1-2 hours of presentation (a documentary video, guest lecture, etc.) and 0.5 - 1 hour of facilitated discussion.

Bi-weekly, one and a half to two hour, maintenance sessions beginning after the core sessions were offered to patients for 6 weeks (i.e. 3 sessions). An additional session was offered in the middle of the remaining 6 months of follow-up. These sessions were tailored to the requests or needs of each group.

The program was presented as a tool to gear participants to adopt a low to moderate fat, whole-foods, plant-based diet. The health, environmental and ethical arguments for moving towards this dietary pattern were presented and discussed during the program. Practical tips (such as recipes and shopping tips) were also made available for participants and were explored in greater depth during the maintenance sessions. Materials that were suitable for the program, but could not be utilized given time constraints, were available for independent study (i.e. homework), which afforded the ability to further tailor information to individual needs and reinforced material covered in the program. The topics of the core sessions are as follows:

Session 1. Introduction: overview of study, sessions, obesity and basic vegan nutrition.

Session 2. Your health: the health benefits of a low-fat, whole foods, vegan diet.

Session 3. Your health and more: an overview of the environmental, ethical and health effects of diet.

Session 4. Ecology: the environmental impact of animal-based agriculture. And: **Optimizing vegan nutrition:** fruits, vegetables, whole grains and important supplements.

Session 5. Where your food comes from: animal biology, intensive confinement practices, factory farms and the treatment of food-animals.

Session 6. Fast food and food safety: health and social rationale for avoiding fast food restaurants.

A more detailed curriculum is provided as the appendix section.

Subject Selection

Who and Why

Obese adults, aged 21 or above, and in stable medical condition, were recruited by primary care providers at the UCSF Weight Management Program, the UCSF Diabetes Clinic or the UCSF Gastroenterology Clinic. Recruitment methods are described below. This generated a convenience sample intended to be somewhat representative of patients seen at a university-based weight management clinic. A portion of the sample (n=6) had already lost 5% or more of their body weight in the prior year, affording the opportunity to study qualitatively the experience of those seeking to maintain weight loss. The inclusion of three referral clinics was for the sake of feasibility. No special populations, such as minors or AIDS patients, were recruited. The baseline characteristics of the participants are presented in the results section.

Sample Size

This pilot trial aimed for a sample size to assess short-term, within group change in selected, clinically relevant variables of dietary pattern (intake of total calories, fat, saturated fat, total fiber, cholesterol, fruit and vegetable servings) with sufficient accuracy. Based on results from Barnard et al's trial,[179] we calculated that a sample size of 25 was required to achieve the accuracy levels given in the table below, using a 95% confidence interval. This N was multiplied by 1.2 to allow for anticipated attrition to give a recruitment goal of 30 participants. These 30 participants would attend either a Monday intervention group or a Wednesday intervention group (i.e. 15 participants per group) as discussed above in the general study design section.

In addition, sample size was calculated using a measure of dietary quality, the Recommended Food Score (RFS). The RFS was developed by Kant et al as 23 item index based on weekly consumption of selected food frequency items using the Block Food Frequency Questionnaire. In a study of a cohort of 42,254 women in the Breast Cancer Detection and Demonstration Project (BCDDP), a 4th quartile score corresponded to a 30% reduction in mortality compared to those in the 1st quartile. In this cohort, the mean RFS was 11.2, and the within group SD was 4.1.[180] A sample size was calculated to detect a mean increase of 3 points (which corresponds to an approximate increase of one quartile in the BCDDP cohort), assuming a within person correlation of measurements near 0.85 and a ratio of control to experimental patients near or just below 0.5. Using the same attrition factor of 1.2 a sample size of 28 was found. Thus, our sample size goal was refined to a minimum of 28 and (desired) maximum of 30 participants.

Figure 1. Sample Size Calculation 1

Variable	Mean	SD	Acceptable Variation	95% CI		Sample size	
				Lower	Upper	Raw	Total*
Drop in Total Kcal	365	612	500	115	615	25	**30**
Drop in Total Fat	44	33	33	27.5	60.5	17	**20.4**
Drop in Saturated Fat	18	15	20	8	28	10	**12**
Drop in Cholesterol	213	129	150	138	288	13	**15.6**
Increase in Total Fiber	9	11	10	4	14	20	**24**
Increase in Fruit Servings	1	2	1.8	0.1	1.9	20	**24**
Increase in Vegetable Servings	1	2	1.8	0.1	1.9	20	**24**

Note: Attrition Factor of 1.2 used to calculate Total N from Raw value.

Source: Barnard Data set (change from baseline to 14 weeks); Vegan Group data only

Figure 2. Sample Size Calculation 2

Reported between person SD	4.1
Correlation of measurements within a person	0.85
Calculated within person SD	4.10
ratio of control to experimental participants	0.5
N of experimental group	15
N of control group	8
Total N*	**23**
N x Attrition Factor (1.2)	**28**

*To detect an effect size of 3 points, with an alpha of 0.05 and power of 0.8, using an independent t test on the change scores.

Inclusion/Exclusion Criteria

The suitability of each patient, according to the inclusion/exclusion criteria (listed in Figure 3 on the following page), was evaluated by medical history, an oral questionnaire, the ability to read and comprehend the consent form, vital signs, and when necessary, contact with a primary care physician, psychiatrist or medical chart review.

Figure 3. Inclusion an Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
Participants must be: At least 21 years of age, male or female, of any ethnic group. In stable medical condition. At a BMI greater or equal to 30. Able to independently perform Activities of Daily Living, including the ability to shop for/prepare meals, and travel to the intervention sessions.	*Potential participants will be excluded if:* They have conditions that might interfere with participation or follow-up. These include: ▪ alcohol or drug addiction, ▪ severe depression or anxiety, ▪ an inability or unwillingness to attend all sessions, ▪ a language barrier, ▪ an inability to read at a grade 8 level, ▪ an uncorrected visual/auditory impairment, ▪ a serious personality disorder (e.g. antisocial, borderline, narcissistic). They have a condition that might interfere or alter weight loss. These include: • being vegetarian (lacto-ovo or vegan) at the time of enrollment, • the use of pharmacotherapy for weight loss, • concurrent use of Very Low Calorie Diet therapy, • prior bariatric surgery, • malignancy, • pregnancy.

Subject Recruitment

Sources

Potential subjects were identified from a database of patients seen at the UCSF Gastroenterology Clinic in the 36 months prior to the recruitment period (n=142 patients), as well as from new or current patients seen by 9 (nine) providers at the UCSF Gastroenterology Clinic, UCSF Diabetes Clinic, and UCSF Weight Management Program during the recruitment period which lasted 2 months, 9 days. (*Please see recruitment flow diagram in the results section*) The study intervention was presented as a complimentary or alternative treatment for either a) aiding dietary improvement, b) the maintenance of weight loss and/or c) weight loss as appropriate.

Enrollment occurred on a first come, first serve basis and recruitment was stopped once the recruitment goal was met.

Initial Contact Methods and Screening

A letter from their care provider at the clinic and a pamphlet that describes the study and the inclusion and exclusion criteria was mailed (in the case of database patients) or given by the care provider (in the case of new or current patients) to all prospective participants along with an invitation to contact a member of the research team by phone for more information or to learn how to enroll in the study. Initial screening took place over the phone after which potentially eligible patients were asked to come to the UCSF General Clinical Research Center for final screening.

A copy of the recruitment pamphlet can be found in the appendix section.

Consent Process and Documentation

The study aims, design, risks and requirements were explained to all potential participants by the study PI. An outline of the sessions' contents (similar to that provided in the appendix) was also given to potential participants to read, after which questions were encouraged. All subjects were asked for a medical history and vital signs to ensure that they were in stable health condition. Once subjects were deemed to be eligible for and interested in the study, they were given a fully-informed written consent form to read and sign. For those who refused participation in the study, reasons for refusal (if given) were documented. All records and questionnaires were kept confidential according to standard medical practice. At the end of the 3 month pilot, all study participants were invited to continue in the study and, if interested, were asked to read an additional fully-informed written consent form outlining the procedures, potential risks and benefits of continuing the study for an additional 6 months. Those who did not wish to continue participation in the study were asked if they were willing to explain why. They were told verbally that they remained free to end their participation without explanation.

A copy of the consent form can be found in the appendix section.

Study Procedures

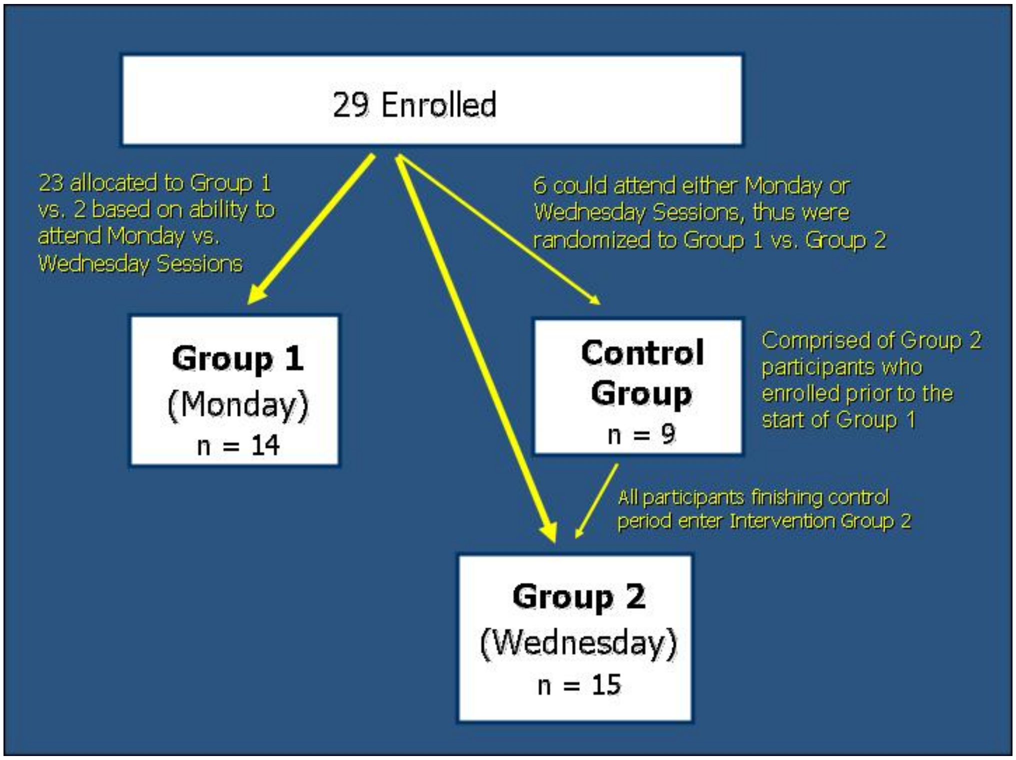
Study Site

All study procedures were conducted at the General Clinical Research Center (GCRC) at the University of California, San Francisco (UCSF), 505 Parnassus Avenue, Room M-1296, San Francisco, California 94143.

Group Allocation and Randomization

Participants were informed that there will be 2 identical groups, one that takes place on Mondays, one on Wednesdays, and that one of these will start before the other. Participants that could only attend the Monday *or* only the Wednesday group were assigned to that group. Participants that could attend either group were randomized (using a 2:1, Monday: Wednesday ratio) to one of the groups. Participants who enrolled in the Wednesday group 4 weeks prior to its commencement were asked to contribute 2 sets of baseline data – one upon enrolling, the other right before their group commenced - so as to contribute “control period” data.

Figure 4. Randomization & Group Allocation



Data Collection and Outcome Measures:

A list of data sessions and outcome measures appears in Figure 5 on the following page. This is followed by description of the standardized techniques used for collecting data and the statistical methods used to generate outcome values (where appropriate). All data was collected by a trained research nurse, the study PI or a co-investigator. Data was entered into a custom designed Microsoft Access 2002 v 10.4 relational database by 2 trained research assistants.

Figure 5. Schedule of Outcome Measures

Measure	Baseline 1*	Baseline 2*	Intervention	Month 2	Month 3	Month 9
Activity Monitor (4 day)	X				X	X
Attendance			X			
Behavioral Questionnaire	X	X		X	X	X
Block FFQ	X	X		X	X	X
Blood Pressure	X	X		X	X	X
Blood Draw (Lipid profile, H_{A1c})	X				X	X
Body Measurements (Weight, height)	X	X		X	X	X
Demographic Questionnaire	X					
DEXA Scan	X				X	X
Exercise Questionnaire (YPAS)	X				X	X
Satisfaction & Acceptability Questionnaires			X		X	X

Abbreviations: FFQ, Food Frequency Questionnaire; H_{A1c}, Glycosylated Hemoglobin; DEXA, Duel-Energy X-Ray Absorptiometry; YPAS, modified Yale Physical Activity Survey

*Baseline 1 refers to data collected upon enrolling in the study. Baseline 2 refers to data collected at the end of the control period.

Figure 6. Standardized Measurement Techniques & Statistical Methods

Blood Pressure:

Participants were asked to sit relaxed, for 5 minutes. The appropriate size cuff was placed on their left arm, directly over skin, with the arm resting so that the cuff was at heart level. Both the systolic and diastolic blood pressures were measured with an electronic cuff (Dynamap™), with 2 minute intervals between each measurement. 3-4 measurements were recorded depending on time availability in the research ward.

Average systolic and diastolic blood pressures were calculated as follows. The first measurement was discarded, then the remaining 2 or 3 measurements were averaged.

Weight:

The same digital scale (capable of weighing up to 350 Kg) was used for each measurement. The scale was zeroed prior to each measurement. Participants were encouraged to void their bladder prior to the measurement. Participant were asked to be bare foot (or wearing socks, but NO shoes), and to wear a hospital gown or street clothes, but NO jacket, sweater, belt, heavy jewelry or items in pockets. The weight was recorded in Kg to 2 decimal places.

Height:

The same wall mounted Harpenden stadiometer (Holtain, Dyfed, UK) was used for each measurement. Participants were asked to be barefoot or wearing socks (but NO shoes). Participants were instructed to stand with their heels together, buttocks and back pressed against the stadiometer. Then they were asked to “look forward and stand tall” while keeping their feet flat on the ground and weight distributed evenly on both feet. Participants were then asked to take a deep breath in, then exhale. During the exhalation the moveable headboard was brought down until it touched the superior-most part of the head, such that their hair was compressed. Height was then recorded in cm to 1 decimal place.

DEXA Scan:

All DEXA body composition measurements were performed using the same LUNAR Prodigy DEXA scanner (Madison, WI), which expressed body composition as total fat mass (g), total lean mass (g), and total body mass (g). Scans were obtained at baseline, 3mo, and 9mo visits. Scanning was performed using a standard protocol with "thick" mode scanning. All scans were performed by the same trained research nurse.

Figure 6 Continued. Standardized Measurement Techniques & Statistical Methods

Activity Monitor (AM):

Physical activity was assessed using RT3 tri-axial research tracker accelerometers (Stayhealthy Inc., Monrovia, CA) at baseline, 3 month, and 9 months after baseline. Participants were given the activity monitors for a minimum of four days, with instructions to wear the monitor at all times except during sleeping and bathing. Participant were instructed to position the AM on their right hip near the Anterior Superior Iliac Spine (ASIS).

After return, data was downloaded from the activity monitor, including Vector Movement, Activity Calories (kcal), and Total Calories (kcal). Based on age, weight, and height, the software calculated Basal Metabolic Rate, Activity Calories, and Total Calories using the following equations:

Basal Metabolic Rate (male): ((473*weight)+(971*height)-(513*age)+4687)/100000
Basal Metabolic Rate (female): ((331*weight)+(352*height)-(353*age)+49854)/100000
Activity Calories: ((average Vector Movement/10)*(weight*1.692))/10000
Total Calories: Activity Calories + Basal Metabolic Rate

A maximum of four and a minimum of two valid measurement days were used for analysis. A valid measurement day was defined as having at least eight hours of non-zero Vector Movement from 8am to 8pm, and at least two hours of non-zero Vector Movement from 8pm to 8am. Average Vector Movement, Activity and Total Calories per day were calculated from a multiple of 24 hours (48, 72, or 96 hours). Subjects with less than two valid measurement days during one session had a second measurement session of four or more days.

In total, five activity monitors were used for all participants. Intra- and inter-monitor reproducibility was assessed on two separate occasions, in which the monitors were placed on a shaker box for a 48 hour period, with the first 24 hours in a prone position and the second 24 hours in an upright position orthogonal to the prone position. For each of the two 24 hour segments, inter-monitor precision was calculated as the average and standard error (SE) of total Vector Movement for each of the five monitors, with precision calculated as the ratio of SE/average (percentage). Intra-monitor reliability was assessed by comparing each of the 24 hour segments in two separate shaker box sessions. For each of the two 24 hour segments, the difference in total Vector Movement was measured and percentage change was calculated as the difference/average (percentage).

To minimize variability, participants were given the same AM at each measurement whenever possible. Although it was intended that each participant would only use one AM, this was not possible as one AM was lost and 2 broke during the testing period and had to be repaired. In addition, the average Vector Movement per day was used as the primary measure to assess change in activity as this measurement has the least variability associated with it.

Labs:

The day prior to their data session appointment, participants were reminded to be fasting from midnight onwards (or for at least 8 hours prior to their appointment). They were encouraged to drink water but asked not to take other fluids or food during the fasting period. They were reminded to take their medications as per usual. All blood draws were performed by a trained research nurse at the GCRC. In the rare case that a blood draw could not be obtained by the research nurses (i.e. for technical reasons), participants were given a requisition slip and note to allow the blood to be drawn at a local Unilab™ office. Two 10 ml SST tubes were drawn for a lipid panel and fasting glucose, and one 3 ml purple-top tube was drawn for a H_{A1c} measurement. All tubes were labeled and sent to Unilab™ for analysis. Participants were free to refuse a blood draw on any visit.

Surveys:

Standardized instructions for all surveys were contained within each survey. Prior to each survey administration, participants were given a verbal summary of the instructions and asked to read all instructions carefully, to take their time answering questions and to ask for clarification at any time. They were free to refuse to answer any questions. A description of each survey used is found below. A copy of the surveys can be found in the appendix section. All survey instruments were reviewed by both the UCSF Committee on Human Research and the UCSF GCRC Advisory Committee.

Figure 6 Continued. Standardized Measurement Techniques & Statistical Methods

The Block 98.2 Food Frequency Questionnaire (FFQ):

This FFQ was validated by Block et al after updating their original FFQ to reflect data from the National Health and Nutrition Examination Survey III (NHANES III).[181] The Block 98.2 FFQ was chosen from available validated FFQs because it contained food items relevant to the study intervention (e.g. soy milk, tofu, meat alternatives) and allowed for separation (during analysis) of the majority of items into plant or animal-origin (see below). In addition, the Block food diagram (a pictorial representation of serving sizes using wooden blocks on plates and bowls) was felt to contribute an advantage over other FFQs because of the likely variability in perceptions of ‘servings’ that may exist in this study population. A 3-7 day food diary would have offered more accurate nutritional data, but this method was not chosen for this pilot study for feasibility concerns. The Block FFQ was used as is, with the exception of the time frame for questions, which was manually changed from “past year” to “past month” on each survey. The ‘Block food diagram’ was explained prior to starting and was used every time the survey was filled out. The completed FFQs were checked for completeness and participants were asked complete any missing items.

Berkeley Nutritional Services (Berkeley, CA) performed all of the raw FFQ analysis by scanning each survey using an Optical Mark Reader and then comparing the item results with a standardized nutrient database. This analysis returned values for each item assessed as well as summary variables for standard macro and micronutrients as well as estimated servings of fruits, vegetables, meats, etc. Average macronutrients, micronutrients, and food servings served as the primary values for assessing change in diet. The raw values for each item assessed were used to calculate a Recommended Food Score (RFS), a measure of overall dietary quality.

In addition to the above analysis, the Block FFQ was coded into plant, animal or other items. Other items included items that described foods that could contain either animal or plant foods (e.g. Chinese food, pizza, etc.) and also included plant-based items with well established deleterious effects (e.g. French fries, candy). Coding decisions were made prior to patient enrollment by the study PI and were reviewed by the research dietitian at the Preventive Medicine Research Institute. The objective of coding the FFQ into plant, animal or other was to allow for the generation of 2 novel dietary indexes that may be able to assess a “shift to a plant based diet”. One index (the PDI) excluded the ‘other’ items as a means of comparing plant to animal items. The other index (the PDIT) included all food items as a means of assessing the proportion of plant calories in the diet. The indexes were calculated as follows:

Plant-based Diet Index (PDI) =
(total plant calories/ total plant calories + total animal calories) x100

Total Plant-based Diet Index (PDIT) =
(total plant calories/ total plant calories + total animal calories + total other calories) x100

A list of the Block FFQ item codes can be found in the appendix section

Behavioral & Demographic Survey:

This survey instrument was designed for this study in an attempt to measure perceived dietary change, behavior change (e.g. stage of change, self-efficacy, intention to change, etc.), as well as relevant attitudes, beliefs, and knowledge. Whenever possible previously validated questions and scales were utilized. For example, the *Vegan-Omnivore Scale* was included in this survey as a validated measure of perceived dietary change, which has correlated well with 3-day food recall.[153] Where it was not possible to find previously validated questions and scales, questions were modeled after similar questions reported in the literature. Once a draft of the survey was complete it was reviewed by several experts in vegetarian nutrition or dietary behavior change to asses face validity. Suggestions were integrated into the survey and sent back to all reviewers for further comments.

A copy of the VHEP Behavioral and Demographic Survey can be found in the appendix section.

Figure 6 Continued. Standardized Measurement Techniques & Statistical Methods

Satisfaction Surveys: Anonymous satisfaction surveys were administered to each participant after every intervention session with goal of measuring satisfaction with learning experience as well as the perceived value and acceptability of the session. Before beginning each survey, participants were reminded that the survey is anonymous and were encouraged to write comments (both positive and negative). They were then instructed to place the survey in a collection box prior to leaving. In the case of a make-up session, participants were not asked to fill out a satisfaction survey as anonymity would not be possible. An additional post-course satisfaction survey was administered to assess the relative perceived value, acceptability and satisfaction of each of the program's components in hindsight. This survey was not anonymous in that it required the participants to place their assigned StudyID on the front page. All surveys were reviewed prior to administration by an experienced biostatistician.

Statistical Methods:

Data was collected and stored as described above. After the data was cleaned, it was exported to SPSS v11.5 for Windows for statistical analysis. A hierarchical analysis was performed as follows. Outcome measures collected at the start and the end of the control period allowed for a comparison of changes in selected variables in the intervention group vs. the control group (i.e. a between group analysis). Since the control period was relatively short and coincided with the start of the intervention period for group 1 only, the between group analysis compared only group 1 participants (n=13) to control participants (n=8). Of most importance is the between group analysis comparing group 1 immediately after the intervention (approximately 7.3 weeks after baseline) to the control group (of approximately 4.3 weeks duration). However, this same analysis was repeated comparing intervention group 1 at both 3 months (n=13) and 9 months (n=8) post baseline to the control group. Please see figure 7, found at the end of this section, for a graphical representation of the analyses.

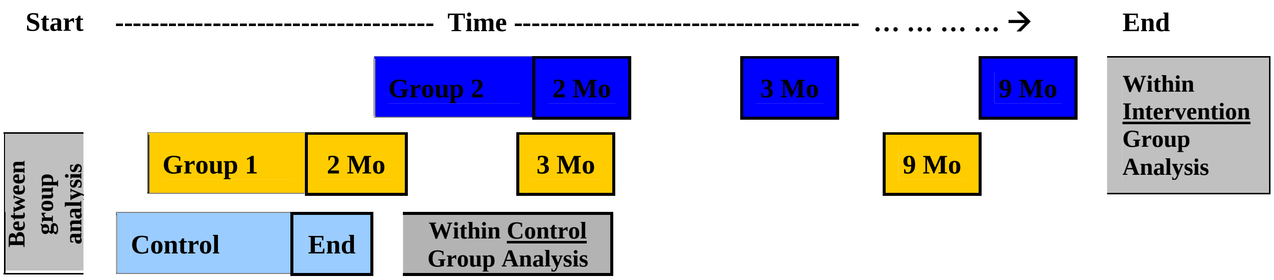
Although the study was designed for 3 months only, an intention to treat between group analysis was also performed on the 9 month changes by carrying forward 3 month changes for participants who dropped out of group 1 after the 3 month period (n=5). For continuous variables, between group differences were analyzed by 2-tailed, independent Student's t-tests on the change scores of the intervention vs. control group. Prior to running the t-tests, Levene's test for equality of variances was run to determine whether or not the Student's t-test should assume equal or unequal variances for each variable. For ordinal or categorical variables, a Mann-Whitney U test was substituted for the Student's t test.

In addition to a between group analysis, within group changes were also assessed on all participants (i.e. group 1 and 2) by 2-tailed, paired Student's t-tests on the before and after scores (for continuous variables) for each time period (i.e. control, and intervention at 2, 3 and 9 months). For ordinal or categorical variables, the Wilcoxon Signed Ranks test was substituted for the Student's t test. An intention to treat analysis was also performed on the 9 month scores by carrying forward 3 month values for participants that dropped out after the 3 month point (n=5).

Correlations were calculated on the within group change scores for each time period. For continuous variables, Pearson's correlation coefficient was calculated. For ordinal or categorical variables, Spearman's correlation coefficient was calculated. When a correlation was assessed between a continuous and an ordinal or categorical variable, the continuous variable was first converted to an ordinal variable by assigning a quintile of change to each variable change score. Then a Spearman's correlation was computed comparing quintiles of change of the continuous variable to either change or end scores of the ordinal or categorical variable.

Finally, logistic regression analysis was performed on within group weight and BMI change to assess the contribution of potential confounders (e.g. activity change) and socio-demographic factors. This analysis was performed on Statistical Analysis System (SAS) for Windows version 8.2 (SAS Institute, Cary, NC).

Figure 7. Diagram Comparing Between vs. Within Group Analyses on Control and Intervention Groups



Solid Boxes represent data collection timepoints (baseline collection not shown)
Group 1 (gold) +Group 2 (dk. blue) = Intervention Group

Intervention Period Procedures:

Each intervention session (i.e. a session of the vegan healthy eating program) was held on the same day of the week (Monday for Group 1, and Wednesday for Group 2), beginning at 6 pm and lasting until 8:30 or 9pm. An outline of the curriculum is found in the Appendix Section. All sessions were facilitated by the study PI. Each session had a number of components including a group check-in, one or two lectures, and one or two discussions or question and answer periods. All components were led by the PI with the exception of the guest lecturers, as listed in the curriculum. Whenever possible, make-up sessions or independent-study options were offered during the intervention period to those that miss a session.

Post Intervention Procedures:

After the 6 week intervention, three additional “maintenance sessions” were offered every second week. As discussed above, these lasted 1.5-2 hours, and focused on more practical matters, such as cooking techniques. After these 3 maintenance sessions the 3 month pilot trial concluded and all participants were invited to continue in the study. Those who remained in the study were offered continued, albeit lesser, support over the next 6 months of follow-up. During this period, one more maintenance session was held, one group mailing was sent out (containing a few relevant recent articles, and a letter of support) and individualized telephone counseling was provided. Telephone counseling was performed by the PI for an average of 34 minutes per phone call, 1.7 times or approximately 57 minutes per participant over this 6 month period. Our goal was to hold 2-4 maintenance sessions, send out 2-4 group mailings, and offer phone counseling for 10-15 minutes once per month. However, resource limitations prevented this level of support from being offered.

Ethics board approval

This research was approved by and conducted under the standards held by the University of California, San Francisco Committee on Human Research, as well as by the UCSF General Clinical Research Center Advisory Committee.

Costs to the Subject

There were no financial costs to subjects that participated in this study.

Reimbursement of Subjects

Participants were compensated $15 for each set of data analysis session they completed, with the exception of the 9 month data session which was not compensated. Thus, a maximum of $60 was given to each participant. Participants were reimbursed for either parking or public transport expenses to attend each intervention session, maintenance session and data collection session.

Confidentiality of Records

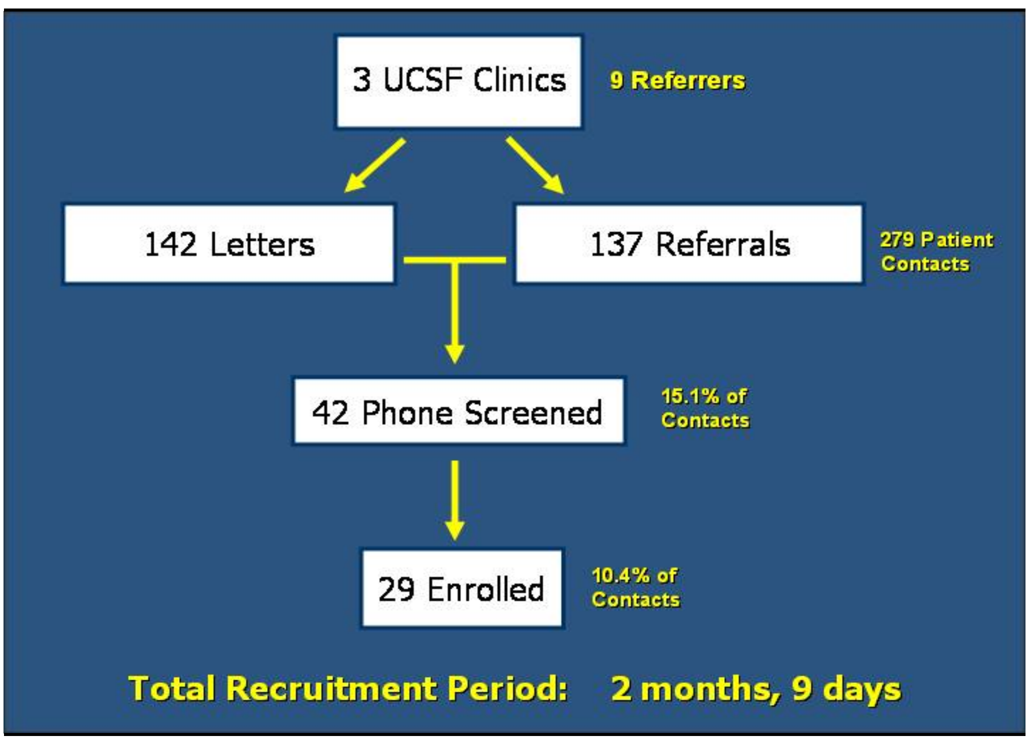
Research records were not anonymous so as to allow for calculation and analysis of change scores. However, all records were coded using a numeric subject ID code assigned when participants enrolled. Data was entered with the subject ID instead of the participant's name. A master key was kept that matches ID's with participants name until data entry and analysis was complete. Consent forms were kept in a secure location within the General Clinical Research Center, Moffitt Hospital.

RESULTS

Recruitment, Retention, Attendance

A recruitment goal of 30 participants was set based on sample size calculations (described above), allowing for 5 dropouts. However time constraints were considered when deciding to close recruitment. At 2 months and 9 days, 29 participants had enrolled and recruitment was closed. Using 3 UCSF ambulatory clinics, 279 patient contacts were made either indirectly by a letter from their care provider (142) or by direct referral (137). Roughly 15.1% of patient contacts contacted the study coordinator to be phone screened. Of these patients, 29 or 10.4% of patient contacts enrolled in the study as they met all inclusion criteria and had no exclusion criteria.

Figure 8. Recruitment Flow Diagram



Of the 29 patients initially enrolled in the study, 4 dropped out by the end of the 3 month study period. The reasons for dropout were: patient elected to have gastric-bypass surgery (n=1), patient seeking rapid weight loss not compatible with the study intervention (n=1), reasons unrelated to the study intervention (n=1), and reasons not given (n=1).

All patients enrolled with the intention of participating in the study for 3 months only. However, an interim analysis suggested positive results warranting an extension of the study. At the end of the 3 month period, all remaining participants (n=25) were asked to continue the study. Of these, 20 participants completed the extended study. Reasons for dropping out or not continuing the study were: patient elected to go on very low calorie diet therapy (n=1), patient elected to go on Atkins-type diet (n=1), reasons unrelated to the study (n=1), and reasons not given (n=2).

Baseline Characteristics

Table 1 on the following page summarizes selected socio-demographic characteristics of the study participants. There were no significant differences in baseline characteristics among intervention and control participants.

Time Changes

Average time between data timepoints was 4.3 weeks (SD=1.2) for the control group. For the intervention group 1 average time from baseline was 7.5 weeks (SD=1.1) at the “2 month” point, 15.6 weeks (SD=1.7) at the “3 month” point, and 41.7 weeks (SD=7.0) at the “9 month” point. For all intervention participants, average time from baseline was 7.3 weeks (SD=1.3) at “2 months”, 14.2 weeks (SD=2.1) at “3 months”, and 35.8 weeks (SD=7.2) at “9 months”.

Table 1. Baseline Socio-demographic Characteristics

	All Participants (n=29)		Group 1 (n=14)		Control (n=9)		
	F* **or mean**	**% or (SD)**	***F*** **or mean**	**% or (SD)**	***F*** **or mean**	**% or (SD)**	***P*** **Value†**
Age	51.1	(10.0)	51.1	(10.7)	49.6	(11.5)	0.756
Baseline BMI	40.4	(8.4)	40.4	(8.7)	38.8	(10.4)	0.679
Baseline VOS	8.0	(1.9)	8.1	(2.0)	8.6	(1.9)	0.447
Baseline PDIT	34.4	(12.3)	32.8	(10.6)	33.5	(12.7)	0.374
Race							0.250
African American or Black	7	24.1	2	14.3	4	44.4	
White or Caucasian	22	75.9	12	85.7	5	55.6	
Ethnicity							0.688
Latino or Hispanic	3	10.3	0	0.0	1	11.1	
Not Latino or Hispanic	26	89.7	14	100.0	8	88.9	
Gender							0.403
Female	24	82.8	11	78.6	9	100.0	
Male	5	17.2	3	21.4	0	0.0	
Education Level							0.688
some college	9	31.0	3	21.4	3	33.3	
associate degree	1	3.4	1	7.1	0	0.0	
bachelor's degree	5	17.2	3	21.4	1	11.1	
some grad school	3	10.3	3	21.4	0	0.0	
master's/doctorate degree	11	37.9	4	28.6	5	55.6	
Marital Status							0.734
single/living alone	16	55.2	9	64.3	5	55.6	
married/living with partner	13	44.8	5	35.7	4	44.4	
Employment							0.829
not seeking employment	11	37.9	7	50.0	3	33.3	
work less than 20 hrs/wk	3	10.3	0	0.0	1	11.1	
work part time (20-39 hrs/wk)	1	3.4	0	0.0	1	11.1	
work full time (40 + hrs/wk)	14	48.3	7	50.0	4	44.4	
Combined Income							0.754
0 - $10,000	3	10.3	2	14.3	1	11.1	
$11,000 - $20,000	3	10.3	1	7.1	1	11.1	
$21,000 - $30,000	2	6.9	1	7.1	0	0.0	
$31,000 - $50,000	3	10.3	1	7.1	2	22.2	
$51,000 - $70,000	5	17.2	4	28.6	1	11.1	
$71,000 -$90,000	4	13.8	1	7.1	3	33.3	
$91,000 or more	7	24.1	2	14.3	1	11.1	
Medical Insurance							0.688
Yes	28	96.6	14	100.0	8	88.9	
No	1	3.4	0	0.0	1	11.1	

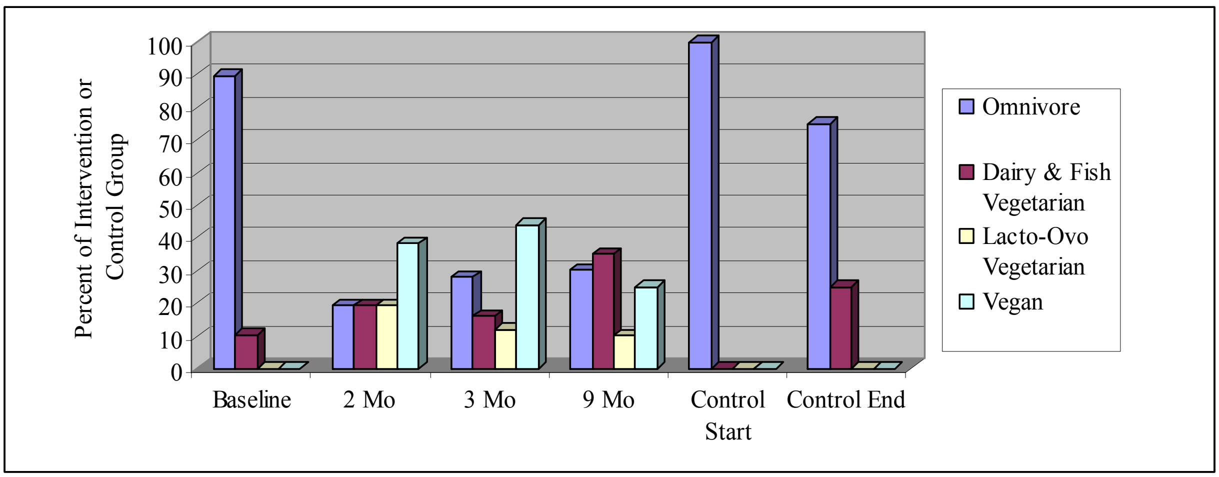
Abbreviations: F, frequency; BMI, Body Mass Index; VOS, Vegan-Omnivore Scale where 1=vegan and 10=omnivores; PDIT, Total Plant-based Diet Index Score

†*P* values derived from 2-tailed, Mann-Whitney U test on categorical variables and 2-tailed, independent Student's t-test on continuous variables, comparing all participants to control participants.

Change in Perceived Dietary Pattern

At each data session participants were asked to select a dietary category that most represented their current diet. The figure below represents responses at each study timepoint. The proportion of control participants who considered themselves vegetarian or vegan was 0% at baseline and 25% (all "dairy and fish vegetarian") at the end of the control period (p for category change =0.16). Among intervention participants, 10.3% considered themselves vegetarian or vegan at baseline (all "dairy and fish vegetarian") compared with 81% at 2 months (p=0.0001), 72% at 3 months (p=0.0001), and 70% at 9 months (p=0.002).

Figure 9. Diet Category Frequencies at All Timepoints



Similarly, compared to changes observed during the control group there was a statistically significant change towards a vegan dietary category in intervention group 1 at 2 months (p=0.002), 3 months (p=0.016) and at 9 months (p=0.023).

In addition to selecting a dietary category reflecting their current diet, participants were asked to rate their current diet on a Vegan-Omnivore Scale (VOS) - a scale from 1 to 10, with 1 labeled as vegan, and 10 as omnivore. Figures 10 and 11 below represent responses in the control group, and responses in the intervention group, respectively. The baseline VOS for the control and intervention participants was 8.6 (SD=1.9) and 7.7 (SD=2.3), respectively (p=0.96). The mean change in VOS in the control period was -1.4 (SD=2.4, p=0.14). The mean change in VOS in the intervention period was -5.4 (SD=2.4, p<0.001) at 2 months, -4.5 (SD=2.6, p<0.001) at 3 months, and -3.8 (SD=3.2, p<0.001) at 9 months. Mean changes are displayed in Figure 12. Compared to changes observed in the control group there was statistically significant change towards the vegan end of the scale in intervention group 1 at 2 months (p=0.004) and at 3 months (p=0.021). However, this difference did not remain significant at 9 months (p=0.11).

Figure 10. VOS Responses for Control Participants

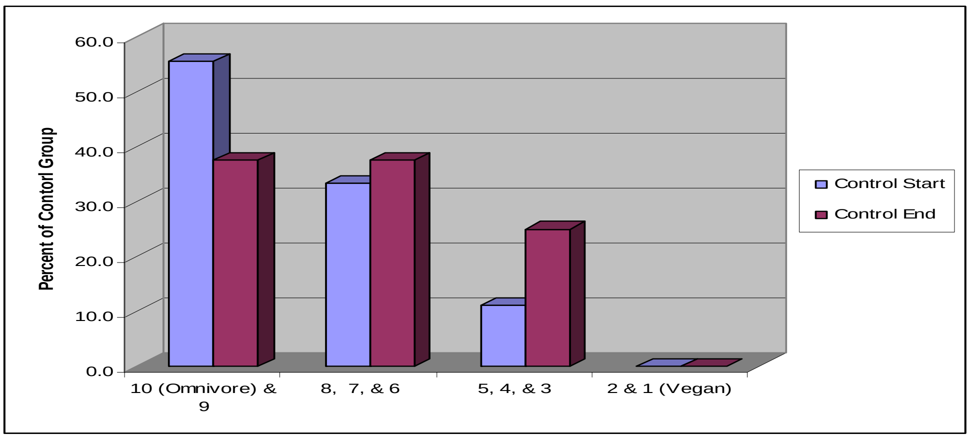


Figure 11. VOS Responses for Intervention Participants

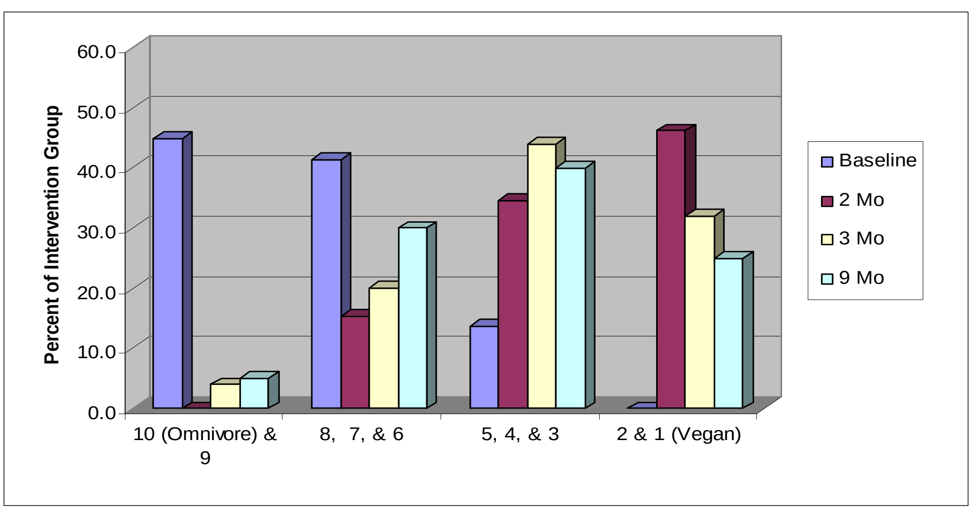
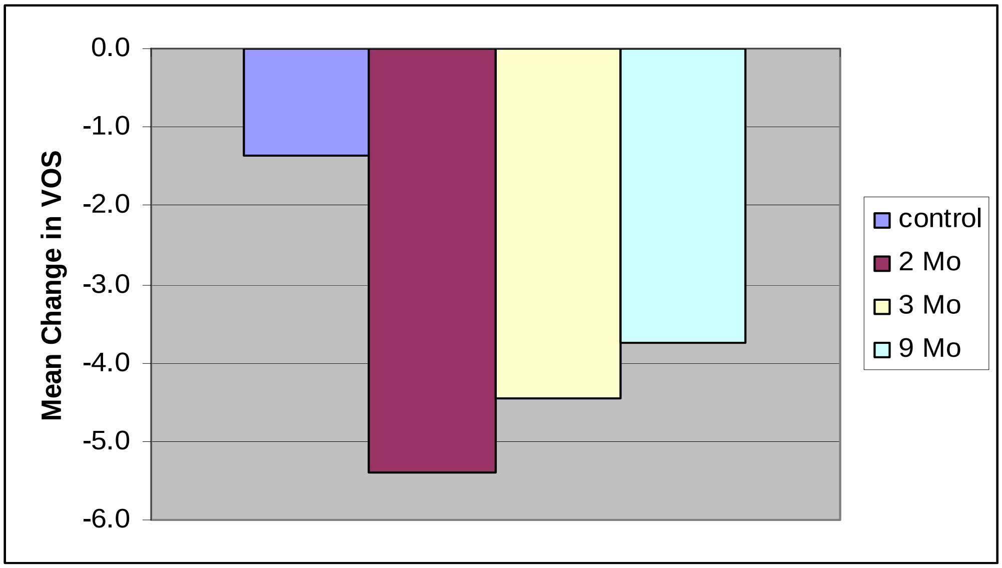


Figure 12. Mean VOS Change in Control vs. All Participants



Changes in both reported diet category and Vegan-Omnivore Scale (VOS) correlated with selected markers of dietary pattern as assessed by food frequency questionnaires. The correlation matrix below (Table 2) presents within intervention group changes in diet category and VOS at 2, 3 and 9 months as correlated with quintiles of change of dietary variables and weight change. In general, changes towards a self-reported vegan diet correlated with expected changes in dietary components such as a reduction in saturated fat and dietary cholesterol and increases in dietary fiber, fruits and vegetable servings, and plant-based diet indexes. A decrease in VOS (i.e. a move towards vegan) correlated more consistently with a decrease in weight than did a change in reported diet category.

Table 2. Correlation Matrix for Changes in Dietary Components, Weight an Perceived Dietary Change

		Intervention Group at					
		2 months (n=25)		3 months (n=25)		9 months (n=20)	
Quintiles of Change in	**Change in**	Diet Category	VOS	Diet Category	VOS	Diet Category	VOS
Kcal	Correlation Coefficient	0.061	0.193	-0.005	0.296	0.238	0.293
	P Value	0.777	0.365	0.983	0.160	0.327	0.223
Fat	Correlation Coefficient	0.181	0.187	0.166	0.372	0.402	0.318
	P Value	0.398	0.382	0.438	0.073	0.088	0.185
Carbohydrates	Correlation Coefficient	-0.085	0.107	-0.075	0.045	-0.069	0.063
	P Value	0.691	0.620	0.726	0.833	0.779	0.799
Saturated Fat	Correlation Coefficient	0.324	0.398	0.283	0.515	0.418	0.526
	P Value	0.122	0.054	0.181	**0.010**	0.075	**0.021**
Cholesterol	Correlation Coefficient	0.531	0.505	0.532	0.650	0.569	0.566
	P Value	**0.008**	**0.012**	**0.008**	**0.001**	**0.011**	**0.012**
Fiber	Correlation Coefficient	-0.539	-0.425	-0.491	-0.481	-0.649	-0.483
	P Value	**0.007**	**0.038**	**0.015**	**0.017**	**0.003**	**0.036**
% Fat	Correlation Coefficient	0.082	-0.002	0.059	0.345	0.563	0.279
	P Value	0.702	0.991	0.784	0.099	**0.012**	0.247
% Protein	Correlation Coefficient	0.082	0.141	0.067	0.178	-0.177	-0.040
	P Value	0.704	0.510	0.755	0.406	0.468	0.871
% Carbohydrates	Correlation Coefficient	-0.185	-0.124	-0.168	-0.405	-0.605	-0.418
	P Value	0.388	0.562	0.433	**0.050**	**0.006**	0.075
Fruits + Vegetable Servings	Correlation Coefficient	-0.353	-0.012	-0.365	-0.394	-0.458	-0.494
	P Value	0.090	0.956	0.080	0.057	**0.048**	**0.032**
Meat Servings	Correlation Coefficient	0.097	-0.017	-0.103	0.183	0.047	0.192
	P Value	0.654	0.939	0.633	0.392	0.850	0.430
PDI	Correlation Coefficient	-0.681	-0.675	-0.554	-0.665	-0.696	-0.726
	P Value	**0.000**	**0.000**	**0.005**	**0.000**	**0.001**	**0.000**
PDIT	Correlation Coefficient	-0.665	-0.564	-0.724	-0.719	-0.851	-0.750
	P Value	**0.000**	**0.004**	**0.000**	**0.000**	**0.000**	**0.000**
Weight	Correlation Coefficient	0.248	0.399	0.174	0.279	0.450	0.740
	P Value	0.233	**0.048**	0.406	0.177	**0.047**	**0.000**

Abbreviations: VOS, Vegan-Omnivore Scale; Kcal, Calories in Kcal; PDI, Plant-Based Diet Index; PDIT, Total Plant-Based Diet Index

Change in Plant-based Dietary Stage of Change

Stage of change in reference to adopting a plant-based diet (defined as “a diet that is mostly made of grains, vegetables, fruit, beans and legumes, nuts and seeds, and includes very little or no foods made from animals, e.g. milk, meats, eggs, cheese, fish, etc.") was assessed by a pre-determined algorithm using two survey questions: 1) are you currently eating a plant-based diet? and 2) if no, are you ready to start eating a plant-based diet now? A pre-contemplative stage was defined by answering "No" to both questions. A contemplative or preparative stage was defined by answering "No" to the first question and "Yes" to the second. An action stage was defined by answering "Yes" to the first question. Participants were selected such that none were in the action stage at baseline. At baseline, 75.9% of intervention participants were at a contemplative or preparative stage and the remaining 24.1% were at a pre-contemplative stage. Among the control participants at baseline, 88.9% were at a contemplative or preparative stage and the remaining 11.1% at a pre-contemplative stage. These differences were not statistically significant (p=0.31). At 2 months 92.3% of intervention participants reported being in an action stage (i.e. currently eating a plant-based diet), 3.8% remained contemplative or preparative and 3.8% remained pre-contemplative (p for within group change <0.0001). At 3 months 80% reported being in the action stage, 16% contemplative or preparative, and 4% pre-contemplative (p=0.0001). At 9 months 65% reported being in the action stage, 10 % in the preparative or contemplative stage, and 25% in the pre-contemplative stage (p=0.012). In contrast, at the end of the control period no participants reported being in the action stage, 37.5% remained in the contemplative or preparative stage and 62.5% reported being in the pre-contemplative stage (p=0.0455). The changes in reported dietary stage of change in intervention group 1 compared to the control group were significant at 2 months (p<0.001), 3 months (p<0.001) and at 9 months (p=0.045).

Change in Dietary Components

Table 3 on the following page summarizes within group changes in selected dietary variables as determined by food frequency questionnaire analysis. In general, small amounts of dietary change were exhibited by the control group, reflecting a small shift towards a plant-based diet. For example, the Total Plant-Based Diet Index (PDIT, which equals plant calories over total calories x 100) increased by a mean of 6% (SD=5.4, p=0.026), dietary cholesterol decreased a mean of 75.2 mg (SD=63.1, p=0.0198), and there was a slight but non statistically significant decrease in total calories (-106.2 Kcal, SD=348.8, p=0.45). However, the Recommended Food Score (RFS) worsened by a mean of 2.4 points (max possible score=21, SD=2.2, p=0.028), otherwise all other variables did not change in a statistically significant manner.

In comparison, larger changes were observed in the intervention participants. At 2 months, for instance, the PDIT increased a mean of 25.1% (SD=18.3, p<0.0001) bringing the mean PDIT to 59.1% (range=25.5% to 86.7%, SD=18.3)[ix], total calories decreased a mean of 395.1 Kcals (SD=631.1, p=0.006), saturated fat decreased 11.2 grams (SD=9.9, p<0.0001), cholesterol decreased 146.6 mg (SD=120.6, p<0.001), dietary fiber increased 8.7 grams (SD=12.7, p=0.003), combined fruits and vegetable servings increased by 2.6 servings (SD=3.8, p=0.003) and the RFS increased a mean of 1.3 points (SD=3.0, p=0.038).

Similar within group changes were observed in intervention participants at both the 3 month and 9 month timepoints as outlined in the table below. In reference to the plant-based diet indexes, the peak shift to a plant-based diet presumably occurred between the 2 and 3 month timepoint,

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[ix] In comparison the Plant-Based Diet Index (PDI, which equals plant calories over plant plus animal calories x 100, and thus excludes "other" calories) increased a mean of 29.8% at 2 months to 85.5% (range=51.7 to 100%, SD=16.3). Thus, the PDIT is likely a more conservative measure of a shift to a plant-based diet because it includes "other" food items which could contain either plant or animal ingredients.

although there were no statistically significant differences in dietary change variables between any of the timepoints.

Table 3. Within Group Analysis of Change in Dietary Components

	Control Changes (n=7)†			2 Month Changes (n=24)†			3 Month Changes (n=24)†			9 Month Changes (n=19)†		
	Mean	**SD**	***P* Value**	**Mean**	**SD**	***P* Value**	**Mean**	**SD**	***P* Value**	**Mean**	**SD**	***P* Value**
KCal	-106.2	348.8	0.4510	-395.1	631.1	**0.0055**	-273.6	590.6	**0.0329**	-313.6	675.4	0.0581
Protein	-11.2	22.3	0.2328	-18.7	30.0	**0.0057**	-16.4	30.2	**0.0141**	-16.4	29.3	**0.0256**
Fat	-1.6	22.9	0.8597	-27.6	30.3	**0.0002**	-21.6	31.2	**0.0026**	-24.7	34.8	**0.0061**
Carbohydrates	-9.7	34.0	0.4801	-11.9	85.8	0.5026	4.1	67.1	0.7675	-4.2	82.0	0.8245
Saturated fat	-3.5	7.6	0.2679	-11.2	9.9	**0.0000**	-9.5	9.1	**0.0000**	-7.1	11.3	**0.0130**
Cholesterol	-75.2	63.1	**0.0198**	-146.3	120.6	**0.0000**	-133.2	122.1	**0.0000**	-91.4	129.3	**0.0064**
Fiber	4.1	5.5	0.0954	8.7	12.7	**0.0029**	10.0	13.7	**0.0016**	3.6	10.2	0.1396
Grams of solid food	-851.0	1168.0	0.1022	684.0	3253.1	0.3137	963.3	2900.0	0.1173	835.1	2564.6	0.1729
% Sugar	3.0	4.5	0.1266	-5.7	9.3	**0.0060**	-3.5	8.8	0.0638	-2.7	7.4	0.1264
% Fat	2.1	4.6	0.2792	-5.6	8.4	**0.0033**	-5.7	7.1	**0.0007**	-7.7	9.4	**0.0021**
% Protein	-1.6	2.3	0.1171	-0.8	3.2	0.2218	-1.5	2.7	**0.0136**	-1.2	2.6	0.0658
% Carbohydrates	0.3	5.2	0.8714	8.3	9.5	**0.0003**	9.2	9.0	**0.0000**	10.2	10.9	**0.0007**
Vegetable servings	-0.1	1.6	0.8728	2.1	3.3	**0.0049**	2.1	2.8	**0.0012**	2.1	2.5	**0.0020**
Fruit servings	-0.4	0.9	0.3551	0.5	1.0	**0.0268**	0.6	0.9	**0.0019**	0.5	1.0	**0.0412**
Meat servings	-0.1	0.8	0.7254	-0.8	1.3	**0.0075**	-0.5	1.5	0.1011	-0.7	1.2	**0.0268**
Dairy servings	-0.9	1.9	0.2380	-0.6	1.3	0.0552	-0.7	1.0	**0.0027**	-0.4	1.1	0.1753
RFS*	-2.4	2.2	**0.0407**	1.3	3.0	**0.0285**	1.6	2.9	**0.0131**	1.2	2.3	**0.0415**
Calories from animals	-228.7	338.2	0.1237	-404.7	361.9	**0.0000**	-388.6	342.7	**0.0000**	-278.2	296.2	**0.0007**
Calories from plants	104.4	211.9	0.2402	294.6	419.9	**0.0022**	327.2	415.2	**0.0008**	99.3	372.7	0.2607
Calories from other	18.1	155.7	0.7686	-285.0	409.7	**0.0024**	-212.2	347.5	**0.0065**	-134.7	454.7	0.2129
PDI	11.2	11.6	**0.0428**	29.8	20.6	**0.0000**	29.9	19.3	**0.0000**	21.0	21.2	**0.0004**
PDIT	6.0	5.4	**0.0260**	25.1	18.3	**0.0000**	23.1	18.1	**0.0000**	14.8	19.3	**0.0036**

Abbreviations: Kcal, Calories in Kcal; RFS, Recommended Food Score; PDI, Plant-Based Diet Index; PDIT, Total Plant-Based Diet Index

Bold: *p* value is less than 0.05

†One participant's food frequency questionnaire was excluded from analysis from both the control and intervention group because they exceeded the number of allowable errors.

*analysis via 2-tailed Wilcoxon Singed Ranks test (all others by 2-tailed, paired, Student's t-test)

Table 4 on the following page summarizes the between group analysis of dietary change variables comparing the intervention group 1 at 2, 3 and 9 months to the control group. Although the control period did overlap with the first 2 months of group 1's intervention period, there were statistically significant differences in time intervals (52.5 days (SD=7.5) or 4.3 weeks vs. 30.3 days (SD=8.7) or 7.5 weeks, $p<0.001$). Still, at 2 months, intervention group 1 demonstrated significantly greater reductions in total fat (-33.7 grams (SD=33.2) vs. -1.6 grams (SD=22.9), p=0.036), saturated fat (-13.3 grams (SD=10.7) vs. -3.5 grams (SD=7.6), p=0.046) and percent of calories from sugar (-5.2 (SD=6.9) vs. 3.0 (SD=4.5), p=0.012), as well as significantly greater increases in the PDI (31.4% (SD=21.1) vs. 11.2% (SD=11.6), p=0.031), the PDIT (28.6% (SD=19.2) vs. 6.0% (SD=5.4), p=0.001) and the RFS (0.6 (SD=3.2) vs. -2.4 (SD=2.2), p=0.0496). Consistent trends were exhibited in changes in fruits and vegetable servings, meat servings, fiber, cholesterol, and total calories but these changes were not statistically significant.

Similar changes were observed in group 1 dietary variables at 3 and 9 months as described in Table 5 (next page). However, statistically significant change (compared with the control period) only remained for decreases in percent fat, and increases in percent carbohydrates, fruits and vegetable servings (9 months only), the PDI and PDIT (3 months only), and the RFS.

Table 4. Between Group Analysis of Dietary Components Change (*continued next page*)

		Control period changes compared to Intervention Group 1 changes at								
		2 months (Group 1 n=13, Control n= 7)			3 months (Group 1 n=13, Control n= 7)			9 months (Group 1 n=8, Control n= 7)		
		Mean	**SD**	***P* Value**	**Mean**	**SD**	***P* Value**	**Mean**	**SD**	***P* Value**
Kcal	Group 1	-522.8	638.8	0.1294	-409.5	708.8	0.3051	-250.3	904.4	0.6993
	Control	-106.2	348.8							
Protein	Group 1	-23.0	37.9	0.4630	-22.6	39.5	0.4916	-17.9	39.4	0.6992
	Control	-11.2	22.3							
Fat	Group 1	-33.7	33.2	**0.0357**	-28.4	38.7	0.1131	-22.7	48.5	0.3139
	Control	-1.6	22.9							
Carbohydrates	Group 1	-26.5	79.0	0.5170	-8.4	68.2	0.9637	10.6	96.7	0.6083
	Control	-9.7	34.0							
Saturated Fat	Group 1	-13.3	10.7	**0.0459**	-11.7	10.4	0.0831	-6.8	16.2	0.6281
	Control	-3.5	7.6							
Cholesterol	Group 1	-148.9	132.4	0.1848	-140.1	137.8	0.2568	-76.1	162.9	0.9892
	Control	-75.2	63.1							
Fiber	Group 1	8.4	12.6	0.3130	8.9	11.9	0.2423	7.1	10.1	0.5036
	Control	4.1	5.5							
Grams of Solid Food	Group 1	-84.4	3215.9	0.4519	116.2	3326.6	0.4705	519.9	3195.6	0.3041
	Control	-851.0	1168.0							
% Sugar	Group 1	-5.2	6.9	**0.0117**	-1.8	8.4	0.1768	-1.5	8.2	0.2072
	Control	3.0	4.5							

Abbreviations: Kcal, Calories in Kcal; RFS, Recommended Food Score; PDI, Plant-Based Diet Index; PDIT, Total Plant-Based Diet Index

Table 4 Continued. Between Group Analysis of Dietary Components Change

		Control period changes compared to Intervention Group 1 changes at								
		2 months (Group 1 n=13, Control n= 7)			3 months (Group 1 n=13, Control n= 7)			9 months (Group 1 n=8, Control n= 7)		
		Mean	**SD**	***P* Value**	**Mean**	**SD**	***P* Value**	**Mean**	**SD**	***P* Value**
% Fat	Group 1	-6.2	10.9	0.0741	-6.7	8.7	**0.0238**	-9.1	12.8	**0.0466**
	Control	2.1	4.6							
% Protein	Group 1	-0.1	3.5	0.3185	-1.2	2.7	0.7517	-1.5	2.8	0.9334
	Control	-1.6	2.3							
% Carbohydrates	Group 1	8.3	12.1	0.1155	10.2	10.7	**0.0345**	12.9	14.2	**0.0459**
	Control	0.3	5.2							
Fruits + Vegetable Servings	Group 1	1.3	3.1	0.1849	2.0	3.2	0.0732	2.6	3.3	**0.0471**
	Control	-0.5	1.7							

Abbreviations: Kcal, Calories in Kcal; RFS, Recommended Food Score; PDI, Plant-Based Diet Index; PDIT, Total Plant-Based Diet Index

Table 5. Between Group Analysis of Dietary Components Change Continued

		Control period changes compared to Intervention Group 1 changes at								
		2 months (Group 1 n=13, Control n= 7)			3 months (Group 1 n=13, Control n= 7)			9 months (Group 1 n=8, Control n= 7)		
		Mean	**SD**	***P* Value**	**Mean**	**SD**	***P* Value**	**Mean**	**SD**	***P* Value**
Meat Servings	Group 1	-0.7	1.5	0.3762	-0.5	1.8	0.5813	-0.7	1.7	0.4454
	Control	-0.1	0.8							
Dairy Servings	Group 1	-0.7	1.1	0.7670	-0.8	0.8	0.8910	-0.4	0.7	0.5116
	Control	-0.9	1.9							
PDI	Group 1	31.4	21.1	**0.0313**	32.1	19.5	**0.0187**	24.2	22.5	0.1907
	Control	11.2	11.6							
PDIT	Group 1	28.6	19.2	**0.0013**	26.0	18.0	**0.0021**	22.0	22.2	0.0842
	Control	6.0	5.4							
RFS*	Group 1	0.6	3.2	**0.0496**	1.2	3.3	**0.0145**	0.5	1.8	**0.0195**
	Control	-2.4	2.2		-2.4	2.2		-2.4	2.2	

Abbreviations: Kcal, Calories in Kcal; RFS, Recommended Food Score; PDI, Plant-Based Diet Index; PDIT, Total Plant-Based Diet Index

*Between group analysis by 2-tailed, Mann-Whitney U test (all others 2-tailed, independent Student's t-test)

As previously described, two novel dietary indexes were calculated to assess a "shift towards a plant-based diet" as reflected by an increased proportion of calories from plant sources relatively to total calories (the PDIT) or animal calories (the PDI). Tables 6 and 7 below describe correlations between these scales and selected dietary changes and behavioral variables respectively within all intervention participants at 2 months. At 2 months, increases in both indexes were strongly and significantly correlated with decreases in saturated fat (PDI r=-.55, p=0.005; PDIT r=-.49, p=0.015), cholesterol (r=-.82, p<0.001; r=-.63, p=0.001) and increases in fiber (r=.58, p<0.001; r=.61, p=0.002).

Quintiles of changes in both indexes also correlated with several related behavioral variables. At 2 months, a lower end Vegan-Omnivores Scale (VOS) score (i.e. closer to 1 or Vegan) correlated with a higher quintile of each index (rs=-.67, p<0.001; rs=-.72, p<0.001) as did a change in the VOS score (rs=-.68, p<0.001; rs=-.56, p=0.004). 2 month self-efficacy scales also correlated with quintiles of each index. A high self-efficacy to eat les animal products (rs=.65, p=0.001; rs=.61, p=0.002), to shop for or prepare vegan meals (rs=.43, p=0.039; rs=.60, p=0.002), and to eat a vegan diet despite the challenges this might pose (rs=.36, p=0.087; rs=0.62, p=0.001) correlated with a high quintile of the plant-based indexes. Similarly, high motivation to eat a plant-based diet (rs=.44, p=0.034; rs=0.62, p=0.001) and low resistance to eating a plant-based diet (rs=-.29, p=0.175; rs=-45, p=0.028) correlated with a high quintile of both dietary indexes.

Table 6. Correlations Between Changes in Plant-Based Diet Indexes and Selected Dietary Variables at 2 Months*

	PDI		**PDIT**	
	Correlation Coefficient	*P* Value	Correlation Coefficient	*P* Value
PDI	1.000	.	0.834	**0.000**
PDIT	0.834	**0.000**	1.000	.
Kcal	-0.113	0.600	-0.133	0.536
Fat	-0.324	0.123	-0.317	0.132
Carbohydrates	0.229	0.282	0.149	0.486
Saturated Fat	-0.553	**0.005**	-0.489	**0.015**
Cholesterol	-0.818	**0.000**	-0.628	**0.001**
Fiber	0.577	**0.003**	0.608	**0.002**
Fruits + Vegetables Servings	0.377	0.069	0.364	0.081
Meat Servings	-0.329	0.117	-0.135	0.529
End RFS Score†	0.303	0.150	0.484	**0.016**

Abbreviations: PDI, Plant-Based Diet Index; PDIT, Total Plant-Based Diet Index; Kcal, Calories in Kcal; RFS, Recommended Food Score

*n=24

†Analyzed by Spearman correlation (all others by Pearson correlation)

Table 7. Correlations between Quintile of Changes in Plant-Based Diet Indexes and Selected Behavioral Variables at 2 Months*

	PDI		PDIT	
	Correlation Coefficient	*P* Value	Correlation Coefficient	*P* Value
End VOS†	-0.668	**0.000**	-0.722	**0.000**
VOS Change	-0.675	**0.000**	-0.564	**0.004**
Self Efficacy to:				
Eat less Animal Products	0.647	**0.001**	0.611	**0.002**
Shop for/Prepare vegan meals	0.425	**0.039**	0.602	**0.002**
Eat a vegan diet despite challenges	0.357	0.087	0.622	**0.001**
Motivation	0.435	**0.034**	0.616	**0.001**
Resistance	-0.286	0.175	-0.447	**0.028**

Abbreviations: VOS, Vegan-Omnivore Scale; PDI, Plant-Based Diet Index; PDIT, Total Plant-Based Diet Index

†All variables analyzed by Spearman correlation; *n=24

Change in Activity Level

Within group changes in activity level were assessed in both the control and intervention periods by the modified Yale Physical Activity Survey (YPAS). Physical activity was also measured by RT3 accelerometers (as described in the methods section) in all intervention participants at 3 and 9 months. Table 8 below describes within group changes in YPAS in the control period and in all intervention participants at 2, 3 and 9 months. No significant changes in YPAS score were observed. Table 8 also describes within group changes in vector measurements derived from the RT3 accelerometers. Here again, no significant within group changes were observed with the exception of a mean decrease of 22.86 vector units (SD=39.64, p=0.02) in intervention participants at 9 months.

Table 8. Within Group Change in activity measures

	Control n=7*			2 Months n=23*			3 Months n=23*			9 Months n=19*		
Change in	**Mean**	**SD**	***P* Value**	**Mean**	**SD**	***P* Value**	**Mean**	**SD**	***P* Value**	**Mean**	**SD**	***P* Value**
YPAS	1.57	11.3	0.724	1.04	17.1	0.773	4.74	20.5	0.280	-1.82	19.7	0.708
Vector Measure	-			-			4.57	36.4	0.535	-22.86	39.6	**0.022**

Abbreviations: YPAS, modified Yale Physical Activity Survey

* 2 YPAS change scores could not be calculated at 2 and 3 month timepoints and 1 change score in the control period and at 9 months because of incomplete surveys. The n for the accelerometer vector measurements was 25 at 3 months and 19 at 9 months.

Correlations between weight and activity level changes are described in the following section.

Change in Weight

Table 9 below describes within group changes in weight and related measures. Over the control period, weight increased on average 1.25 Kg or 2.8 lbs (SD=1.35 Kg, p=0.035). Among intervention participants weight decreased on average 1.54 Kg or 3.4 lbs (SD=2.25 Kg, p=0.002) after 2 months, 2.66 Kg or 5.9 lbs (SD=3.5 Kg, p=0.001) after 3 months and 4.02 Kg or 8.8 lbs (SD=6.43, p=0.012) after 9 months. Similar statistically significant changes were also observed in body mass index (BMI) and percent of body weight lost. Physical activity as measured by survey and activity monitor did not reveal significant within group changes except for a decrease in activity observed by accelerometer changes at 9 months as described above.

Table 9. Within Group Change in Weight and related variables

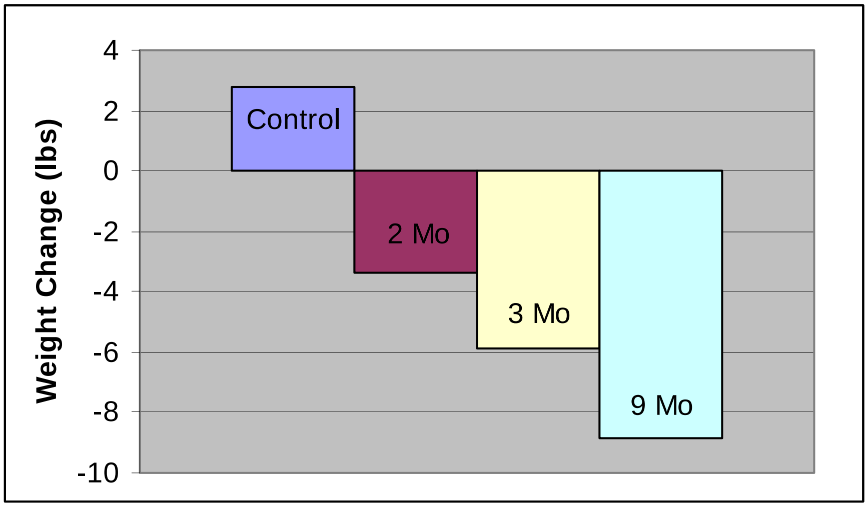
	Control n=8*			2 Months n=26*			3 Months n=25*			9 Months n=20*		
Change in	**Mean**	**SD**	***P* Value**	**Mean**	**SD**	***P* Value**	**Mean**	**SD**	***P* Value**	**Mean**	**SD**	***P* Value**
Weight (Kg)	1.25	1.35	**0.035**	-1.54	2.25	**0.002**	-2.66	3.50	**0.001**	-4.02	6.43	**0.012**
Body Mass Index (Kg/m^2)	0.55	0.86	**0.112**	-0.63	0.86	**0.001**	-1.02	1.29	**0.001**	-1.50	2.34	**0.010**
Percent Body Weight	1.29	1.27	**0.024**	-1.57	2.10	**0.001**	-2.44	3.13	**0.001**	-3.80	6.02	**0.011**
YPAS	1.57	11.25	0.724	1.04	17.12	0.773	4.74	20.50	0.280	-1.82	19.73	0.708
Vector Measure							4.57	36.36	0.535	-22.86	39.64	**0.022**

Abbreviations: YPAS, modified Yale Physical Activity Survey

* n for YPAS was 7 for the control period, 23 at 2 and 3 months and 19 at 9 months. The n for the accelerometer vector measurements was 25 at 3 months and 19 at 9 months.

Figure 13 on the following page displays mean changes in body weight (lbs) among control participants and intervention participants at 2, 3 and 9 months.

Figure 13. Mean Weight Change in Control vs. All Participants



An intention to treat analysis was performed on 9 month (within group) changes among intervention participants by carrying forward the previous (i.e. 3 month) values of the 5 participants that dropped out or discontinued the follow-up study. In this analysis, weight decreased a mean of 3.54 Kg or 7.8 lbs (SD=6.06 Kg, p=0.008).

Table 10. Intention to Treat Analysis on within group 9 Month Changes

	9 Months (n=25)		
Change in	**Mean**	**SD**	***P* Value***
Weight (Kg)	-3.54	6.06	**0.008**
Body Mass Index (Kg/m^2)	-1.31	2.23	**0.007**
Percent Body Weight	-3.26	5.63	**0.008**

*2-tailed, paired, Student's t-test

Table 11 on the following page describes changes in weight and related measures in the control period as compared to intervention group 1 change at 2, 3 and 9 months. At 2 months, group 1 lost an average of 2.2. Kg (SD=2.1) compared to a gain of 1.3 Kg (SD=1.4) in the control period, p=0.0006. Similar differences were seen in BMI, p=0.0013 and percent body weight lost, p=0.0004 at 2 months. Physical activity as measured by the modified Yale Physical Activity

Survey did not reveal significant differences at the 2 month timepoint compared to the control period (4.3 (SD=14.8) vs. 1.6 (SD=11.3), p=0.97).

Table 11. Between Group Analysis of Weight Change and Activity Change

		Control Period Changes compared to Intervention Group 1 Changes at								
		2 months (Group 1 n=13, Control n=8)			3 months (Group 1 n=13, Control n=8)			9 months (Group 1 n=8, Control n=8)		
Change in		**Mean**	**SD**	***P* Value**	**Mean**	**SD**	***P* Value**	**Mean**	**SD**	***P* Value**
Weight (Kg)	Group 1	-2.2	2.1	**0.0006**	-3.1	3.6	**0.0040**	-5.6	8.8	0.0632
	Control	1.3	1.4							
Body Mass Index (Kg/m^2)	Group 1	-0.9	0.8	**0.0013**	-1.0	1.5	**0.0131**	-1.9	3.3	0.0764
	Control	0.6	0.9							
Percent Body Weight	Group 1	-2.2	2.0	**0.0004**	-2.9	3.3	**0.0029**	-5.5	8.1	**0.0494**
	Control	1.3	1.3							
YPAS	Group 1	4.3	14.8	0.9671	7.7	22.6	0.2268	3.7	22.0	0.2496
	Control	1.6	11.3							

Abbreviations: YPAS, modified Yale Physical Activity Survey

Correlations between within group changes in weight and dietary changes are described in Table 12 (on the following page) for intervention participants at all timepoints. At 2 months, weight change only correlated significantly with a change in Vegan-Omnivore Scale (rs=.40.p=-.048). At 3 months, a decrease in weight was significantly correlated with an increase in percent carbohydrates (r=-.55. p=.005), an increase in combined fruits and vegetable servings (r=-.50, p=0.014), a decrease in meat servings (r=.42, p=.044), and an increase in both PDI (r=-.43, p=0.038) and PDIT (r=-.47, p=0.020). At 9 months, a decrease in weight was significantly correlated to a decrease in dietary cholesterol (r=.56, p=0.012), a decrease in calories from animal products (r=.58, p=0.010), a decrease in the Vegan-Omnivore Scale (i.e. a shift to vegan, rs=.74, p<0.001) and an increase in both the PDI (r=.49, p=0.035) and PDIT (r=-.50, p=0.031).

Table 12. Within Group Correlations between Weight Change and Dietary Variables

	Changes in Weight at					
	2 months (n=24)		3 months (n=24)		9 months (n=19)	
Change in	**Correlation Coefficient**	***P* Value**	**Correlation Coefficient**	***P* Value**	**Correlation Coefficient**	***P* Value**
Kcal	0.062	0.775	0.187	0.382	0.297	0.217
Protein	0.034	0.876	0.343	0.101	0.369	0.120
Fat	0.064	0.766	0.211	0.322	0.252	0.297
Carbohydrate	0.019	0.928	-0.056	0.795	0.194	0.425
Saturated Fat	0.079	0.712	0.264	0.213	0.391	0.097
Cholesterol	-0.142	0.509	0.349	0.095	0.563	**0.012**
Fiber	-0.088	0.682	-0.312	0.138	-0.276	0.252
% Sugar	0.043	0.843	-0.039	0.855	0.101	0.681
% Fat	0.285	0.176	0.382	0.066	0.039	0.874
% Protein	-0.068	0.753	0.377	0.069	0.365	0.124
% Carbohydrate	-0.312	0.137	-0.551	**0.005**	-0.271	0.262
Fruits + Vegetable Servings	-0.097	0.651	-0.496	**0.014**	-0.260	0.283
Meat Servings	-0.154	0.471	0.415	**0.044**	0.444	0.057
Calories from animals	-0.012	0.956	0.359	0.085	0.576	**0.010**
Calories from plants	-0.05	0.817	-0.079	0.714	-0.167	0.494
Calories from other sources	0.156	0.466	0.058	0.789	0.203	0.405
PDI	-0.132	0.540	-0.426	**0.038**	-0.487	**0.035**
PDIT	-0.347	0.096	-0.471	**0.020**	-0.496	**0.031**
RFS†	0.046	0.832	0.463	**0.023**	0.011	0.965
VOS*†	0.399	**0.048**	0.279	0.177	0.740	**0.000**

Abbreviations: Kcal, Calories in Kcal; PDI, Plant-Based Diet Index; PDIT, Total Plant-Based Diet Index; RFS, Recommended Food Score; VOS, Vegan-Omnivore Scale

*n= 25 at 2 months, 25 at 3 months, 19 at 9 months;

†test is Spearman Correlation on Quintiles of Weight Change (all others are Pearson Correlation on Weight Change)

Changes in activity as measured by both survey (YPAS) and RT3 accelerometer did not correlate with changes in weight (or related measures) at any timepoint as described in the Table 13.

Table 13. Correlations between within group changes in activity measures and weight measures

			Intervention Group at		
		Control period (n=7)	2 months (n=23)	3 months (n=23)	9 months (n=17)
Quintile of Change in		YPAS	YPAS	YPAS	YPAS
Weight	Correlation Coefficient	0.060	-0.034	-0.188	-0.1266
	P Value*	0.899	0.879	0.391	0.6283
BMI	Correlation Coefficient	0.401	0.077	-0.101	-0.1567
	P Value*	0.373	0.725	0.647	0.5482
% Body Weight	Correlation Coefficient	0.060	0.029	-0.119	-0.2168
	P Value*	0.899	0.897	0.589	0.4032

		Intervention Group at	
		3 months (n=25)	9 months (n=19)
Change in		VM	VM
Weight	Correlation Coefficient	-0.063	0.103
	P Value†	0.765	0.674
BMI	Correlation Coefficient	-0.156	0.065
	P Value†	0.456	0.792
% Body Weight	Correlation Coefficient	-0.114	0.054
	P Value†	0.588	0.826

Abbreviations: BMI, Body Mass Index; YPAS, modified Yale Physical Activity Survey; VM, average daily Vector Measurement from RT3 accelerometer

*test is Spearman Correlation on quintiles of continuous variable change vs. change in YPAS

†test is Pearson Correlation on continuous variable change vs. change in VM

Finally, logistic regression was performed on weight change and BMI change for the control period and the intervention group at 2 months. After adjustment for activity changes (as measured by the YPAS), gender, race, age, education level and household income, weight change for the control period was 0.86 Kg (SD=2.8, within group change p=0.24) compared with -1.4 Kg (SD=3.0, p=0.009). This difference between group remained statistically significant, p=0.01. Similar results were found for BMI change after adjustment for the same factors. BMI change for the control period was 0.41 Kg/m^2 (SD=1.3, p=0.20) compared with -0.58 Kg/m^2 (SD=0.002). This difference between group remained statistically significant, p=0.01.

Change in Body Composition

Body composition was assessed by Duel Energy X-Ray Absorptiometry (DEXA Scans) on all participants at baseline, 3 months and 9 months. However, the DEXA scanner is limited in its width of scan and is only standardized up to 300 lbs. Thus, scans that did not fit comfortably within the limits of the machine or scans on patients weighing 300 lbs or more were excluded from analysis.

Within group decreases were observed in total fat mass, total lean mass, and total tissue mass at 3 and 9 months. Changes in total fat mass did not reach significance. Decreases in lean mass decreased significantly at both 3 and 9 months (-2810 grams (SD=1777.5), p<0.001 and -2869.8 grams (SD=3502.1), p=0.016). Note that lean mass includes both visceral and skeletal muscle, and that it may include some peri-visceral and intra-muscular fat. Total tissue mass also decreased significantly at both timepoints (-2810.4 grams (SD=2809.6), p=0.001 and-5815.2 grams (SD=7294.7), p=0.019). Increases were observed in total bone mineral content but these were not statistically significant. Percent fat did not change significantly at 3 months, but decreased by 1.8% (SD=2.8) at 9 months, p=0.043.

Table 14. Within Group Changes in DEXA Scan Variables

	Intervention Participant Changes at					
	3 months (n=16)			9 months (n=12)		
Change in:	**Mean**	**SD**	***P* Value**	**Mean**	**SD**	***P* Value**
Total fat mass (g)	-634.5	2805.8	0.380	-2945.3	5269.6	0.079
Total lean mass (g)	-2175.6	1777.5	**0.000**	-2869.8	3502.1	**0.016**
Total tissue mass (g)	-2810.4	2809.6	**0.001**	-5815.2	7294.7	**0.019**
Total BMC (g)	75.6	164.1	0.085	99.3	278.8	0.243
Total % fat mass	0.8	2.1	0.164	-1.8	2.8	**0.043**

Abbreviations: BMC, Bone Mineral Content; g, grams

Change in Blood Pressure

Since some patients were mildly hypotensive at baseline, within group changes in blood pressure were analyzed in control and intervention participants with above normal average baseline blood pressure, i.e. a systolic blood pressure (SBP) > 120 mmHg or a diastolic blood pressure (DBP) > 80 mmHg. Findings are found in the table on the following page. Both control (n=6) and intervention participants (n=20 at 3 months, n=15 at 9 months) experienced a reduction of systolic blood pressure, whereas only the intervention group experienced a reduction in diastolic blood pressure. The control SBP decreased a mean of 5.4 mmHg (SD=18.6, p=0.5). The intervention SBP decreased a mean of 8.7 mmHg (SD=15.5, p=0.02) at 3 months and 7.5 mmHg (SD=12.8, p=0.04) at 9 months. The control mean DBP did not change significantly (0.2 mmHg, SD=10, p=0.95). The intervention DBP decreased a mean of 5.9 mmHg (SD=10.6, p=0.02) at 3 months and 3.5 mmHg (SD=9.4, p=0.17) at 9 months.

Table 15. Within Group Analysis of Changes in Blood Pressure in Participants with Baseline SBP>120 or DBP>80

	Changes within control or intervention participants								
	Control (n=6)			3 months (n=20)			9 months (n=15)		
Change in mean:	**Mean**	**SD**	***P* Value**	**Mean**	**SD**	***P* Value**	**Mean**	**SD**	***P* Value**
Systolic blood pressure*	-5.4	18.6	0.505	-8.7	15.5	**0.022**	-7.5	12.8	**0.040**
Diastolic blood pressure*	0.2	10.0	0.954	-5.9	10.6	**0.022**	-3.5	9.4	0.172

Abbreviations: SBP, Systolic Blood Pressure; DBP, Diastolic Blood Pressure
* units: millimeters of mercury

Between group analysis was also conducted on the subset of control (n=6) and intervention group 1 (n=10) participants with an average baseline SBP >120 or a DBP >80. At 3 months, group 1 SBP decreased on average 14.5 mmHg (SD=13.7) and DBP decreased 7.1 mmHg (SD=12.9). At 9 months, group 1 SBP decreased on average 17.1 mmHg (SD=9.5) and DBP 5.4 (SD=9.6). However, compared with control changes none of these differences were statistically significant as described in Table 16 on the following page.

Table 16. Between Group Analysis of Changes in Average Blood Pressure in Participants with Baseline SBP>120, or DBP>80

		Control changes compared to intervention group 1 changes at					
		3 months (Group 1 n=10, control n=6)			9 months (Group 1 n=5, control n=6)		
Change in mean:		**Mean**	**SD**	***P* Value**	**Mean**	**SD**	***P* Value**
Systolic blood pressure (mmHg)	Group 1	-14.5	13.7	0.278	-17.1	9.5	0.238
	Control	-5.4	18.6				
Diastolic blood pressure (mmHg)	Group 1	-7.1	12.9	0.256	-5.4	9.6	0.369
	Control	0.2	10.0				

Abbreviations: SBP, Systolic Blood Pressure; DBP, Diastolic Blood Pressure ; mmHg, millimeters of mercury

Change in Lipids

Fasting blood lipids were measured at baseline, 3 and 9 months on intervention participants only. Table 17 below describes within group changes at 3 and 9 months for participants with one or more criteria for a dyslipidemia, i.e. total cholesterol >200, or LDL cholesterol >130, or HDL cholesterol <40, or triglycerides >150, at 3 months (n=15) and at 9 months (n=11). Within group changes were only statistically significant for a reduction in HDL (and HDL ratios) at 3 months (-7.73 mg/dl, SD=6.95, p=0.001) and at 9 months (-5.0 mg/dl, SD=6.05, p=0.021).

Table 17. Within Group Analysis of Changes in Blood Lipids in Intervention Participants with a Baseline Dyslipidemia

	3 months (n=15)			9 months (n=11)		
Change in	**Mean**	**SD**	***P* Value**	**Mean**	**SD**	***P* Value**
TCHL	-6.27	20.53	0.257	-9.27	35.05	0.401
HDL	-7.73	6.95	**0.001**	-5.00	6.05	**0.021**
LDL	-1.33	20.13	0.801	-4.73	30.08	0.614
VLDL	2.80	11.95	0.380	0.45	8.13	0.857
TG	14.53	60.50	0.368	0.73	40.90	0.954
TCHL/HDL	0.63	0.74	**0.005**	0.34	0.94	0.262
LDL/HDL	0.40	0.48	**0.006**	0.24	0.84	0.358

Abbreviations: TCHL, Total Cholesterol; HDL, High Density Lipoprotein cholesterol; LDL, Low Density Lipoprotein cholesterol; VLDL, Very Low Density Lipoprotein cholesterol; TG, Trigylcerides

Table 18 below describes within group changes at 3 months for the subset of intervention participants who lost 5% or more of initial body weight (n=4). Within group changes were significant for a reduction in total cholesterol of 39.3 mg/dl (SD=21.3, p=0.034) and a reduction in HDL (and related ratios) of 18.0 mg/dl (SD=5.8, p=0.009).

Table 18. Within Group Analysis of Changes in Blood Lipids in Intervention Participants with 5% or More of Body Weight Lost

	3 months (n=4)		
Change in	**Mean**	**SD**	***P* Value**
TCHL	-39.25	21.27	**0.034**
HDL	-18.00	5.83	**0.009**
LDL	-22.00	23.08	0.153
VLDL	0.75	5.12	0.789
TG	3.50	28.24	0.820
TCHL/HDL	0.38	0.54	**0.262**
LDL/HDL	0.21	0.54	**0.499**

Abbreviations: TCHL, Total Cholesterol; HDL, High Density Lipoprotein cholesterol; LDL, Low Density Lipoprotein cholesterol; VLDL, Very Low Density Lipoprotein cholesterol; TG, Trigylcerides

Change in Glycemic Control

Glycemic control was assessed in intervention participants by measuring fasting blood sugar, and glycosylated hemoglobin (H_{a1c}) at baseline, 3 and 9 months. Table 19 below describes within group changes in participants with diabetes or “pre-diabetes”, i.e. a baseline fasting glucose of 100 mg/dl or higher, at 3 and 9 months. A reduction in fasting glucose was observed at both 3 and 9 months (-17 mg/dl, SD=33.1, p=0.16; and -8.2 mg/dl, SD=24.5, p=0.45) but these changes were not significant. Glycosylated hemoglobin did not change significantly at 3 months but increased on average 0.55% (SD=0.29, p=0.006) at 9 months.

Table 19. Within Group Analysis of Glycemic Changes in Participants with Baseline Fasting Glucose > 100

	3 month (n=9)			9 month (n=6)		
Change in	**Mean**	**SD**	***P* Value**	**Mean**	**SD**	***P* Value**
Fasting Glucose	-17.00	33.05	0.161	-8.17	24.50	0.451
Ha1c	0.16	0.28	0.133	0.55	0.29	**0.006**

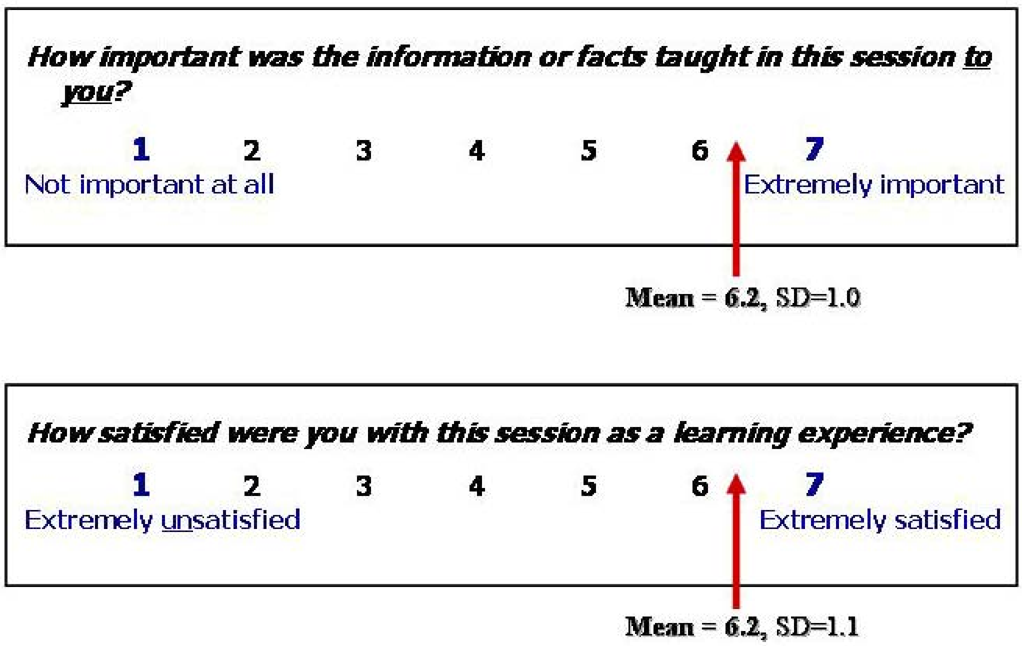
Abbreviations: Ha1c, glycosylated hemoglobin

Intervention Attendance and Satisfaction

The intervention was given twice, as described above. Average attendance for both groups (n=14 and n=15 at baseline) was 12 participants per session (standard deviation, SD=1.5).

Satisfaction with the study intervention was assessed by both anonymous post-session satisfaction surveys and by a non-anonymous post-intervention survey. As detailed in Figure 14 on the following page anonymous surveys assessed perceived importance of each of the 6 sessions by asking on a scale of 0 to 7 *“How important was the information or facts taught in this session to you?”* The mean response for all participants and all sessions was 6.22 (SD=0.98, max=7, min=2). Similarly, satisfaction with the learning experience offered by each session was assessed by asking on a scale of 0 to 7 *"How satisfied where you with this session as a learning experience?"* The mean response for all participants and all sessions was 6.20 (SD=1.10, max=7, min=2).

Figure 14. Average Perceived Importance and Satisfaction with All Intervention Sessions



Distinct components of each session were also evaluated by anonymous post-session surveys by asking on a scale of 0 to 7 *"How much will the information or facts about X covered in this session help you make healthier or "more-informed" food choices?"* (where X is each separate component) On average the highest ranked component was "Animal Ethics" with a mean of 6.2 (SD=1.0, min=4, max=7). All components were ranked roughly 6.0 or above. A 2-tailed, Mann-Whitney U test on the components did not reveal statistically significant differences between the components. Table 20 on the following page summarizes these results.

Table 20. Descriptives of Anonymous Satisfaction Ratings of Program Components

Component	N*	Min	Max	Mean	SD	*P* Value†
Animal Ethics	57	4	7	**6.19**	1.0	-
Health, Obesity or Nutrition	139	2	7	**6.16**	1.0	0.919
Practical Components	37	4	7	**6.08**	0.9	0.502
All Socio-political Components	140	1	7	**6.07**	1.1	0.634
Environmental	40	3	7	**6.03**	1.2	0.641
Food Politics	43	1	7	**5.95**	1.3	0.447

*N is the number of survey responses addressing each component, e.g. if 20 participants attended Sessions # 2 and 4 which covered environmental topics, this gives an N or 40 responses.

†Test is 2-tailed, Mann-Whitney U comparing "animal ethics" to each other component.

A non-anonymous post-intervention survey asked participants to rate each component on a scale of 0 to 7 as to *"How valuable or important was it for you to learn about how X in this program?"* (where X is each separate component). On average, the highest ranked component was "how food affects your health" with a mean of 6.76 (SD=0.5, min=5, max=7). All program components, with the exception of "fast food and food politics" (mean=5.72, SD=1.9) ranked above 6.0. A 2-tailed Wilcoxon Signed Ranks test revealed a statistically significant difference between the health component and "animal ethics", "all socio-political components combined", and "fast-food and food politics" as summarized in Table 21 below.

Table 21. Descriptives of Non-Anonymous, Post-Intervention Perceived Importance of Program Components

Component	N	Min	Max	Mean	SD	*P* Value*
Health	25	5	7	**6.76**	0.5	-
Obesity	25	5	7	**6.52**	0.8	0.250
Group Experience	25	4	7	**6.48**	0.8	0.148
Animal Ethics	25	4	7	**6.44**	0.8	**0.008**
Practical Components	25	4	7	**6.36**	1.0	0.078
All Socio-political Components	25	4	7	**6.24**	0.9	**0.001**
Environmental	25	4	7	**6.16**	0.9	**0.001**
Fast Food, Food Politics	25	0	7	**5.72**	1.9	**0.007**

*test is 2-tailed Wilcoxon Signed Ranks comparing "health" to each other component

DISCUSSION

This study aimed to pilot a novel approach to facilitating dietary change in obese adults. Specifically, the study intervention (i.e. a vegan healthy eating program) consisted of a group dietary educational program that departed from the traditional model of discussing diet solely in relation to health and disease. Instead, approximately two-thirds of the 6 weekly educational sessions focused on the impact of dietary choices on the environment, the current treatment of farm animals and the socio-political implications of the fast-food and animal agricultural industries.

Feasibility and Satisfaction

There were three anticipated barriers existed to implementing this type of intervention. First, it was not known whether patients seen in a university-based ambulatory setting would be willing to participate in a vegan healthy eating program and undergo the inconveniences associated with being a research participant. Yet roughly 15% of patients contacted (in person or by mail) expressed desire to participate in our study. After screening for inclusion and exclusion criteria we enrolled just over 10% of patients contacted. Every patient that met inclusion and exclusion criteria enrolled in the study. These rates demonstrate that some patients are in fact interested in participating in such an intervention, at least in a research setting. Financial compensation for participation was minimal ($45 to $60 over a 3 month period) and we do not believe this contributed to successful recruitment efforts.

Second, it was not known how patients would react towards the content examined in our vegan healthy eating program. We were especially concerned about untoward reactions to discussions concerning intensive confinement animal agriculture (or "animal ethics"). However, in anonymous post-session surveys the animal ethics components ranked higher than any other component (including health, obesity and nutrition related components) for perceived importance and satisfaction. In fact, all components of the program were highly rated (6 or higher out of 7) and no statistical difference was observed between components. Interestingly though, in a non-anonymous post-intervention survey assessing perceived importance the health component was rated highest followed by obesity, the group experience, and animal ethics. This time there was a statistically significant difference between health and animal ethics related components, although all components were again rated highly. From these results we can conclude that in this self-selected patient population, discussions of animal ethics and other non-health related dietary topics can be perceived to constitute a positive learning experience. We can also conclude that all components on the vegan healthy eating program were valued highly. However, since different lecturers covered different components, it can not be known whether the subtle perceived differences between components was attributable to the delivery or the content of each component. Response rates were close to 100% for both anonymous and non-anonymous surveys and thus we do not think a response bias existed. If anything, the survey questions used to assess perceived importance biased respondents towards rating health-related components the most favorably (as the questions asked how each component would enable the respondent to make "healthier or more-informed food choices"). The high ratings of non-health related components were thus consistent with our hypothesis that these components can be successfully incorporated into a dietary change program.

Third, given the sensitive nature of the topics discussed, it was not known whether the intervention would foster a high degree of recidivism. 4 out of the initial 29 participants dropped out of the 3 month study. We were satisfied with this outcome as we anticipated 5 dropouts in our sample size calculations. 20 out of the remaining 25 participants elected to continue with the study after 3 months. We had no apriori expectations about retention after 3 months but again feel that this rate is acceptable given that few dietary interventions are effective for all participants and that dropouts are an inevitable reality in clinical research. Thus we feel that recidivism observed was within the normal limits of behavioral research standards and does not reflect a major concern with the study intervention.

A shift towards a plant-based diet?

This pilot study was designed to detect within group changes in selected dietary variables as well as between group differences in change in the recommended food score (RFS) – a measure of dietary pattern quality. The main goal of the study intervention was to facilitate a "shift towards a plant-based dietary pattern" in intervention participants. Interestingly, control participants exhibited changes in dietary pattern (in a plant-based direction) that may have stemmed from enrolling in the study. However, these changes were smaller than those observed in intervention participants and with the exception of a worsening of the RFS by 2.4 points (max=21) were not statistically significant. However, it is possible that a lack of statistical power contributed to this result.

In contrast, within group changes among intervention participants demonstrated statistically significant changes consistent with a shift towards a plant-based diet, including reductions in total calories, fat, saturated fat, dietary cholesterol, meat and dairy servings and increases in fruits and vegetable servings, fiber and the recommended food score. Both plant-based dietary indexes also increased significantly. For example, the Plant-based Diet Index (PDI, the proportion of total food calories derived from plant source, where only foods that could be clearly labeled as being of either plant or animal origin where included in the denominator) increased by 30% at 2 and 3 months and 21% at 9 months compared to baseline.

A comparison between intervention group 1 at 2 months and the control group revealed statistically significant differences in fat, saturated fat, percent of calories from sugar, the recommended food score and both plant-based diet indexes. Here again, though, statistical power likely limited these observations as we employed a fairly conservative statistical approach (excluding participants whose group did not overlap in time and thus substantially limiting our sample size). Still, this suggests that changes observed in intervention participants were related to participating in the study and/or the study intervention (i.e. the vegan healthy eating program), rather than random dietary fluctuations or the effect of simply enrolling in the study.

Dietary changes were preserved throughout the study period, at least among participants who remained in the study (n=20 out of 29 enrolled, or 70% of the original sample). There were no statistically significant differences between changes in dietary variables at 2, 3 or 9 months. However, with the exception of a decrease in % fat and increase in % carbohydrates, all other dietary variables changed maximally at either the 2 or 3 month timepoint. This suggests that the maximal degree of dietary change occurred between the 2 and 3 month point (i.e. at the end of the study intervention) but also that despite a minimal amount of post-intervention support, dietary changes were maintained to a significant degree up until the end of the study. Support for this conclusion also comes from observations of weight loss (discussed below) which progressed throughout the study period.

It is not known whether changes observed at 2 and 3 months could have been furthered or better maintained had more support or a continued educational intervention been offered. Since, support is a well-recognized enhancer of plant-based dietary change[150] and maintenance and because the degree of change is typically proportional to the intensity of intervention,[45, 55, 56] it is more likely than not that 9 month changes could have been even greater if a more intensive intervention was offered.

Although, a sub-maximal shift of dietary pattern likely occurred during the study intervention period, it is unlikely that a maximal shift to a whole foods, low-fat, plant-based dietary pattern was achieved. For example, percent of calories from fat moved from a baseline mean of 39.3% to 34.0% at 2 months. This is a relatively small (although potentially meaningful) shift relative to more intensive interventions that have achieved a mean of less than 10% of calories from fat.[137] Saturated fat, however, decreased from a mean of 24 grams to 13.3 grams at 2 months, and combined fruits and vegetable servings increased from 6 servings (considerably higher than the national average[x]) to 8.6 (near the recommended maximal goal of 9 servings). We also saw a significant change in both our plant-based diet indexes although not a maximal change. The PDIT (the more conservative of the two measures - the proportion of plant-calories out of all calories - which excludes ambiguous and clearly established deleterious items from the numerator) increased from a baseline mean of 34.4% to 59.1% at 2 months. The recommended food score, however, only increased on average from 8.7 to 9.8 points at 2 months (p=0.04, max possible =21 points). Thus, while meaningful change likely occurred, maximal change likely did not.

[x] In 1994-1996, only 28% of the US population ate 2 or more servings of fruit, and only 49% ate 3 or more servings of vegetables per day.[184]

An explanation for this observation can be attributed to at least 6 factors: 1. our intervention was tailored to each group but not (to a large degree) to each individual. One-on-one dietary counseling, for example, may have been useful at maximizing change within each individual and thus within the group as a whole; 2. Our intervention sought to change individual perceptions and dietary habits but did nothing to address the environment in which dietary patterns play out. For instance, we did not go into our participants' homes or workplaces to help improve their daily nutritional environment; 3. Family support, which is known to aid efforts at initiating and maintaining dietary change,[150] was not incorporated into our intervention; 4. Our intervention was not maximally intense as only 6 educational sessions and 4 maintenance sessions were held over the 9 month period; 5. Our ability to detect dietary change was limited by the outcome measures utilized (i.e. a food frequency questionnaire) as discussed below; and 6. We did not offer participants a structured dietary plan (e.g. daily menus, pre-prepared meals, etc.) but instead sought to educate our participants about diet in a broad sense and then to observe what change would result from this effort alone.

There were 3 major constraints limiting our ability to accurately detect dietary change in this study (2 of which apply to all our observations). First was our use of a food frequency questionnaire (FFQ). FFQs, and indeed all dietary measures, are notorious for underreporting dietary intake. For example, in our study, baseline total calories (as reported by FFQ) were found to be 1968 Kcals (SD=655). Given that our study participants had a mean baseline BMI of 40.4 Kg/m^2 (placing them just above the class 3 or "severely" obese cutoff), this caloric value can only be consistent with the measured BMI by one of three mechanisms: 1. The FFQ value is too low and reflects substantial underreporting of dietary intake for whatever reason; 2. The value is accurate and suggests that participants had acutely lowered their dietary intake just prior to the study; and/or 3. The value is accurate and participants have extraordinarily low daily activity levels. With the exception of the last reason (which we believe may reflect reality for two-three participants at most), either of the first two reasons would have limited our ability to detect dietary change attributable to our intervention. A 3-7 day food diary would have allowed for more accurate reporting, but this was not feasible given resource limitations for this pilot trial. Still, all self-reported dietary intake measures are subject to social reporting bias. (Whereas most other established methods that do rely on self-report do not allow for real-world observation) Thus, we made a sincere attempt to minimize social reporting bias by repeatedly explaining (in depth) the importance of honest reporting to our research participants (both to the group and to each individual at each data collection session). However, our study intervention was designed to influence the social bias of the group towards plant vs. animal products. If successful, this effort would be predicted to effect both reporting of intake and actual intake, but possibly to differing degrees.

Second, our sample size was small leading to increased likelihood of type 2 error (i.e. a real change occurred but we could not detect it). Still, we felt the total n was appropriate given the pilot nature of this program and appeared to be sufficient to capture some degree of change at least.

Third, our control arm was both small in size (n=8) and duration (t=4.3 weeks). This is clearly a major limitation but it is not unique to our study. Participants in obesity behavioral studies (or other lifestyle modification trials) will rarely remain in a long-term no-treatment arm. This problem can be solved by a comparative randomized trial, but this required resources that were not available for this pilot study.

Perceived Dietary Change

In this study, a relatively simple measure of perceived dietary pattern, the Vegan-Omnivore Scale (VOS), demonstrated changes consistent with dietary change measured by the more elaborate food frequency questionnaire. Here again, the control group exhibited a small but non-significant shift towards a vegan or plant-based diet (moving 1.4 points to a mean of 7.2 on this 10 point scale, where 1=vegan, 10=omnivore, $p=0.14$) whereas the intervention group moved 5.4 points after 2 months to a mean of 2.3 ($p<0.001$). Mean VOS change at each timepoint also supports our conclusion that peak change among intervention participants likely occurred between 2 and 3 months.

At 2 months, the VOS correlated modestly with several (but not all) expected dietary variables such as cholesterol (rs=0.51), fiber (rs=-0.43), and the plant-based diet indexes (e.g. PDI rs=-0.68) and, importantly, with weight change (rs=-0.40). Similar results were found at other timepoints as well as with change in dietary category (another marker of perceived dietary change). In these analyses a Spearman correlation was calculated on quintiles of dietary change variables and weight, and this conservative approach may have limited our observations. Still, these simple measures of dietary pattern appeared rather robust in this study and their use in future studies seems warranted.

In some ways this is a surprising conclusion, because self-reported dietary categories are usually vague representations of reality at best. For example, in a recent review article, it was reported that up to two-thirds of self-reported 'vegetarians' eat meat, fish or poultry on a regular basis.[66] However, the scales used in our study included detailed definitions of each dietary category or pattern, which may account for our results.

Novel Dietary Indexes

Although the phrase is often used, there exists no standard definition for a "shift to a plant-based diet" nor any standardized measure to quantify this shift. Thus, we began development of two indexes, which we named the Plant-based Diet Index (PDI) and the Total Plant-based Diet Index (PDIT). We defined these scales prior to collecting data on our participants with the hope that changes in these scales would a) be observed, and b) correlate with other desired changes.

As described above, significant changes were observed in both indexes at all timepoints. These changes were also statistically significant when compared to those observed in the control period. Both indexes suggested that the intervention effected a sub-maximal but significant shift towards a plant-based diet by facilitating a reduction in intake of foods of animal-origin and/or and increase in intake of foods of plant-origin. Although both indexes did correlate modestly with several relevant dietary change variables, we can't draw conclusions about these correlations because all variables were derived from the same outcome measure (i.e. the FFQ). However, both indexes also correlated modestly with changes in perceived dietary pattern, self-efficacy and motivation to eat a plant-based diet, and with weight changes. In general, the PDIT appeared to have slightly stronger correlations, perhaps because it was the more conservative measure of dietary change and did not exclude any food items.

Both indexes were affected by the strengths and weaknesses of the Block FFQ used in this study. We selected this FFQ in part because it included several important plant-based items (such as soy milk, tofu or meat-alternatives) that would not be captured by other FFQs. However, like most FFQs, the Block FFQ contained items of mixed plant and animal origin as well as items that could be prepared with or without animal-origin foods (e.g. pizza, Chinese food, etc.). We were forced to label these items as “other” and excluded them in the PDI and only included them in the denominator of the PDIT. At baseline, these “other” items accounted for almost 40% of reported calories in our participants. Thus, we would expect that such a large “other” category would limit our ability to detect a shift to a plant-based diet by these indexes. This problem could be easily avoidable in future research by employing a food-dairy method of measuring dietary change or by modifying the FFQ accordingly.

Another weakness of these indexes is their limited ability to distinguish between high and low quality plant-based foods, as the indexes are only a measure of caloric contribution. This is important because many (if not most) healthy plant-based foods are of very low caloric content (e.g. fruits and vegetables) and many unhealthy plant-based foods are of high caloric content (e.g. French fries, refined carbohydrates, etc.). We were able to minimize this problem by the creation of the “other” category, which contained the majority of the “more unhealthy” plant-based items. Although the goal might be to eventually limit the contribution of the “other” category in future indexes as discussed above, the nature of this phenomenon must be accounted for somehow. Perhaps the solution will be to delineate sub-categories within the “plant” category that reflect dietary quality.

In this study, our novel indexes correlated well with an objective measure of clinical improvement, i.e. weight change. Future research is needed to further elucidate the value of these indexes and their ability to predict outcome.

Improvements in weight management?

This pilot study was successful at demonstrating modest and progressive short-term weight loss. By 9 months post baseline, intervention participants had lost 5.5% of their initial body weight (8.8 lbs) on average. As discussed, this observation is limited by our small control period (during which participants gained an average of almost 3 lbs in 4.3 weeks). Thus whether the weight change observed in intervention participants was due to our intervention or to some other unknown factors can not be known with certainty. However, we did not observe increases in activity that could account for the weight loss. In fact, if anything, activity decreased during the study period. We retained about 70% of our participants until the end of the study, but loss of participants may have influenced our results. Including dropouts in our intention to treat analysis did not significantly change our outcome (7.8 lbs vs. 8.8 lbs at 9 months), but we can not know how outcomes would have changes were we able to retain 100% of participants. We also attempted to adjust for several socio-demographic variables, none of which appeared to make major contributions to the observed weight change. With no intervention we would expect these participants to gain weight over time (as occurs in the general population). Thus, we feel modestly confident that our intervention aided weight management efforts in our participants.

In addition, our study of body composition changes on the subset of participants that fit on our DEXA scanner revealed consistent findings (a mean of 12.8 lbs weight loss at 9 months with roughly equal loss of lean and fat mass). The loss of lean mass in addition to fat mass is not too surprising but is notable. That said, we can not be sure what proportion of the “lean” mass included loss of peri-visceral fat or intramuscular fat.

At different timepoints, weight loss correlated modestly with a decrease in dietary cholesterol, an increase in percent carbohydrates, an increase in fruits and vegetable servings, a decrease in meat servings and calories from animals, increases in plant-based indexes and the recommended food score and a decrease in the Vegan-Omnivore Scale (i.e. movement towards vegan). These observations are consistent with findings in the literature that suggest a plant-based diet improves weight management.[179, 182]

What is intriguing about our pilot was that we did not observe a peak in weight loss. This suggests that our participants achieved a small but significant caloric deficit that was maintained throughout the study. This is exciting because our goal was to facilitate the adoption of a sustainable dietary pattern conducive of improved long-term weight management.

As with dietary change, we expect that a more intensive intervention would have produced more dramatic results. However, we specifically elected to study dietary change and not comprehensive lifestyle modification. How this intervention would contribute to a comprehensive lifestyle modification program for weight loss or maintenance is not known, but certainly worthy of study. Unfortunately, this study did not afford the opportunity to compare our intervention with other available treatment approaches.

Blood Pressure, Lipids and Glycemic Control

This study was not designed to detect statistically significant changes in the physiologic outcomes measured. Still by the 9 month point we observed changes in weight that should be sufficient to induce changes in physiology in some patients. (Generally, 5-15% loss of initial body weight is required, we observed 5.5%).

Average blood pressure dropped in both control and intervention periods. However, significant within group change was only observed in the intervention group at 3 months (both systolic and diastolic, -8.7 and -5.9 mmHg) and at 9 months (systolic only, -7.5 mmHg). Between group changes were not statistically significant, likely because blood pressure exhibits large degrees of within person variability and out sample size was small.

Blood draws were not done in the control group and thus only within intervention group changes were observable. We observed progressive decreases in total cholesterol and LDL cholesterol at 3 and 9 months, but these were not statistically significant. Reductions in HDL were also observed at both timepoints and these were statistically significant. A short-term reduction in HDL is often observed in patients who increase carbohydrate intake (e.g. those who move towards a plant-based diet). The significance of this is a topic of great debate. In studies of patients with severe coronary disease, shifting to an almost exclusive plant-based diet was associated with a transient reduction in HDL but improved clinical outcomes both in the short term and in the long term.[135] The explanation offered for this observation is that the reduction in HDL does not reflect a decreased ability to remove cholesterol from the body (as it likely does in epidemiological studies that have strongly associated low HDL levels with risk of heart disease) but rather reflects a decreased need to excrete cholesterol (thanks to a change in dietary pattern). Nonetheless, it was encouraging that total and LDL cholesterol continued to decrease over time in our participants, whereas HDL decreased maximally at 3 months and thus the ratios of total and LDL cholesterol to HDL cholesterol did not change significantly at 9 months.

Triglycerides did not change significantly at either 3 or 9 months although we saw wide variation in triglyceride changes (SD=61 and 41 mg/dl at 3 and 9 months). Similar to HDL, triglycerides may worsen with increasing carbohydrate loads. For some of our participants prone to hypertriglyceridemia these changes may have been clinically significant (although, the mean baseline triglyceride was only 130 mg/dl, SD=54). This highlights the potential benefits of incorporating individualized dietary and exercise counseling into a vegan healthy eating program.

We observed decreases in fasting glucose at both 3 and 9 months in participants with impaired fasting glucose at baseline, but these too were not statistically significant. Curiously, glycosylated hemoglobin did change significantly in this subset except at 9 months (+0.55%). These results are inconsistent with each other, but since glycosylated hemoglobin is a more chronic measure of glycemic control it is likely the more representative of the two measures. Assuming that glycemic control did worsen slightly at 9 months this may be accounted for partially by the decrease in activity observed at 9 months (which was not observed at 3 months) and was possibly compounded by an increase in carbohydrate load. Interestingly, at baseline our participants reported consuming only 46% of calories from carbohydrates. This suggests that our participants were consciously or unconsciously restricting carbohydrate intake, which may be a common reaction to worsening insulin resistance (which often accompanies worsening obesity). In this context, a worsening of glycosylated hemoglobin should not be interpreted as a worsening of insulin resistance or diabetes but rather as an unmasking of insulin resistance.

Other limitations

The three main limitations to this study have already been discussed – the small sample size, the lack of a long-term control group, and the use of food frequency questionnaires to measure dietary change. Other limitations include our inability to accurately distinguish between the contributions of the various intervention components (e.g. the health and nutrition education vs. the group support inherent to group interventions vs. the environmental and animal ethics education, etc.). The degree of randomization was also a limitation to our between group analysis. Although we did randomize participants who could attend either a Wednesday or Monday group to one or the other, this only constituted 6 of the 29 participants enrolled. Nonetheless a comparison of control vs. intervention groups did not reveal any significant differences in socio-demographic, weight and selected behavioral and dietary variables. Finally, the short length of this study is also a major limitation.

The use of non-traditional motivators for dietary change

Social marketing tactics to curb behavior have been widely utilized in public smoking cessation campaigns but much more rarely in dietary change efforts. Yet the potential use of motivators other than a concern for health in a manner analogous to social marketing warrants exploration given the widely held understanding that dietary choices are shaped by numerous factors beyond a concern for personal health. This pilot trial was the first study we know of to utilize a range of "vegan motivators" to influence dietary choices in an obese population. As discussed above, the feasibility of employing such an approach, the satisfaction with the approach reported by our participants, and the outcomes achieved supports the inclusion of such motivational tactics in future research trials.

Beyond the implications this study has on future research are its implications on the nature of dietary discussions. For it is perhaps remiss to discuss diet from a clinical or public health perspective without acknowledging the larger implications of dietary recommendations. Population wide dietary patterns have substantial influence on (and in turn, are influenced by) agricultural and food-related industries – two of the world's largest industries. Collectively, these industries have a dramatic impact not only on public health but also on the health of our global environment and our economy. The interactions between diet, agriculture, the environment, public health, and the economy are understandably complex. Still, they are worthy of consideration when offering dietary advice to the population at large. For example, recommendations to consume large quantities of fish for cardiac protection should be tempered with the recognition that the world's oceans have been perilously over-fished. Likewise, proponents of high animal protein diets (aka 'low carb' diets) should recognize the enormous resource strain and pollution caused by widespread adoption of these dietary patterns. Given that there are many dietary options available to western populations, these factors should be considered in weighing the pros and cons of each pattern. Furthermore, it can be argued that clinicians, researchers and public health advocates have a responsibility to develop and advocate dietary health promotion and disease prevention strategies that benefit not only human health but the larger world we depend upon.

The use of vegan diets in clinical settings

This study did not aim to place participants on a vegan diet. However, the benefits of a vegan dietary pattern were emphasized throughout the intervention and a number of our participants elected to adopt a vegan or near vegan dietary pattern. There are important limitations to the use of vegan diets for both short and long-term dietary interventions, however these limitations are often poorly understood in both the scientific and lay communities. The largest perceived limitations are nutritional adequacy, supplementation, social stigma, costs, and the reality of the current nutritional environment.

Fears of vegan diets being nutritionally inadequate are often over-blown. It is the joint position of both the American and Canadian Dietetic Associations that vegan diets can be nutritionally adequate.[67] Even low-fat, vegan diets used in long-term clinical trials have been shown to be nutritionally adequate.[183, 184] However, it is true that planning both an "adequate" and an "optimal" vegan diet requires both skill and attention and benefits from the use of supplemented foods (see below), but the same must be said for non-vegetarian diets. Of course, a vegan diet, in the most general sense of this term, is not guaranteed to be nutritionally adequate, as discussed in the background section. This may be especially true for people who adopt a vegan diet for non-health based reasons. Thus, it is probable that clinically applied vegan diets are more often nutritionally adequate than freely adopted vegan diets; although, this is a matter worthy of scientific study.

Vegan diets, in the modern nutritional environment, should be supplemented for certain micronutrients, especially vitamin B12. Some individuals eating a vegan diet would also benefit from individualized dietary counseling and/or supplementation with iron, zinc, vitamin D, calcium and essential fatty acids.[67, 185] Fortunately, a multi-vitamin/mineral supplement and/or fortified soy or rice drinks can be utilized with relative ease to meet these needs. Given that most vegetarians meet or exceed the RDA for protein, there is no general indication for protein supplementation. Similarly, protein-combining at each meal in unnecessary.[67] Finally, in both vegan and non-vegetarians alike there is potential for insufficient and excess caloric intake, and care should be taken to avoid either of these extremes.

Contrary to popular perception, vegan diets are not inherently more expensive than non-vegan diets. In fact, the reason why the majority of the world's population subsists mainly on foods of plant origin is because of cost. However, fast, convenient or ready-made vegan foods may in fact be more expensive than non-vegan options (e.g. McDonalds).

Labeling a dietary pattern with a name tends to bring on stigmatization and social isolation. Historically, some self-defined "vegetarians" and "vegans" in Western populations experienced significant degrees of social isolation.[154] This probably remains true today, but to a lesser degree. In general, stigmatization and social isolation are associated with poorer health outcomes. Whether these social forces have a significant impact on vegetarian populations is an intriguing question that has not been well studied. Fortunately, trends indicate that "vegetarianism" is slowly gaining popularity,[67] and this may lead to less stigmatization and social isolation.

The fact that vegan options are not as accessible as non-vegan options in the current nutritional environment is both an advantage and disadvantage. For example, having less food available could be theorized to decrease caloric intake, which given the current obesity epidemic would be advantageous. On the flip side, decreased food availability might make a vegan diet less sustainable for a variety of reasons. However, it should be argued that decreased access to some vegan options (such as fresh fruits and vegetables) is a major disadvantage for both vegans and non-vegans alike. It is also important to note that access to vegan food options has been increasing steadily over the past few decades because of increased demand.[67] Importantly, advocating a plant-based or vegan diet should also have the effect of increasing demand and thus increasing access to plant-based foods.

Future directions

Like most research, this pilot study has raised more questions than it set out to answer. Several potential directions for future research have been alluded to in the above discussion. For example, it would be interesting and worthwhile to assess the impact of a vegan healthy eating program on the maintenance of dietary change and weight loss as achieved by a more intense dietary change or comprehensive lifestyle modification program. In addition, methods to enhance the impact of this type of dietary education (e.g. behavioral psychological techniques) may be worth exploring. Whether this type of education is more effective in individual vs. group vs. a combined setting should be studied, as should the impact of this approach compared to more standard means of dietary counseling. **Above all, a long-term randomized controlled trial is warranted to explore the impact of using motivators beyond health on our ultimate goal: the long-term maintenance of healthy dietary change and weight loss for the prevention and treatment of obesity.**

APPENDIXES

Announcing the pilot study of…

V.H.E.P.

The Vegan Healthy Eating Program

for

Adults with Obesity

INSIDE:

- ***Learn more about an exciting new educational program that could change the way you think about food…***
- ***Find out if you're a candidate to join this free study…***

Mark Berman
V.H.E.P. Study Director
415-332-2525 ext. 290

What is the Vegan Healthy Eating Program (*V.H.E.P.*)?

V.H.E.P. is an educational program designed for adults with obesity.

It is a unique program that teaches participants how to make food choices that can dramatically impact their **health** and may improve their ability to manage their weight.

Participants will also learn compelling facts about the **environment** and the treatment of **animals** that could change the way they eat…

The program provides an overview of 'vegan nutrition' and will explain the many benefits of:

- *Increasing the amount of fruit, vegetables, whole grains, and beans we eat*
- *and decreasing or eliminating foods made from animals…*

The program will be taught by specialists in obesity, medicine, nutrition, psychology, politics and food production.

This is not a diet!

Participants will **not** be asked to count calories or follow a specific diet.

We believe people can make food choices that are best for themselves, when given the appropriate tools. This program will provide important information, an opportunity to learn new skills as well as a unique learning experience designed to help participants make "well informed food choices" that may prevent weight gain or enable weight loss.

Program Overview: When & Where?

The study period will last 3 – 4 months.

The program consists of 6 *core sessions*, each 2.5-3 hours long. Held once a week, over a 6 week period, each session will be a mix of lectures, videos and discussions.

These will be followed by 1.5-2 hour *maintenance sessions*, every second week, for another 6 weeks. These will be practical sessions about cooking, shopping and other related topics of interest.

All sessions start at 6pm and will take place on either a Monday or a Wednesday night. They will be held at UCSF (505 Parnassus Ave).

Dinner will be provided at core sessions.

What else is involved?

In order for us to determine whether the program has any affect on diet, health or weight, participants are asked to take tests (described below) before, during and after the program.

The before and after tests include:

- Food and Opinion Surveys**
- A body composition scan (*a DEXA scan*)
- A blood draw (*to look at cholesterol and other lipids, and blood sugar*)
- Body measurements (*height, weight, waist and hip*) & blood pressure.**
- Wearing a physical activity monitor (*it sits on your waist like a pager*) for 4 days.

*** These tests will be repeated in the middle of the program as well.*

Appendix – Recruitment Pamphlet: Front & Inside Covers

Am I eligible to join the study?

To find out – Check each box that pertains to you:

- ☐ I am 21 years of age or older
- ☐ I am overweight and for my height might be considered obese[†]
- ☐ I can shop for food and prepare meals for myself
- ☐ I am not currently a strict vegetarian
- ☐ I have not had bariatric (stomach stapling) surgery
- ☐ I am not using drugs or a liquid-only diet to lose weight
- ☐ I am not pregnant
- ☐ I do not have cancer
- ☐ I can be free on either Monday or Wednesday night for the next 3 months
- ☐ I am interested in learning about food choices and healthy eating.
- ☐ I am not planning on joining another weight management program in the next 3-4 months.
- ☐ I am willing to be an active member of the participant team – to learn with, learn from and teach other participants when possible!

If you checked every box then you are probably eligible to join the study!

[†] If you have a **Body Mass Index** (BMI) of 30 or more you would be considered obese. To calculate your BMI, divide your weight (in Kg) by your height (in meters), then divide this by your height (in meters) again. Or use pounds for weight and inches for height and multiply the final number by 705. *We can help you with this calculation!*

Answers to Frequently Asked Questions:

How much will this cost me?

Nothing! Participating in this study is FREE. Aside from the time and effort needed to participate, there should not be any costs to you for participating in the study.

You will also be reimbursed for parking expenses and given $15 for each data collection session.

What does "vegan" mean?

Vegan is a general word used to describe a dietary pattern that does not include foods made from animals (milk, meats, eggs, fish, etc.)

Do I have to become vegan in order to participate?

No. The educational program might enable you to change your *dietary pattern* but this study is not designed to test a specific *diet*. You will learn many of the pros and cons of eating vegan foods and will be encouraged to shift your diet towards a vegan dietary pattern, but joining this study does not require you to change your current diet.

Can I still use other weight loss strategies and programs?

You are free to continue using some other weight-management strategies, including support groups and exercise counseling. However, we ask that you not start additional programs during the study period.

Is it still worthwhile to participate if I don't lose weight?

Yes! Participating in the program should be a worthwhile experience even if you don't lose weight. There are many other health and psychological benefits that may result from learning about and adopting healthy eating. You may also enjoy this group education format and learning first-hand from a diverse group of experts.

Will the program be challenging?

Some people may find the program more challenging than others. Trying to adopt healthier eating habits can be difficult, but we will support you with our best efforts to make this transition easier.

Also, learning about some of the topics, such as the treatment of animals in modern farms or how obesity affects health may be disturbing. We will address these topics in the most sensitive way possible. Many people who have learned about these topics have used their new knowledge to transform their lives in a positive way. We hope that you will find this program to be an important vehicle for improving your life.....

How to sign up or find out more:

Contact the V.H.E.P. Study Director:

Mark Berman
(W) 415-332-2525 ext. 290
(C) 415-205-6202
markberman@yale.edu

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO BE A RESEARCH SUBJECT

The Pilot Trial of the Vegan Healthy Eating Program for Obese Adults

A. PURPOSE AND BACKGROUND

Mark Berman from Yale University School of Medicine and a Doris Duke Clinical Research Fellow at UCSF, Robert Baron, MD, from the Department of Medicine and the Principal Investigator of this study, Ruth Marlin, MD from the Preventive Medicine Research Institute (PMRI), and Dean Ornish, MD, from the Department of Medicine and PMRI are conducting a study to learn whether an experimental educational program can help obese individuals eat a healthy vegan diet that will maintain their recent weight loss or cause them to lose weight. A vegan diet is based on vegetables, fruits, grains, beans and other legumes, nuts, and seeds and does not contain foods made from animals (e.g. milk, red meat, chicken, fish, etc.).

This study is being funded in part by the Doris Duke Charitable Foundation and by the General Clinical Research Center (GCRC) at UCSF.

You are being asked to participate in this study because you are obese and are interested in maintaining your current weight loss or loosing additional weight.

B. PROCEDURES

If you agree to be in this study, the following will happen:

1. You will be asked whether you are able to join the Monday or the Wednesday group. Both groups meet at the same time and place, but one only on Mondays, the other only on Wednesdays. One of these groups will begin 4-6 weeks after the other. If you can only attend Monday or only Wednesday, you will be placed in that group if there is still room in it. If you can attend either group, your placement into one of the groups will be assigned by a computer (i.e. by chance).
2. You will be asked to fill out a number of questionnaire forms about your current health and your eating habits. Then your weight, height, waist, hip and blood pressure will be measured. This should take 70 to 100 minutes.
3. You will be asked to return to the GCRC after fasting overnight to have a small amount of blood (approximately 2 tablespoons) collected. This blood will be analyzed to look at your cholesterol and lipid values and blood sugar. The blood draw should take about 5 minutes.
4. After the blood draw your body composition will be analyzed to determine how much muscle, fat and bone you have. This will be done using a dual energy X-Ray absorptiometry (DEXA) scan. The DEXA scan will give information about the amount of muscle, fat and bone in your body. For this measurement, you will lie on your back on a table and be scanned from head to toe by a machine that measures the absorption of X-Ray energy through your body. This should take 15-20 minutes. If you are a female of child-bearing age you will be required to have a pregnancy test

performed prior to the DEXA scan. This involves collection of a urine sample. If the pregnancy test is positive, the DEXA scan will not be done.

5. After the DEXA Scan you will be given an Activity Monitor to wear for 4 days. This is a little box about the size of a pager that measures movement. This will give us an idea of how much daily activity you do.
6. You will be notified by phone of the exact starting date of the educational program.
7. If you are in the second group, you may be asked to return to the GCRC to fill out the food questionnaires and repeat the body measurements (height, weight, waist, hip, blood pressure). This should take 70-100 minutes.
8. The first and main part of the educational program will be held once a week for 6 weeks, starting at 6pm on either Monday or Wednesday. Each session will last 2.5 to 3 hours and about 30 minutes of 'homework' will be assigned each week. The course will be held at the General Clinical Research Center (address below).
9. Each session will have several parts: Most sessions will begin with a "group check-in" where every participant will be asked to share their recent experiences or thoughts about their current diet. One or two lectures or videos will be presented followed by a question, answer and discussion period. *The topics of each session are included on a separate paper, please review them and ask any questions now.* The fifth session will include a video about animal farming which contains some graphic material about how cows, chickens and pigs are raised for food. This material is representative of current factory farming conditions. At the end of the session you will be asked to fill out a short survey to tell us your thoughts about that particular session. The survey should take 5 to 10 minutes maximum. Some of the lectures given during the sessions may be videotaped for the purposes of improving future courses or providing make-up sessions. However, the video recorder will be set up so that none of the participants will be videotaped.
10. If for some reason you miss a session, we will try to provide you with alternative materials that cover the same topic as the session. This may involve reading or watching one or more videos.
11. Within 1 to 2 weeks of ending the 6th session you will be asked to return to the GCRC to repeat the questionnaires, body measurements, and blood pressure.
12. The second part of the education program will begin within 1 to 2 weeks of the last session (i.e. the 6th session) and will run on the same day (i.e. Monday or Wednesday) but for only 1.5 - 2 hours and only every 2nd week for 3 sessions. These sessions will be designed to help you maintain any dietary change that occurs during the first part of the program. The content of the sessions will be similar but will be focused more on practical aspects of food preparation, eating and shopping. The content will be designed based on the feedback and desires of each group.
13. At the end of the study period (3 months from the start of the course) you will be asked to return to the GCRC one last time to repeat the questionnaires, body measurements, blood test, DEXA Scan and Activity Monitor.

Participation in the study will take a maximum of 3.5 hours per week for 6 weeks, then a maximum of 2 hours every second week for another 6 weeks. There will also be 3 (or 4) separate sessions for the questionnaires and blood draw which will last about 1.5 - 2 hours. In total, this is a minimum of about 27 hours and maximum of 35 hours over a period of 3 months.

All study procedures will be done at The General Clinical Research Center at U.C. San Francisco, 505 Parnassus Avenue, Room M-1296, San Francisco, California 94143. Telephone: 415-476-6148.

C. RISKS/DISCOMFORTS

The following risks/discomforts may occur if you participate in this study:

a) Some of the videotapes that will be shown in the educational sessions (mostly in session 5) are likely to produce unpleasant or strong feelings as they will contain some graphic material representative of current factory farming conditions (e.g. animals confined in tight quarters, animal handling practices that occur in the US, including animals being hit by frustrated workers, and the dragging of lame animals; as well as the transport, auction, living and slaughter conditions of factory farmed animals.), but you will be able to stop watching at any time, if you feel too uncomfortable. Similarly, some of the group discussion questions (e.g. what was your reaction to the information you just learned?) may make you uncomfortable or upset, but you are free to decline to answer any questions you do not wish to answer or to leave the group at any time.

b) Confidentiality: Participation in research will involve a loss of privacy; however, your records will be handled as confidentially as possible. The researchers will ask you and the other people in the intervention group to use only first names during the group session. They will also ask group members not to tell anyone outside the group what any particular person said in the group. However, the researchers cannot guarantee that everyone will keep the discussions private. No individual identities will be used in any reports or publications that may result from this study.

c) Venipuncture (Blood draw): The risks of drawing blood include temporary discomfort from the needle stick and bruising, and rarely, infection.

d) Vitamin B12: if you choose to adopt a completely vegan diet, you may have inadequate Vitamin B12 intake. While a B12 deficiency would likely take many months or years to develop and would not manifest during this study, this is an important and easily avoidable risk. Taking a multivitamin or using supplemented foods (e.g. fortified soy or rice milk, cereals, etc.) is an easy way to avoid this risk.

e) You may find participating in this study and the need to have testing and fill out questionnaires burdensome, frustrating or boring.

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f) Duel Energy X-Ray Absorptiometry (DEXA) Scan: The amount of X-Ray you will be exposed to is less than .05 mrem, which is significantly less (about 1/4) than a single chest X-Ray.

g) Activity Monitor: There is no risk associated with using the activity monitor.

Treatment and Compensation for Injury:

If you are injured as a result of being in this study, treatment will be available. The costs of such treatment may be covered by the University of California depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Committee on Human Research at (415) 476-1814.

D. BENEFITS

The potential benefit to you is that the educational program you receive may help you adopt a healthier dietary pattern and achieve weight loss or maintain weight loss, although this cannot be guaranteed.

Alternatively, you may receive no direct benefit from participating in this study. However, it is hoped that the information gained from the study will help the researchers learn more about how to improve people's ability to maintain a healthy diet and/or weight loss.

E. ALTERNATIVES

If you choose not to participate in this study, you could choose to receive no treatment for weight management or you could participate in any treatments aimed at maintaining weight loss without having to undergo the tests and education program involved in the study. These treatments include dietary counseling, group support sessions, very low calorie diets, exercise counseling, prescription drugs, bariatric surgery and commercial weight loss programs. With the exception of very low calorie diets, prescription drugs, surgery and commercial weight loss programs, you will still be free to participate in these other treatments while participating in this study. Information about vegan diets and their effect on health and the environment is available to the public in other forums.

F. COSTS

There is no cost for participating in this study.

G. PAYMENT

You will be paid a maximum of $60 for your participation in this study, $15 for each time you complete a set of questionnaires and a blood draw. You will be paid in cash immediately after you complete the set of questionnaires and blood draw. Your parking fees or public transportation fees for attending the sessions and completing the questionnaires and blood draw will also be reimbursed at the end of each session.

H. QUESTIONS

This study has been explained to you by Mark Berman, Dr. Robert Baron or Dr. Ruth Marlin or the person who signed below and your questions were answered. If you have any other questions about the study, you may call Mark Berman at (415) 332-2525 extension 290 or Ruth Marlin at (415) 332-2525 extension 228, or Robert Baron at (415) 476-0438.

If you have any comments or concerns about participation in this study, you should first talk with the researchers. If for some reason you do not wish to do this, you may contact the Committee on Human Research, which is concerned with the protection of volunteers in research projects. You may reach the committee office between 8:00 and 5:00, Monday through Friday, by calling (415) 476-1814, or by writing: Committee on Human Research, Box 0962, University of California, San Francisco/San Francisco, CA 94143.

I. CONSENT

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without jeopardy to your medical care at UCSF.

If you wish to participate, you should sign below.

________________________ ____

Date Subject's Signature

____________________ ____________________________________

Date Person Obtaining Consent

Appendix Figure 1. Designation of Plant, Animal or Other Category for Block 98.2 FFQ Items

Plant	Animal	Other
Tomato juice, V- juice	Cooking Fat - Butter	Cooking Fat - PAM OR NO OIL
Orange juice, grapefruit juice	Cooking Fat – Lard	Cooking Fat - Stick margarine
Real fruit juice excl. orange, grapefruit.	Reduced fat % Milk	Cooking Fat - Soft margarine
Drinks w. some juice, Sunny D	Cream in coffee	Cooking Fat - Half margarine, half butter
Peaches, apricots, fresh, seas	Cream/milk in tea	Cooking Fat - Diet margarine
Cantaloupe in season	Eggs or egg biscuits	Cooking Fat - Vegetable oil
Strawberries in season	Bacon	Cooking Fat - Olive oil, canola oil
Watermelon in season	Breakfast sausage	Cooking Fat – Crisco
Other fruits in season	Yogurt, frozen yogurt	KoolAid, Hi-C,Vit.C-rich drinks
Bananas	Cheese and cheese spreads	Soft drinks or Snapple not diet
Apples or pears	Cheese dish like macaroni/cheese	Breakfast or diet shakes, Ensure
Oranges, tangerines	Hamburger, cheeseburger	Beer (regular)
Grapefruit	Tacos or burritos*	Wine or wine coolers
Canned fruit, applesauce, etc	Beef (roast, steak, sandwiches	Liquor or mixed drinks
Cooked cereal or grits	Pork chops, roasts, dinner ham	Coffee
High fiber cereals	Veal, lamb or deer meat	Tea or iced tea (not herb tea)
Cold Cereal (Total, Just Right, etc.)	Ribs, spareribs	Pancakes, waffles, Pop Tarts, French toast
Cereal excl. fiber or fortified	Liver, liverwurst	Breakfast bars, Power bars, granola bars
Broccoli	Gizzard, neckbones, chitlins	Salad dressing
Carrots	Mixed dishes with beef or pork	Chili with beans (with or without meat)
Corn, fresh, frozen or canned	Mixed dishes with chicken	French fries, fried potatoes
Green beans or peas	Fried chicken	Coleslaw, Cabbage†
Spinach (cooked	Chicken not fried	Vegetable-beef/chicken soup, etc.*
Greens like collards	Oysters	Other soups (Chicken noodle, chowder, etc.)*
White potatoes baked, mashed	Shellfish (shrimp, crab, etc.)	Spaghetti, lasagna, pasta w. tomato sauce*
Sweet potatoes	Tuna casserole, tuna sandwich	Pizza
Green salad	Fried fish	Chinese dishes
Raw tomatoes	Fish not fried	Salty snacks (chips, popcorn)
Other vegetables	Hot dogs or dinner sausage	Crackers
Refried beans, bean burritos	Ham, boloney, lunch meats	Doughnuts, pastry
Baked beans, black-eye peas, pintos	Ice cream	Cake – regular
Vegetable stew	Butter	Cookies, regular
Lentil, pea or bean soup		Pumpkin pie, sweet potato pie
Pasta salad, other pasta dish		Pie or cobbler
Tofu, bean curd		Chocolate candy, candy bars
Meat substitutes (not just soy)		Candy (not chocolate)
Peanuts, other nuts & seeds		Biscuits, muffins
Dark bread, whole wheat, rye		Bagels, English muffins, buns, rolls
White bread, French, Italian, etc.		Cornbread or hush puppies, corn muffins
Rice or dishes with rice		Margarine
Tortillas - Corn or flour		Gravy
Peanut butter		Jelly, jam, syrup
Salsa, ketchup, taco sauce		Mayonnaise, sandwich spreads
		Mustard, BBQ sauce, other sauce

*note: analysis uses items with meat & dairy
†note: analysis includes mayo
Block 98.2 FFQ & Block Food Portion Diagram available from Berkeley Nutrition Services www.nutritionquest.com

The Vegan Healthy Eating Program – SURVEY

A BIT ABOUT YOU:

Please complete the following information to tell us a little bit about you. The information collected from this page will help us to tell how the participants in our study compare to other patients seen at UCSF clinics or the broader US population. It will also help us determine whether some groups of individuals do better than others in this program. We recognize that many of the questions are very personal, and we will ensure that your responses are kept confidential. Only the study directors and their research assistants will view these forms. Please leave blank any questions that you are uncomfortable answering.

1. What is your highest level of education?

☐ finished Grade School or less ☐ some High School ☐ High School Diploma or equivalent (GED) ☐ some College

☐ Associate Degree ☐ Bachelor's Degree ☐ some Grad School ☐ Master's or Doctorate Degree

2. Are you currently single, married or living with a partner?

☐ I am single or living alone ☐ I am married or live with my partner

3. What is your current employment status?

☐ I work full time (*40 hours of more per week*) ☐ I work part time (*20-39 hours per week*) ☐ I work less than part time (*less than 20 hours per week*)

☐ I am unemployed (seeking employment) ☐ Not seeking employment (e.g. retired, homemaker, etc.)

4. What is your approximate yearly **combined household** income?

☐ 0 – $10,000 ☐ $11,000 – $20,000 ☐ $21,000 – $30,000 ☐ $31,000 – $50,000

☐ $51,000 – $70,000 ☐ $71,000 – $90,000 ☐ $91,000 or more

5. Do you currently have medical insurance?

☐ Yes ☐ No

PART A: Your Current Diet:

The next 3 pages ask you about your current eating habits and how confident you are that you could change your diet, if you wanted to.

NOTE: *It is very important that you answer these and all questions on this survey to best reflect how you feel right now. Although some people may have strong opinions about these issues, this should not influence your responses. The quality of this research depends on your honesty. Please try to answer all questions but feel free to leave blank any questions that you are uncomfortable answering. Thank you!*

1. Please pick the 'diet style' that best reflects what you currently eat:

- ○ **omnivore** (e.g., a person who eats most animal, seafood, and fish products in addition to vegetables, fruits, and grains),
- ○ **dairy and fish vegetarian** (e.g., a person who eats vegetables, fruits, grains, dairy products, eggs, seafood, and fish but no white or red meat),
- ○ **lacto-ovo vegetarian** (e.g., a person who eats vegetables, fruits, grains, dairy products, and eggs but no seafood, fish, white meat, or red meat),
- ○ **vegan** (e.g., a person who eats absolutely no animal products including dairy products, eggs, seafood, fish, white meat, and red meat)

2. Please circle the number that best reflects what your current diet is like:

1	2	3	4	5	6	7	8	9	**10**
Vegan									**Omnivore**

3. Please fill in the circle the best answer to this question:

"Are you <u>currently</u> eating a plant-based diet (a diet that is mostly made of grains, vegetables, fruit, beans and legumes, nuts and seeds, and includes very little or no foods made from animals, e.g. milk, meats, eggs, cheese, fish, etc.**)?"**

- O YES (*please skip question 4*)
- O NO, I have **never** eaten this type of diet
- O NO, I used to, but **recently stopped** temporarily
- O NO, I have tried one or more times, and have **given up**

*If you picked any of these 3 options, please **go to question 4**.*

*4. A*re you <u>ready</u> to start eating a plant-based diet now?

- O YES
- O NO

Please answer each question below by circling a number on the scale underneath each question.

If it were recommended that you do any of the following, starting <u>right now</u>, how confident would you be that you could:

5. Eat less animal products (e.g. cheese, meat, eggs, butter) both at home and outside your home?

1 2 3 4 5 6 **7**
Not at all confident **Very Confident**

Feel free to explain why: ____

____

6. Eat more whole-grains (e.g. brown rice, whole wheat bread, oatmeal) both at home and outside your home?

1 2 3 4 5 6 **7**
Not at all confident **Very Confident**

Feel free to explain why: ____

____

Please answer each question below by circling a number on the scale underneath each question.

If it were recommended that you do any of the following, starting right now, how confident would you be that you could:

7. Eat less refined, processed or fast foods (e.g. white bread, white rice, margarine, French fries, oils, candy, etc.)?

1 2 3 4 5 6 **7**
Not at all confident **Very Confident**

Feel free to explain why: ____

8. Shop for and prepare meals that do not include animal products?

1 2 3 4 5 6 **7**
Not at all confident **Very Confident**

Feel free to explain why: ____

9. Eat a vegan diet despite the challenges this may pose?

1 2 3 4 5 6 **7**
Not at all confident **Very Confident**

Feel free to explain why: ____

10. Take a daily multivitamin containing vitamin B12?

1 2 3 4 5 6 **7**
Not at all confident **Very Confident**

Feel free to explain why: ____

The next section asks about your thoughts on eating a plant-based diet…

PART B: A Plant-Based or Vegan Diet

The next 3 pages ask about your thoughts on eating a plant-based or vegan diet.

List all the advantages and disadvantages that are important to you for decreasing the amount of foods, drinks or meals you eat that are made from animal products (e.g. milk, meat, cheese, eggs, etc.) and for increasing the amounts of food, drinks or meals you eat that are made from plant products (e.g. fruits, veggies, tofu, brown rice, etc.):

DECREASE THE AMOUNT OF ANIMAL-PRODUCTS *(beef and other meats, milk, eggs, etc.)*		**INCREASE THE AMOUNT OF PLANT-PRODUCTS** *(Fruits, Vegetables, Beans/Soy, Whole Grains, etc.)*	
Advantages		**Advantages**	
Disadvantages		**Disadvantages**	

A plant-based diet is a diet made of grains, vegetables, fruit, beans and legumes, nuts and seeds, and includes very little or no foods made from animals, e.g. milk, meats, eggs, cheese, fish, etc.

Please circle the number that best answers each question below:

1. How motivated are you to eat a plant-based diet?

1	2	3	4	5	6	**7**
Not motivated at all						**Extremely Motivated**

2. How difficult is it for you to eat a plant-based diet?

1	2	3	4	5	6	**7**
Not difficult at all						**Extremely Difficult**

State how much you agree with the following statements by circling a number next to each statement:

	Strongly Disagree	**Disagree**	**Undecided**	**Agree**	**Strongly Agree**
3. "I plan to eat a plant-based diet for the next month"	1	2	3	4	5
4. "I plan to eat a plant-based diet for the next year"	1	2	3	4	5
5. "In the future, I plan to eat a plant-based diet most or all of the time."	1	2	3	4	5

You Are HALF-WAY done!

PART C: Your Opinion about Food, Animals & the Environment

*The following questions ask for your opinion. There are **no** right or wrong answers to these questions. Please select the answer **you** most agree with.*

*Please read each statement below **VERY carefully**. State how much you agree with the following statements by circling a number next to each statement:*

	Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
1. "Eating a vegan diet would **not** improve my health."	1	2	3	4	5
2. "Eating a vegan diet would make it easier for me to maintain a healthy weight."	1	2	3	4	5
3. "I consider myself an animal lover."	1	2	3	4	5
4. "I **do not** consider myself an environmentalist."	1	2	3	4	5
5. "I know **more** about the treatment of farm animals than most people my age."	1	2	3	4	5
6. "I am **not** concerned about how farm animals are raised for food."	1	2	3	4	5
7. "Because of what I know about how animals are raised for food, I eat l**ess** meat and other animal products."	1	2	3	4	5
8. "I am concerned about the state of the environment."	1	2	3	4	5
9. "I know **less** about the state of the environment than most people my age."	1	2	3	4	5
10. "I am concerned about the impact of raising animals for food on the environment."	1	2	3	4	5
11. "Because of what I know about the impact of raising animals for food on the environment I eat **less** meat and other animal products."	1	2	3	4	5
12. "I know more about the fast food industry (working conditions, food safety, healthiness of fast foods, advertising practices, etc.) than most people my age."	1	2	3	4	5
13. "I am **not** concerned about the nature of the fast food industry or the foods sell."	1	2	3	4	5
14. "Because of what I know about the fast food industry, I eat **more** fast-food."	1	2	3	4	5
	Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree

PART D: A Food Quiz

The following questions are about diet and health, obesity, the environment and farming. Warning: THESE ARE VERY CHALLENGING QUESTIONS. We have purposefully made these difficult to see if our educational course has taught information that most people do not know. It is ok if you don't know the right answer to many or all of these questions, but try to guess the answer that seems most reasonable to you.

Circle the best answer:

1. Eating fruits and vegetables every day:

(A) Is not healthy, because it adds harmful sugar to my diet

(B) Helps protect against cancer and heart disease

(C) Should be limited because it adds too many calories to the diet

(D) Should be limited because fruits and vegetables may be sprayed with pesticides

2. Eating meat and dairy every day:

(A) Is the only way to get enough protein and calcium in the diet

(B) Is necessary in order to be healthy

(C) Adds fat and cholesterol to the diet and is not needed for good health

3. Losing a 'modest' amount of weight (e.g. 10-20 pounds) and maintaining that weight loss:

(A) Can significantly lower blood pressure, cholesterol and prevent the development of diabetes

(B) Will not make me any healthier

(C) Can only be achieved by eating meat and cutting out breads, pastas and sugars.

4. Most farm land in the US is used to:

(A) Grow fruits and vegetables for humans to eat

(B) Grow grains, cereals and legumes (beans) for animals to eat

(C) Grow grains to export to other countries

5. Today, the leading cause of species "dying out" (becoming extinct) in the US and in the Amazon rainforests is:

(A) Livestock (farm animals) grazing and growing food for animals

(B) Cutting down trees for housing, paper and firewood

(C) Natural disasters (hurricanes, floods, earthquakes, etc.)

6. Which of the following is most true?:

(A) It is **not** important to conserve (save) water unless there is a drought.

(B) It is recommended that we conserve water at all times and eating less meat is one of the most effective means to do this.

(C) It is recommended that we conserve water at all times and using less tap water (for example, taking shorter showers, using less water when washing dishes or clothes, etc.) is **more** effective than eating less meat.

7. To make 1 gram of animal protein or 1 gram of plant protein requires the same amount of energy:

○ TRUE

○ FALSE

8. Most manure from farm animals in the US is re-used as natural fertilizer:

○ TRUE

○ FALSE

9. The routine use of antibiotics in farm animals does <u>not</u> cause "antibiotic resistance" that affects humans:

○ TRUE

○ FALSE

10. Animal farming uses about four times <u>less</u> antibiotics than is used by humans (i.e. by doctors):

○ TRUE

○ FALSE

11. Animals are <u>not</u> fed to other animals in the US and the reason is because this may increase the risk of transmitting diseases like Mad Cow Disease:

○ TRUE

○ FALSE

12. Which of the following is most true?:

(A) About 90% or more of all animals raised for food in the U.S. are raised in "factory farms" (i.e. not on small family farms).

(B) About 50% of all animals raised for food in the U.S. are raised in factory farms

(C) Less than 20% of all animals raised for food in the U.S. are raised in factory farms

13. Every year, the number of animals killed for food in the US is about:

1. 1 **m**illion (1,000,000)
2. 10 **m**illion (10,000,000)
3. 100 **m**illion (100,000,000)
4. 1 **b**illion (1,000,000,000)
5. 10 **b**illion (10,000,000,000)
6. 100 **b**illion (100,000,000,000)

Thank You Very Much for completing the V.H.E.P. Survey!

Please take a minute to look over your answers and respond to any question you may have skipped. If you have questions please feel free to ask them before you turn this in!

There are some words in the survey that you may not be familiar with.
Here are some definitions that might be useful:

Animal products are foods that are made from animals. These include:

- **Meats** -- beef, pork, chicken, turkey, etc.
- **Fish and Seafood**
- **Dairy products** -- milk, cheese, ice cream, butter, yogurt, etc.
- **Eggs**

Some of these foods are contained in other foods (e.g. there is often eggs and dairy in muffins and cakes).

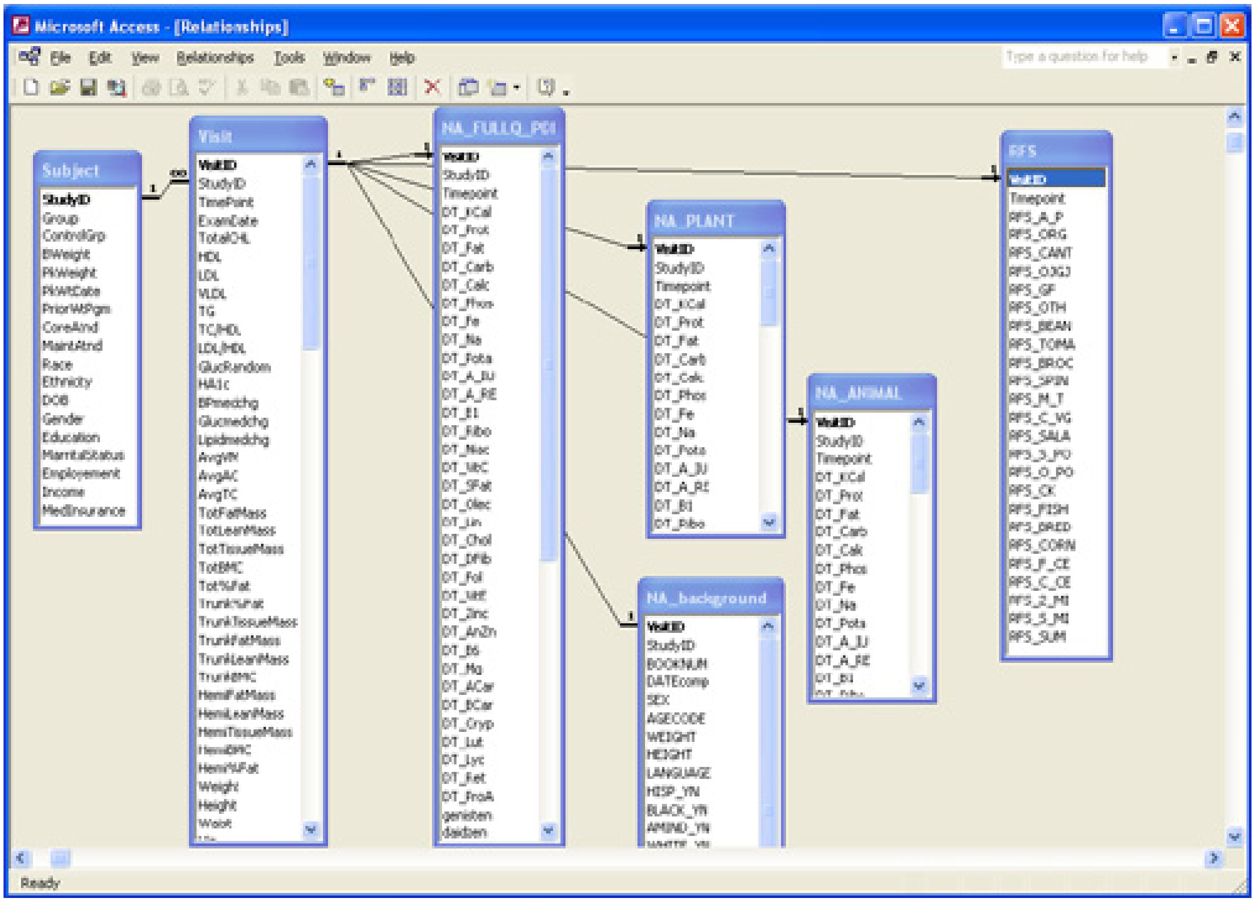
Plant products are foods that are made from plants. These include:

- **Grains** -- rice, wheat, oats, corn, etc.
- **Fruits** -- apples, oranges, berries, bananas, melons, etc.
- **Vegetables** -- broccoli, yams, lettuce, squash, cabbage, string beans, peppers, etc.
- **Beans and Legumes** -- chick peas, lentils, soy beans, tofu, split peas, kidney beans, black beans, etc.
- **Nuts and Seeds** -- peanuts, cashews, sesame seeds, walnuts, pumpkin seeds, sunflower seeds, etc.

A Plant-Based diet is a diet made mostly of grains, vegetables, fruit, beans and legumes (e.g. soy, tofu), nuts and seeds, and includes **very little or no** foods made from animals (e.g. milk, meats, eggs, cheese, fish, etc.)

A Vegan diet is a type of plant-based diet that contains **no** foods made from animals.

Appendix Figure 2. MS Access Relational Database used for Data Entry and Export (for analysis)



Selected Abbreviations: NA, Nutrient Analysis; RFS, Recommended Food Score

The Vegan Healthy Eating Program
Curriculum Overview

Session 1. Introduction – *Overview of study, obesity and vegan nutrition*

Part 1. Group check-in: introductions, instructions for future check-ins	**Mark, Dr. Marlin**	**30 mins**	Distribute name tags; Person-by-person intro (name, occupation/location, motivation for participating in VHEP…)
Part 2. Overview of study and all sessions: content and aims	**Mark**	**15 mins**	PPT: intro to ecological nutrition concepts, overview of sessions, speakers, study goals, expectations, procedures…
Dinner Break		**20 mins**	
Part 3. Discussion: Obesity – what is it and why does it matter? Health consequences of obesity and common co-morbidities.	**Dr. Baron**	**40 mins**	Definition; Risks – mortality, morbidity, diabetes, cardiovascular diseases, arthritis, cancers, etc.; psychosocial implications; Benefits of modest weight loss; available treatments for long-term weight loss maintenance; questions.
Break		**10 mins**	
Part 4. Lecture: Basic Vegan Nutrition – vegan food groups, sample meals	**Stacey Dunn-Emke**	**45 mins**	Definition of vegan; brief summary of health benefits of vegan diet; vegan food pyramid; getting 'enough' protein; sample menu and nutritional breakdown; tips for getting started; overcoming expected pitfalls. Questions.
Recap & Homework Overview	**Mark**	**5 mins**	Finish Vegan starter kit; Sample menu forms
	Total	**2 hrs, 45 minutes**	

Materials and Notes: *Vegan starter kits and recipe book given out upon enrolling. Example menus or recipes, a vegan food pyramid, and food substitution guide will be given for take home.*

Homework*: read vegan starter kit if haven't done so. Create a 2 day vegan menu and shopping list for yourself / family. Participants can take out an item from the library if desired.*

SESSION 1 GOALS:

- ☐ **Check – in:** participants should understand the purpose of check-ins: to share experiences, get to know other members of the group, support each other, learn from each other's experiences, voice concerns and fears, and brainstorm how to overcome them.
- ☐ **Study Overview:** participants should leave the overview excited about the program and the opportunity to learn. They should feel empowered to maximize their educational experience during the program, to challenge what they are taught, and to contribute as much energy as possible to the program; they should understand the nature of all sessions, including session 5 and the maintenance sessions.
- ☐ **Obesity Discussion:** participants should understand the utility of understanding obesity as a chronic imbalance between energy intake and expenditure. They should understand that genetics, the modern nutritional environment and factors that contribute to a sedentary lifestyle are important contributors to obesity, but that this only increases the importance of taking control of one's food and activity choices. Participants should be given a basic understanding of the biological basis for overeating and fat accumulation, and the worsening epidemic of overweight and obesity, as a means for minimizing self-blame and increasing understanding of their condition. Participants should also be reminded of the health, socio-economic and psychological impacts of obesity, as a means of reinforcing the value of this program and validating their struggles. Participants should understand the importance of maintaining modest weight loss and setting reasonable, long-term goals.

- ☐ **Basic Vegan Nutrition Lecture:** Participants should understand the meaning of the terms vegetarian, lacto-ovo, and vegan. They should become aware of the breadth of health benefits that come from adopting a whole-foods, plant-based diet (by citing examples of epidemiological and clinical research). They should be given a basic model for understanding this phenomenon, e.g. the wide range of protective factors found in whole plant foods, pathogenic components in animal and processed foods. They should come away with knowledge of all the food groups needed to make a wholesome vegan diet, and the relative calorie densities between animal and plant foods, etc. They should gain an appreciation for the extremely high prevalence of animal products in commercial foods, so that they do not blame themselves for some inevitable exposure to animal products. However, they should also appreciate the benefits of maximizing adherence to a low-fat, whole foods, vegan dietary pattern. They should understand why it is important to take a vitamin B12 supplement (e.g. multivitamin with B12), to make use of fortified foods. The downside of overemphasizing protein requirements should be very clear and other protein myths should be addressed (e.g. complete protein). Tips for transitioning to a vegan diet and a simple meal plan should be presented, as a means of demonstrating that eating a vegan diet can be achievable and satisfying.

Session 2. Your health – the health benefits of a vegan diet

Part 1. Group Check-in: Homework Review	**Mark**	**10 mins**	Thoughts on Meal Planning exercise
Part 2. Lecture: Health benefits of a low-fat, whole foods, vegan diet – overview of clinical and epidemiological evidence with respect to obesity and related chronic diseases.	**Dr. Ornish**	**50 mins**	Overview of heart & prostate ca research (including case-studies); summary of evidence on diet and obesity; low-fat vs. high protein debate; other health benefits of a low-fat, whole foods, plant-based diet.
Part 3. Question, answer & discussion period	**Dr. Ornish**	**20 mins**	
Dinner Break		**20 mins**	
Part 4. Group Discussion: Challenges to eating a healthy plant-based diet.	**Mark, Dr. Marlin**	**30 mins**	Facilitated group brainstorm on challenges/barriers to eating healthy plant-based foods and how to overcome them.
Recap & Homework Overview	**Mark**	**10 mins**	Choose item from the resource library
Break & Homework Selection		**20 mins**	
Total		**2 hrs, 45 minutes**	

Materials and Notes*: Lectures from Co-I (Dr. Ornish). Handouts include tips on: dealing with food cravings, eating healthy but inexpensively, minimizing flatus, and experimenting with new plant-based foods.*

Homework: "*Choose a book, video, audio-cd, pamphlet or practical assignment from library. Make list of new vegan foods in each food group to add to your diet."*

SESSION 2 GOALS:

- ☐ **Health lecture:** participants should understand the important contribution of diet to health promotion and disease prevention. They should understand the dose-response effect of diet in reversing heart disease, and slowing the progression of prostate cancer. Participants should be given an overview of recent dietary trends and how they have contributed to the worsening obesity epidemic. In this context, they should come to understand the advantages of a low-fat vs. a high-protein approach to weight loss and health promotion. Participants should be inspired by hearing case-reports of previous research participants and gaining insight into the speaker's own journey.
- ☐ **Group Discussion:** Participants will have an opportunity to express the obstacles they face in transitioning to a vegan or plant-based diet. The goal of this check-in is to validate the participants' unique experiences while providing a means for individual participants to benefit from the collective knowledge and experience of the group. Participants should leave feeling their challenges are real but can be overcome by exercising creative problem-solving, persistence and patience.

Session 3. Your health & much more – an overview of how diet affects the environment, farming practices, personal and public health

Part 1. Group Check-in: Homework Review	**Mark**	**20 mins**	Thoughts on resource-library item review.
Part 2. Lecture: The power of personal food choices.	**John Robbins**	**45 mins**	How the standard American diet contributes to environmental destruction (in the US and globally), chronic disease (including obesity) and inhumane conditions for farm animals. An emphasis will be placed on the significance of personal dietary pattern and the interconnection between all these issues.
Part 3. Question, answer & discussion period	**John Robbins**	**25 mins**	
Dinner & Break		**30 mins**	
Part 4. Group Discussion & Decision Balance exercise	**Mark, Dr. Marlin**	**35 mins**	Group brainstorm on pros & cons of increasing proportion of plant-foods.
Recap & Homework Overview	**Mark**	**10 mins**	instructions for revising decision balance
	Total	**2 hrs, 45 minutes**	

***Materials and Notes**: Lecture given by John Robbins – author of Diet for a New America and The Food Revolution. Handouts include local vegan-friendly restaurants, tips for eating out and a 'meal card' for restaurants/chefs.*

***Homework:** "Revise vegan decision balance form."*

SESSION 3 GOALS:

- ☐ **Food-choices lecture:** By tracing the origin of the food we eat back to the modern farm, participants should become more aware of the interconnection between health, environmental and ethical food-production issues. Thus, they will learn that their individual food choices have widespread implications beyond their personal health. Participants will hear briefly about the living conditions of animals existing on most modern factory farms and will gain insight into the scale of production needed to meet current consumer demand; as a result, they will become aware of the role that consumer pressure plays in necessitating intensive confinement farming. In a similar way, the link between animal agriculture, which is inherently inefficient, and environmental pollution will also be explored. By demonstrating the strong links between these 3 issues, participants should be empowered with the knowledge that small changes in their daily lives can have widespread and meaningful implications. Participants will also be inspired by the author's own tale of personal transformation as well as by his vision of the power of personal food choices.
- ☐ **Group Discussion:** By using a decision-balance format to discuss the pros and cons of both changing dietary pattern and not changing (i.e. maintaining current) dietary pattern, participants will have an opportunity to examine the relative weight of the perceived pros vs. the cons. In doing so, the goal is to discuss the means by which participants can minimize the cons while maximizing the pros, such that the decision to change is made consciously and independently despite known barriers.

Session 4. Ecology – the environmental impact of animal-based agriculture

Part 1. Group check-in:	**Mark, Dr. Marlin**	**25 mins**	early experiences, questions& concerns, homework review
Break		**10 mins**	
Part 2. Lecture: Food Choices for a Healthy Planet	**Dr. Riebel**	**40 mins**	The inefficiency of animal-based agriculture and the environmental consequences that result from massive consumer demand; how a meat-based diet contributes to substantial water, land and energy strains, both locally and globally; the impact of this resource strain and agricultural pollution on the major current environmental challenges -- global warming, deforestation, water and air pollution, top-soil erosion, a loss of biodiversity, and the 'clear-cutting' of oceans The environmental benefit of transitioning to a plant-based diet.
Part 3. Question, answer & discussion period	**Dr. Riebel**	**20 mins**	
Dinner Break		**20 mins**	
Part 4. Lecture: Optimizing vegan nutrition	**Stacey Dunn-Emke**	**40 mins**	The importance of fruits & vegetables, whole grains, supplementing your diet (B12, essential fatty acids, calcium, iron, & zinc) with foods or supplements. Questions.
Recap & Homework Overview	**Mark**	**10 mins**	
Total		**2 hrs, 45 minutes**	

Materials and Notes: *Environmental lecture given by Linda Riebel Ph.D – author of Eating to Save the Earth: Food Choices for a Healthy Planet, and a psychologist specializing in eating disorders. Handouts will include sample menus and healthy snack ideas, tips on optimizing calcium, iron and zinc intake.*

Homework: *Create another different 2 day menu and shopping list.*

SESSION 4 GOALS:

- ☐ **Environmental Lecture:** Participants should become more aware of the gravity of current environmental challenges facing our nation and the earth as a whole. They should understand that our consumption practices, and especially our dietary choices, play a major role in creating and exacerbating these problems. The basic concept of why eating high on the food chain is inefficient and wasteful should become clear to participants. Participants should be inspired to use their food choices as a means to support sustainable, environmentally friendly agriculture. The lecturer will also draw from her experience as a psychologist specializing in eating disorders to help participants integrate the knowledge they have been exposed to into their own framework for making food choices. The importance of a 'continuum of choices' model vs. an 'either-or' model will be emphasized.
- ☐ **Vegan Nutrition Lecture:** This talk should reinforce the value of eating more whole, unprocessed plant-foods in replace of processed/refined foods. Nutritional issues that participants should be aware of – like how to get sufficient calcium/iron/B12/zinc – should be explained. Nutritional issues that often confuse patients and prevent patients from adopting a plant-based diet (e.g. the notion that meat and dairy are essential to good health) should also be clarified or reinforced. The value of taking a daily multivitamin (which includes vitamin B12) should also be reinforced.

Session 5. Where your food comes from – intensive confinement practices, factory farms and the treatment of food-animals

Part 1. Group Check-in	**Mark, Dr. Marlin**	**20 mins**	Early experiences, questions& concerns, homework review.
Break		**10 mins**	
Part 2. Comparative Animal Biology	**Mark**	**40 mins**	This lecture provides background material necessary for the intensive-confinement farming lecture. Topics covered include: evolutionary human biology; comparative anatomy & physiology between carnivores, omnivores and herbivores; emotional lives of other animals
Dinner Break		**20 mins**	
Part 3. Intensive Confinement Farming	**Mark**	**40 mins**	An overview of modern animal farming techniques is presenting after a brief discussion on the recent evolution of these techniques. The scope of animal agriculture is described followed by a discussion of how meat, milk, veal, eggs, pork, chicken & duck is produced in the US.
Part 4. Question, answer & discussion period	**Mark**	**30 mins**	Following check-in style responses.
Recap & Homework Overview	**Mark**	**10 mins**	
Total		**2 hrs, 50 minutes**	

Materials and Notes: *The treatment and slaughter of farm animals can be visually disturbing to many individuals. These presentations aimed to show the minimal amount of content to inform and impact food choices. Care was taken to present and discuss this material in a sensitive, responsible and non-judgmental manner. It was emphasized that the purpose of exposing the participants to this material is to allow them to make more informed food choices, and is* ***not*** *to make them feel guilty about their choices.*

Please see Selected Slides from Session 5, following description of Session 6

Homework: *Choose from library or share your knowledge using a video tool (e.g. babe, chicken run, the witness)*

SESSION 5 GOALS:

- ☐ **Animal Biology Lecture:** The environment our ancestors evolved in has important implications for our current dietary requirements. Participants will understand that with the exception of the past century our ancestors ate a plant-based diet. The important contribution of hunting and animals products to our survival and social/cultural evolution will be placed in perspective. By comparing the anatomy and physiology of humans to carnivores, herbivores and omnivores it should become clear that we have evolved primarily to eat plant-products but like all animals can ingest and digest a wide range of substances of plant and animal origin. Finally, a discussion of the central nervous system of other animals (focusing on farm animals) along side an overview of Dr. Jefferey Masson's work on the emotional lives of animals should convince participants that all animals live with emotions that can be compared to ours.
- ☐ **Intensive-Confinement Farming Lecture:** Participants will gain historical perspective into the creation of "factory farms" (i.e. intensive confinement operations) and will be introduced to the scale of demand for animal-products that necessitates their existence. Participants will gain appreciation for the fact that factory farming accounts for the vast majority of animal agriculture and that small, family farms are becoming virtually non existent. The consequence of turning livestock into a commodity in the modern world will be explored throughout the presentation to give participants a framework for digesting the material. A brief discussion of the lives of each of the major farm animals will be presented, with emphasis on the how they are raised rather than how they are slaughtered. By becoming more informed about the nature of animal agriculture in this country, participants should feel more able to make informed and conscious food choices. The overall goal of this lecture is to provide a non-threatening, non-judgmental and sensitive environment to enable open discussion of the ethics of raising animals for food.

Session 6. Fast Food, Food Safety & Public Health

Part 1. Group Check-in	**Mark, Dr. Marlin**	**30 mins**	Thoughts on session 5, homework review.
Break		**10 mins**	
Part 2. Lecture & discussion: Fast Food, Food Safety and Food Politics	**Michele Simon**	**40 mins**	An overview of Eric Schlosser's *Fast Food Nation* – an in depth exploration of the fast food industry. Food borne illnesses, worker conditions, marketing campaigns, and health consequences of fast food. Insights into food policy and your role as a consumer.
Part 3. Question, answer & discussion period.	**Michele Simon**	**20 mins**	
Dinner Break		**20 mins**	
Part 4. Group discussion – Healthy Fast Food	**Mark**	**40 mins**	Practical tips for preparing, buying or ordering healthy, vegan 'fast food'.
Recap & Homework Overview	**Mark**	**10 mins**	Overview of Maintenance Sessions
Total		**2 hrs, 50 minutes**	

Materials and Notes: *Lecture will be given by Michele Simon, MPH, founder and director of the Center for Informed Food Choices. Handouts include a guide to understanding ingredient lists and nutrition labels on foods.*

Homework: *Create list of topics you would like covered during maintenance sessions*

SESSION 6 GOALS:

- ☐ **Fast Food & Food Politics Lecture:** By giving participants an overview of topics found in Eric Schlosser's *Fast Food Nation*, participants will gain appreciation for the economic and political forces that shape the modern dietary environment. Participants will learn about the marketing practices of soda and fast food companies, working conditions in the fast food industry, food-production techniques and the implications for food safety and public health. By getting a better understanding of fast food products and the industry which supports these products, participants will be equipped to make more-informed food choices.
- ☐ **Healthy Fast-Food Group Discussion:** Participants will have an opportunity to learn about strategies that can help them find convenient, quick yet healthy plant-based alternatives to fast-food. Participants should leave the discussion feeling like many alternatives are available to be explored. They should also have the opportunity to share their discoveries with other members of the group.

Overview of other intervention components:

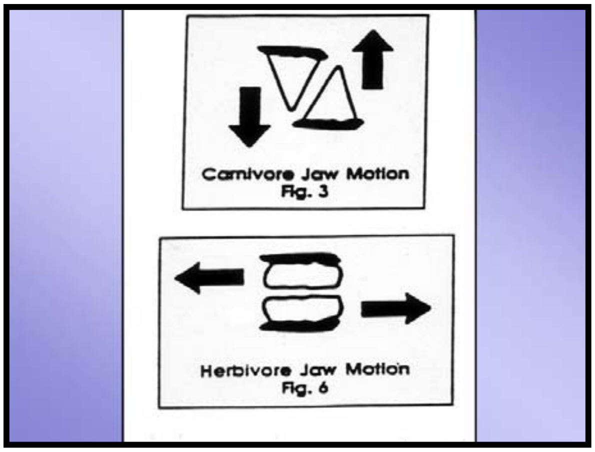
Homework: this is an opportunity to reinforce what was learned in the previous session. Homework will be tailored to the needs of individual participants.

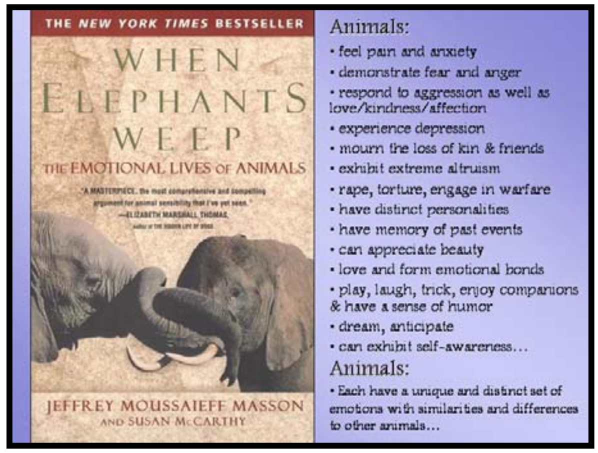
Meals: Light vegan meals will be provided by the GCRC kitchen. This will provide participants incentive to attend sessions and introduce them to a variety of plant-based dietary options.

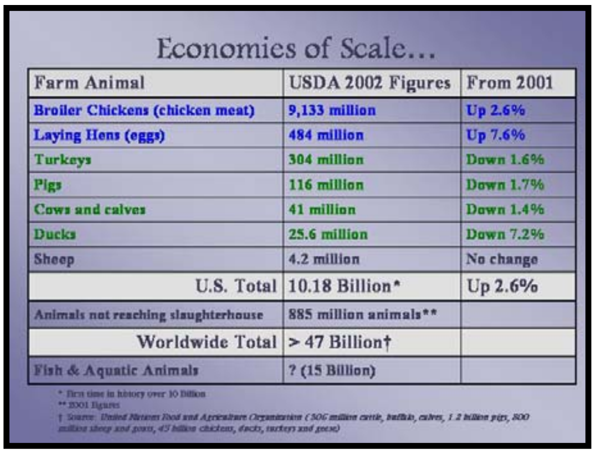
Resource Library: This will be a portable collection of videos, nutrition and cook books, audio-tapes, pamphlets

Maintenance Sessions: These will be tailored to the needs of the group participants. 4 Sessions were provided for each group including a cooking demonstration. Each session lasted 1.5-2 hours.

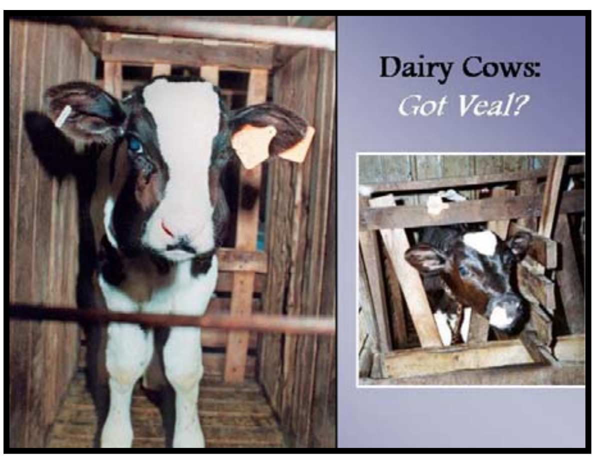
Selected Slides from Session 5

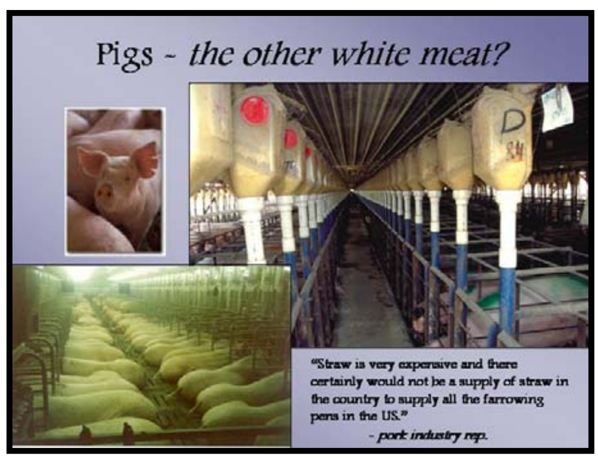






Farm Animal	USDA 2002 Figures	From 2001
Broiler Chickens (chicken meat)	9,133 million	Up 2.6%
Laying Hens (eggs)	484 million	Up 7.6%
Turkeys	304 million	Down 1.6%
Pigs	116 million	Down 1.7%
Cows and calves	41 million	Down 1.4%
Ducks	25.6 million	Down 7.2%
Sheep	4.2 million	No change
U.S. Total	10.18 Billion*	Up 2.6%
Animals not reaching slaughterhouse	885 million animals**	
Worldwide Total	> 47 Billion†	
Fish & Aquatic Animals	? (15 Billion)	





Description of Slides: *Top from 'animal biology', middle & bottom from 'intensive-confinement farming' lecture.*

Top left: Comparison of herbivore and carnivore jaw structure. (The ability to move in a horizontal plane allows for chewing (i.e. of plant-material) but sacrifices power and stability (needed for killing prey).

Top right: Summary slide of Dr. Masson's *When Elephants Weep.*

Middle left: Scale of US and Global animal agriculture as described by annual slaughter rates.

Middle right: Intro slide to diary production, showing cows with chronic mastitis and hamburgers (dairy cows → 25% US beef)

Bottom left: Intro slide to veal production, a by-product of the dairy industry (veal is from male calves).

Bottom right: Intro slide to pork and bacon production. Pigs are likely the most intensely confined farm animals.

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