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Health at Every Size Program Intervention Versus Traditional Weight Loss Intervention: Impact on Diet and Physical Activity

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HEALTH AT EVERY SIZE PROGRAM INTERVENTION VERSUS TRADITIONAL WEIGHT LOSS INTERVENTION: IMPACT ON DIET AND PHYSICAL ACTIVITY

BY

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HEALTH AT EVERY SIZE PROGRAM INTERVENTION VERSUS TRADITIONAL WEIGHT LOSS INTERVENTION; IMPACT ON DIET AND PHYSICAL ACTIVITY

This thesis is approved as a creditable and independent investigation by a candidate for the Master of Science in Dietetics degree and is acceptable for meeting the thesis requirements for this degree. Acceptance of this thesis does not imply that the conclusions reached by the candidate are necessarily the conclusions of the major department.

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To Rylee and Keegan who have been by my side through this entire journey.

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ABSTRACT

HEALTH AT EVERY SIZE PROGRAM INTERVENTION VERSUS TRADITIONAL WEIGHT LOSS INTERVENTION; IMPACT ON DIET AND PHYSICAL ACTIVITY

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Background. A shift from a weight-focus to a health focus -Health At Every Size (HAES)-has been suggested. Yet, little research has compared the impact of this approach to a traditional weight loss program on diet, while physical activity, anthropometric and health indicators have been mixed. *Objective.* This study evaluated diet, physical activity, anthropometric measurements, blood pressure, blood sugar and cholesterol in participants in these two interventions. It was hypothesized that the HAES group would consume a more nutrient dense diet, more whole foods, higher fiber and lower sodium, while the traditional group would consume lower calories, fat and fiber and that physical activity would increase in both. *Study design. A* convenience sample controlled trial. *Participants.* 46 adults (n=29 in HAES and n=17 traditional) in the community, registered to one of the four medical facilities, without diabetes or an eating disorder. Attrition rate was (n=4) 14% in HAES and (n=10) 59% in traditional group. *Intervention.* Parallel interventions on Manitoulin Island were run from April to July 2015. The HAES group focused on mindful eating and movement and body and food acceptance. The traditional group focused on calorie and fat reduction and increasing physical activity to achieve weight loss and diabetes prevention. *Statistical analysis.* T-tests were used to compare baseline data. Regression analysis was used to compare follow-up demographic and health indicator data, mixed model regression was used for follow-up diet data and changes within groups were assessed using paired t-tests. Group, age and caloric intake were controlled for as applicable. *Results.* Both groups lost weight and the traditional group significantly lowered waist circumference (all p=0.01). Systolic blood pressure and hemoglobin A1c decreased in the HAES group (p=0.01). Healthy Eating Index score increased (7.41±2.31; p=0.01) and sodium intake decreased (-1298.26±612.20; p=0.05) in the HAES group. The traditional group ate more calories (p=0.05) and less fiber (p=0.01) than the HAES group. The traditional group consumed significantly less vitamin C from pre- to post-intervention (-46.63±17.77, p=0.05). *Conclusions.* Both groups lost weight but the traditional approach resulted in a more favorable change in body composition, while the HAES approach facilitated health indicator and dietary improvements.

Introduction

Obesity has been cited as a problem reaching epidemic proportions in the United States. Between 1999 and 2010, prevalence of adult obesity rose and the body mass index (BMI) distribution changed. Numbers in all BMI categories increased, but the most significant increases were in higher BMI categories[1-3]. According to the Center for Disease Control and Prevention (CDC) approximately 34 to 35 percent of the population in United States was obese between 2005 to 2012[4].

Obesity Definition

Obesity is defined as a BMI equal to or greater than 30 kg/m^2 [4] or body fat content $\geq$ 25% for men or $\geq$ 30% for women[5]. It is a condition characterized by excess accumulation of adipose tissue[5]. Obesity is very complex and caused by many intrinsic, extrinsic, environmental and social factors.

BMI

Body mass index measures weight in proportion to height. It was developed in 1832, as an application of probability calculus to study growth[6]. It was renamed BMI in 1972 by an obesity researcher and called the best height-weight formula that matched body fat percent[7]. By 1985, the National Institutes of Health (NIH) used it to define obesity[8].

BMI targets have been adjusted over time. Originally, normal cut-off was 27.8 kg/m^2 for men and 27.3kg/m^2 for women, based on a strong association with several conditions (CVD risks, cancer and diabetes) in NHANES II data[8]. In 1998, BMI categories were consolidated for men and women[9] and the overweight category was included[8,10]. This more than doubled those considered above ideal BMI[8]. The adjustment was based on increased risk of disease in NHANES III data[10]. Additionally, normal weight was lowered from 20 kg/m^2 to 18.5 kg/m^2 [11]. Current guidelines are as follows:

Underweight: < 18.5 kg/m^2

Normal: 18.5-24.9 kg/m^2

Overweight: 25-29.9 kg/m^2

Obese: 30-39.9 kg/m^2

Extremely Obese: 40-54 kg/m^2 [9,12]

The BMI tool has strengths and weaknesses. It is a simple, quick, inexpensive[11], non-invasive[13], readily available[11], practical tool and can categorize the degree of overweight or obesity[11]. BMI provides standardized cutoffs for weight categories[12] and is described as the “most useful indicator” of health risks[14]. BMI levels correlate with body fat (according to some), future health risks and death[13]. BMI was found to increase strength of association to predict mortality with elapsed time[15]. Additionally, longstanding use of BMI makes it useful for comparisons across time, regions and populations[13]. As with every weight categorizing tool, BMI comes with limitations.

BMI classifications have been criticized for many reasons. Variables such as gender[13,16], age[17-23], ethnicity[13,21,24-29], body composition[7,30-32], body shapes, sizes[33], fat distribution[13], adiposity[7] and bone mass[13] are overlooked. Typically, women compared to men[34] and older compared to younger adults, have more body fat than those with the same BMI[13]. Women are more likely to be labeled obese class II and

III[16]. Additionally, nutritional status is not considered and eating disorders could be masked[35]. Moreover, an original advocate of the BMI warned against the limitations of its use for individual diagnoses[7].

It is unlikely that any index provides an accurate indication of adiposity at normal BMI[7]. As lean mass increases, accuracy of classification decreases[10,11,36,37], yet health risks may not be increased[10]. Moreover, adipose tissue may be underestimated when less muscular development exists[11]. Furthermore, fat distribution more accurately predicted risk, for cardiovascular disease than obesity[38]. However, guidelines suggest those with a BMI over 25 kg/m^2 are at higher risk than normal BMI, even if waist circumference is lower than recommendations, despite opposing evidence[39-41]. Interestingly, longer legs were associated with a lower BMI than shorter legs in those with similar torso sizes[42]

Causes of Obesity

Several factors contribute to the development of obesity. Intrinsic causes of obesity include: aging and the concurrent slowed metabolism causing an increase in adipose tissue and decrease in lean tissue. Additionally, gender, race and illnesses such as hypothyroidism[43], may contribute to development of obesity. Furthermore, we have a biological tendency to protect against starvation[11.] This was a survival mechanism known as the thrifty genotype, which was protective in times of famine[39]. Some suggest our primitive genes have not evolved to accommodate food abundance[39]. Moreover, genetics may contribute 25 to 40% of weight gain susceptibility as well as hormones such as ghrelin and leptin that impact our appetite and intake[40]. Additionally, intentional energy restriction through diet and exercise causes leptin and insulin to drop and initiation of metabolic processes to return to original weight[40], and possibly higher[44,45]. Furthermore, resting energy expenditure can decrease by 15% with a 10% weight loss[40]. Body weight is also influenced by our hedonic and homeostatic systems[40]. Numerous intrinsic factors demonstrate the complexity of obesity. However, there are also extrinsic factors such as lifestyle and environment that are purported to contribute to obesity.

Lifestyle factors that are thought to contribute to obesity include sedentary behavior and diet. Sedentary habits have increased since agricultural advances[39,40]. Additionally poor diet, large portions[40], sugared beverages[40,43], and increased intake of fast foods[43] are suggested to have contributed to obesity. However, the association of increased intake and obesity is not clear[31,46]. Calorie intake increased from 1971 to 2005[46,47]. However, intake decreased from 2005 to 2009-2010 data[47], during the time frame in which obesity rates stabilized[4]. Comparison of energy and macronutrients intake in different weight categories from 1971-1975 (n= 13,106) to 2005-2006 (n=4381) NHANES data was analyzed[46]. Obesity prevalence increased from 11.9% to 33.4% and 16.6% to 36.5% in men and women, respectively. Modest changes in percentage of energy from carbohydrates (44.0% vs. 48.7%), fat (36.6% vs. 33.7%), and protein (16.5% vs. 15.7%) occurred. Intake trends were nearly identical across all weight categories. During the NHANES 2005-2006 data, normal-weight men consumed 247 additional calories per day, overweight men consumed 165 additional calories, and obese men consumed 225 additional calories compared to NHANES 1971-1975 data. Normal weight women consumed an additional 183 calories, overweight women consumed an additional 304 calories, and obese women consumed an additional 341 calories, per day. Additionally, several studies have found that vegetarians are often leaner, than omnivores[48-54], despite eating similar or more calories[49]. NHANES data also illustrated that people of all sizes were sedentary and would benefit from more exercise[46]. Several potential extrinsic factors have contributed to the increase in overweight and obesity, but as illustrated, the contribution of increased caloric intake is unclear. Environmental factors may have also contributed to the increase in obesity.

Environmental changes speculated to contribute to obesity are the economy[55,56] and increase in food insecurity[56]. Additionally, increases in technology[55] with the increasing numbers of automated equipment[43] , which contributed to inactivity thereby increasing the tendency toward weight gain[40]. Societal changes that influence expectations and value systems have also contributed to obesity[40,43]. Many of the environmental changes have led to energy from the food supply usually exceeding opportunities for energy expenditure[39,40] due to the process of procuring foods being much easier[39]. Environmental contributions to the obesity epidemic are important, but changes in social environments have also been cited to contribute to the increasing prevalence.

Numerous social issues are purported to have contributed to the increase in obesity rates. Socioeconomic status (SES), defined by income and education level, is inversely related to increasing overweight and obesity[29,43,57,58]. In the US, the highest rates of obesity are found among the groups with the highest levels of poverty and the least education[58]. Some studies suggest an inverse relationship exists between socioeconomic status and body weight[59,60]. A strong positive association between food insecurity and obesity is found in women[58]; whether one causes the other or if they influence each other at all, is unclear[61]. However, in the USA, Europe and Australia, the risk of obesity is 20 to 40 percent greater in women who experience food insecurity regardless of income, lifestyle behaviors or education[62]. When looking at mortality risk in low SES, estimates were not changed by statistical adjustments for confounding factors including body weight, therefore it only made up a small portion of the mortality risk[63]. Epidemiological studies have mirrored this finding[64]. Numerous potential causes are suggested to be contributing to the high rates of obesity in this population. The effects on population health have been debated and vary in different subgroups, but an association between obesity and increased morbidity and mortality exists.

Optimal BMI for Lowest Mortality Risk

Optimal weight for lowest mortality originated from the Metropolitan Life Insurance Company (MetLife)[65], who asserted that its tables indicated ideal weights at the lowest mortality and greatest longevity[65] However, MetLife's 1979 study, demonstrated an increase in optimal BMI for lowest mortality as age increased[65,66].

Several studies have examined ideal BMI for least mortality risk in elderly populations[18-23,65,67,68]. Findings for increased mortality risk and associated BMI for age vary; BMI ≤ 22 kg/m^2 [18,20,23], < 23 kg/m^2 [17] and significantly higher when < 25 kg/m^2 [22] have been cited. Ideal BMI for lowest mortality risk also varied; women with a BMI of 25-29.9 kg/m^2 and 25-32.4 kg/m^2 for men[22], overweight and normal

BMI were comparable[69] and 23-33 kg/m^2 [17] were found. Morality risk associated with obesity was also inconclusive; a modest increase[22], no association[69] and risk started to increase at BMI $\geq$ 33 kg/m^2 [17] were all found. Evidence for ideal BMI varies in the elderly, but an increased range appears to be ideal. Ideal BMI for older adults remains controversial, as does evidence for ideal BMI for diverse ethnicities.

BMI was originally developed for Caucasians[35,61,70]. Ideal BMI varies between different ethnic groups. In China, overweight and obesity was defined as BMI $\geq$ 24 kg/m^2 and $\geq$ 28 kg/m^2, respectively[71]. However, overweight people lived longer[28]. Similarly, ideal BMI varied for African Americans[21,25,27]. Obesity rates between Caucasian and African-American women, doubled when BMI was used instead of body fat percent[27]. Risk of death associated with high BMI in African Americans was lower than all ethnicities[21,25], despite higher prevalence of abdominal obesity[25]. BMI of $\geq$ 35 kg/m^2 in African American women had a small, statistically insignificant associated increase in mortality risk. Additionally, no change in probability of death existed in black men aged 62 to 85, with a BMI of 30 kg/m^2 or aged 67 to 85 with a BMI of 35 kg/m^2. Similarly, no statistically significant increase in mortality risk existed for black women aged 60 to 85 years with a BMI of 30 kg/m^2 or aged 67 to 85 with a BMI of 35 kg/m^2 [26]. Similarly, more than 450,000 human follow-up years, demonstrated a greater association between BMI $\geq$ 35 kg/m^2 and coronary heart disease as well as cardiovascular disease mortality among white compared to black subjects after adjusting for confounders[24].

Many epidemiological studies found BMI was not a strong predictor of death rates, aside from in those in the extreme categories[40,72]. NHANES I, II and III data demonstrated a weak association[40] and longitudinal cohort studies reported no direct relationship or a negative relationship between weight and mortality[73]. Several large studies demonstrated that overweight BMI was associated with similar longevity compared to normal BMI and was protective in some cases. For example:

- The Cardiovascular Health Study on nearly 5000 participants[69]
- Women's Health Initiative Observational Study on 90,000 women[74]
- A Chinese study on nearly 170,000 adults in China[28].
- A German study on 20,000 construction workers for 10 years[75]
- Finnish study on 12,000 women for 29 years[76]
- A Norwegian epidemiological study on 1.7 million[77]
- Comprehensive review of 26 studies on 350,000 people[41]
- Review of NHANES I, II, III datasets[40]
- Meta-analysis of 97 studies (n=2.88 million)[78]

High-normal and overweight BMI range accounts for over half of the United States[78]. Moreover, Grade I obesity, the category in which most obese people fall, was associated with lower[78] or similar all-cause mortality risk compared to normal BMI[40,78]. However, Grade II and III obesity were associated with significantly higher risk[78]. Underweight was associated with the highest mortality risk[40,63,78]. Relative risk of dying from being underweight was 2.03, whereas relative risk for high weight was 0.94, after controlling for socioeconomic status in American's Changing Lives study[63]. Aside from BMI, weight trajectory is also an important predictor of risk.

Mortality and Weight Trajectories

Weight trajectories, including stability, loss and gain, have been evaluated for effect on mortality risk[39,79,80]. Stable weight with optimized physical and metabolic fitness was associated with the least risk[39]. Evidence suggested that quality of life improved and lower mortality risk existed when individuals with obesity-related comorbidities lost weight. However, weight loss in healthy obese increased mortality risk and weight loss was rarely sustained[39]. Review of NHANES III nationally representative data also found that mortality from all causes increased in overweight men and women who lost weight. This finding persisted after controlling for maximum BMI[81]. Similarly, lowest weight fluctuations (0-5%) were associated with the best physical and mental health compared to those with larger fluctuations in 20,000 adults[80]. Highly variable weights were associated with increased total mortality as well as morbidity and mortality from coronary heart disease in the Framingham population study. These remained significant when factoring in obesity and weight trends over time[79]. The following table depicts mortality risk across BMI categories and weight trajectories.

Table 1: Influence of Body Size and Weight Trajectory on Mortality According to Bosomworth (p. 520)[39]

				OBESE			
WEIGHT TRAJECTORY	UNDERWEIGHT	NORMAL WEIGHT	OVERWEIGHT	CLASS 1	CLASS 2	CLASS 3	ELDERLY
Stable	Increased	Optimal	Optimal	Optimal	Increased	Increased	Optimal
Weight gain	Reduced	Optimal	Optimal	Increased	Increased	Increased	Optimal
Weight loss							
• Intentional, healthy	Increased	Increased	Increased	Increased	Increased	Increased	Increased
• Intentional, morbidity	Increased	Increased	Increased	Reduced	Reduced	Reduced	Reduced
• Not intentional	Increased	Increased	Increased	Increased	Increased	Increased	Increased

NHLBI recognized limitations of BMI and suggested that waist circumference is necessary to assess for increased risk of obesity-related conditions[9]. Waist circumference was suggested to be the most practical measurement for assessing abdominal fat content as it appears to be a risk factor when BMI is not markedly increased[9]. Despite appreciated limitations, BMI continues to be widely utilized to define mortality risk. It is important to consider other health indicators when determining ideal BMI. To reduce obesity, weight management guidelines are provided by numerous professional organizations.

Weight Management Guidelines Suggested to Reduce Obesity

Guidelines from several health authorities were analyzed for weight loss recommendations and strategies suggested. The following commonalities in weight management for prevention and management of various chronic conditions by The Academy of Nutrition and Dietetics[55], North American Association for the Study of Obesity and the American Society for Clinical Nutrition Practice Guidelines[82], Obesity Society and the American Society of Hypertension[83], National Institute of Health National Heart Lung and Blood Institute[11] and The American College of

Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society, in collaboration with American College of Cardiology, American Heart Association and National Heart, Lung, and Blood Institute[84]. These guidelines are endorsed by several professional organizations.

Who should lose weight:

- Those with a BMI > 25 kg/m^2 [55,82]
- Those with a BMI ≥ 25 kg/m^2 with two or more risk factors or BMI ≥ 30 kg/m^2 [11]
- All obese individuals[84].

Amount of weight loss suggested

- 5-10% body weight for prevention of HTN and diabetes[55]
- 10% initially to ameliorate risk of morbidity[11]
- At least 3% for those with a BMI > 25 kg/m^2 to prevent and manage CVD[84]
- 10 kg to reduce systolic blood pressure by 6 mm HG for HTN prevention[83]

Level of calorie restriction suggested per day:

- 500-1000 kcal deficit[55,82,83] for diabetes prevention and management[82]
- 300-500 kcal deficit when BMI 27-35 kg/m^2 or 500-1000 kcal deficit when BMI ≥ 35 kg/m^2 [11]
- 500 or 750 kcal/day or 30% energy deficit and *Ad libitum* when specific food groups eliminated or prescription of energy restriction[84]

Daily caloric intake suggested to achieve weight loss included:

- 1000-1200 kcal for women and 1200-1500 kcal for men[11]
- 1000-1200 kcal for women and 1200 – 1600 kcal for men[82]

- 1200-1500 kcal for women and 1500-1800 kcal for men[84]

Weight loss Goal:

- Progressive weight loss of 1-2 lbs. per week[11,55,82] over 6 months[11]
- At minimum prevent further weight gain[11,55]

Guidelines suggested for achieving weight loss via:

- Therapeutic lifestyle including reduction in energy and physical activity[11,55,82-85]
- Dietary Approaches Suggested for Hypertension Management; sodium reduction for HTN prevention[82]
- Several diets, meal replacements and pharmacological agents suggested, no consensus or favored diet existed[11,55,82,84]
- Cognitive behavioral therapy[55,84]

Analysis of Guideline for the Management of Overweight and Obesity

Some of the recommendations have been criticized. Guidelines are often based on expert opinion when evidence is lacking[55,84]. For example, when The American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society, in collaboration with American College of Cardiology, American Heart Association and National Heart, Lung, and Blood Institute developed their guidelines on obesity management, inadequate evidence on health risks associated with current versus alternative waist circumference and BMI cut points existed as they relate to CHD, stroke, CVD, overall mortality and diabetes risk were acknowledged (pg 30)[84]. Recognition that further studies to identify elevated risk were recognized (p. 50)–yet weight loss was recommended to reduce risk for these conditions in all obese individuals. However, the other guidelines presented evidence of improvements of health with weight loss interventions[11,55,82-84]. Additionally, diets were graded as high for achieving weight loss. However, slow weight regain in 66-75% of subjects at two-year follow-up was acknowledged in the guidelines (P. 33)[84]. There was no mention of follow-up beyond two years[86]. However, significant evidence has found that the more time that passes between weight loss interventions and follow-up, the more weight will be regained by many participants[45,87-97]. Some weight loss studies have found that successful weight loss and maintenance in 15[87] to 20[39] percent of participants. In addition to evidence of health benefits associated with weight loss being limited, strategies by which weight reduction be achieved, lacked or had mixed evidence.

Slow weight loss of one to two pounds per week, through daily caloric deficit, was suggested by all of the guidelines analyzed[11,55,82-84,98]. Presumably, the recommended 500 to 1000 daily calorie deficit (3500 to 7000 calorie deficit per week), to achieve a one to two pound loss per week was based on the 3500 calorie deficit rule[99]. The 3500-calorie deficit originated from a 1958 calculation that 3750 calories were in one pound of adipose tissue, consisting of 395 grams of fat. This calculation assumes that lost weight is exclusively adipose tissue; however, loss of protein, carbohydrates (glycogen) and body water (3 lbs. for each 1 lbs. protein lost) were recognized. According to Hall, this calculation assumes that no energy expenditure adaptation occurs[100]. Applebaum, also criticized the daily 500 to 1000 calorie restriction recommendation, explaining it would be impossible for this restriction to produce a loss of one to two pounds per week[101] . Moreover, evidence on the best rate of weight loss is inconsistent[86,94,96]. Some studies found that no significant difference in weight loss at long-term follow-up existed[86,94], and weight regain was similar (71%) in both fast and slow weight loss groups[96]. Despite lacking evidence, recommendation for slow weight loss and a 500-1000 calorie deficit are suggested to guide weight management programs. Weight management programs have many benefits, as well as some weaknesses.

Weight Loss Programs: Benefits and Potential Limitations

A review of meta-analysis' and weight loss trials, including numerous types of interventions, showed favorable health and body composition changes with weight loss, decreased visceral fat ratings, waist circumference[90,102,103] and fat mass[90,103]. Physical activity data could have contributed to these changes[90].

Statistically significant reduction in weight was achieved in several trials[90,102-111] and maintained at 36-week follow-up[109]. Changes were in favor of intervention groups when compared to controls[102,110]. Achieving weight loss was associated with adherence[107], not diet[102,107,111] or intervention type[102]. A small number of participants maintained weight loss[8,14,16,2.39,87.]

Intervention groups more frequently achieved five to over 10% body weight loss than controls[102], which had clinically important effects, most notably a 38-55% reduction in type 2 diabetes incidence in high-risk populations[102,108]. However, improved blood glucose was not consistent[107] and decrements occurred with weight regain[106]. Interestingly, participants lowered fasting insulin levels[106,107], which was significantly associated with weight loss[107]. In addition to blood glucose, data on cardiovascular risk factors was also inconsistent.

Slight reduction in pulse[90] as well as blood pressure decrements occurred in weight loss groups[90,102,103,106], however, not consistently[107]. Moreover, several trials found improved cholesterol[102,103,106,107,111], but this finding was also inconsistent[90,111], Possibly the low carbohydrate diet contributed to unfavorable changes[111]. Furthermore, C-reactive protein decreased in participants with elevated levels[90,107] and was significantly associated with weight loss[107]. No evidence that effects of treatment differed based on focus of the intervention in most health indicators[102]. Cardiometabolic profile improved in weight loss interventions when losses were sustained[106] and in some cases persisted after weight regain[112]. Participants of diet interventions also experienced psychological improvements, but the association with weight loss is not consistent across studies.

Depressive symptoms improved following some interventions, independent of amount of weight lost[113,114], but not consistently[114]. Additionally, self-esteem improvements were consistent in those who lost weight[113,115,116], with a linear association to weight loss[113,116].Improvements in body image were experienced[116-119], in intervention[116-119] and control groups[119]. Improvements were sustained up to 16 months[115] and significantly correlated[119] or concurrent[117-119] with losses. Exercise was cited as a potential contributor to improvements[119]. Improvements in psychological well-being, can result in health related quality of life (HRQoL) improvements.

HRQoL changes in weight loss studies were mixed. Several studies saw improvements[114,120-124], but not all[114]. Vitality was most responsive to weight loss[120-124] and maintained at one-year when weight loss was maintained[120,123] and persisted at 12 and 24 months despite some weight regain[120]. However, it worsened in those with weight regain in another study[125]. Largest variability in weight including those who lost weight had lower HRQoL, even when adjusting for confounders[80]. Poor quality design produced inconsistent results in HRQoL according to one meta-analysis[114]. Moreover, significant improvements in Impact of Weight on Quality of Life-Lite scale with a 10% weight loss[123].

In some cases, psychological improvements occurred in the absence of weight loss[120,123,126] and in one case persisted with weight gain, though effect sizes were small[120]. However, psychological well-being can also be negatively impacted from weight loss interventions. A decline in participant's psychological well-being after weight was regained was experienced[105,123,125,127] as well as in those with highest weight variability –losses and gains[80]. Dieting experiences were overwhelmingly negative for women with a BMI over 30kg/m^2 [44]. However, aside from some decrements in psychological well-being, no major adverse reactions directly related to lifestyle interventions were reported[90,102,107,110,114,120-124,126].

Major weaknesses of diet studies included: short duration[86,102,106,110], infrequently sustained weight loss[39,45,79-97,104,105,110,128] and high attrition rates[39,45,102-105]. High attrition rates pose the risk of reporting bias as well as methodological limitations thereby reducing the strength of evidence[129]. Reporting bias may occur because many studies use a per protocol analysis, in which analysis is conducted only on those who completed the intervention. A method that results in less bias is the intention-to-treat approach, in which all data are analyzed whether or not participants dropped out[129].

Some confounding factors include: self-reported weight[130] by phone or mail rather than measured[45]; low-follow-up rates that make it unknown if weight loss was maintained or regained or higher than initial weight because those who regained a significant amount of weight are less likely to come back for follow-up tests.

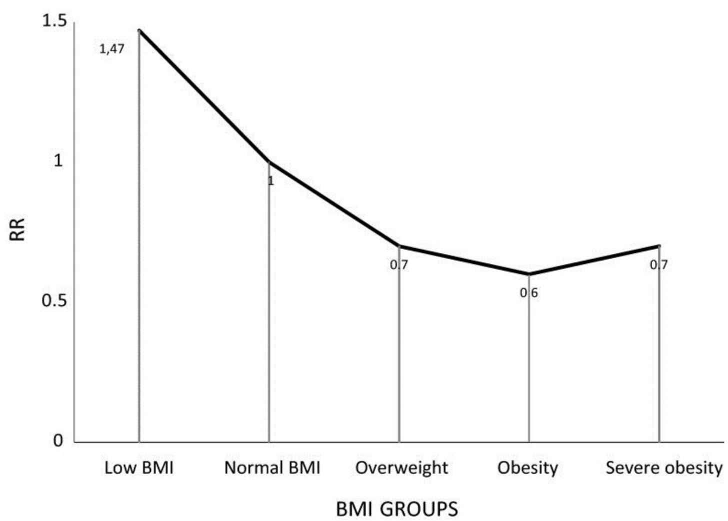
Overall, evidence of health benefits of dieting are mixed[45,106,130] and are frequently not maintained[105,106,120,127], especially when weight is regained[16,17,29,34,35]. Mortality from cardiovascular disease was also increased[29] by almost double from yo-yo dieting compared to those who remained overweight or obese[34]. Even partial regain was associated with increased risk for type 2 diabetes and cardiovascular disease when regained within a year[35.] While another study found that risks were higher than baseline, when weight regain occurred[106]. Weight lost during weight management programs is often regained in follow up[45,79-97,104,105,110,128,131-142], despite maintenance care[95,140-142]. Additionally, dieting predicts future weight gain according to several studies[44,92,97,143-147]. Women with the highest weight were more likely to have dieted before age 14 and had more weight loss attempts (> 20 attempts) than those who dieted later[44]. Diet frequency has been directly associated with weight gain[145-148]. A statistically significant relationship between current BMI and dieting experiences existed[44]. Interestingly, energy and dietary intake patterns were not predictive of weight change[3146] Unfortunately, weight regain possibly posed health risks in several studies[16,17,29,34,35]. Despite the emphasis on weight loss for individuals who are obese in weight management guidelines[9,16,55,82,84,98], some studies have found that obesity may have a protective effect for some chronic conditions, although evidence is inconclusive.

Obesity Paradox

The obesity paradox suggests that obesity may be protective for patients with certain chronic diseases[71]. Some studies have found this for cardiovascular disease[149-153], Type 2 diabetes[154,155], chronic kidney disease[156-158] and many other diseases[156-159]. However, findings are mixed[150,156-162].

Several studies have demonstrated that the obesity paradox exists for those with cardiovascular disease. According to a 21-month prospective study measuring all-cause mortality of over 45,000 Caucasian patients with acute coronary syndrome (ACS), 92% of whom had significant stenosis[149], all-cause mortality was highest in underweight (BMI < 18.5kg/m^2), followed by normal weight (BMI 18.5 to 24.9 kg/m^2) patients. Researchers adjusted for age, smoking status, history of malignancy, dementia, renal failure, HF, and chronic obstructive pulmonary disease, but were unable to adjust for unintentional weight loss. Mortality risk at three-year follow-up was similar across groups with a BMI between 23.5 to 35 kg/m2, but increased in those with a BMI over 35 kg/m^2. However, less than five percent fell into this category therefore, data were lacking[149]. Furthermore, pooled data from 218,532 participants with ACS, had similar findings[152]. After adjusting for covariates using multivariate analysis, the risk ratios (RR) for mortality compared to normal BMI were: low BMI RR 1.74 (95% CI 1.47-2.05), Normal BMI RR 1.00, overweight RR 0.70 (95% CI 0.64-0.76), obese RR 0.60 (95% CI 0.53-0.68), and severe obese (BMI $\geq$ 35 kg/m2) RR 0.7 (95% CI 0.58-0.86)[152]. The figure below demonstrates the U shaped BMI-mortality risk association findings of the meta-analysis by Niedziela et al., 2014.

Mortality Risk Compared to Normal BMI in Patients with ACS[152]



It appears that people with ACS are at a lower risk of mortality when their BMI is in the overweight and obese categories, studies are finding similar results for those with heart failure (HF). All-cause mortality, in 525 patients with CHF whom had no history of weight loss cachexia, was observed over a mean follow-up of 53 $\pm$ 25.2 months. Greatest survival was in the moderately obese category (29 $\pm$ 0.8 kg/m^2)[151], although differences between this group and severely obese (34.1 $\pm$ 2.8 kg/m^2) were not significant. These results persisted once confounding factors were taken into account[151]. Similarly, 10-years of follow-up of 1487 patients after development of incident HF, concluded that being overweight or obese prior to HF diagnosis, had a protective association with survival, compared to those with a normal BMI[153]. These findings were consistent in subgroups with a history of cancer, smoking and diabetes. Researchers adjusted for demographics and comorbidities[153]. Another study on patients with heart failure had a similar finding when combined with low cardiorespiratory fitness[150]. However, high cardiorespiratory fitness attenuated the obesity paradox. In a study, examining pooled data of more than 23,000 participants, to determine the association of BMI with major cardiovascular events and mortality after percutaneous coronary intervention[163] and another Japanese population of over 12,000[164], a low BMI was associated with the highest risk of major event and death. However, there was no excess risk of events associated with a high BMI ($\geq$ 30 kg/ m2). A similar association was seen with BMI and all-cause mortality[163,164]. Evidence of the obesity paradox appears to be strong for a variety of cardiovascular conditions, especially when low cardiorespiratory fitness exists.

The evidence for the obesity paradox as it relates to type 2 diabetes is less clear. One study found that in data on over 10,500 people and almost 16 years of follow-up, a J-shaped relationship existed between BMI and mortality risk, suggesting the obesity paradox does not exist for type 2 diabetes[162]. The association between BMI, mortality and fitness was studied in 2,013 African American and 2,000 Caucasian men with type 2 diabetes[155]. The BMI-mortality association was significantly higher in those with a BMI between 18.5 and 24.9 kg/m^2 compared obese participants after adjusting for age, BMI, race, CVD and cardiac medication. This association was heightened in African American subjects. Another study analyzed 2,625 adults who developed incident diabetes to determine the association with mortality[154]. Researchers found that larger waist circumference was associated with increased total mortality, yet concluded that adults who were normal weight

(BMI 18.5 to 24.9 kg/m^2) at the time of diabetes incidence had a higher mortality in both cardiovascular and non-cardiovascular related deaths than adults classified as overweight or obese. Elderly and Asian people were more likely to be normal weight when diagnosed. Interestingly, a recent study found that a BMI between 27 and 40 kg/m^2 appeared protective for those newly diagnosed with type 2 diabetes until controlling for waist and hip circumference[161]. After controlling for these factors, the BMI-mortality association faded and authors concluded that BMI and fatness contributed to mortality, in the opposite direction. The obesity paradox appears to be present in some studies, while not in others, suggesting further research and accounting for confounding factors (such as level of physical activity, cardiorespiratory fitness, waist and hip circumference, or presence of other comorbidities) is warranted.

Data are also mixed on the relationship between kidney conditions and the obesity paradox. One systematic review and meta-analysis of 305,392 kidney transplant participants who were underweight, overweight or obese pre-transplant. Compared to normal weight subjects, associated mortality in underweight [HR:1.09;95% CI:1.02-1.20], overweight (HR: 1.07; 95% CI: 1.04-1.12) and obese (HR:1.20;95% CI:1.14-1.23) were elevated[160]. The highest risk was in the obese group. This was especially pronounced in children. Contrarily, over 81,000 patients between 1966 and 2012 on long-term hemodialysis experienced lower all-cause mortality when BMI $\geq$ 25 kg/m^2 [156]. Similar findings have been demonstrated in other studies on hemodialysis patients[157,158] including over 20,000 South Koreans compared to 10,000 Caucasians and 10,000 African Americans in the United States and across ethnicities[158]. The obesity paradox was not demonstrated in patients who were overweight pre-transplant in one study but was demonstrated in those receiving hemodialysis across all ethnicities studied.

After analyzing available studies on the obesity paradox (specifically ACS) and the metabolically obese phenotype), von Haehling et al., stated that available findings permitted the conclusion that weight loss should not be recommended in individuals with chronic diseases who have a BMI < 40 kg/m^2 [71]. He suggested that no studies have demonstrated that weight loss increased longevity in those living with chronic diseases[71]. However, evidence on the obesity paradox in some health conditions is inconclusive.

Cardiorespiratory Fitness and Metabolically Obese Healthy

The inconsistencies in the obesity paradox are suggested to result from differences in cardiorespiratory fitness[150,165] . Physical inactivity and sedentary behavior have been associated with cancer, heart disease, osteoporosis, hypertension, abnormal glucose metabolism, type 2 diabetes, metabolic syndrome, psychological health problems, lower self-esteem, reduced bone mineral density and weight gain[31]. One study found that being obese versus normal weight was not associated with a greater risk of developing or dying from cancer or heart disease, if metabolically fit[72]. Similarly, cardiorespiratory fitness was more important in reducing cancer mortality risk independent of BMI, waist circumference or percent body fat[65,166]. Researchers also found that the more fit obese participants lowered their risk for all-cause mortality[165,167], including in diabetics[155]. Over 43,000 people were examined to determine the reason for obese people being metabolically healthy (no more than one metabolic syndrome criterion)[167]. Over 18,000 subjects were obese as defined by BMI (n=5649) or body fat (n=12,829) and three times as many healthy non-obese subjects were examined for cardiorespiratory fitness. Of the obese groups, 30.8% and 46.3% respectively were metabolically healthy (MH), which was associated with better baseline fitness. MH was associated with lower risk of morbidity and mortality than the metabolically abnormal group[167]. Once adjusted for fitness, risks for differences in weight became insignificant suggesting that level of fitness is a better variable to determine metabolic fitness[167]. Similarly, fit obese men were not at an increased risk for all-cause mortality than fit non-obese men, while both unfit non-obese men and obese men were 2.2 and 1.9 times more likely to die, respectively[165]. The findings outlined above suggest that level of cardiorespiratory fitness is a better indicator of mortality than obesity and should be assessed and taken into consideration when examining the impact of BMI on chronic disease outcomes.

A Shift In Focus Is Needed

Reducing the rate of obesity has not been successful because obesity, as illustrated above, is far more complex than simply reducing caloric intake and increasing calories expended[55,168]. Our bodies are extremely resistant to changes in weight[169] . Long-term effectiveness of diets and weight loss attempts are difficult to measure because very few long-term studies exist[45]. However, 15[87] to 20[39] percent has been cited as the number of people who lose and sustain reduced weight[87]. One obesity doctor purports that nearly 100% of severely obese people regain lost weight[170]. Interestingly, body sizes are similar whether people are attempting to lose weight or not[39]. Over a six-year period, 36 percent intended to lose weight while 64 percent had no intention to lose weight. Of those who intended to lose weight, 39 percent lost weight (20 percent sustained), 30 percent had stable weight and 31 percent gained weight (weight cycling). Meanwhile, of those who had no intention to lose weight, 37% lost weight, 30 percent had stable weight and 33 percent gained weight[39]. What is important however is that participants experienced health improvements post-interventions, independent of weight loss[39,104,105,169,171-173]. Additionally, limitations of BMI for defining ideal category for lowest risk in certain subgroups and extensive evidence demonstrating that the overweight and obese class I categories are not at increased mortality risk compared to normal weight causes question for the need to reduce body weight. There does appear to be an association between excess adipose tissue and mortality, especially in the higher BMI groups[40]. However, this association was attenuated in some studies when obese individuals were physically fit. Furthermore, stable weight has been found to be associated with lower mortality risk[39] and obesity appears to be protective in some individuals who have certain chronic diseases. The lack of success in achieving long-term sustained weight loss, decreased mental health outcomes resulting from failed attempts, lack of causative relationship between obesity and morbidity or mortality as well as contributing to societal weight stigma are reasons that some researchers have suggested that prescribing weight loss is unethical[168,170]. A health care professional's primary goal is "first do no harm"[170]. For these reasons, it is time to shift the focus away from weight and toward improved health.

Obese people who adopt a healthy lifestyle with habits such as five or more fruits and vegetables daily, moderate exercise, smoking cessation and moderate alcohol intake, do not have any long-term health risks worse than a thin person who does the same[168]. Outcomes are better for people following these lifestyle habits regardless of weight compared with those engaging in unhealthful lifestyle factors. These lifestyle factors do not always result in weight loss but can improve health[168] [39,104,105,169,171,172] and often do result in a stable weight[104,105,131,133,138,174-179]. Shifting the focus to health outcomes rather than weight change, should enable us to make significant progress in improving the health[39,104,105,169,171,172,180] and self-esteem of all Americans[104,105,131,133,138,174-176,178,180-183] as well as reduce social stigma of “fat” people[168,170,184-186]. This shift in focus is known as Health At Every Size (HAES).

What Is HAES?

An exciting alternative to the common weight loss attempts to improve health is the Health At Every Size (HAES) approach[187]. The basic conceptual framework includes acceptance of:

- Natural diversity in body shapes and sizes
- Ineffectiveness and dangers of dieting for weight loss
- Importance of relaxed eating in response to internal cues (hunger and satiety)
- Critical contribution of social, emotional, spiritual and physical factors to health and happiness [187]

The HAES philosophy promotes the concept that an appropriate, healthy weight for an individual cannot be determined by numbers on a scale, BMI or body fat percentages. “Healthy weight” (also called “Best Weight”[188] and “Setpoint”[189]) is defined by HAES as the weight at which a person settles while moving toward a more fulfilling and meaningful lifestyle by eating according to hunger, appetite and satiety as well as participating in a reasonable and sustainable level of physical activity[104,105,187]. Similarly, The Academy of Nutrition and Dietetics also suggests striving for healthier lifestyle, instead of a normal BMI[55]. Additionally, this philosophy is an example of a conclusion made at the 1992 National Institutes of Health Consensus Conference was that, “…a focus on approaches that can produce health benefits independently of weight loss may be the best way to improve the physical and psychological health of Americans seeking to lose weight.” [180]

The HAES approach does not suggest that all people are currently at a weight that is most healthy for their circumstances[104,105,168,187,189] It strongly purports that movement toward a healthier lifestyle over time will produce a healthy weight for that person rather than the weight cycling demonstrated by focusing on weight loss. Changing the focus from weight does not imply ignoring health risks or medical conditions. HAES suggests that health professionals offer the same approaches as they would offer to thin clients presenting with the same problem[187.]

HAES is a holistic view of health, which promotes feeling good about one’s self; eating well in a natural, relaxed way and being comfortably active. This approach aims to help people with eating and weight-related struggles through self-acceptance, physical activity, and normalized eating. Self-acceptance –affirmation and reinforcement of human beauty and worth regardless of weight, size and shape is critical. Physical activity –support for increasing social, pleasure-based movement for enjoyment and enhanced quality of life is integral. Normalized eating – support for discarding externally imposed rules and regimens for eating and attaining a more peaceful relationship with food by relearning to eat in response to physiologic hunger and fullness cues is vital. The overarching goal for health professionals is to help people live healthier, more fulfilling lives by caring for their bodies[187].

HAES is a compassionate alternative to traditional weight loss approaches. A significant body of literature demonstrates that many health conditions are treated effectively with little if any weight loss[104,105,187]. Additionally, NHANES data from 1989-1997 illustrated that participants in intervention groups experienced as many health benefits, even in those who gained weight, when compared to those who lost a significant amount of weight[173]. Most importantly, recent research found the HAES approach to be superior to state-of-the-art behavioral weight-loss intervention for improving long-term health in obese participants[187].

HAES may not always help make people thinner, but by embracing this approach, can help people be healthier at all sizes. By avoiding weight loss as a primary goal, prevention of the development of eating problems, body loathing, engaging in risky weight-loss strategies and dying to be thin can occur in future generations of children, women and men[187].

HAES has been found to be superior to weight loss strategies in many respects[168]. First of all, attrition rates common in diet programs were minimized in most studies[104,105,134]. In one study, participants in the HAES group (n=39) had the lowest dropout rate (8%) compared to the social support or control (diet) group[104]. As many as 92% of participants completed the program and those who did not complete the HAES intervention (n=3) did not report feeling like they failed[104]. Two studies found similar attrition rates between the HAES and diet group[132,133]. However, nearly half (42%) of the weight loss group (n=39) dropped out and reported feeling like they had failed. This high attrition rate is consistent with other findings from weight loss programs[45,102,103,128]. Program adherence has proven important for achieving the several benefits resulting from interventions.

A review of several studies that focused on intuitive eating (also known as mindful eating), non-diet approach to health management (some of which took place before HAES was named) and some of which included physical activity and/or body acceptance were conducted. A HAES-like approach was associated with statistically and clinically relevant improvements in many psychological, physiological and lifestyle indicators.

The improvements in psychological health in HAES-like studies, have been described as the "clearest positive association"[190] of all health outcomes in one review[190]. Importantly, none of the studies using a HAES-type approach found psychological decrements in the HAES groups[104,105,131,138,172,191,192], contrary to diet groups[105,138,171,172]. Significant reductions in depression was experienced in HAES study groups[105,131,133,135,138,177,191,193,194]. While in some studies, the 'diet group' scored better (although similar) on the depression index than the HAES groups up to one year[105,133]. However, in the long-term, intuitive eating participants continued to show improvements, while the 'diet group' regressed[104,105,133]. Increased optimism, positive affect, improvements in proactive coping abilities were also experienced[182]. Decreased negative self-talk[132] and negative affect[194], as well as improvements in measures of ineffectiveness[138] were also experienced. A positive association in satisfaction with life[182,183], general wellbeing[171] and quality of life[133] with a HAES program existed in some studies.

Body image was also improved in HAES participants. For example, participants in several HAES-like studies experienced improvements in self-esteem[104,105,131,133,138,174-176,178,182,183,195], positive body image and body esteem[85,95,140-142,183,196-198]. Additionally, HAES groups experienced reductions in body dissatisfaction[104,105,131,133,175,178] and improvements in body acceptance[105,174,191,198]. Additionally, a recent study found a HAES approach was effective for treatment of body dissatisfaction[199]. Contrarily, body dissatisfaction increased in control groups[138,171,186,200-202], which in some studies resulted in less favorable lifestyle choices[201,202]. According to David Sarwer, America's leading body image researcher, even after weight loss, most people have residual negative self-image[168], suggesting that weight loss would not be superior to a HAES approach. Improvements in many psychological and self-image indicators are suspected to have contributed to a reduction in disordered eating patterns.

Reductions in eating disorder pathology was examined in many studies and improvements were seen in most[189,193,199]. Moreover, a reduction in eating restraint was experienced in many studies[104,137,168,203]. A high level of eating restraint was associated with weight gain overtime in a few large-scale studies[92,97,143,204]. This high BMI and weight gain association with restrained eating remained after controlling for genetics and shared environment in a study of 1587 twins[205].

Although none of the studies analyzed used a weight-focused approach, some measured weight pre and post-intervention. There is little clinical evidence that a cause-and-effect relationship exists between participation in intuitive eating and significant weight reduction. Two studies that found a reduction in weight were limited due to inadequate sample size of groups (n=8)[206], lack of control group[194] and short follow-up[194,206]. However, evidence exists that traditional dieting resulted in initial weight loss followed by regain, while intuitive eating participants maintained weight[104,105,131-139]. Several studies found that overweight and obese participants who learned to eat intuitively achieved a significant reduction in body weight[133,136,137,177,194,195]. Interestingly, one study suggested that caloric deprivation was not the only reason for weight loss. For example, the HAES group lost 1.4 kg from an energy decrease of 15 kcal/day whereas the control group lost 0.5 kg from an energy deprivation of 176 kcal/day [136]. The authors recognized that underreporting of intake influences the precision of the assessment for energy intake. Another study had mixed results on weight, with normal weight participants maintaining weight, while participants with high blood glucose levels, lost weight[207]. Furthermore, in one study, the majority (nearly 60%) lost or maintained weight, but at 1-year follow-up, over 40% had gained weight and over 30% had lost weight[175]. Participants in studies with longer follow-up (18 months or more) maintained their weight[105,133,134]. Bradshaw, et al, 2010, found that completion of intuitive eating programs, defined by attendance of 80% of sessions may result in weight loss[208].

Despite the lack of weight loss among some non-weight focused groups, several studies have found that intuitive eaters have a significantly lower BMI than non-intuitive eaters[85,133,182,183,206,209-214]. Two studies found an exception in the negative correlation between BMI and intuitive eating. The first was among Chinese students, but not among those from Japan, Thailand, Philippines or USA[210], while the second was in participants aged 18 to 25 in a study by Augustus-Horvath et al. (2011), but not in participants aged 25 to 65[85]. Despite little if any weight loss, some studies have seen improvements in physiological measurements and importantly, none have reported decrements.

Blood pressure findings in HAES-like programs has been mixed. Some studies saw improvements in blood pressure[104,105]. However, results were not straightforward. For example, a decrease in systolic blood pressure was seen in two studies[104,105,172] including at two-year follow-up[105], while no change occurred in diastolic blood pressure[104,105]. Meanwhile, other studies found improvement in diastolic blood pressure, but not systolic[131,134,171]. One randomized controlled trial did see an improvement in both systolic and diastolic blood pressure[172].

Changes in blood lipids have occurred independent of weight loss[104,105,171,172]. Improvement in total cholesterol was seen at one study[172] and at two-year follow-up[105]. Additionally, an increase in HDL cholesterol was seen in one short-term study[171] and a two-year follow-up[105]. Furthermore, a decrease in LDL[104,105,172] and triglycerides were seen[104,105].

Few studies examined changes in blood glucose control using HAES interventions. Studies that did examine the impact of HAES groups on fasting blood glucose[171,172,215] and oral glucose tolerance test[194] did not see significant results. However, Miller et al. saw a significant decrease in hemoglobin A1c in their mindful intervention group of participants living with type 2 diabetes[215]. Moreover, premeal blood sugars significantly decreased after training of the initial hunger meal pattern in another study[207]. Similar to the mixed findings on the metabolic indicators, lifestyle changes have not been consistent across studies.

Improvements in health behaviors included increased[105,135,171,174,177,191] and sustained physical activity at two-year follow-up[105]. This study found an increase in the moderate intensity exercise and overall activity level in the HAES group. Meanwhile, the diet group increased exercise initially, but did not sustain higher levels of activity at follow-up[105]. Two studies found there was no improvement in the level of physical activity[132,136]. In addition to an increase in physical activity in some interventions, participants in some studies also observed cardiorespiratory fitness improvements as measured by oxygen consumption during exercise[104,105,131,171]. In one study, improvements in metabolic fitness of the HAES group were similar to those who lost weight in the control (weight loss) group[104]. Improvements in physical activity have not been consistent across all studies, suggesting a need for further research in different populations.

Diet improvements in HAES programs have been consistent across studies, although data is limited. Two studies on changes in dietary intake and eating patterns in premenopausal overweight women found that participants experienced a decrease in hunger and external hunger[136,137], which was associated with a decrease in overall energy intake[137]. While not significant, quality of diets did improve[193,195,207]. Improvements included variety and nutrient intake[193], decreased energy and fat intake[195] and increased fruit and vegetable intake[207]. Limited data on changes in dietary quality and nutrient intake in HAES groups exists, suggesting a need for further research in this area.

Summary

Current evidence indicates lack of effective strategies to achieve sustained weight loss. Additionally, the BMI category associated with the least risk of mortality is not clear-cut, especially when considering subgroups within the population, suggesting it may not be necessary for participants to reduce their weight to improve health. Furthermore, interventions have observed improved health and psychological well-being in subjects, independent of weight loss, suggesting that a shift toward a non-weight centered approach may be beneficial. The current study aims to compare a 12-week traditional weight loss program to a twelve-week HAES curriculum, which incorporates mindfulness, intuitive eating, body acceptance and fitness to determine the impact that each program has on dietary intake and physical activity patterns of participants. Secondary outcome measures will include blood lipids, blood pressure, fasting blood sugar, glycated hemoglobin, weight and waist circumference. It is hypothesized that participants of the HAES approach will eat a more nutrient dense diet at the end of the intervention consisting of more whole foods, higher fiber and lower sodium. Meanwhile, lower calorie, fat and fiber intake are predicted in the traditional group, compared with the HAES group. Secondly, increased frequency of light to moderate intensity activity is predicted in both groups, post-intervention.

Material and Methods

Research ethics approval was received from South Dakota State University Institutional Research Ethics Board in April, 2015.

Recruitment and Participants

Recruitment for both groups was via health care provider referral and patient request in April 2015, on Manitoulin Island, Ontario, Canada. Advertisement included recruitment posters, for both groups, in each community, as well as radio broadcast for the Health At Every Size program.

Participants targeted were males and females over age 18, registered to one of the participating health facilities (Manitoulin Central Family Health Team, North East Manitoulin and the Islands Family Health Team, Assiginack Family Health Team or Gore Bay Medical Clinic). Exclusion criteria included: children aged 18 years or younger, diagnosis of diabetes, people actively trying to lose weight or in a weight loss group, those not appropriate for group settings (eg. social anxiety, learning disability requiring additional one-on-one assistance learning new concepts) or people with a self-reported eating disorder. Sixty-two participants were screened for study inclusion, 46 were eligible and voluntarily agreed to participate.

Study Design

The intervention was a controlled trial comparing a 12-week traditional weight loss program to a HAES program. Both interventions were conducted between April 2015 and July 2015, using a convenience sample. Participants chose the group in which they would like to participate.

Measurements of the dependent variables were collected at week 1 and 12 for all groups of the study. Primary measures included physical activity, using short International Physical Activity Questionnaire (IPAQ) and 24-hour dietary recall using the ASA24™ website. Participants independently filled out a short IPAQ questionnaire and were assigned a personal code and completed their 24-hour dietary recall using the ASA24™ website on their own or were assisted by the primary investigator.

Secondary measurements included: weight, waist circumference and blood pressure, which were taken in a private area by a trained researcher. Furthermore, a laboratory requisition for fasting blood sugar, glycated hemoglobin, triglycerides, total cholesterol (TC), low density lipoprotein (LDL) cholesterol, high density lipoprotein (HDL) cholesterol, and total cholesterol: HDL (TC:HDL) ratio was provided to participants at week 1 and 11. Participants were asked to attend their local laboratory to have labs drawn during the first week and during or soon after week 12 of the study. Additionally, at the last session, participants completed a program evaluation.

All data collected were stored on the personal password protected computer of the primary investigator using participant's personal identification code assigned from the ASA24™ website.

Treatment Conditions

All intervention groups consisted of 12 consecutive 1-2 hour information sessions facilitated in small groups of varying size, based on interest, in different communities. A registered dietitian facilitated the four HAES groups while two trained Lifestyle coaches facilitated the two traditional groups. At the initial session of each group, participants were informed about the study and their respective program, pre-screened for study eligibility, provided an information sheet and signed an informed consent.

The HAES intervention (n=29) focused on healthy lifestyle and body acceptance. The main goal was to enhance awareness of body cues, healthy lifestyle, promote peace with all foods and body acceptance. Session topics included overview of HAES, mindfulness, hunger and satiety cues, emotional and stress eating, cravings, mindful movement, various nutrition topics, evolving tastes, fueling our bodies to optimize energy and body acceptance and the media. Participants received resources weekly and were encouraged to set weekly goals and fill out awareness journals. Resources included: HAES for friends and family (to gain support), hunger and fullness scale, intuitive eating cycle and principles, positive mantra, recognizing hunger, mindful eating articles and tips, tips on achieving wellness, hand-out on the benefits of exercise, food guide depicting carbohydrates, protein and fat, tips on optimizing enjoyment of food flavors and recipes. Sessions also consisted of weekly mindful eating experiences with a variety of foods (legumes prepared in different ways, vegetable salads, cauliflower pizza, quinoa salads, Yonana 'ice cream') provided by the primary investigator. The aim of mindful eating activities was to practice engaging sense of sight, smell, taste and touch to fully experience various flavors, tastes and textures of foods to enhance enjoyment.

The traditional weight loss intervention (n=17) focused on calorie and fat gram counting and lifestyle change. The main goal was awareness of calories, weight loss and diabetes prevention via reduction of calories and fat. Session topics included calories and fat, healthy eating, physical activity, balancing calories in versus calories out to achieve weight loss, strategies for eating at restaurant and social events, achieving lifestyle change and staying motivated. Participants received a manual, designed for the Group Lifestyle Balance program, with all resources at the beginning of the intervention and journals for recording intake with calories and fat grams as needed throughout the intervention. Weekly weigh-ins were completed prior to weekly one-hour information sessions.

Measurements of Dependent Variables

24-Hour Dietary Intake Recall. ASA24™ was used for collection of dietary intake. This site utilizes self-administration of dietary intake and allows input of multiple 24-hour intakes for several participants. The website utilizes several food and portion size probes to obtain the most accurate possible recall. Participants received a personal identification code to fill in dietary data. Dietary intake data were entered under the same code at the beginning and at the end of the 12-week curriculum. The website analyzed the dietary information and calculated food group and nutrient intake for each participant. Dietary intake data will be stored indefinitely under participant's codes on the ASA24™ website.

Physical Activity Record. The International Physical Activity Questionnaire (IPAQ) short version, a validated tool, was used to capture physical activity patterns before and at the end of the 12-week curriculum.

Program Evaluation. At the end of the 12-week core curriculum, participants were asked how satisfied they were with the length and content of the program as well as to report how the program helped them.

Statistical Analysis

Data analysis was conducted using STATA® software (version 14 College Station, TX: StataCorp LP). Prior to analysis, data were analyzed for accuracy and completion. Missing physical activity data and outliers were removed according to IPAQ criteria. Additionally, the first and last complete 24-hour recalls were used, when participants entered more than two 24-hour recalls in ASA24™ website. The significance level was set to $p \leq 0.05$.

Baseline data were analyzed using t-tests to compare HAES and traditional group demographic characteristics with program defining groups to determine similarity. The p-values obtained during the baseline t-tests were compared for similarity between groups.

Follow-up data were analyzed using linear regression to compare differences between groups. Age and baseline characteristics were controlled for, to determine if follow-up variables were significant by age or group.

When analyzing follow-up diet data between groups, mixed model regression was used to accommodate for missing data, different facilities for groups, due to the longitudinal nature of the study and to allow for controlling for significant variables including age, group and calories. The p-value indicated whether group was significant in the model.

Comparison of all baseline to follow-up data within groups was completed using paired t-tests. Paired t-tests were used so only participants with complete data were analyzed.

Diet Data Analysis

The ASA24™ website analyzed dietary intake data that were entered and calculated the amount of each nutrient consumed during each 24-hour recall. A batch of the nutrient analysis for all 24-hour dietary intakes was run and an excel spread sheet of all diet information was downloaded. The dietary intake spread sheet was entered into SAS® Statistical Software. A program provided by the ASA24™ website was used in the SAS® software to obtain HEI scores for each dietary intake.

Results

Sixty-two potential participants were screened for study eligibility. Three did not meet eligibility criteria and 14 declined participation. The sample ultimately consisted of 46 participants (42 females). Participants chose which group to attend during recruitment. There were 29 in the HAES group and 17 in the traditional group who consented to participate in the study. Attrition in the HAES group was 4 (14%) and 10 (59%) in the traditional group.

Baseline characteristics are shown in Table 2. Baseline characteristics were similar for each intervention group, except age. The age ranged from 30 to 83 years old. The mean age of the HAES group was 52.14±1.90 while the traditional group was 59.76±2.35. Although not reported, the majority of participants were Caucasian.

Baseline diet data are shown in Table 3. There were no significant differences in baseline diet between groups, besides starchy vegetable and refined grain intake. The HAES group consumed significantly more refined grains (5.05±0.61 vs. 2.61±0.51; p=0.01) and significantly less starchy vegetables (0.07±0.26 vs. 0.25±0.07; p=0.01), respectively.

Post-intervention descriptive findings are reported in Table 4. Group (HAES vs. traditional) was a significant predictor of follow-up waist circumference when accounting for baseline waist circumference and age. Mean waist circumference was significantly lower (p=0.04) for the traditional group (40.06±0.70 inches) than for the HAES group (41.69±0.39 inches). There was no difference in mean weight between groups at the end of the interventions. Neither group nor age were significant predictors of blood pressure, glycemic, lipid or physical activity variables, between the groups at post-intervention.

Follow-up diet data comparing traditional and HAES groups are shown in Table 3. The difference in HEI scores between the groups post-intervention was trending towards significance (p=0.06). The HEI score for the HAES group was 70.77±3.00 and the traditional group had 55.97±6.57. Significantly more calories were consumed by the traditional group compared with the HAES group (2096.52±254.86 vs. 1525.63± 120.91; p=0.04) post-intervention. There was no significant difference in total protein, total carbohydrates, any fat, grains (total, whole or refined), sodium, sugar, added sugar, dairy, total fruit, whole fruit, calcium, iron, vitamin C, caffeine or alcohol intake between groups. Significantly (p=0.01) less fiber was consumed by the traditional group (12.74±3.28 g.) compared to the HAES group (23.7±1.50 g.). Additionally, significantly more vegetables were consumed by the HAES group compared to the traditional group (1.92±0.14 vs. 0.98±0.31 cup equivalents; p=0.01), however, there was no significant difference in starchy or green vegetables.

Table 5 shows the changes in descriptive data within the HAES and traditional groups from baseline to post-intervention. A significant decrease in percent weight loss was seen in both the HAES (-2.05±0.74 %, p=0.01) and traditional groups (-6.71± 1.26 %, p=0.01). The traditional weight loss group saw a significant reduction in waist circumference (-2.125±0.49 inches; p=0.01), while there was no significant change within the HAES group (-0.545±0.374 inches; p=0.16). A significant decrease in systolic blood pressure (-7.43±2.74 mmHg, p=0.01) and a decrease in diastolic blood pressure trending towards significance (-3.81±1.91; 0.06) was seen within the HAES group. No significant change in systolic (-13.50±9.50; p=0.39) or diastolic (-13.50±10.50; p=0.42) blood pressure was seen within the traditional group, however data was only collected on two participants for blood pressure variables. Neither group had a significant decrease in fasting blood sugar, but the HAES group did achieve a significant decrease in Hemoglobin A1c (-0.15±0.04; p=0.01) from baseline to post-intervention. No significant change occurred in lipid profiles, or physical activity METs or minutes for either group. However, both groups had a decrease in physical activity METs, and the traditional group had a decrease in physical activity minutes.

Dietary changes within groups are shown in table 6. HEI score significantly increased within the HAES group (7.41±2.31;p=0.01) while the score did not change in the traditional group (-0.45±6.37; p=0.95). Neither group had a significant change in calorie, total protein, any type of fat, added sugar or fiber consumed from beginning to the end of the intervention. However, the HAES group did change caloric intake by -549.80±313.84 (p=0.10). There was no significant difference in total sugar intake, but 19.61±15.03 grams (p=0.21) less within HAES and 6.10±16.41 grams (p=0.73) less within the traditional group. The HAES group had a significant decrease in sodium intake (-1298.26±612.20; p=0.47), while no change occurred within the traditional group (-206.36±0.653; p=0.65). There was no significant change in total grain, whole grains, refined grains, any vegetables or fruit, diary, calcium, iron, alcohol or caffeine consumption within either group. The traditional group had a significant ($p=0.05$) decrease in vitamin C (-46.63 ± 17.77) intake, while the HAES group did not change (-16.23 ± 9.84; $p=0.11$).

Discussion and Conclusions

An urgent need to shift the focus from weight loss to sustainable healthy lifestyle is needed and has started over the past decade. Years of dieting have established that weight loss is infrequently sustained[45,87-97]. Meanwhile, studies focusing on improvements in lifestyle result in enhanced health[39,104,105,131,134,169,171-173,207,215], psychological indicators[104,105,131-133,135,138,177,182,183,191,193,194] and self-esteem[104,105,131,133,138,174-176,178,182,183,195], positive body image and body esteem[85,95,140-142,183,196-198], independent of weight loss. However, limited evidence on dietary intake in HAES-type studies exists, but HAES-type studies that have examined diet, found improvements in variables measured[137,193,195,207,210] and reductions in eating disorder pathology[189,193,199]. The purpose of this study was to examine the impact of a HAES intervention compared to a traditional weight loss program on anthropometric and metabolic health as well as diet and physical activity habits of participants.

This study is the first that we know of to compare the nutrient density of diets measured by HEI scores in a HAES intervention compared to a traditional weight loss intervention. It was hypothesized that participants in the HAES group would increase the nutrient density of their diet and consume more whole foods, higher fiber and lower sodium at the end of the intervention. Meanwhile, lower calorie, fat and fiber intake were predicted in the traditional group at the end of the intervention. Secondly, increase in light to moderate intensity activity was predicted in both groups, post-intervention. As hypothesized, the HAES group significantly increased their diet quality (HEI score) and decreased sodium intake, but had no change in fiber intake. However, they did consume more fiber post-intervention than the traditional group. There was no change in whole grains, whole fruits or whole vegetable intake within the HAES group. Within the traditional group, there was no change in calorie, fat or fiber intake, but they did consume significantly more calories and less fiber than the HAES group, post-intervention. Neither group had a change in amount or level of intensity of physical activity post-intervention.

Each group had a significant weight loss, but no significant difference in weight loss was seen between groups. Similarly, two other HAES-type intervention groups of short follow-up achieved significant weight loss[194,206]. Additionally, short-term weight loss is well documented in traditional weight loss trials[90,102-111]. The traditional weight loss group achieved a weight loss of nearly seven percent. A 5-10% weight loss has been associated with a 38-55% reduction in type 2 diabetes incidence in high-risk populations[102,108]. Additionally, the traditional weight loss group had a significantly lower waist circumference post-intervention than the HAES group. Similarly, other weight loss interventions have had a significant reduction in visceral fat and waist circumference[90,102,103]. A positive association between waist circumference and all-cause mortality was found in a large U.S. cohort, independent of BMI[216]. This suggests that both interventions in the current study were effective for short-term weight loss, but the traditional group potentially resulted in an improvement in body composition, which could reduce all-cause mortality. More accurate measurement of body composition (as opposed to waist circumference as a proxy) is warranted in future studies.

Systolic blood pressure significantly decreased within the HAES group, while improvements in diastolic blood pressure were trending towards a significant decrease. Similarly, two other HAES studies[104,105,172] including a two-year follow-up[105] saw a reduction in systolic blood pressure, but not all HAES-type studies saw this improvement[131,134,171]. Additionally, two HAES studies found no significant difference in diastolic blood pressure [104,105], while several others had a significant improvement[32,135,172,173]. There was no significant difference in blood pressure between the traditional and HAES groups and no significant decrease within the traditional group. Despite lacking statistical signficance, the decrease in both systolic and diastolic blood pressure within the traditional group could be clinically meaningful and may have reached statistical significance if data on more participants were collected. Blood pressure improvements have been seen in several weight loss groups[90,102,103,106], however, not consistently[107]. Findings in the current study suggest that the HAES intervention may be effective for improving blood pressure as well as blood sugar control.

Hemoglobin A1c significantly decreased within the HAES group, while the traditional group remained the same. However, similar to some HAES studies[171,172,215], no significant decrease in fasting blood sugar occurred in either group. There were no significant differences between groups and the traditional weight loss group did not experience any significant changes in metabolic parameters, however the number of participants who completed the traditional group was low (n=7). Similarly, other weight loss trials have not had consistent blood glucose control improvements[107]. The decrease in hemoglobin A1c within the HAES group, provides preliminary evidence that this approach may be effective in improving blood glucose control and possibly prevention of diabetes. Further trials are required.

Physical activity recommendations for adults according to the Center for Disease Control include 150 minutes of moderate intensity aerobic physical activity per week plus muscle strengthening of all major muscle groups on two or more days per week[217]. Physical activity was not covered in depth in the current interventions. The HAES intervention encouraged mindful and enjoyable movement and discussed the medical implications of sedentary behavior as well as the dose required for health protection, whereas the traditional group discussed physical activity for the calorie burning potential and health benefits. No data on type of exercise was collected. However, neither the HAES nor traditional groups met the 150-minute per week physical activity recommendations at baseline or follow-up and although not statistically significant, physical activity levels decreased in both groups at follow-up, which could potentially impact health. Similarly, two other studies[132,136], saw no significant difference in physical activity for the HAES group post-intervention, however increased physical activity has been seen in several HAES studies[105,135,171,174,177,191]. Another study comparing a HAES and a traditional weight loss group, found that the traditional group increased physical activity initially, but did not sustain this behavior at follow-up[105]. Physical activity is beneficial for reducing all-cause mortality, especially in normal weight and obese individuals[218].

Contrary to the lack of change in physical activity, improvements in diet quality and some diet variables occurred.

A HEI score of 80 is considered good, while 51 to 80 needs improvement and less than 51 is poor[219]. The mean HEI score in the HAES group increased from approximately 60 to 70, which, although still below the recommendation of 80, could be clinically important. Additionally, a significant increase in HEI score within the HAES group and a difference trending towards significance between the HAES and traditional groups was seen, post intervention. Meanwhile, no change was seen within the traditional weight loss group. However, the HEI score of the traditional weight loss group started at approximately 65 but was 55 post-intervention, which although not statistically significant, could have a clinically meaningful impact on health. However, the number of participants who completed the traditional weight loss arm of the study was small (n=7). The average American score during NHANES 2009-2010 was 57[220]. Therefore, both groups started with a score above American average, while the HAES improved their score and the traditional group fell below average. These findings suggest that group was a significant predictor of HEI score.

The HEI score is a 100-point scale, measuring conformance to dietary guidelines. It was originally developed in 1995 by Kennedy et al. to measure conformance to American dietary guidelines[221]. The scoring patterns are used to set scoring standards for the HEI. The higher the score in all components, the more closely the diet conforms to dietary recommendations[222].

HEI scoring is based on the below criteria provided by the USDA[222]:

HEI- 2010[1] component	Maximum	Standard for maximum score	Standard for minimum score of zero
▲ Adequacy *(higher score indicates higher consumption)*			
Total Fruit[2]	5	≥ 0.8 cup equiv. / 1,000 kcal[10]	No fruit
Whole Fruit[3]	5	≥ 0.4 cup equiv. / 1,000 kcal	No whole fruit
Total Vegetables[4]	5	≥ 1.1 cup equiv. / 1,000 kcal	No vegetables
Greens and Beans[4]	5	≥ 0.2 cup equiv. / 1,000 kcal	No dark-green vegetables, beans, or peas
Whole Grains	10	≥ 1.5 ounce equiv. / 1,000 kcal	No whole grains
Dairy[5]	10	≥ 1.3 cup equiv. / 1,000 kcal	No dairy
Total Protein Foods[6]	5	≥ 2.5 ounce equiv. / 1,000 kcal	No protein foods
Seafood and Plant Proteins[6,7]	5	≥ 0.8 ounce equiv. / 1,000 kcal	No seafood or plant proteins
Fatty Acids[8]	10	(PUFAs + MUFAs) / SFAs ≥ 2.5	(PUFAs + MUFAs) / SFAs ≤ 1.2
▼ Moderation *(higher score indicates lower consumption)*			
Refined Grains	10	≤ 1.8 ounce equiv. / 1,000 kcal	≥ 4.3 ounce equiv. / 1,000 kcal
Sodium	10	≤ 1.1 gram / 1,000 kcal	≥ 2.0 grams / 1,000 kcal
Empty Calories[9]	20	≤ 19% of energy	≥ 50% of energy

[1] Intakes between the minimum and maximum standards are scored proportionately.
[2] Includes 100% fruit juice.
[3] Includes all forms except juice.
[4] Includes any beans and peas not counted as Total Protein Foods.
[5] Includes all milk products, such as fluid milk, yogurt, and cheese, and fortified soy beverages.
[6] Beans and peas are included here (and not with vegetables) when the Total Protein Foods standard is otherwise not met.
[7] Includes seafood, nuts, seeds, soy products (other than beverages) as well as beans and peas counted as Total Protein Foods.
[8] Ratio of poly- and monounsaturated fatty acids (PUFAs and MUFAs) to saturated fatty acids (SFAs).
[9] Calories from solid fats, alcohol, and added sugars; threshold for counting alcohol is > 13 grams/1,000 kcal.
[10] Equiv. = equivalent, kcal = kilocalories.

Several dietary variables contributed to the increase in HEI score within the HAES group, many of which were not statistically significant but contributed to improved diet quality. For example, fruit intake decreased, but was at the recommended level of ≥ 0.8 cup equivalents / 1000 kilocalories, with a greater proportion of fruit intake being whole at post-intervention. Furthermore, an increase in whole grains and decrease in refined grains from pre to post intervention contributed to an improved HEI score. Additionally, a significant decrease in sodium intake improved HEI score and decreased saturated fat intake is purported to have contributed to this improvement. Several variables also contributed to the reduction in HEI score seen in the traditional weight loss group.

A reduction in HEI score in the traditional group resulted from several statistically insignificant decreases in some of the components used to formulate the HEI score. For example, total fruit and vegetable as well as green vegetable intake decreased to below recommendations at post-intervention. Additionally, an increase in refined grain and decrease in whole grain intake, post-intervention, contributed to the decrease in HEI score. A high sodium intake would have also contributed to the low score; however, the amount of sodium remained similar from pre to post-intervention.

A higher HEI score was associated with a reduction in risk of depression in a Spanish population[223]. Furthermore, higher diet quality, measured by several diet indices including HEI-2010 found a high degree of correlation and that consistent 11-28% reduction of risk of mortality from all causes, CVD, cancer[224-226] and type 2 diabetes[225], independent of confounding factors, when compared to diets of low quality[224-226]. However, some studies have shown weak or no association between the HEI and chronic disease risk[227] and lipid biomarkers[228], although the HEI-2005 was found to be predictive of some lipid biomarkers[229]. Aside from HEI, several other dietary differences occurred between groups.

Contrary to hypothesis, higher caloric intake was seen in the traditional group, compared to the HAES group. According to the U.S. Department of Agriculture and U.S. Department of Health and Human Services Dietary Guidelines for Americans 2010, the estimated amounts of calories needed to maintain calorie balance for sedentary women age 51 and over is 1600 kcal and men 2000-2200 kcal[230]. These findings may be significant for long-term weight management.

Contrary to what was hypothesized, fat intake was not significantly lower in the traditional group. There was no significant difference in fat intake within or between either group. However, differences in consumption of total fat (78.07±8.00 vs. 66.68±3.66 g) and saturated fat (27.17±3.54 vs. 19.5±1.62 g) in the traditional versus the HAES group, may be clinically meaningful.

Consumption of grains (total, whole or refined) was not significantly different between or within groups, but was above recommendation at between five and seven ounce equivalents pre-intervention and approximately six-ounce equivalents post-intervention for both groups. The recommendation for grains is three ounces or equivalent each day for women or three and a half to four ounces or equivalent for men[231]. Intake in the current study was similar to the American average of 6.3 ounce-equivalents[232]. At least half of total grain intake (approximately 3 oz. equivalents of current average) should be whole grains[230]. However, less than 1-ounce-equivalent of whole grains is typically consumed by Americans per day[232]. Although not statistically significant, the change in refined grains from pre and post-intervention from 5.05±0.61 to 2.70±0.53 ounces within the HAES group and the change in the lifestyle group from 2.61±0.51 to 4.24±0.9 ounces, from pre to post-intervention, may influence health. Whole grain intake may reduce the risk of cardiovascular disease, developing type 2 diabetes and is associated with a lower body weight and contributes to meeting daily nutrient needs[230]. Despite no significant difference in grains, fiber consumption differed between groups.

As hypothesized, fiber consumption was significantly higher in the HAES group, compared to the traditional group, post-intervention. Contrarily, there was no significant within-group change in fiber intake. However, calories, age and group were not controlled for statistically in the within group data analysis. Leblanc et al., found that participants in all groups had similar fiber intake and insignificant changes from before to after the intervention[136]. In the current study, the HAES group consumed close to the recommended 25 grams of dietary fiber for women[230], whereas the traditional group only consumed 12.74±3.3 grams. Similarly, most Americans under consume fiber[233]. According to 1999-2008 NHANES data, the usual American fiber intake is 15 grams per day. Fiber may help reduce the risk of cardiovascular disease, obesity and type 2 diabetes and also promotes healthy lipid profile, improved glucose tolerance and promotes normal gastrointestinal function[230]. The higher fiber intake in the HAES group compared to the traditional group, may have partially resulted from higher vegetable consumption.

Despite significantly more vegetables consumed at post-intervention in the HAES group, compared to the traditional group and an increase in fruit intake among the traditional group, both groups consumed less fruit and vegetables than recommended, post-intervention. According to the 2010 American Dietary Guidelines, two and a half cup equivalents each of fruits and vegetables should be consumed daily[230]. Similar to the findings of this study, the majority of Americans do not consume adequate fruits or vegetables daily. Fruits and vegetables are major contributors to adequacy of under consumed nutrients in the United States, including dietary fiber and vitamin C[232]. It is probable that vegetable and fruit intake below recommendations contributed to the significant decrease in vitamin C within the traditional group and intake below the recommended daily allowance (RDA) of

75 mg for female and 90 mg for male non-smokers[234] seen in both groups. Not all foods and nutrients were consumed at or below recommended amounts.

Sodium intake was higher than recommended for both groups, however, the HAES group decreased intake by approximately 1300 mg per day. Sodium consumption above recommendations increases risk for increasing blood pressure and is a major cause of heart disease and stroke[235]. Sodium consumption for both groups was below American average intake of 3436 mg. The target is to consume less than 2300 mg sodium until the age of 51[230]. However, more than two out of three adults should consume 1500 mg of sodium daily[235], including: those age 51; of African American decent; living with hypertension; living with chronic kidney disease or diabetes[232]. Participants may also be at increased risk because of inadequate dairy and calcium intake.

Dairy consumption was low (less than 2 cup equivalents) within each group and both groups consumed less dairy post-intervention. The recommended amount of milk and milk products for adults is three cups (or equivalent) per day of fat-free or low-fat milk and milk products[230]. Some evidence suggests that adequate milk and milk product intake is linked to improved bone health, reduced risk of cardiovascular disease and type 2 diabetes development as well as lower blood pressure in adults[230]. Inadequate consumption of milk and milk products contributed to the inadequate calcium intake seen in both groups.

Calcium intake did not change significantly over the intervention however; the decrease seen in both groups may have clinical significance. Post-intervention, both groups consumed approximately 750 mg of calcium daily. This is below the

1000 mg recommended for adults aged 31-70 years and the 1200 mg recommended for those over age 70 years[236]. Similarly, most Americans have an inadequate calcium intake[230]. Adequate calcium is important for optimal bone health, and serves vital roles in nerve transmission, constriction and dilation of blood vessels and muscle contraction[230].

Study Strengths and Limitations

This study had many strengths. Some of the strengths include similar baseline characteristics between groups, except age. Additionally, the group ran in four different communities for participant convenience. Furthermore, the same Registered Dietitian facilitated all the HAES groups and the Lifestyle coaches were trained and had a well-established curriculum to follow. In addition to strengths, there were a few limitations in this study.

Limitations included small sample size, participants were not randomized and group sizes between and within each intervention varied based on interest in different communities. Furthermore, not all follow-up data (blood pressure) was collected on the traditional group because only one researcher was collecting this data for all groups. Moreover, both groups had participants drop out. The traditional weight loss group had a high attrition rate, consistent with the high rates seen in other weight loss studies[39,45,102-105]. Participants reasons for dropping out of the traditional group included time restraints and did not enjoy the group facilitation.

Conclusions

In conclusion, both groups lost weight, while the traditional group also decreased waist circumference. The HAES approach resulted in positive improvements in health indicators and diet, namely decrease in sodium, increase in Healthy Eating Index score and vegetable intake. However, intake of several food groups and nutrients were lower than recommended in both intervention groups, which could negatively affect health. Neither group improved levels of physical activity. Findings of this study suggest that a Health At Every Size intervention may be more beneficial for blood pressure, blood sugar and diet quality, however neither group was effective for increasing level of physical activity.

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Table 2: Baseline Descriptive Characteristics of Participants in a Study Assessing the Effects of a Health-At-Every-Size (HAES) Program compared to a Traditional Weight Loss Program on Dietary Intake, Physical Activity Patterns, Metabolic and Anthropometric Variables

Parameter	Mean±SEM	HAES (n=29)	Traditional (n=17)	P Value
Age (years)	53.5±2.10	52.14±1.90	59.76±2.35	0.02
Anthropometrics				
Weight (lbs.)	199.50±7.70	201.70±7.04	204.73±9.78	0.81
Waist (inches)	42.70±0.93	43.51±0.86	40.83±1.34	0.09
Systolic BP (mmHg)	131.20±1.86	130.55±2.03	133.75±1.88	0.43
Diastolic BP (mm Hg)	81.90±1.60	81.10±1.64	83.00±3.43	0.60
Glycemic Variables (mmol/L)				
Fasting glucose	5.16±0.12	5.18±0.14	5.68±0.13	0.16
HbA1C (% total Hb)	5.33±0.76	5.328±0.07	5.68±0.26	0.08
Lipid Variables (mmol/L)				
Triglycerides	1.27±0.10	1.45±0.18	1.42±0.29	0.93
Total cholesterol	5.34±0.19	5.39±0.21	5.37±0.10	0.98
LDL cholesterol	3.33±0.17	3.31±0.19	3.29±0.15	0.93
HDL cholesterol	1.42±0.76	1.38±0.08	1.44±0.19	0.78
TC/HDL (ratio)	4.17±0.26	4.20±0.30	4.02±0.51	0.80
Physical Activity (per week)				
Activity METs	1434.09±426.95	1463.99±403.35	787.29±168.47	0.22
Activity Minutes	73.64±11.40	84.38±15.28	54.117±16.05	0.20
▪ T-tests compared HAES and Traditional with program defining groups				

Table 3: Baseline and Follow-Up Diet Data Comparing Between a 12-week HAES Curriculum vs. Traditional Weight Loss Curriculum

Variable	Baseline HAES (n=29)	Baseline Traditional (n=17)	P Value	12-Week HAES	12-Week Traditional	P Value
HEI Score	60.60±2.41	65.46±2.41	0.19	70.77±3.00	55.97±6.57	0.06
Kilocalories	2206.61±193.43	1825.75±151.00	0.14	1525.63±120.91	2096.52±254.86	0.04
Total Protein (g)	91.92±9.87	79.48±6.89	0.38	67.92±7.40	70.85±3.39	0.74
Total Carbohydrate (g)	277.53±23.44	228.07±21.08	0.16	199.66±8.67	172.57±18.96	0.23
Total Fat (g)	94.90±12.81	69.33±8.13	0.16	66.68±3.66	78.07±8.00	0.23
Saturated Fat (g)	31.70±23.67	23.67±3.23	0.24	19.50±1.62	27.17±3.54	0.07*
Monounsaturated Fat (g)	34.79±5.26	23.14±2.57	0.11	21.47±1.66	28.79±3.62	0.09
Polyunsaturated Fat (g)	20.91±2.98	16.49±2.47	0.31	19.36±1.51	15.54±3.31	0.10
Sugar (g)	112.99±13.32	93.17±12.73	0.34	79.08±6.54	74.50±14.30	0.78
Added Sugar (tsp)	11.20±2.56	11.90±2.00	0.83	9.23±1.18	9.89±2.59	0.83
Sodium (mg)	4088.80±482.62	3336.35±296.35	0.27	2918.59±192.67	3368.96±421.48	0.37
Total Grains (oz.)	7.25±0.65	5.34±0.85	0.08	5.85±0.53	5.95±1.17	0.94
Whole Grains (oz.)	2.19±0.44	2.72±0.63	0.48	2.81±0.40	1.70±0.89	0.30

Refined Grains (oz.)	5.05±0.61	2.61±0.51	0.01	3.04±0.44	4.24±0.96	0.30
Fiber (g)	27.89±2.79	22.50±1.85	0.18	23.70±1.50	12.74±3.28	0.01*
Total Dairy (cup Eq)	1.82±0.41	1.65±0.38	0.78	1.18±0.15	1.63±0.32	0.24
Total Vegetables (cup Eq)	2.04±0.21	2.34±0.16	0.38	1.92±0.14	0.98±0.31	0.01
Green Vegetables (cup Eq)	0.29±0.08	0.27±0.11	0.90	0.31±0.07	0.19±0.15	0.50
Starchy Vegetables (cup Eq)	0.07±0.26	0.25±0.07	0.01	0.08±0.03	-0.04±0.07	0.14
Total Fruits (cup Eq)	2.51±0.60	1.79±0.43	0.41	1.32±0.22	1.22±0.48	0.87
Whole Fruit (cup Eq)	2.14±0.54	1.66±0.39	0.54	1.24±0.22	1.19±0.49	0.93
Calcium (mg)	1022.46±150.40	860.37±119.08	0.46	752.95±44.80	757.58±97.98	0.97*
Iron (mg)	17.81±1.76	16.94±3.51	0.80	14.85±2.51	9.58±2.51	0.08
Vitamin C (mg)	104.38±18.08	109.37±21.16	0.86	68.37±7.97	66.49±17.44	0.93
Alcohol (drinks)	0.16±0.09	0.07±0.07	0.51	0.01±0.19	0.11±0.19	0.97
Caffeine (mg)	205.82±36.32	225.62±51.73	0.75	159.71±29.05	167.96±63.56	0.37

- T-test was used to determine baseline program defining groups
- Mixed model regression was used for follow-up diet data to accommodate for missing data, different research facilities and because of the longitudinal nature of the study
- All follow-up diet data were controlled for age and caloric intake, besides calorie intake for which only age were controlled
- An astericks * indicates age was significant (in follow-up data)

Table 4: Follow-Up Descriptive Characteristics of Participants in a Study Assessing the Effects of a Health-At-Every-Size (HAES) Program Compared to a Traditional Weight Loss Program on Dietary Intake, Physical Activity Patterns, Metabolic and Anthropometric Variables

Parameter	All	HAES	Traditional	P Value
Anthropometrics				
Weight (lbs.)	191.69±6.88	192.93±1.56	187.98±2.99	0.07
Waist (in)	41.24±0.99	41.69±0.39	40.06±0.70	0.04
Weight lost (lbs.)	-6.39±1.48	-5.10±1.60	-10.26±3.07	0.18
% wt loss	-3.21±0.74	-2.45±0.76	-5.51±1.45	0.09
Systolic (mm Hg)	122.78±2.41	123.89±2.48	111.20±9.52	0.23
Diastolic (mm Hg)	77.26±2.04	77.77±1.91	71.88±7.16	0.45
Glycemic Variables (mmol/L)				
Fasting glucose	5.30±0.17	5.34±0.13	5.04±0.38	0.49
HgbA1c (% of total Hb)	5.45±0.11	5.48±0.05	5.23±0.17	0.22
Lipid Variables (mmol/L)				
Triglycerides	1.51±0.21	1.51±0.12	1.49±0.36	0.97
T-Chol	5.44±0.25	5.45±0.09	5.37±0.28	0.26
LDL-C	3.36±0.22	3.28±0.09	3.32±0.27	0.90
HDL-C	1.40±0.10	1.41±0.03	1.32±0.09	0.39
Chol:HDL (ratio)	4.20±0.40	4.15±0.08	4.49±0.26	0.25
Physical Activity (per week)				
Total METs	927.37±268.47	968.36±280.65	857.45±375.19	0.82
Total minutes	67.27±16.21	82.04±20.67	40.49±28.37	0.26

- Linear regression was used to determine differences between groups
- Controlled for age and baseline variable
- Note: p-value indicates group was significant in model
- Age was not significant in any variable

Table 5: Changes in Anthropometric, Metabolic Variables and Physical Activity Patterns Within Groups in a Study Comparing the Effects of a HAES Program to a Traditional Weight Loss Program

Parameter	HAES	P Value	Traditional	P Value
Anthropometrics				
Weight lost (lbs.)	-4.33±1.60	0.01	-12.57±2.24	0.01
Waist (in)	-0.55±0.374	0.16	-2.13±0.49	0.01
**Percent Weight Loss	-2.05±0.74	0.01	-6.71±1.26	0.01
Systolic (mm Hg)	-7.43±2.74	0.01	-13.50±9.50	0.39
Diastolic (mm Hg)	-3.81±1.91	0.06	-13.50±10.50	0.42
Glycemic Variables (mmol/L)				
Fasting glucose	0.14±0.13	0.31	0.35±0.15	0.26
HgbA1c (% of total Hb)	-0.15±0.04	0.01	0.00±0.30	1.00
Lipid Variables (mmol/L)				
TG	0.12±0.14	0.39	0.19±0.13	0.38
T-Chol	0.88±0.10	0.40	0.26±0.25	0.49
LDL-C	0.02±0.12	0.86	-0.23±0.31	0.30
HDL-C	0.01±0.03	0.94	0.11±0.07	0.36
Chol:HDL (ratio)	0.13±0.52	0.81	-0.67±0.97	0.52
Physical Activity (per week)				
Total METs	-395.43±288.58	0.18	-100.75±393.26	0.80
Total minutes	1.03±25.15	0.97	-23.125 ± 24.26	0.36

- Paired t-test was used to compare pre and post variables for complete data within the same group
- ** Unpaired t-test used for analyzing percent weight loss
- Note: p-value indicates group was significant in model

Table 6: Changes in Diet Variables Seen Within HAES and Traditional Weight Loss Groups

Variable	HAES	P value*	Traditional	P value*
HEI Score	7.41±2.31	0.01	-0.45±6.37	0.95
Kilocalories	-549.80±313.84	0.10	-58.63±215.95	0.29
Total Protein (g)	-23.25±14.18	0.12	-9.74±11.70	0.44
Total Carbohydrate (g)	-59.66±28.29	0.05	-21.28±24.81	0.43
Total Fat (g)	-25.43±18.89	0.19	8.99±11.53	0.74
Saturated Fat (g)	-9.77±6.36	0.14	-0.46±5.59	0.94
Monounsaturated Fat (g)	-13.60±7.79	0.10	6.97±3.79	0.13
Polyunsaturated Fat (g)	-1.35±4.70	0.78	1.58±5.74	0.79
Sugar (tsp)	-19.61±15.03	0.21	-6.10±16.41	0.73
Added Sugar (g)	-1.71±2.51	0.50	1.71±2.64	0.55
Sodium (mg)	-1298.26±612.20	0.05	-206.36±0.65	0.65
Total Grains (oz.)	-1.58±1.15	0.18	0.96±0.56	0.15
Whole Grains (oz.)	0.31±0.71	0.67	0.42±0.78	0.61
Refined Grains (oz.)	-1.89±0.99	0.07	0.55±1.10	0.64
Fiber (g)	-3.73±2.56	0.16	-3.10±2.40	0.25
Total Dairy (cup Eq)	-0.65±0.58	0.27	-0.73±0.61	0.29
Total Vegetables (cup Eq)	-0.08±0.23	0.74	-0.89±0.59	0.19
Green Vegetables (cup Eq)	0.10±0.08	0.21	0.07±0.28	0.81
Starchy Vegetables (cup Eq)	-0.02±0.06	0.67	-0.14±0.13	0.31
Total Fruits (cup Eq)	0.45±0.26	0.10	-0.80±0.30	0.04
Whole Fruit (cup Eq)	-0.43±0.27	0.13	-0.65±0.31	0.09
Calcium (mg)	-246.95±203.86	0.24	-265.08±133.16	0.10
Iron (mg)	-2.21±2.33	0.35	-1.60±1.96	0.45
Vitamin C (mg)	-16.23±9.84	0.11	-46.63±17.77	0.05
Alcohol (drinks)	-0.04±0.28	0.89	-0.03±0.03	0.33
Caffeine (mg)	-80.18±49.27	0.12	-55.82±143.92	0.71
▪ Paired t-test were used to determine differences within groups; no variables were controlled for using paired t-test				